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TRANSCUTANEOUS EAR DOPPLER BLOODFLOW MEASUREMENT SYSTEM

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NOTICES

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The voluntary, fully informed consent of the subjects in this research was obtained in accordance with AFR 169-6.

The Office of Public Affairs has reviewed this report, and it is releasable to the National Technical Information Service, where it will be available to the general public, including foreign nationals.

This report has been reviewed and is approved for publication.

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The contractor was unsuccessful in developing an acceptable and reliable ear Doppler sensor for use on the centrifuge as an indicator of impending loss of consciousness. Information for this special report has been extracted from an earlier report.

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SUMMARY

After 2 years of a 4 year research program 57% of the proposed money was expended without significant progress toward the development of an ear Doppler sensor system. USAFSAM/VN 6.2 funding was discontinued for several reasons: 1) 6.2 contract dollars were less than anticipated in FY 87 and 88, and 2) SAM/VN personnel felt that the return on investment for this effort was not adequate for continued funding.

TRANSCUTANEOUS EAR DOPPLER BLOODFLOW MEASUREMENT SYSTEM

The objective of this research effort was the design, development, and implementation of a transcutaneous, pulse-gated Doppler ultrasonic measurement system for monitoring of bloodflow to the head. The projected application for the ear Doppler was predicting, detecting, and monitoring G-induced loss of consciousness (GLOC) in high-performance aircraft crewmembers. The non-invasive system would be in the form of a prefitted hearing-aid-type device, containing the flow-sensing element positioned to monitor bloodflow in the anterior auricular branch of the temporal artery.

METHODS

The hearing-aid sensor was to be molded to the specific ear characteristics of each wearer. A single crystal Doppler transducer or transducer array insert would be placed into the mold and oriented to measure both bloodflow velocity and vessel dimensions from the temporal artery branch. Simultaneous measurement of these parameters would permit estimation of volume flow to the head. The signal conditioning instrumentation would consist of a pulsed-excitation Doppler measurement system. A precision crystal oscillator would provide stable transducer excitation. The proposed system would consider excitation frequencies in both the 7-8 and 20 MHz ranges to evaluate signal resolution and attenuation tradeoffs to determine optimal excitation frequencies. The receive circuitry would incorporate a tunable radio frequency (RF) front end to increase the signal-to-noise ratio, reduce the overall bandwidth required to process the signal, and minimize the effects of external RF interference. Hybrid analog/digital instrumentation would be employed to increase overall system efficiency and provide interfaces to external equipment.

PROGRESS

First Year (FY 1986)

A baseline theoretical evaluation and review was completed to define parameters and review potential instrumentation systems which might be applicable. Guidelines were set for a coordinated program including ultrasonic sensor and instrumentation concerns, measurement techniques, mathematical modeling, in-vitro calibrations, and computer simulations.

Considerations were made for eventual study of the relationship of temporal bloodflow to brain oxygen transport. The potential for the use of dual flow measurements to mathematically derive arterial pressure by means of the simultaneous solution of the one-dimensional continuity and momentum

equations was also evaluated. Anatomical and material properties and characteristics of the ear and head required for these computations, as well as sensor design and placement, were defined.

A baseline feasibility study of anatomical considerations for placement of probes and sensors was conducted. Contacts were made with suppliers of anatomical models of the head with the intention of determining the optimum sensor configuration, understanding tissue and material transmission properties, and designing an in-vitro calibration system capable of repeatable, accurate simulation of temporal vascular properties as seen from inside the ear.

Representative anatomical models were obtained. The models were considered for use as phantoms for simulating tissue propagation speeds, absorption coefficients, and temporal vascular geometries found in the region of the ear and head. The ability to vary those parameters to represent characteristics of different subjects would allow rigorous evaluation of any measurement/sensor system developed under this program. Preliminary tests confirmed the feasibility of the ear system and emphasized the problem of sensor placement in locating the artery from within the ear.

The use of impedance plethysmography was suggested as an alternative measurement technique for the GLOC system. The impedance technique offers the possibility of measuring changes in blood volume and its relative concentration. The sensitivity to shifts in the orientation of sensors and other artifacts would be minimized. Possible disadvantages using the impedance system were also discussed. It was suggested that a parallel program of animal studies be undertaken to rigorously investigate the feasibility of this technique. Three alternative instrumentation configurations were recommended, in addition to the pulsed-Doppler system originally proposed.

The three alternative configurations recommended were:

1. Single crystal continuous wave (CW) system (ear mounted).
2. Electrical Impedance Cephalography.
3. Photoelectric Plethysmography.

Efforts to design an ear-mountable Doppler sensor began with a survey of commercially available hearing-aid manufacturers to review fabrication techniques and apparatus. Configurations evaluated ranged from the generic earphone-type to custom, individually molded versions. It was quickly ascertained that, because of required acoustical coupling, and to maximize the chronic applicability with minimal artifact, the custom molded system presented the only viable option.

Members of the project team visited several custom hearing-aid manufacturers/fitters to have ear molds made and observe the molding techniques. Materials for constructing the ear molds were purchased for use by the project team in making test molds of Ames Research Center (ARC) volunteers. Three single-channel 5 MHz CW flowmeters were constructed using the design employed for the initial breadboard prototype. Ear molds were made for five members of the ARC project team for baseline engineering evaluations. Observations of the five test molds clarified two important points: (1) Mold

casting and sensor placement is an art requiring extreme care by two skilled individuals. (2) Vascular geometries (angle, depth, and location) were significantly different with different individuals. Sensor placement and vessel location procedure needed to be simplified. Vessel movement during high $+G_z$ studies may alter sensor-vessel alignment, and could require different transducer characteristics or arrays. Projections were made for continued sensor and instrumentation requirements, and initial planning began for the second year efforts.

Second Year (FY 1987)

Sensor development efforts during the second year concentrated primarily on refinement and enhancement of the ear-mounted Doppler probe for use with the single-channel CW Doppler instrument. In-depth analyses of the first sensors were made with respect to sensitivity, physical dimensions, fabrication techniques, and acoustic matching.

Adding a quarter-wave matching layer to the front surface of the transducer allowed crystal operation over a larger range of excitation frequencies, thus minimizing the need to tune the Doppler circuitry to each crystal. Alternatives would be to tune the instrumentation or take extreme care to construct crystals which are at their maximum efficiency at the preset flowmeter excitation frequency. Quarter-wave matching was accomplished with a mylar faceplate.

Ear molds and sensors were made for 4 U.S. Air Force School of Aerospace Medicine (USAFSAM) centrifuge subjects. Control measurements from the 4 centrifuge subjects revealed that the temporal artery and vein in 1 individual was suspected of being transposed. This situation accentuates the need for a range-gated, directional, pulsed-Doppler system, with possibly some sort of transducer array or scanner assembly.

The centrifuge subjects were instrumented for ECG as well as temporal ear Doppler flow. The front-end CW system, containing the exciter/demodulator, was mounted on the centrifuge and connected to the ear sensor. Frequency-shifted Doppler audio and analog voltage outputs were brought out through slip rings to monitoring equipment in the experimental control room. The audio signal was amplified and made available to speakers so that pulsatile flow could be heard by observers. The analog signal was input to an analog chart recorder for correlation with the other signals. In addition to the analog flow and ECG outputs, reference signals from the light bar as well as $+G_z$ were simultaneously recorded on the chart recorder.

The subjects were exposed to 1G/sec $+G_z$ profiles, up to a maximum of 6 G. The anti-G straining maneuver (AGSM) was performed to increase cerebral blood flow. Increases and decreases in flow were observed during initiation and cessation of the AGSM, and a definite reduction of flow was seen as $+G_z$ increased. The flow recordings were correlated with peripheral vision limits measured from recordings of data obtained during these tests.

A significant problem encountered with the ear Doppler system during the USAFSAM experiments was ground loop interference with the ECG instrumentation on the centrifuge. This interference was found to be due to the Doppler

crystal being in electrical contact with the subject. Upon analysis, the problem was attributed to an anomaly in the transducer fabrication procedure. Briefly, the original procedure entailed attaching the cable electrodes to the crystal, covering the back of the crystal, quarter-wave matching on the front surface, and then sealing the entire unit to isolate the crystal from body contact. Because some rough edges were seen on the crystal on final inspection, the edges were sanded smooth to avoid possible damage to the ear. When the edges were sanded, the coating material was removed and the crystal surface was exposed. This problem was easily corrected by sanding first, then coating, a procedure which has since been adopted.

Another significant baseline test of the ear Doppler system has since been conducted by the project team at ARC. Simultaneous measurements were obtained with the ear Doppler and the L&M 1012 transcutaneous blood flowmeter using a temporal bloodflow sensor. No electrical interference was seen between the two units. The outputs of the two devices correlated quite acceptably when flow was increased and decreased by performing partial carotid occlusion and the AGSM. The temporal flow parameter should be added to the centrifuge measurement suite during future USAFSAM evaluations.

Based on observations of instrumentation performance during the USAFSAM initial centrifuge tests, the prototype single-channel CW measurement system was modified to optimize its performance. The improved system has internal capability for varying the exciter power and fine tuning of the excitation frequency to optimize transducer performance. Precision electronic components assure stable operation. The frequency-to-voltage converter was redesigned and precisely calibrated. The flowmeter was repackaged into an improved, ruggedized system capable of extended centrifuge operation and delivered to NASA. This process effectively completed the initial development efforts for the single crystal CW system, pending further $+G_z$ testing.

Baseline planning and preliminary specifications for a pulsed-Doppler system was also begun in this work unit. The design approach was based upon the premise that either a synchronous array or scanning-type transducer assembly may be needed, especially in the initial development phase. Accordingly, a multiple-channel system has been purchased (Valpey-Fisher VF-1).

NASA SUMMARY AND RECOMMENDATIONS

The initial field tests have shown that the ear Doppler system has definite possibilities for GLOC measurement applications. Placement of the sensor in the ear may eliminate or minimize problems encountered with other physiologic measurement systems. Primary concerns are accuracy of measurement and correlation with brain bloodflow/oxygen transport in the operational, tactical, aerospace environment. Other major considerations are ease of placement, alignment of the sensor, positioning and movement at high $+G_z$, and long-term operation (4-8 h) without acoustic coupling gel. The single crystal CW system has functioned adequately and has important implications for continued sensor development.

Two very important recommendations have evolved from this continued sensor development work. The first recommendation is to develop the originally proposed pulsed-Doppler flowmeter system. The multichannel pulsed-

Doppler approach addresses the problems of sensor fit and orientation, vessel alignment, and chronic flow monitoring during G-induced motion in actual and simulated operational environments. In addition, the pulsed-Doppler system would permit depth and vascular dimensional resolution, allow measurement of actual volume flow, and provide a direct pathway to correlation of head bloodflow with brain oxygen transport.

The second recommendation is to develop controlled, standardized, acoustical phantoms and in-vivo calibration and characterization apparatus. This procedure would facilitate rigorous testing of sensors and hardware and allow detailed characterization of various configurations.

Because of the reorganization of the NASA-Ames Life Sciences Division, it is not presently known if this program can be supported in the future. Should interest arise for continuation of the program, engineering support is available through in-house and contractor resources.

The above information was extracted from a Final Technical Progress Report from NASA-Ames Research Center, dated 30 August 1987. The report period was from March 1985 to August 1987.

IN-HOUSE COMMENTS

1. Contractor had proposed and was expending time and money on various other techniques before adequately developing and testing the original proposal for an ear Doppler system.

2. The failure of the prototype ear Doppler system which was tested at USAFSAM could have been prevented if the contractor had tested the equipment at their facility on their own centrifuge or even in their laboratory.

3. When the expertise and experience of the personnel involved in this contract with Doppler flow technology are considered, the product tested at USAFSAM after 2 years of development and considerable expenditure of money was very basic, undeveloped, and preliminary.

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