

XIV. Miscellaneous

Foreign Body Reaction in the Lung to Intravenously Injected Biomaterials

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Sponsor: Veterans Administration Rehabilitation
Research and Development Service

This is the final report on a project in which we have defined a nonsurgical model system for evaluating the cellular inflammatory response to biomaterials embolized to the mouse lung. This system also has proved useful for evaluating the effectiveness of anti-inflammatory agents at various dosages and time periods. The test system consists of divinyl benzene copolymer beads measuring 45 to 53 micrometers in diameter that lodge in the arterioles of the mouse lung after intravenous injection.

Both early and late stages of granulomatous inflammation were observed by electron microscopy progressing from the presence of a very few polymorphonuclear leukocytes at 3 hours to granulomas maximum in size after 48 hours and composed of both polynuclear and mononuclear leukocytes. Granulomas older than 8 days were composed of mononuclear leukocytes almost exclusively. The rate of granuloma formation was quantitated in paraffin sections by tracing the bead and granuloma and measuring the areas with a digitizer attached to a microcomputer. The measurements were stored on a floppy disk, and data from similar experiments merged and analyzed with a statistical program.

This basic model was used to compare the bioreactivity of such materials as poly D, L-lactide (used for drug transport) and various formulations of bioglasses (used in joint replacement). The system was quantitatively useful in evaluating the relative effectiveness of both steroidal and non-steroidal anti-inflammatory agents.

Flexible Glow Discharge Polymer Leaching Barriers

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The investigator proposes the deposition of a new polymer onto the surface of a bulk polymer using the glow discharge plasma technique in order to prevent the leaching of plasticizers from the bulk polymer. This project is aimed at the preservation of the physical properties of a polymer that will be placed in service. The investigator proposes to improve the properties of the new polymer by varying its crosslink density. The efficiency of the hydrocarbon plasma polymer as a barrier to leaching of plasticizers from the bulk polymer will be correlated with the degree of crosslinking and the chemical nature of the new surface. It is anticipated that this technique will be valid for coating the inside of small vessel prostheses.

Microsurgical Techniques Applied to Orthopaedic and Hand Surgery

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We have completed the dog experiments for the second half of the program titled Microsurgical Techniques Applied to Orthopaedic and Hand Surgery. We are reporting the current status on 48 canine experiments studying the radiographic, angiographic, and blood flow data in 48 paired hindlimb orthotopically placed tibia autografts. Forty-eight skeletally mature beagles had both hindlimbs operated on simultaneously. The nutrient artery of the tibia was dissected free using an anterolateral approach. Transverse osteotomies were performed to obtain a 4-cm tibia graft. On the vascularized tibia side, the periosteum was left intact although all muscle attachments were freed. The graft blood flow was retained through the nutrient vessel providing endosteal circulation. The medullary blood flow to the isolated graft was measured using hydrogen washout technique. The contralateral nonvascular graft was harvested similarly except that the nutrient vessels were cauterized and

the periosteum stripped. A seven-hole compression plate was used to rigidly fix both osteotomies on each tibia. Eight dogs were killed at 1 week, 3 weeks, 6 weeks, 3 months, 6 months, and 1 year.

At the conclusion of the experiment, the animals were restudied with graft endosteal blood flow measured using the hydrogen washout technique and then after sacrifice, the perfusion of each limb with barium sulphate-prussian blue mixture via the femoral artery. X-rays were taken postoperatively, at four weeks, and at kill. Radiographic analysis consisted of measurement of graft cortical width, graft width, presence of periosteal and endosteal callus, callus bridging, obliteration of the loosening osteotomy line, and medullary recanalization. Angiographic assessment determined vessel patency and the extent of vascular ingrowth invading the graft.

Our preliminary results have shown that all animals tolerated the procedure and were weight bearing within 2 days postoperatively. All animals were killed on schedule. Vascular grafts demonstrated earlier laying down of periosteal callus (75 percent at 3 weeks) and endosteal callus (81 percent at 3 weeks) as compared to nonvascular grafts (31 percent and 44 percent, respectively). At 6 weeks, 69 percent of vascular grafts showed callus bridging the osteotomy, compared to 19 percent of nonvascular. At 3 months, 87 percent of osteotomies of the vascular side healed and 75 percent had medullary recanalization, while only 43 percent of the nonvascular graft osteotomies healed and 36 percent recanalized. At 6 months, the recanalization rate was 86 percent versus 50 percent vascular to nonvascular.

The degree of osteoporosis measured by changes in cortical width from surgery to kill differed between the groups. The nonvascular graft showed a steady decline in cortical width to -34 percent at 6 months compared to -9 percent in the vascular graft. A vascularized graft blood flow peaked at 3 weeks then decreased and stabilized by 3 months. The blood flow to the nonvascularized graft increased linearly up to 3 months. At that time and thereafter, flow to the vascular and nonvascular grafts was similar. The invasion of vascularity from either end of the graft progressed linearly, but at markedly different rates. The nonvascular graft had vascular invasion at a rate of 0.36 cm per week while the vascular graft was 0.94 cm per week. This increase leveled off following 3 weeks.

We have demonstrated a significant advantage of a vascularized bone graft over a nonvascularized bone graft and the ability to lay down callus, and then the union rates, when bridging large idaphyseal defects. The nonvascular graft showed a greater degree of

osteoporosis with time. The increased blood flow to the vascular grafts in the first 3 weeks postoperative seems to be due to a faster rate of vascular invasion across the osteotomy rather than hypertrophy of the nutrient vessels. Segmental bone grafts appear to heal in a fashion similar to segmental fractures, and this process is accelerated in the vascular graft as compared to the nonvascular graft.

A Program for Evaluation and Monitoring of the Dysvascular Patient

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The technique of cutaneous pressure photoplethysmography (CPP) reflects physiologic tissue perfusion and does not depend directly on the shape of the arterial pulse of the trunk arteries. As such, this instrumentation may be useful in predicting a successful level of amputation as well as the results of revascularization procedures. In an attempt to determine the usefulness of this technique, we have evaluated a series of patients with atherosclerotic occlusive disease of varying levels of severity and a series of subjects without incidence of occlusive disease.

Twenty-five patients and nine subjects without vascular disease have been evaluated. To evaluate the cutaneous pressure required to maintain a healed stump, 10 of the 25 patients were postoperative amputees. They ranged in age from 35 to 78 years (mean: 63.4) with a follow-up of 3.0 ± 3.4 years. They were all below-knee amputees: five were diabetic and five non-diabetic. Five of the 25 patients were scheduled for revascularization procedures for disabling claudication. They ranged in age from 50 to 70 years (mean: 57) with a follow-up of 3 ± 1.2 months. The remaining 10 patients were prospective amputees and ranged in age from 53 to 76 years (mean: 66.4) with a follow-up of 4 ± 3.1 months. The nine normal subjects ranged in age from 23 to 67 years (mean: 44.4).

In the retrospective amputees, CPP measurements were made at the stump; in the prospective patients and normals measurements were made at four locations: 10 centimeters proximal to the knee joint, at mid-calf, over the dorsum of the foot, and at the chest.

CPP senses the blood flow in the skin at various

skin-bearing pressures using a handheld probe. The photoplethysmograph consists of a sensing probe containing a small light source and a photosensitive cell that responds to light reflected from the cutaneous vascular bed. The photoplethysmograph, connected to a recorder, prints out a permanent waveform. The skin-bearing pressure probe is calibrated using a known force loading on the bearing surface of the probe. The skin-bearing pressure is shown on a digital display directly in mm Hg while the waveform is printed.

The probe initially is placed at the site desired and a waveform is obtained. With the manual application of gradually increasing pressure, the waveform is obliterated. Pressure is then gradually released and the pressure reading at the point where the photoplethysmographic waveform returns is recorded as the cutaneous pressure.

Most techniques of blood pressure measurement in the extremities are designed to measure pressure in the main arterial pathway. For example, Doppler segmental pressures record systolic pressure at various levels of the extremity by means of a probe placed over an artery, most frequently the posterior tibial artery. The technique of cutaneous pressure photoplethysmography (CPP), however, does not entail use of a main artery. The basis of this technique, similar to that detailed by Holstein, is measuring skin perfusion pressure as the amount of external pressure required to halt isotope washout. Increases are seen in tissue perfusion pressure, as well as in the venous pressure and the microcirculation in general, in an attempt to overcome an applied external pressure. Blood flow ceases with sufficient external pressure and tissue pressure becomes zero, thus making venous pressure equal to arterial pressure. The external pressure at this point is a reflection of the pressure head in the main supply artery. Thus, if local venous pressure approximates zero when external pressure is applied, that external pressure, in mm Hg, is a measure of the local perfusion pressure.

In normals, there is no gradient in cutaneous pressure from the chest to the dorsum of the foot; cutaneous pressure at each level of the leg was higher than that of the chest. In patients with vascular disease, marked gradient in cutaneous pressure occurs from the chest to the dorsum of the foot. Cutaneous pressure is much lower in the presence of rest pain, gangrene, or ulceration than with intermittent claudication. A cutaneous pressure of about 50 mm Hg is required to assure wound healing.

CPP is effective in differentiating normals from diseased patients, the severity of the vascular disease, and the optimal level for amputation. This study

is ongoing; a preliminary report on the use of CPP has been submitted for publication.

A Life-Span Approach to Product Design and Development for the Aging Population

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Problem—The demography of the United States is changing rapidly as the older segment of the population increases. As a result, the needs, wants, and capabilities of the average user are changing too. This will soon necessitate the reassessment of the standards by which products are now developed and evaluated. The human factors profile currently used by designers is based on the ergonomic and anthropometric characteristics of a male 21-30 years old. Less than 10 percent of all older adults match this profile. There is a need for a human-factors profile that takes into account the human values and the physical characteristics of the aging population.

Hypothesis—We hypothesize that technology which is developed through an interactive process and coupled with an approach to design and development based on a lifetime continuum, will be more appropriate to, and therefore more accepted by, the end-user population. This interactive process requires user involvement at all stages of the development cycle. It is believed that user-focused research will insure a well-defined need statement, which is necessary to optimize the relationship between human and machine and will aid in the diffusion process.

Approach—The Interactive Evaluation Model is used to focus on a life-span approach to product design and development. The project seeks to:

1. Involve student design engineers and older people in intergenerational needfinding and design;
2. Provide students with a broader perspective to design and development;
3. Develop methodologies to better educate engineering design students to meet the needs of older users;
4. Develop a model from structuring communication between users and designers;

5. Develop criteria for evaluation of marketed assistive devices;
6. Provide feedback to manufacturers of assistive devices;
7. Facilitate interaction between academia, industry, and government; and,
8. Identify new projects which promise to benefit the aging through the application of microcomputer technology.

Status—The VA RR&D Center and the Stanford University Mechanical Engineering Design Division have collaborated on two student projects in the past year. Both were designed to highlight the needs of the elderly and to educate the students in a life-span approach to design. In one of the VA/Stanford projects, the interaction between academia, government, and industry was of primary concern. This interaction is continuing as the manufacturer considers the student ideas in the upcoming redesign of their product.

In the evaluation effort, retired professionals are involved in the identification of needs and definition of appropriate technology for their peers. Currently a computer class at one of the local senior centers (average age of the programmers: 69) is helping in the evaluation of a commercial robot for use by the infirmed. Other seniors are serving as advisors and community liaisons for a project in "needfinding" at Stanford. The results of this research were scheduled to be presented at the 30th Annual Meeting of the Western Gerontological Society in March of 1984.■

Rehabilitation Engineering Center for Product Evaluation

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Evaluation of technology is the core area of study for the Southwest Research Institute-Rehabilitation Engineering Center, which was funded in May 1983. The center's primary mission is to test, evaluate, and disseminate information concerning the suitability and application of new rehabilitation equipment to rehabilitation clinicians and consumers.

The center has accomplished a number of tasks during its first year of operation leading to the establishment of a viable center for product evaluation. These tasks include an international assessment

of prior rehabilitation evaluation experiences, development of a standard methodology for product evaluation, and participation in a cooperative process for selecting evaluation items.

Two product evaluations were begun. These products are the Storable Crutch, developed through the Stanford Children's Hospital REC program, and the Automatic Leg Bag Emptier, developed through the REC program at Rancho Los Amigos Hospital. Engineering tests and user pretests of both items have been completed and clinical evaluations are in progress through the University of Texas Health Science Center, Department of Physical Medicine.

The project staff has developed and identified numerous channels through which to disseminate rehabilitation technology information and make potential users of such information aware of the REC. Specific tasks include development of the Tech Eval newsletter to be used for reporting, announcing, and presentation of instructional information related to technology evaluation. Additional dissemination tasks accomplished include article contributions to various publications, paper presentations, panel participation, booth exhibits at numerous conferences, and visits to rehabilitation programs and facilities.

Cooperation has been developed with the REC at the Electronic Industries Foundation (EIF), which shares the responsibility for the total mission of evaluation of technology and stimulation of industry. EIF will focus on selecting products to be assisted by both programs and will interact with prospective manufacturers to develop the product for market, while this center will concentrate its resources on developing sound engineering and clinical testing procedures aimed at informing the intended purchaser(s).

As the center begins its second year of operation, plans call for intensifying efforts to identify and catalog prior and current experience in evaluation and testing of rehabilitation devices and methods. The center also will work toward attracting commercial and nongovernmental support for evaluation service.■

Rehabilitation Information Project

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Problem—The rehabilitation community, while sharing many common aims, means, and professional commitments, is also characterized by the geographical dispersion of its many members, and by the differences in professional specialties and levels of training inevitable in an essentially multidisciplinary field. With growth, this community has developed some special needs.

Among these emerging needs is one defined by the broad area of information exchange. Particular aspects are the need for better intracommunity communication, and the need for consumer involvement.

As important as these needs are, the current means for accomplishing them appear inadequate, as the literature suggests. Without efficient communication, informationally isolated islands of community members persist. As a result, research activities and funding are often duplicated, new techniques and devices are not widely disseminated, the experiences of members are not communicated, and the intended users of aids do not have a voice in their development.

Significance—An ideal solution to this situation would be a mechanism that enabled rehabilitation community members to make informed decisions based upon an enhanced ability to interact in an effective and synergistic manner. If such a mechanism existed, the barriers that distance, schedule, finances, ability, and possession of equipment impose on information access would be reduced, permitting wider participation by all. However, such a solution does not now exist.

Background—The RR&D Center and the VA's Western Blind Rehabilitation Center (WBRC) have cooperated on numerous projects during the past several years. These projects include a joint VA/Stanford project to develop a personal information system for the visually impaired. Preliminary work conducted at the RR&D Center has demonstrated the feasibility of a universally accessible information system serving the rehabilitation community. The WBRC has operated the

Electronic TeleCommunications, Education, Training, Evaluation, and Research Activity (ETCETERA) and more recently the Computer Training and Education Program (C-TEP) which provides a community locus for training and research on computer-based aids for the visually impaired. Other local resources, including the Sensory Aids Foundation, provide a vocational setting for the practical application of this training.

While other systems such as Abledata, Special Net, Wellnet, and Handicapped Education Exchange offer information in computer form, they all require the use of a modem and terminal or computer. A system that requires no special equipment for access, provides interaction between users, is easy to learn and use, and is equally suited for all those interested in rehabilitation issues would promote a significant improvement in information dissemination and informed decision making.

Hypothesis—It is hypothesized that a computer-based information system accessible by Touch-Tone input and machine produced synthetic speech can be developed and employed within the local rehabilitation community to foster increased information exchange and consumer involvement. The system's specific goals are to: improve employment opportunities, reduce social and economic dependence, improve information dissemination, and improve communication among rehabilitation researchers.

Approach—The goal of this project is to develop a universally accessible mechanism. Its potential users are both agencies and individuals. Federal and private organizations such as the Veterans Administration (RR&D and WBRC Centers) and Sensory Aids Foundation will be involved initially. Individual participants include those with disabilities, physicians, manufacturers, therapists, policy makers, employers, those seeking employment, educators, and senior citizens.

The information in this system would reside in a telephone-accessible central storehouse from which users could select a specific subset for decision making, evaluation, interaction, inquiry, or response. For example, one would be able to make a purchase decision between several functionally identical devices based upon the centrally held documented experiences of others.

The central system would manage data, convert selected information to synthetic speech, and transmit it over the telephone. The user's Touch-Tone keypad could provide unrestricted interactive input. In operation, one would telephone the system and respond to a series of spoken prompts with Touch-Tone button presses. The system would decode these

keystrokes and select information to be spoken from its store. Messages could be sent to the system by employing a two-button entry scheme.

In such a system, both information retrieval and generation could be performed by users without their purchasing specialized equipment (terminal and modem communication would also be supported, to accommodate those with impaired hearing). A human information specialist to aid new users and provide advanced assistance for others would reduce demands upon the user/system interface's versatility.

To achieve enhanced communication, there could be several methods of information exchange within the system. On-line newsletters could facilitate the dissemination of information from a central organization to its members. Separate publications would be created to cater to the interests of the spinal cord injured, visually impaired, and those desirous of data on vocational aids. An electronic employment service could also be implemented, acting as an information node among prospective employees, potential employers, and an employment counselor. A continuing advertising section on the system would provide users with an up-to-date list of jobs available and situations wanted. Interviews could be conducted and resumes exchanged in privacy over the proposed system. Finally, Design Circles will allow consumers to interact with designers at all stages of development of new products. Meetings of the group could also include both consumers, potential manufacturers, and health care professionals.

Although this one system could not possibly serve the entire national rehabilitation community, it could serve as a local model for other identical microcomputer-based systems, or for a national network connected to a large computer.

Status—Several speech synthesizers have been acquired and their characteristics have been investigated. Microcomputer hardware systems have been surveyed for their suitability for this project and a database software search has begun.

While the need and problem have been determined, a concerted effort on this project awaits funding. A proposal requesting funding for this project has been submitted for VA merit review. If approved, the 2-year project would receive initial funding in October 1984. ■

Topical Anesthesia and Muscular Hypertonicity

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Sponsor: Liberty Mutual Insurance Company

Muscular hypertonicity is among the most disabling symptoms affecting patients with central nervous system disorders. It appears as spasticity in patients with stroke or cerebral palsy and as muscular rigidity in patients with Parkinson's disease. Increased joint stiffness during movement, coupled with muscle weakness in the upper and lower extremities, reduces these patients' functional capabilities. Pharmaceutical treatments are not often effective.

Our recent neurophysiological studies led us to develop and test a new treatment technique using topical anesthesia. Details of the double-blind research design involving the topical anesthesia and a placebo were reported in our 1982 Activities Report.

A controlled study of chronic stroke patients demonstrated that 5 out of 10 treated with topical anesthesia on the lower limb had short-term benefits, requiring less time to complete ten rapid repetitive movements of the limb joint. Longer-term treatments, consisting of three sessions per week for 1 month, yielded even better results: all nine patients tested in a long-term application achieved faster movement capability at the knee joint. At the elbow joint, three patients showed substantial improvement immediately after treatment and four showed a substantial improvement in the long-term treatment.

During the past year, we conducted a controlled study to measure the ground reaction forces on the affected and nonaffected legs of stroke patients and obtained stabilograms (pattern and degree of sway of the center of gravity) before and after immediate and long-term application of topical anesthetic. We observed an improving trend in all measures of gait immediately after anesthesia. The long-term treatment resulted in considerable progress toward normal values by the end of the treatment.

Numerous health professionals have expressed interest in using our technique and have written us for information. Since we wanted to evaluate the perceptions, practical experience, clinical findings, and complaints of health professionals who applied our techniques, we sent a questionnaire to all who had received our information. The responses were numerous and favorable. Of the 230 questionnaires that we sent out, 13.4 percent indicated that they had used the

technique on at least 109 patients. An overwhelming number of these reported improvements in their spastic patients' movement capabilities■

Topical Anesthesia and Parkinson's Disease

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Parkinson's disease is a movement disorder of the central nervous system and affects about 500,000 people in the United States. Neurochemical studies of patients with Parkinson's disease show an imbalance in the brain neurotransmitters, dopamine, and acetylcholine. But since causal factors are still unknown, rehabilitation plays the major role in functional recovery for these patients. Surgical, medical, and physical therapies all have been used with varying success.

Since we had demonstrated the usefulness of the topical anesthetic technique in mitigating symptoms of spasticity in other patients, we began a pilot study during 1983 to test the efficacy of a topical anesthetic spray with people suffering from Parkinson's disease. Individuals with this disease tend to walk with difficulty due to muscular rigidity. They take smaller steps at slower speeds and are more rigid while walking as a result of diminished central nervous system control of their peripheral musculature. They also usually exhibit some resting tremor and difficulty with other activities of daily living.

Our controlled double-blind study measured ground reaction forces, step length, and the temporal components of gait. Specific variables included stride, support, swing, step times, and sway patterns during quiet standing.

Preliminary results demonstrate some improvements in the ground reaction force pattern as the foot strikes the ground. Before treatment, as the weight-bearing phase of their gait began, patients exhibited force-vector profiles indicating reduced progression of the center-of-pressure of their weight. Weight acceptance was slow and showed abnormally sequenced force vectors indicating an abnormal movement of the body. After application of the topical anesthetic, their profiles shifted toward a normal pattern. We observed no measurable changes in the temporal parameters of gait. Electromyographic recording may help us to elucidate the factors leading

to the changes. More subjects need to be tested before we can make any informative conclusions■

Topical Anesthesia with Normal Subjects

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We have previously published reports with evidence for increased excitation of motor activity in the spinal cord following desensitization of the skin by topical anesthetics. These increases have been associated with alterations in the gait of spastic patients.

In the past year, we have investigated these phenomena in the gaits of normal subjects. We tested six normal subjects on an instrumented walkway before and after the application of a topical anesthetic. Vertical ground reaction forces were measured from a computer-controlled force plate while the subject ambulated or walked in place. (Walking in place was tested because of the ease with which multiple steps could be recorded on a single-force platform.) Foot switches attached to the sole of the foot at the heel and toe recorded the foot contact history. A topical anesthetic was sprayed to all skin areas of one lower limb except for the skin overlying the front of the shin and the sole of the foot. Measurements were repeated at 15-minute intervals up to 1 hour after the anesthetic.

We found increases during gait and while walking in place in the vertical ground-reaction-force peaks following topical anesthesia; no consistent change occurred in the timing of foot contact or in the walking speed. These effects observed during gait and while walking in place are consistent with an increased excitability of the spinal neurons related to the extensor muscles. Therefore, the motor control of stereotyped movement patterns, such as those occurring in gait, can be modified by reducing the skin's sensory input.

The observed effect of topical anesthesia on ground reaction forces was more dramatic and more consistent for walking in place than for gait. This may have resulted from the greater stretch during walking in place to the extensors of the ankle; greater stretch occurs with the toe-heel sequence of walking in place than with the heel-toe sequence normally used in gait. Marching in place thus offers a useful new method of gait analysis■