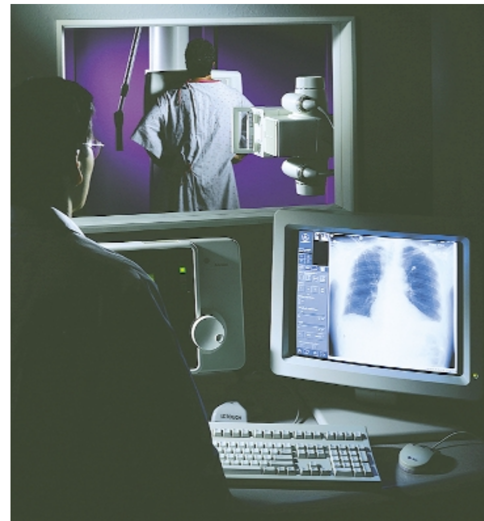
OVERVIEW

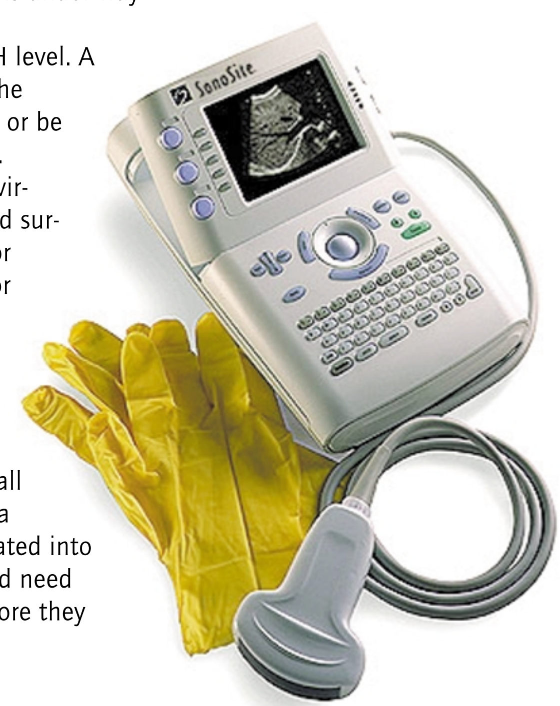


All casualty care begins with location and diagnosis of the injury. The concept assumes that every soldier will be wearing a Personnel Status Monitor (PSM) system like the Sarcos, Inc PSM, consisting of geolocation positioning satellite (GPS) location, telecommunication, and full suite of vital signs monitors. Thus, when a soldier is wounded, the location and vital signs are sent to the closest medic. The PSM system can communicate with the LIFE SUPPORT FOR TRAUMA AND TRANSPORT (LSTAT) portable intensive care unit, so as soon as the soldier is placed on the LSTAT the vital signs can be sent back to the MASH. In addition, the next generation system will incorporate a "smart tee shirt" (being developed jointly between Georgia Technological Institute and U.S. Navy Research Labs [SPAWAR] at San Diego, CA) with the vital signs monitors woven into the shirt, or microsensors from Oak Ridge National Labs incorporated into the fabric and electronic grid. There is also a grid which identifies the site of wounding on the body through algorithms developed at Mission Research Corporation, and which calculates probable organs injured. All this information can be sent to the medic as well as the MASH as soon as the wounding occurs. The medic will carry a hand-held, portable ultrasound unit developed jointly by the University of

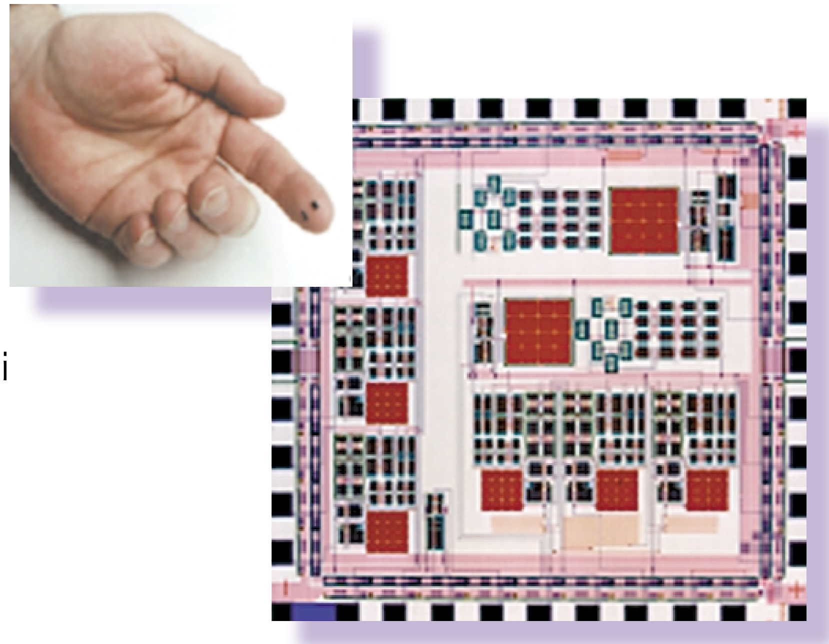
DIAGNOSTICS

Washington and ATL Inc, which can "look inside" the body for internal wounding. Images can be reconstructed into full 3-D rendering by the Sandia Laboratory software. All these capabilites have been integrated into a larger backpack size system, the Medical UltraSound Three-Dimensional-Portable with Advanced Communications (MUST-PAC) from Battelle Pacific Northwest Laboratories. The PSM system has been field tested during Ranger training at Camp Rudder, Florida. The ATL ultrasound has been spun off as a separate company, SonoSite, Inc., and provides the hand-held ultrasound as a commercial product, which is also being used on the Space Shuttle. The MUST-PAC has been used in Bosnia and on Mt. Everest for remote ultrasound telemedicine, and commercial development is under way.

Additional systems were developed for advanced diagnostics at the MASH level. A General Electric (GE) direct digital X-ray system will acquire the X ray of the wounded soldier without X-ray film and be instantly available for viewing or be able to transmit in real time the image to the radiologist in rear echelons. Using algorithms developed by Harvard's Brigham Women's Hospital for virtual endoscopy to perform 3-D visualization on the images, physicians and surgeons will view digital images in full 3-D, be able to fly through, rotate, or view them from any direction. Non-invasive sensors will be able to monitor blood lactate in shock (Princeton Electronics), or used to accurately determine the depth of burn (Physical Optics, Inc.). For those tests requiring a microscope diagnosis, a direct digital pathology system from Kensal Corporation can scan in slides and transmit the images for consultation with a pathologist. Thus the spectrum of care from acute trauma to non-battle injury can be supported by the technologies. And coordination on all levels of care through telemedicine is supported. The GE direct digital X ra commercial product, with the algorithms from Brigham Hospital incorporated into its system. Non-invasive sensors are being developed in the laboratory and need clinical testing to determine efficacy. FDA approval must be obtained before they are released as products.



MEMS Microsensors



Miniaturized Biosensor/Transmi Systems

Project Summary

A medical telesensor ASIC (application specific integrated circuit) is an integrated-circuit which is self-contained and which functions in a completely wireless manner. Each such chip (two temperature telesensors are shown above left) contains a sensor for one or more vital signs—pulse, blood pressure, body temperature, blood oxygen, or other signals of use in monitoring health or in diagnostics. Each type of sensor is produced on a silicon chip along with digital signal processing electronics and transmission electronics. A lithium-ion, thin-film, battery, an antenna, and a crystal are deposited on the undercarriage. This permits the chip to be free of any housing. Each chip transmits data when queried and uses direct-sequence, spread-spectrum, radio-frequency (rf) transmission to permit operation in electronically sensitive or noisy environments with unique ID coding. Transmission to an intelligent monitor is made upon query or problem detection and the duty cycle can be programmed remotely. With added power it has been shown to transmit through 3 floors of a Navy cruiser with all doors closed.

Body-Temperature Telesensor Test Chip

A typical telesensor chip is 3 mm × 3 mm in area. (Artwork shown above right has a temperature sensor accurate to 0.1 C .°) Unlike ordinary integrated circuits, the lack of need for a housing (for connections to a printed circuit board) permits innocuous placement on the body due to the resulting very small size. An array of medical telesensor ASICs may be mounted at various points on a person using a non-irritating adhesive similar to that used in waterproof band-aids or by using a ring or other removable hardware. Placement in the ear canal is effective for thermometry and oximetry.

Medical telesensors prototype chips were developed for use on troops in the combat zone. Production quality chips remain to be devised and tested. A PCMCIA card was used for the receiver, but other forms could be placed in a helmet.

Technology Transfer

Civilian applications include the long-term, wireless, monitoring of intensive-care patients in hospitals, monitoring of high-risk outpatients, monitoring of construction workers, policemen, and firemen in hazardous situations. Electroencephalographic, blood pressure, respiration, and electrocardiographic data systems were demonstrated with a wireless non-ASIC system.Technology transfer activities carried out to date have established collaborative projects with the private sector which will culminate in commercial development of the medical telesensors.

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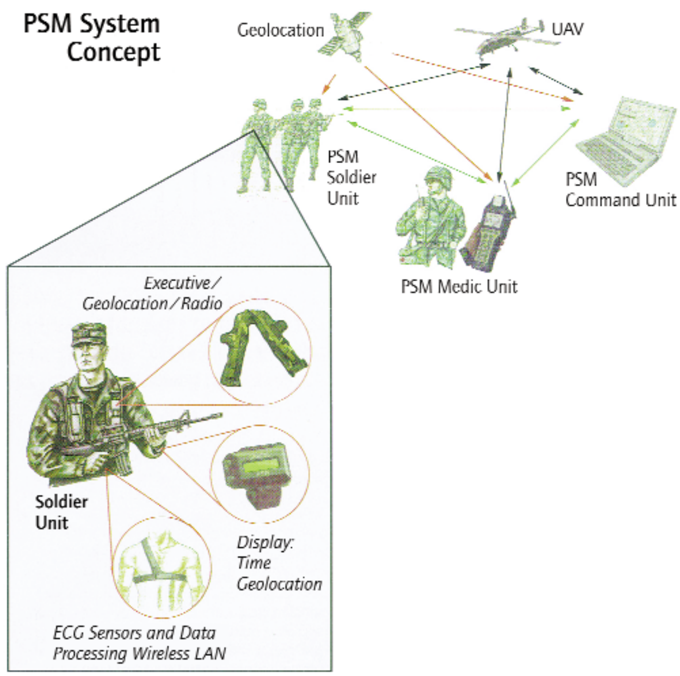
PSM

Personnel Status Monitor



Project Summary

The Personnel Status Monitor (PSM) system is a wearable core platform of the digital medical battlefield that consists of a Global Positioning Satellite (GPS) locator, a suite of vital sign sensors, a telecommunications system, and display devices for individual medic and higher level incorporation of battlefield medical data. It is an individual system for the soldier and medic, and it can be integrated into other advanced technologies such as the "smart T-shirt" and Life Support for Trauma and Transport (LSTAT). The PSM addresses many of combat casualty care's most critical requirements. Through the use of the GPS locator, it can locate and identify friendly forces to enhance battlefield situational awareness and reduce fratricide. Wearable microelectromechanical systems (MEMS) sensors remotely determine life status and physiologic state, permitting medical attention to be directed promptly to those casualties who will benefit most. This results in the ability to rapidly identify the occurrence and precise location of a casualty to avoid delay by initiating care within the "golden hour." The availability of physiologic data and protocols enhance initial evaluation and management to improve trauma care in the field. Ongoing monitoring and recording of the physiologic data during evacuation avoids discontinuity and reduces risk of care during transport to, and through, higher levels of care. The system can also be configured to simulate and present physiologic data representing a variety of combat conditions to help develop, train, and maintain combat casualty care skills during peacetime.

In addition, the PSM integrates associated protocols for medical decision support, device control and communications with the system interface. Medical protocols provide diagnostic and therapeutic guidance and create and maintain associated medical records. There are device control protocols which permit therapeutic devices to communicate with and be controlled by the PSM. Communications protocols allow radio transmission between PSM units with low probability of detection and intercept. The system interface links PSM to higher levels of medical care and communications on and beyond the digital battlefield.

In July, 1997, the PSM system was successfully deployed in a field training exercise in the U.S. Army Ranger School at Camp Rudder, Florida. The system performed 24 hours a day for the full five days of training, providing physiologic status assessment and accurate geolocation.

Technology Transfer

Sarcos, Inc., is prepared to commercialize the system using a variety of arrangements including licensing of the technology. The company is positioned to move forward aggressively.

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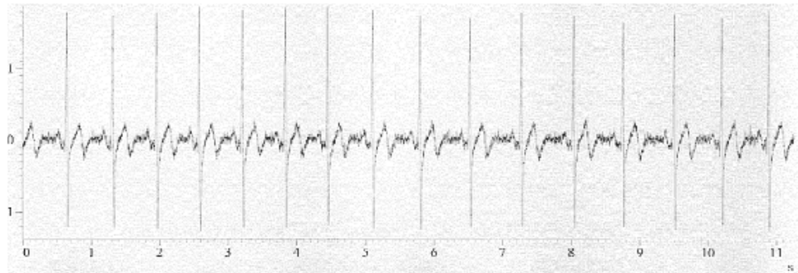
Smart T-Shirt

Figure 1



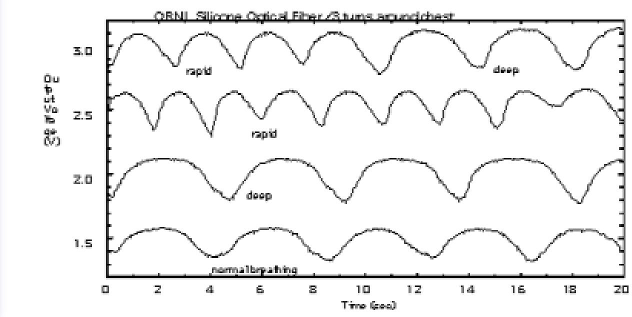


Figure 2
Example of EKG and respiration signal acquisition

Torso Penetration Sensors

Project Summary

The Torso Penetration sensor garment was initiated to save casualties on the battlefield. The majority of fatally wounded soldiers exsanguinate simply because their wounded status is not known quickly enough to permit effective intervention. Since Global Positioning Systems (GPS) have become field deployable, this program supplemented the available personnel localization data with near instantaneous detection of severe biological damage. Damage from high speed fragments penetrating the soldiers torso has historically been by far the most statistically significant cause of battlefield mortality.

In order to detect the occurrence of these wounds the torso penetration garment (Figure 1) is a novel suite of sensors woven into a garment for biological damage assessment. Dr. Robert Eisler of Mission Research Corporation generated an accurate wound tract from analysis of processed ultrasound detected by body contact acoustic sensors, and confirmed with complementary sensors providing blood presence and oxygenation, velocity, penetrant caliber and obliquity, and body motion utilizing coincidence verification. Mr. Tony McKee of ILC Dover Inc. developed an overlay mesh sensor providing further confirmation (for false alarm suppression) via haptic entrance and exit wound detection. In order to provide for the practical effective mounting of the scores of sensors required for biological damage assessment Dr Eric Lind of SPAWAR System Center invented a core technology termed "wearable electo-optical circuit garments" to enable the cost effective field deployment of the suite of sensors required for biological damage assessment, as well as vital sign monitoring. This novel concept included the conduction of electrical energy throughout the garment on insulated electrically conductive fibers together with cut-and-paste mass producible electrical interconnection technology. Optical energy for the purposes of display, signal conduction or phenomenological sensing could be conducted via optical fibers similarly embedded in the textile weave. Professor Sundaresan Jayaraman of Georgia Tech designed, developed and integrated the proof of concept Smart T-shirt prototypes that have been utilized in numerous forums demonstrating vital sign data acquisition.

Technology Transfer

A commercialization effort is ongoing to license out the product to companies and investors which have already expressed interest. Safety and performance benefits are expected by applying this technology in the areas of law enforcement, fire fighting, geriatric patients, in and out-patient care, etc. Each application can be addressed with an appropriately designed specific suite of embedded sensors.

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The Wearable Motherboard

An Intelligent Garment for the 21st Century

Figure 1
Embedded optical fibers may be utilized for data transmission, phenomenological analysis, or display (such as adaptive camouflage).

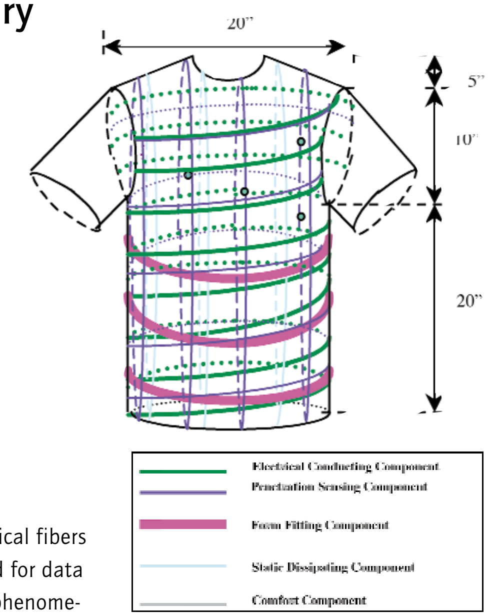

Figure 2
Schematic of the Woven Wearable Motherboard™

Project Summary
Research at Georgia Tech has led to the realization of the world's first Wearable Motherboard™ or an "intelligent" garment for the 21st century. The Georgia Tech Wearable Motherboard (GTWM) or the Smart T-Shirt (Figure 1) uses optical fibers to detect bullet wounds, and special sensors and interconnects to monitor the body vital signs during combat conditions. This provides an extremely versatile framework for the incorporation of sensing, monitoring, and information processing devices. The principal advantage of the GTWM is that it provides a systematic method of monitoring vital signs of humans in an unobtrusive manner.

Appropriate sensors have been "plugged" into the motherboard using the developed Interconnection Technology (Figure 2) and attached to any part of the individual being monitored, thereby creating a flexible wearable monitoring device. The flexible data bus integrated into the structure transmits the information to a monitoring device. The bus also serves to transmit information to the sensors (and hence, the wearer) from external sources, making GTWM a mobile information infrastructure. GTWM is lightweight and can be worn easily by any individual from infants to senior citizens. GTWM is applicable to telemedicine, healthcare monitoring of patients in post-operative recovery, the prevention of Sudden Infant Death Syndrome (SIDS), and the monitoring of astronauts, athletes, law enforcement personnel and combat soldiers. Woven and Knitted versions of the GTWM have been produced. The developed interconnection technology has been used to integrate sensors for monitoring the following vital signs: temperature, heart rate, and respiration rate. In addition, a microphone has been attached to transmit the wearer's voice data to monitoring locations. Other sensors can be easily integrated into the structure.

Technology Transfer
The GTWM has been patented by Georgia Technology Institute and is available for licensure through the School of Textile and Fiber Engineering.

Awards
In a Special Issue of LIFE Magazine—Medical Miracles for the Next Millennium, Fall 1998—the Smart Shirt was featured as one of the "21 Breakthroughs that Could Change Your Life in the 21st Century".

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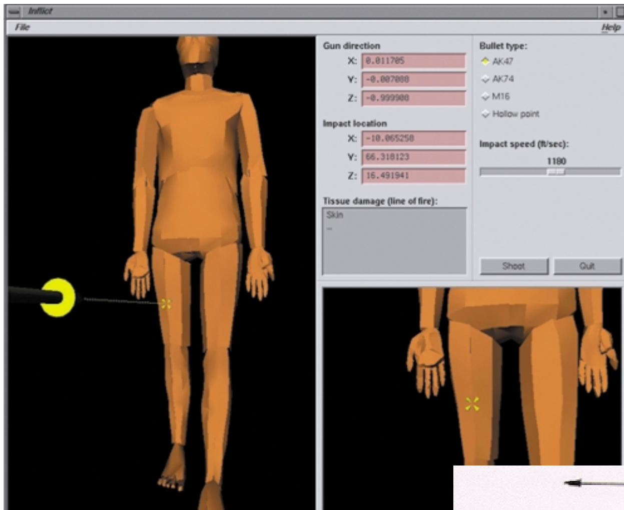
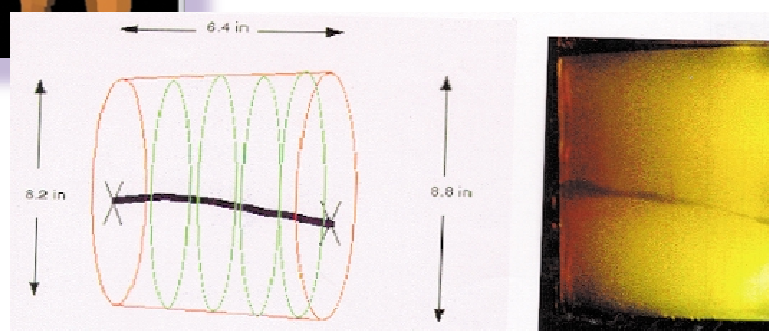
Ballistic Wounding Simulation



Simulation and Assessment of Musculoskeletal Trauma due to Missile Penetration

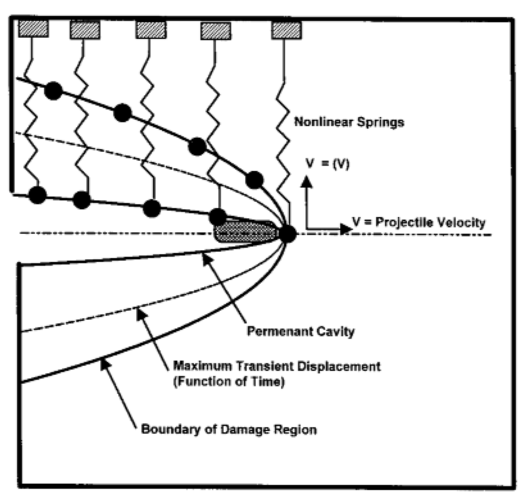


Wound track estimate of gel phantom derived from processed penetrant generated ultrasound

Project Summary

A software package has been developed that simulates tissue damage from small arm projectiles and fragments. The effort used different configurations of ordnance gelatin as surrogate materials to develop an analytical and experimental methodology that describes mechanical damage to human tissue from penetrating wounds. The assumptions employed were specific to the lower extremities and battlefield threats but could be relaxed to generalize the methodology to other body regions, other threats, and other types of wounds. The software package based on this methodology uses the NLM *Visible Human* database to predict tissue damage and bone interaction, including fracture mode and distribution of ejected bone fragments.

The algorithms and methodologies developed in this effort are being used by MRC for its development of a *Character Simulator for Battlefield Virtual Environments,* its bioeffects study in support of MRC's Development of a *Pulsed Chemical Laser*, and the signal processing algorithms in support of the Sensate Liner System for Combat Casualty care.



Technology Transfer

This effort has led to an additional $3.5M of DoD contract research and development. Sponsors have included the U.S. Army Soldier System Command in Natick, Massachusetts, the Joint Non-Lethal Weapons Directorate in Quantico, Virginia, and the U.S. Navy Research and Development Directorate of NOSSC in San Diego.

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Medical Smart Textile

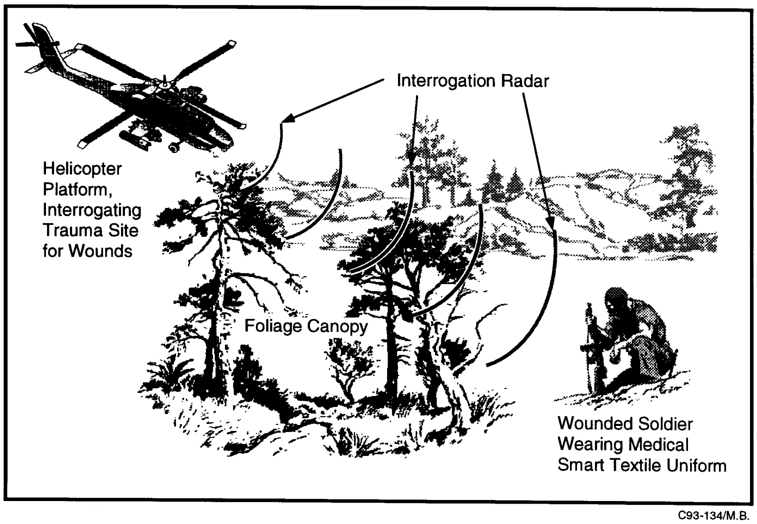

Figure 1
Medical smart textile worn by a wounded soldier in the passive wear-and-forget mode is being interrogated remotely by an illuminating radar for advance wound information.

Medical Trauma Assessment Through the Use of Smart Textiles

Project Summary
Medical smart textile, an innovation by Science, Math & Engineering, Inc. (SME), allows advance wound information to be gathered from a remote medical trauma site within the golden hour. Survival rates at military and civilian trauma sites decrease dramatically if medical attention is delayed for more than the golden hour. SME *medical smart textile* is an electrically conductive fabric possessing a cross-hatched network of conducting paths etched into the textile. Open wound information registers in the textile as holes that result from penetrating projectiles breaching the fabric. Interrogation of the textile for open wound information can occur passively, as a wear-and-forget fabric, or actively, as a wear-and-activate fabric. The passive mode of the textile is remotely interrogated by a radar for wound holes whereas the active mode of the textile senses wound holes as changes in conductor network resistance. Detection of holes by a radar in the passive mode was successfully demonstrated at the MIT Lincoln Laboratory indoor radar range.

Technology Transfer
The SME medical smart textile concept is currently being developed by the U.S. military as the *Sensate Liner Program.*

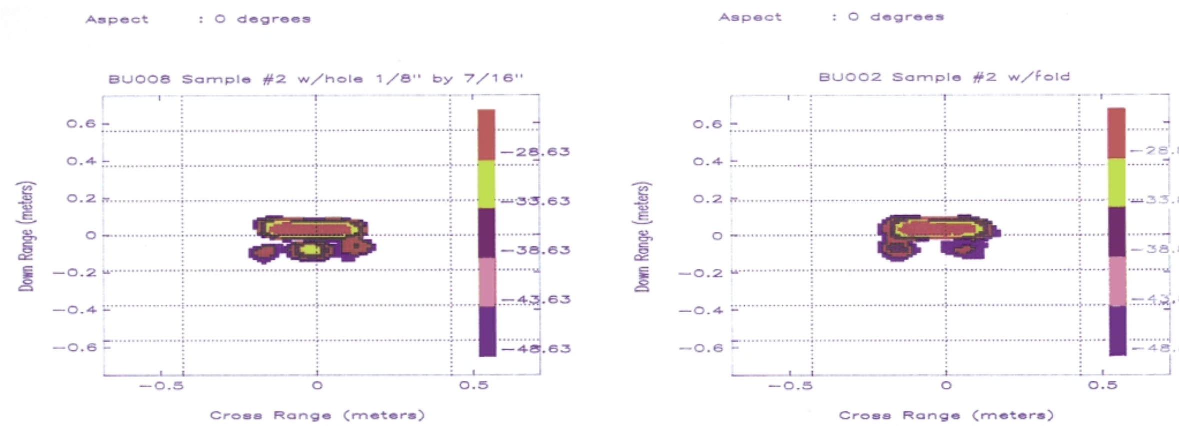

Figure 2
Comparison of the radar return from an electrically conductive *medical smart textile* containing a 3 caliber sized (1/8 inch) hole (left contour) to the radar return from the same textile without a hole (right contour). The central feature in the radar return on the left identifies the wound hole (measurements performed at MIT Lincoln Laboratory indoor radar range).

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Non-Invasive Burn Analyzer

Portable Neural Network-Based Burn Injury Analyzer Using Visible and Near-IR Spectroscopy

Project Summary

During this successful project, POC developed a compact, imaging, noncontact burn wound scanner. This prototype BurnAlyzer™ consists of a dual spectrometer burn injury analyzer and POC's proprietary spectral signal matching for recognition and testing (SSMART™) software. The BurnAlyzer and the SSMART software are shown on Figure 1. BurnAlyzer units were delivered to the Cedars-Sinai Medical Center in Los Angeles, CA, and to the University of Washington, Harbor View Medical Center in Seattle, WA, where the instruments were tested for their sensitivity, specificity, and accuracy in diagnosing the burned skin depth in animal models, and in clinical trials on burn patients. The animal testing demonstrated an overall accuracy of 95.7% with 0% false positives and 8.8% false negatives. In preliminary clinical trials, the BurnAlyzer was over 90% accurate in diagnosing the burned skin depth of partial- or full-thickness burns.

Technology Transfer

A patent application was modified to include use of the BurnAlyzer for diagnosing other tissue wounds. POC is discussing the licensing of this technology to the Mierce Tech Co. (Taipei, Taiwan) with Mierce's CEO, Dr. Charles Ho. EG&G Optoelectronics recently indicated an interest in co-developing this technology for U.S. and European markets with POC. Perkin Elmer has also expressed an interest in the BurnAlyzer.

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HO

Non-Invasive Lactate Sensor

Compact Fiberoptic Non-Invasive Vital Body Chemistry Sensor

Project Summary

There is a need for real-time unobtrusive monitoring of the vital body chemistry and general health status of military personnel during training and in hostile battlefield environments. The most accessible measure of a person's health at any given instant is his/her anaerobic metabolism rate (O_2 debt); that is, the changes in skeletal muscle and cerebral oxygenation. Not only is the knowledge of a person's metabolic state of vital importance in determining his/her ability to accomplish a given mission, anaerobic metabolism data can be used by "golden minutes paramedics" to save his/her life. Lactate level is an important indicator of oxygen debt. Lactate is a weak acid produced by cells when they break down glucose to produce energy by anaerobic metabolism.

Technology Transfer

A compact personal optic sensor for monitoring lactate via sweat metabolite analysis was developed, constructed, and tested. The sensor quantifies the change of the optical property caused by lactate chemistry. Our noninvasive lactate sensor measures minute changes of the lactate between 10 - 80 mM in near real time. Physical Optics Corporation is continuing development and final commercialization pathway following clinical trials and FDA approval.

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Non-Invasive CO2 and O2 Sensor

High Precision and Fast Response Medical Gas Diagnosis via Diode Laser Spectroscopy

Project Summary

There is a need to continuously monitor in real time the inspired and expired respiratory gasses. Such a device could be incorporated into the ventilatory system of the Life Support for Trauma and Transport (LSTAT) for combat casualty care. Development of a monitor prototype to accurately measure medical gases such as O2 and CO2 content in the expired air is the objective of this program (phase I). By using tunable diode laser absorption spectroscopy technique, Princeton Electric System (PES) has solved numerous engineering challenges and successfully developed a sensor prototype for measuring O2 content in various concentration range. This prototype provides fast response time (<300 ms), large detection dynamic range (~105), good detection accuracy and signal-to-noise ratio. In addition, the prototype possesses a graphic display feature for better waveform display and for easy user/instrumentation interface. Due to the nature of spectrally narrow bandwidth of the diode laser used, the detection scheme possesses an excellent interface-free feature for accurately measuring desired species. The expired air analysis for medical gas diagnosis requires a detection technique with fast response time (<300 ms) and high degree of accuracy for catching human breath-breath information. Considering this crucial requirement, optical detection based techniques probably are the best candidates for the purpose of the program. Tunable diode laser spectroscopy possesses its unique features of compactness, low cost, high detection sensitivity, and fast response time. In addition, its unique finger-print detection feature results in unambiguous detection for desired species.

Technology Transfer

The prototype sensor system was delivered to Walter Reed Army Institute of Research for evaluation and incorporation into LSTAT configuration.

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SCHODEK

Intelligent Bathroom

Inquisitive Bathroom Environments

Project Summary

Future directions in medicine are indicating that continuous, multiparametric monitoring of health status (vital signs, imaging, physiology, biochemistry, etc) will be enabled by unobtrusive, non-invasive sensors on micro and nano scale. Acquisition of these data and subsequent networking with intelligent decision support systems with real-time feedback will provide individuals information about their health, subclinical or clinical diseases, and status of their medications in order to proactively (preventive medicine) take measures to remain healthy. Key to such a scenario is the ability to acquire the important health data. One opportunity would be to embed sensors throughout the bathroom, the only place where a person privately does daily hygiene in a manner that the data could be acquired. Thus, sensors in the toothbrush could look at dental health, in the toilet could check for blood, protein, sugar, and medication levels, and in the shower ultrasound could be used for imaging, to mention a few opportunities.

Technology Transfer

This feasibility study reviewed the literature, and searched laboratories for devices currently being investigated in order to support such an infrastructure. There is only one manufacturer, Toto, Inc., of Tokoyo, Japan, which has prototyped any device: a toilet with sensors in an armrest for pulse and blood pressure. There are numerous micro-sensors and MEMS devices which are being developed to non-invasively monitor many of the requisite parameters; however, none are being embedded into bathroom appliances to do routine healthcare maintenance. A conceptual design of what sensors could be integrated is illustrated above. The conclusion of the study is that such a concept is possible; however, neither the scientific nor the commercial interest currently exist.

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Intelligent Garment

Development of a system for Remotely Assessing Trauma: "*Remote Triage*"

Project Summary
In May, 1995, Bio-Stimu Trend Corporation began development of a prototype system for assessing the physiological and diagnostic status of trauma victims. The heart of the Bio-Stimu Trend system is a garment with interwoven electrodes, which could be comfortably worn by field personnel. Preliminary tests of the garment indicate that it provides an efficient and effective way of measuring heart rate, respiratory rate and motor responsiveness in active people.

Transcutaneous Transducer Garments utilize bundled conductive fibers incorporated into full or partial body garments, which eliminate the need of wires and conventional electrodes. With the advantage of long-term comfort, no direct interface of skin and conductive electrode, this system provides a simple and effective means of monitoring or stimulation without impeding natural movement.

Technology Transfer
Since the inception in 1983, Bio-Stimu Trend Corp has been instrumental in the development and production of electrode systems for the conveyance of signals through the use of Transcutaneous Transducer Garments. Technology transfer will be through licensing agreements.

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Handheld Ultrasound

Telemedical Portable Ultrasound

Project Summary
This project involves the development of a sophisticated portable digital handheld diagnostic ultrasound (US) system with telemedicine capability for combat casualty care. The primary goal has been to provide diagnostic triage at forward echelon levels in order to decrease the incidence of exsanguination on the battlefield. The main focus has been detection of internal bleeding from blunt abdominal trauma (BAT). The handheld ultrasound unit (HHU) can be carried by a medic, incorporated into the "Trauma Pod," HMMV, Combat Support Hospital (CSH), and used with FAST units.

The cooperative effort between DARPA, the University of Washington, and three major corporations (Advanced Technology Laboratories [ATL], Harris Semiconductor, and VLSI Technology resulted in the development of an easy to use high quality self-contained battery powered US unit using ASICs (application specific integrated circuits) and weighing about 5 lbs (including batteries). The diagnostic quality and added benefit of color "power doppler" for visualizing blood vessels along with telemedicine capability allowed the project to significantly exceed the original goal of detecting internal abdominal bleeding (hemoperitoneum). Some of the additional diagnostic capabilities include gall bladder and kidney stones, appendicitis, fractures, thoracic trauma, cardiac tamponade, detection of foreign bodies (including plastic), vascular bleeding and disruption, and ectopic pregnancy.

The telemedicine capabilities have expanded the diagnostic capabilities both by allowing remote experts to aid in diagnosis and in the ability to direct the US examination remotely when needed. We now have the ability to get the diagnostic unit to the soldier/patient (rather than the patient to the unit) and to get the diagnostic information to the expert when needed, regardless of location. Telemedicine and compression with video codecs has been successfully tested including sophisticated satellite (using the ACTS mobile terminal [AMT] developed by NASA), ISDN phone lines, the Internet, and POTS (plain old telephone service). Specific techniques of compression (including wavelet) have been developed and tested. Clinical protocols have been developed for remote diagnosis for a number of clinical applications for use with and without telemedicine extending from novice to expert levels.

Technology Transfer
This project has resulted in the formation (spin-off) of a separate corporation from ATL (Sonosite) to market a commercially available model of the HHU with a wide range of clinical applications.

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MUSTPAC™ 3-D Ultrasound

Real-Time 3-D Ultrasound for Physiological Monitoring Imaging System

Project Summary

This project has developed the world's first ultrasound imaging system designed specifically for telemedicine. The MUSTPAC™ system (Medical UltraSound, Three-dimensional-Portable, with Advanced Communication) allows a patient to be scanned at any convenient location, then be diagnosed by an expert at a center of excellence anywhere in the world. This technology has potentially widespread application in rural, emergency, and military healthcare, resulting in both improved quality of care and reduced costs.

The uniqueness of MUSTPAC™ is that it allows diagnostically useful ultrasound scans to be taken by an operator with limited training, no diagnostic skills, and no expert assistance. This is accomplished by providing the operator with a simple "point-and-shoot" method for data acquisition. Using this method, the system scans a fairly large 3-D (three-dimensional) volume of the patient's anatomy at one time, without interpretation.

Scans in the form of 3-D volumetric datasets are sent over any standard digital network to a qualified diagnostician. The diagnostician then interprets each 3-D scan using a Virtual Ultrasound Probe that simulates a conventional real-time hands-on examination procedure. This allows the diagnostician to display arbitrary 2-D slices from the 3-D dataset simply by moving the probe as if he/she were interactively examining the patient. The Virtual Ultrasound Probe and corresponding screen displays are very natural to diagnosticians, leading to rapid acceptance and productivity.

Beginning in 1996, a series of prototype MUSTPAC™ systems have been developed to demonstrate and evaluate the concept of 3-D ultrasound telemedicine. These systems have been tested in a variety of environments, including a U.S. Army telemedicine network in Europe, a Mt. Everest climbing expedition, and several medical institutions in the U.S. Clinical studies are underway to evaluate MUSTPAC™ for routine application in rural and remote settings.

Discover Award

The MUSTPAC™ system was named winner of the prestigious 1997 Discover Award for Technological Innovation in the category of Computer Hardware and Electronics.

Technology Transfer

MUSTPAC is an add-on 3-D image acquisition and processing tool for use with existing diagnostic ultrasound systems. MUSTPAC systems are currently being produced as research prototypes. FDA 510(k) approval is expected in late 2000. The technology is available for licensing as a commercial product.

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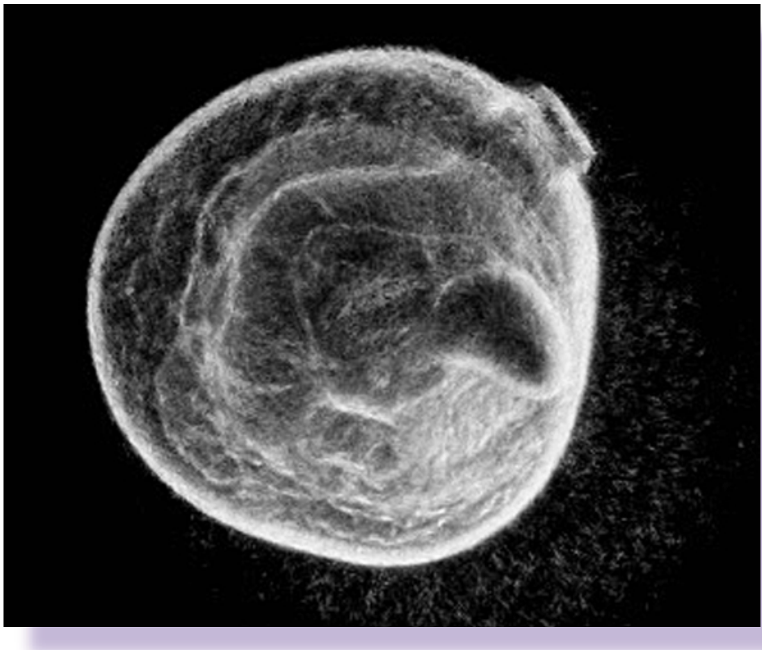
3-D Ultrasound Imaging



Project Summary

In conventional ultrasound, the sonographer essentially uses the transducer to "paint-in" a 3-D image of the anatomy into his/her mind as the transducer sweeps over the region of interest. Unfortunately only a select number of views are saved as individual slices for the final diagnosis. The remainder of the data viewed by the sonographer, including relative position of anatomy and surrounding structures, is lost. The 3-D Ultrasound Imaging system developed at Sandia National Laboratories attempts to capture this essentially lost data and use that data to improve on the basic methodology of ultrasound image formation for overall improved diagnostic benefit. The project has been partially funded through DOE as well as DARPA. Similar to CT and MRI, the system acquires image data, processes the data, and provides high quality slice and 3-D reconstruction images that can later be used by physicians for diagnosis and therapy planning. Full-thickness, slice images are provided as the standard format, similar to CT or MRI, which has been proven beneficial in diagnosis. Unlike CT and MRI, the system is small and portable. The resulting images are free of artifacts, shadowing, or limited definition provided by conventional ultrasound. Because the system stores the relative position of individual frames, all data is preserved for future manipulation, and individual slices can still be accessed. This can be most useful in complex cases in which the radiologist will often request special views of an area of interest. Because the system can utilize all aspects of ultrasound, it can potentially provide doppler information as an overlay to overall anatomy or provide 3-D doppler reconstructions. In summary, the 3-D Ultrasound Imaging system provides new and uniquely evolving ultrasound imaging with quality similar to CT and MRI and the benefits of ultrasound—portability, doppler, and relatively low cost. Applications in breast imaging, obstetrics, gynecology, gastroenterology, urology, musculoskeletal, cardiac, and neuroimaging as well as intracorporeal imaging are all areas that could benefit from this technology, especially as miniaturization, computing, and processing improve in the future.

Technology Transfer

The software is complete and the office to technology transfer at Sandia National Labs is seeking opportunities to license the technology.

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Combat Ultrasound

A High Performance 1.5D Array for Adaptive Beamforming with Low Cable Count

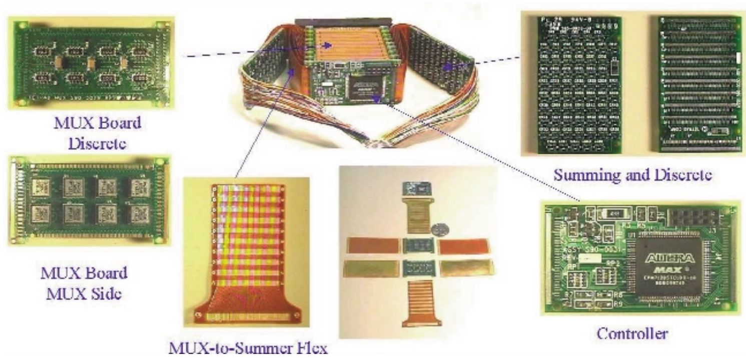

Figure 2
Multirow array with integrated multiplexing capability

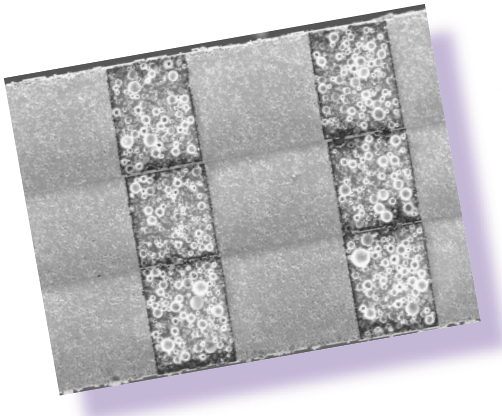

Figure 1
An SEM Photo of a 3-layer composite. Light gray is 183 m wide piezoelectric ceramic. Bubbles are microballoons in a polymer. Because of alignment and small bondlines, the performance of this material is substantially better than that of multilayer ceramic or of single layer composite.

Project Summary
The challenge in making a small handheld 3-D ultrasound is to obtain high resolution with a portable device. One method is doing adaptive beamforming.

The objective of this program is to develop and demonstrate a 1.75-D (multi-row) ultrasonic array for medical imaging capable of out-of-plane beam control and adaptive beamforming while retaining high spatial and contrast resolution along the beam axis. This should produce a substantial improvement in image quality that will enable new applications in combat casualty care and civilian trauma centers. It will also be of value in more traditional radiology applications. The array is based on layered composite technology with integrated electronics to reduce the cable count to or below that currently required for a 1-D array. The electronic architecture separates the out-of-plane from the in-plane focusing. Out-of-plane focusing and adaptive beam forming will be done on the array itself. Multiplexed subapertures are cabled to the host system where all adaptive corrections will be calculated and in-plane corrections will be applied. The goal of this program is thus to develop the array and electronic interface technologies that will enable practical utilization of in-plane aberration correction in 1.75-D, and, ultimately, in 2-D arrays.

During Phase I several technologies have been developed that have significant commercial potential. These include the development of the multilayer piezoelectric composite, the development of 1.75-D array technology, and the development of a chip set that can be used in the array or in more standard imaging systems. The multilayer composite has been demonstrated to improve both sensitivity and bandwidth in ultrasonic transducers. Transducers based on this technology should be commercially available within the next year. Tetrad is currently prototyping 1.5-D arrays for large imaging system manufacturers. The first product introduction is scheduled in 2000. Multi-row arrays with multiplexer chips integrated into the handle have been constructed and Tetrad is discussing the integration of the multiplexer and other chips developed under this program into commercial probes.

Technology Transfer
Tetrad is actively seeking additional customers for the multilayer composite, 1.5-D probes, and probes with integrated electrical components. More in-depth partnerships that involve licensing of these technologies and/or use of the chips are also possible. Partners interested in completing the original goals of the program would be welcome.

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Direct Digital X-ray System

Project Summary

The Direct Digital X-ray technology, funded in part by DARPA, is now being used in panels manufactured by GE and EG&G. In development for more than 10 years and at a cost of $100 million, the technology is now being used in a variety of commercial products.

Direct Digital X-ray is an enabling technology that propels the world of X-ray imaging into the digital information age. Digital imaging has tremendous benefits to the user, both military and commercial.

It eliminates the delays and hassles of processing, handling and archiving film and the associated chemicals and, with digital archiving, reduces the space required and the complexity of retrieving images. Film handling accounts for approximately 50% of some exam times, so the improved workflow provides the potential for substantial exam time reduction.

Digital detectors also provide the ability to instantly view an image. Instant viewing and wide dynamic range mean fewer repeat examinations. Meanwhile, a digital image can be immediately sent to a distant location for consultation.

A digital image has higher sensitivity and detective quantum efficiency (DQE), which means it captures more diagnostic information at a lower dose, potentially reducing patient exposure.

Technology Transfer

The U.S. product introduction is the Revolution XQ/i Digital Radiographic Imaging System. It is a floor-mounted head-to-toe system that is optimized for chest imaging. Some of the leading military and non-military clinicians have begun receiving their pilot units. Early sites include Duke University Medical Center, the MD Anderson Cancer Center at the University of Texas, The Baltimore VA Hospital, and the National Naval Medical Center. One of these sites is already imaging 50 to 80 patients per day using this new tool.

Domestically, the next products to incorporate the digital technology are mammography, general radiography, and cardiology. The Full-Field Digital Mammography product, while not yet through FDA clearance in the U.S., has begun to ship internationally.

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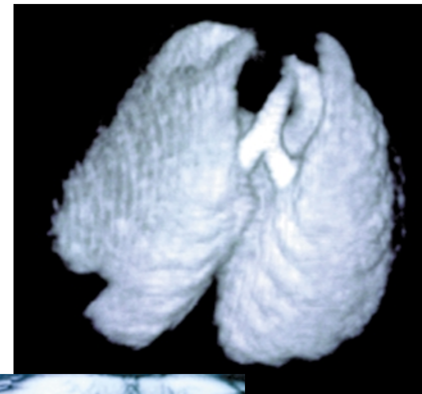
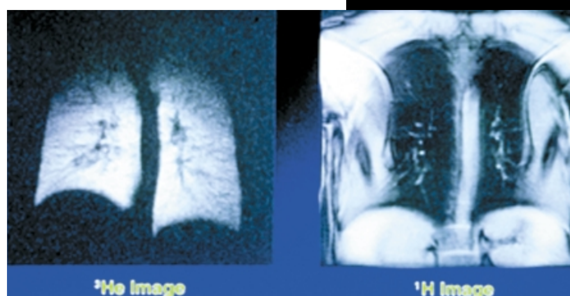
Noble Gas-Enhanced MRI



Laser Spin Exchange Polarize He-3 and Xe-129 for Diagnos of Gas-Permeable Media with Nuclear Magnetic Resonance Imaging



Project Summary

The quality of diagnostic imaging depends upon the resolution of the image, and, for magnetic resonance imaging, the important variable is the electronic spin polarization. Major advances in the physics and technology for the production and utilization of laser-polarized He-3 and Xe-129 have resulted from DARPA sponsored research. A high-capacity polarizer and accumulator for Xe-129 has been developed and has been successfully transferred to the commercial sector. We have developed a powerful new method for imaging the three-dimensional distribution of the electronic spin polarization of the alkali-metal vapors used for spin-exchange optical pumping of He-3 and Xe-129. Absolute electronic spin polarizations are obtained. We have demonstrated that the intrinsic spin-exchange efficiency for polarizing He-3 is ten times better with optically pumped K vapor than with the currently used Rb vapor. Using equipment with key technological features resulting from this work, collaborators at the University of Virginia Medical School now make routine use of He-3 lung images of patients scheduled for lung resection surgery.

Technology Transfer

Gas polarization technology has been transferred to Magnetic Imaging Technologies, Inc., a small startup company recently acquired by Nycomed Amersham, an international healthcare company.

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Telepathology Database

"Development and Demonstration of a Networked 3-D Imaging, Databasing, and Communications System: Phase I"

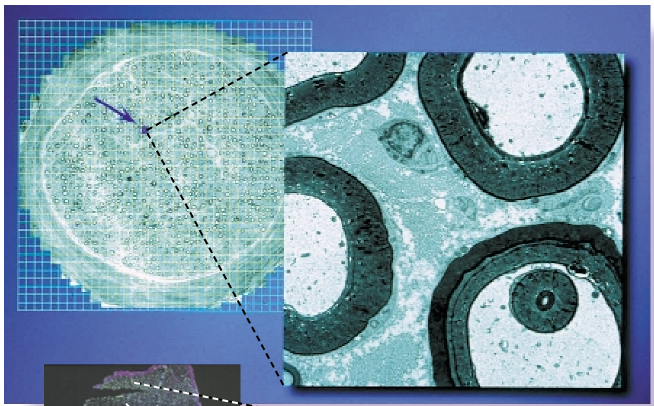

Figure 1
Electron microscopic photo-mosaic image of over 1225 electron microscopic images of the Seural Nerve.

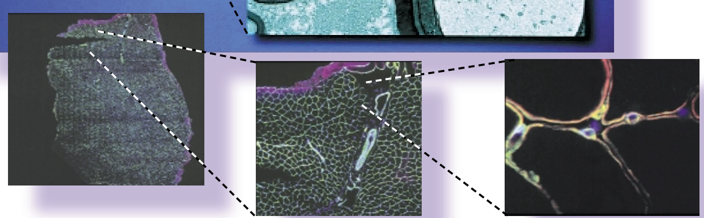

Figure 2
3-color fluorescence light microscopic images of rat EDL muscle fiber bundle

Project Summary

This two-year project involved creation of WWW-enabled telepathology capabilities for use by military and civilian researchers and clinicians. A virtual slide capability that was the prototype for several current telepathology platforms, ranging from Electron microscopic to 3-D fluorescence imaging platforms. Image processing applications were developed for tiling images in 2-D and 3-D. Color feature extraction methods to identify potential satellite cells in muscle tissue were developed. Initial software was produced by ERIM (Ann Arbor, MI), which was the first group to develop and apply these techniques to SAR and LANDSAT imagery. Later, more portable codes were developed and are now in use. All capabilities are addressable by Internet connection, which can be provided using Java applet software modules embedded in a Netscape delivery platform. Tests of ATM OC-3 network transmission (155Mbit/s) were performed between University of Michigan (UM) and Naval Research Laboratory (NRL) to determine the enhancement of throughput as the image datasets were as large as 2.5GB. Results of these tests showed a transmission efficiency of only 3% owing to computer overhead in early packetization protocols. Extensions to M-PEG video streams are possible and planned in the future. Although expensive UNIX workstations were employed for this project, this work can now be performed on inexpensive PC or Mac systems. An object-oriented database methodology was developed to track and store for reacquisition imagery in the virtual slide mosaics and extracted features in the imagery. Valuable input and direction was obtained by Col. R. Becker, M.C. (USAF) Armed Forces Institute of Pathology (AFIP). Programming efforts of Mr. Alex Ade and Mr. Justin Laby are gratefully acknowledged. Microscopy and figures by Mr. Walter Meixner.

Technology Transfer

This project led to follow-on work on two DARPA Biological Warfare Defense Program (BWD) grants (R. Kopelman and J. Baker, University of Michigan; and others nationally) and NIH contracts (Athey-NLM Visible Human). Extensions of the virtual slide and processing capabilities are being evaluated currently by the NSF ITR program. Some work was transferred to Pittsburgh Supercomputing Center (PSC) for evaluation by Mr. Art Wetzel, and is being considered for use in his DARPA telepathology program efforts (HINS Subcontractor to Professor M.J. Becich, UPMC). It is anticipated that this work will be transferred to Uniformed Services University of the Health Sciences (Professors Rigamonti and Kaufmann).

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Virtual Endoscopy

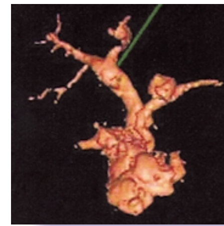

Figure 2

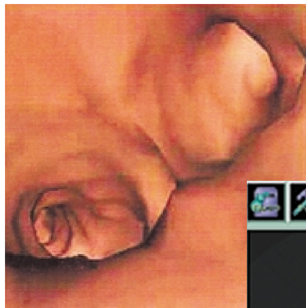

Figure 3

Virtual Endoscopy Software Program

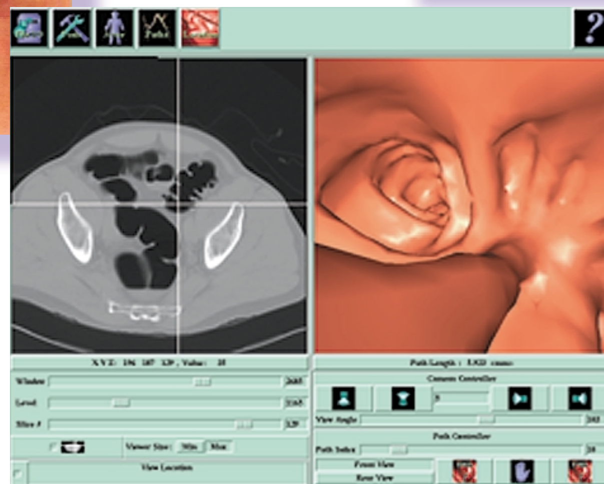

Figure 1

Project Summary

Virtual endoscopy is the technology of using standard CT scans of the body with sophisticated software to create full 3-dimensional images of individual organs. These images can be "flown through", giving the same view as that of a real procedure with a video endoscope.

The Brigham Women's Hospital is using Virtual Endoscopy Software Application (VESA) developed with General Electric Corporate Research and Development (GECRD). VESA generates a 3-D model with surface rendering method and a fly-through trajectory.

In virtual endoscopy (VE), staying inside the lumen caused the following difficulties in observing the image. It was hard to navigate VE completely in long hollow organs (e.g. colon); in addition, information of the exact location was not available when the observer tried to match the findings of VE with 2-D images. VESA is oriented to improve these weak points of VE. The interface of VESA (Figure 1) has two windows, providing the option of concomitantly viewing images of 2-D, 3-D and VE. Between these two windows, a point-to-point correspondence is established and the exact location is continuously updated. The operator can move and rotate the camera for any direction. We applied VESA to clinical cases including colon, aortic dissection (Figure 2) and biliary duct (Figure 3). VESA enables a trajectory to be generated automatically. Simplifying the model and fly-through generation procedure will make VE more practical.

Technology Transition

Accomplished by incorporating the VESA as part of the full software package that is available on General Electric CT scans.

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