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2 Rehabilitation Research and Development

Meeting the Challenge

Fifty years ago the nation turned to Veterans Administration researchers to improve care for the 21,000 soldiers who returned from the World War II battlefields with amputations. Great men of vision convinced the medical profession that medical care did not end when the wound healed. They changed the way we look at amputation surgery, and the way we approach prosthetic fitting. The challenge, they told us, lies in healing the whole person.

Time has changed the face of the veteran population. Those who survived World War II are now experiencing macular degeneration, hearing loss, or consequences of stroke. Within each generation who served is a group of veterans with amputations, spinal cord injuries, traumatic brain injuries, hearing impairments, low vision or blindness, and communications disorders. No matter the condition, the challenge remains the same-to treat, and heal, the whole person.

As part of the VA Health Care System serving our patients, VA Rehabilitation Research and Development researchers are positioned uniquely to respond to the needs of these veterans. We fund over 150 clinically important research projects designed to elucidate the pathophysiology of impairment, create accessible environments, and improve the personal technologies used by persons with disabilities. Investigations have impact in myriad areas of disability management including amputation prevention, joint replacement, efficient wheelchair propulsion, orientation techniques for persons who are blind, and early detection of hearing loss.

New initiatives undertaken in 1997 seek to secure an infrastructure to carry responsive rehabilitation research into the 21st Century. A cadre of six Rehabilitation Research Centers of Excellence has been established with specific foci in areas of great importance to veterans with disabilities: Aging with a Disability, Aural Rehabilitation, Functional Electric Stimulation, Geriatric Rehabilitation, Prosthetics and Consequences of Amputation, Rehabilitation Engineering and Spinal Cord Injury. With future funding, additional Centers may be added that include an emphasis in Traumatic Brain Injury.

A structured Career Development program was initiated in 1997 providing opportunities for new rehabilitation investigators at the Pre-Doctoral and Post-Doctoral level. These training opportunities, at the interface of clinical care and research, enhance the clinical experience through pursuit of research questions. At once, this approach places the critical research problems in the context of real life health care needs. Those who were part of the RR&D program's revered past are now building for a strong future.

Our Rehabilitation Research Program faces the challenges of the 1990's and the next century with hope and anticipation. The Research Program brings tremendous dedication and intellectual capital to the challenges posed by the diseases and disabilities that effect our veteran patients. We must realize our great potential to improve the health of our veterans, and to remember the real challenge-to heal the whole person.

John R. Feussner, M.D. Chief Research and Development Officer

4 Rehabilitation Research and Development

PROSTHETICS/AMPUTATION/ORTHOTICS

Amputation Prevention

Limb threatening ulcerations in diabetic patients were significantly reduced through the use of customized insoles combined with depth-inlay shoes.

Eighty-four percent of diabetes-related lower extremity ulcerations lead to amputation. Foot ulceration is a multifactoral event, including such elements as foot deformity, loss of sensation and poor circulation. Proper orthotic support provides reduced risk of trauma related to these elements. *Pecoraro, R., Reiber, G. et al Pathways to Diabetic Limb Amputation: Basis for Prevention, Diabetes Care, 13, 1990*

VA researchers have developed several footwear options based on the relationship of foot shape to the shoe and inlay shape. Computer driven determination of circulation difficulties and pressure points on patient's feet create the design basis for custom molded shoes to ameliorate ulcerations. A combination laser scanner and custom software system allows researchers to obtain data on more than 16,000 points over the entire foot. Initial designs required custom fitting of the complete shoe, resulting in an effective, but expensive and aesthetically displeasing product.

A second generation of customized footwear provides the same protection with more normative shoe styles by confining customization to the insole. The insole is then combined with a mass manufactured shoe design based on diabetic foot shape analysis. Current studies are incorporating the addition of weightbearing factors to refine design for further ulceration risk reduction. Borchers, R., Boone, D., et al Numerical Comparison of 3-D Shapes: Potential for Application to the Insensate Foot Journal of Prosthetics and Orthotics, Volume 7, Number 1, Winter 1995.

Prosthetics: Design, Manufacture, Fitting

Laser optical digitizer improving accuracy of residual limb shape measurement; designed and ready for clinical trials.

Deployment of Automated Fabrication of Mobility Aids (AFMA), a prosthetics manufacturing system, reduced costs of transtibial prostheses by 85% and saved VHA \$4,000,000. AMIS Report, 1995, VA Prosthetics and Sensory Aids Service

VA developed Modular Electromechanical Lock Actuator (MELA) became commercially available, reducing the force required for above elbow amputees to operate elbow lock.

The historic roots of VA Rehabilitation Research and Development, and the overall VA research program, are in the design and development of prostheses. The most widely known prosthesis to be developed through the VA research program is the Seattle foot, and the subsequent generations of the Seattle Limb System. Based on the use of lightweight, plastic, and composite materials to replace complex mechanical

PROSTHETICS/AMPUTATION/ORTHOTICS

devices, these prostheses have opened up an entire range of athletic activities to persons with lower limb amputations. A below knee limb employing an ankle shank and alignment device became commercially available in 1990. A limb for persons with above knee amputations utilizing a modular knee remains under development.

The VA introduction of Computer Aided Design and Manufacture (CAD/CAM) for the design and manufacture of prosthetic aids has lead to higher level of comfort for users, as well as dramatically reduced costs. Investigations in the 1990's have demonstrated potential to eliminate major pieces of equipment, such as milling machines, to further lower manufacturing costs. The design of laser optical digitizers to complement this design and manufacturing system promises to provide more accurate assessment of tissue strengths and weaknesses of residual limbs. This information allows the design of a socket that reduces tissue stresses and increases function through optimized proprioception. *Houston, V., Mason, C. et al The VA-Cyberware Optical Laser Digitizer, Journal of Rehabilitation Research and Development, February 1995*

Several prosthetic design enhancements funded through VA studies have reached the commercial market. First, an electrically powered lock actuator known as MELA (Modular Electromechanical Lock Actuator) provides ease and control for persons with above-elbow amputations who have difficulty manually manipulating elbow locks. MELA can be retro-fit to most existing above elbow prostheses. Second, an "off-the-shelf" lifelike cosmetic cover for lower limb prostheses also became commercially available. This design offers a durable, functional, and affordable option to custom-made covers without sacrificing cosmesis.

An additional promising prototype is an extended physiological proprioception (e.p.p.) position controller for electric-powered upper limb prostheses. E.p.p. developers have demonstrated the possibility of successfully using two independent, but coordinated, electric components in a prosthesis, thus allowing for greater range and ease of manipulation.

Clinical evaluations of a new prosthesis for high level, above elbow amputees, known as the Body-Powered Ad*VA*ntage Arm, are currently underway. The design of the Ad*VA*ntage Arm promises to offer a light weight prosthesis with improved functionality for amputees with limited shoulder motion.

PROSTHETICS/AMPUTATION/ORTHOTICS

Prosthetic Joint Implants

Discovered current use of gamma radiation for sterilization of polymer components in orthopaedic prostheses causes early failure and breakdown after implant.

Experimental and computer models used to explain adverse bone changes after hip replacement and to improve implant designs.

Orthopaedic studies focus on minimizing joint implant failures through more durable prostheses and fixatives. Continuing investigation into why many polyethylene bearings in orthopaedic prostheses fatigue and fail earlier than laboratory testing would indicate revealed use of gamma radiation for sterilization of the polymer components resulted in inititation of a breakdown process which continues in the patient. As a result of this study, done in collaboration with investigators at Dartmouth College and DePuy DuPont Orthopaedics, orthopaedic manufacturers have altered their modes of sterilization. In response to a related study, orthopaedic manufacturers have modified their design and manufacturing processes based on findings of VA funded retrieval analysis to document joint implant performance and failure modes. VA researchers have also developed methods to increase longevity of artificial joints in the human body by decreasing aseptic loosening, a condition which necessitates revision surgery in over 50% of patients within eight years. These methods are nearing widespread clinical implementation.

Sutula, L, Collier, J., et al Impact of Gamma Sterilization on Clinical Performance of Polyethylene in the Hip Clinical Orthopaedics and Related Research, Number 319, October 1995.

Investigators at the VA Palo Alto Health Care System have developed state-of-the-art simulation programs that are being used to predict the long term outcome of hip and knee replacement surgery. Used in conjunction with experimental and clinical studies, these simulation studies enable implant manufacturers to identify shortcomings of existing implant designs and to evaluate the performance of new and improved designs prior to testing in patients.

Levenston, M., Beaupre, G. et al Computer Simulations of Stress-Related Bone Remodeling Around Noncemented Acetabular Components, Journal of Arthoplasty 8, 1993.

Mandell, J., Beaupre, G. et al Prosthesis Collar Geometry Strongly Affects Initial Stress Shielding and Micromotion, Society for Biomaterials, Boston 1995.

Giddings, V., van der Meulen, M. et al The Effect of Femoral Collar on Surface Strains in the Proximal Femur after Hip Arthroplasty, Proceedings 19th Annual ASB Meeting, 1995.

Spinal Cord Injury: Engineering Solutions

Initiated multi-site evaluation of a wheelchair mounted robotic arm designed to enable persons with quadriplegia to perform reaching and grasping activities.

VA rehabilitation researchers apply engineering principles to design, development, and evaluation of products in hopes of expanding the range of activities available to persons with spinal cord injuries. Adjustments to wheelchairs, revisions of vocational environments, and adaptations of recreational equipment, all serve as examples of how modifications of existing technology can contribute to improved quality of life.

A wheelchair-mounted robotic arm shows promise for persons with high level quadriplegia to independently accomplish tasks such as opening a door, operating an appliance, or self-feeding. This may be the first robotic assistive device whose cost and portability lend itself to commercial availability and broad use. A preliminary evaluation was conducted using 19 subjects at seven medical centers. An upgraded model was developed based on the feedback from this evaluation.

Sheredos, S., Taylor, B. et al Preliminary Evaluation of the Helping Hand Electro-Mechanical Arm, Technology and Disability, 5 1996.

Individuals with quadriplegia need the ability to independently control the speed and direction of their electrically powered wheelchairs. The VA RR&D developed Ultrasonic Head Control Unit is an add-on interface for wheelchairs, providing a non-contact alternative to chin control for this population. Two ultrasonic transducers calculate the user's head position. Tilting the head forward-backward and left-right controls the wheelchair's movements. Twenty subjects with levels of spinal cord dysfunction ranging from C3 to C6 were recruited from VA Medical Centers to evaluate four prototypes. The results from this study are being used to prepare the unit for commercial availability. Beyond this wheelchair control application, the Ultrasonic Head Control unit can provide computer mouse control.

Ford, J., Sheredos, S. Clinical Report: Ultrasonic Head Controller for Powered Wheelchairs, Journal of Rehabilitation Research and Development, Vol 32, No. 3, October 1995.

Designers at the VA Palo Alto Rehabilitation R&D Center have developed the Handbike, an arm-powered bicycle for individuals with lower limb disability. Compared to arm-powered tricycles, the Handbike design is closer to standard bikes, allowing riders to bike on two wheels and lean into turns. Adjustable side casters are poised to smoothly touch down at the desired lean or fasten down for four-wheeled maneuverability indoors. The visibility of the Handbike in the community heightens public awareness by drawing attention to a common desire for persons to be mobile and participate in recreational activities, unmitigated by disability. In 1996, the VA handbike was used to carry the Olympic torch through Maryland on its way to the 1996 Paralympic Games.

An interactive vocational training facility has been designed by VA researchers in Palo Alto to teach desktop publishing skills to students with high level quadriplegia. A combination of adaptive access equipment,

including a voice controlled robot for manipulation assistance, is aimed at modifying the workplace environment to accommodate independent activity. The first "class" of sixteen students participated in a 12-week course, followed by an internship, before pursuing job opportunities. Currently, seven students are engaged in additional education or gainful employment, while six are actively pursuing educational, internship or job opportunities.

The Handtyper, also developed at the Palo Alto VA, is a simple and effective typing aid that is popular with occupational therapists. It is intended for individuals with spinal cord injury and others with limited hand function, and provides a way for the user to type, turn pages, and move paper on desks, It offers a secure fit, gives visual access to keyboards, and is padded to protect the dorsal surface of the hand. The Handtyper is commercially available. In 1996/97, 275 units were sold.

Spinal Cord Injury: Functional Electrical Stimulation (FES)

Multi-center trial initiated to assess efficacy of Functional Electrical Stimulation (FES) hand-grasp system for persons with quadriplegia.

Functional Electrical Stimulation (FES) uses controlled electrical current to activate muscles paralyzed as a result of spinal cord injury or other central nervous system disorder. The aim is to bypass the damaged portion of the nervous system with pacemaker-like implants to restore useful function. VA has funded varying investigations throughout the country to harness this technology for over 15 years and supported a focused Rehabilitation Research & Development Center in FES for over six years. FES has implications for many aspects of spinal cord injury including activities of daily living; mobility; cardiovascular health; integrity of skin, muscles, bones, and joints; respiratory function; and bladder/bowel control. People with other central nervous system disorders, such as stroke and head injury, may also benefit from FES advances.

An upper extremity system for control of hand grasp and release for individuals with quadriplegia promises to successfully return some grasping function. This system has been implanted in 50 individuals enabling persons to grasp large objects (like a cup) in their palm and hold small objects (like a pen or fork) with their thumb and index finger. Ongoing VA-supported research to advance the system focuses on improving hand dexterity, increasing the user's functional workspace by adding control for elbow extension, forearm pronation, and bi-manual function. In May of 1997, the first dual FES hand grasping system was implanted in a patient, allowing an individual return of function in both hands.

Peckham, P., Keith, M., et al Tendon Transfers and Electrical Stimulation for Restoration of Hand Function in Spinal Cord Injury, Journal of Hand Surgery, 21, 1996

Applied to the lower limbs, FES has been successful in assisting persons with paraplegia to achieve standing positions and, for some subjects, to produce walking movement for useful distances. Current VA research efforts are directed toward refinement of implanted systems in the lower body in preparation for initiating multi-center studies.

Marsolais, E., Kobetic, R., et al Orthoses and Electrical Stimulation for Walking in Complete Paraplegia, Journal of Neurological Rehabilitation, 5 (1/2), 1991

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An implantable FES system for control of the bladder was originally developed in Europe and initially tested in the United States with VA research support. The FES implant activates the spinal nerves that control the bladder and bowel and is designed to help individuals with spinal cord injury that suffer significant bladder complications. The FES implant can generally restore continence with possible additional benefits of reduction or elimination of urinary tract infections, and reduction in the cost of bladder management supplies. *Creasey, G. Electrical Stimulation of Sacral Roots for Micturition after Spinal Cord Injury, Urologic Clincis of North America, Volume 20, Number 3, 1993*

Neural Regeneration

Experiments utilizing carbon filaments to support regrowth of injured axons after spinal cord injury resulted in partial functional recovery in animals.

Cautious optimism exists among rehabilitation and medical researchers alike engaged in studies of regeneration of the spinal cord after traumatic injury. VA has committed approximately \$6,000,000 in the last five years to the many avenues of study pursued in hopes of "curing" spinal cord injury. Investigators have approached restoration of nerve function through nerve cell replacement, repair of nerve fibers, and regeneration of damaged nerves. Acute phase treatments developed by VA researchers have utilized steroids to minimize damage resulting from spinal cord trauma.

VA investigators at Brockton VA Medical Center have enabled the successful regeneration across a 15 mm gap of peripheral nerves in rats through the growth of supporting cells within a silicone tube. Work is now being carried out in enhancing the ability to heal nerves and will be applied to spinal cord damage. *Yannas, I., Spector M. Rehabilitation R&D Progress Reports, August 1995*

At the Hines VA Hospital, investigators have revealed that carbon filament implants in combination with electric field application results in partial functional recovery in cats. Co-implantation of carbon filaments with fetal spinal cord in rats also demonstrated some functional recovery. Related studies are attempting to elucidate the molecular mechanisms underlying nervous system damage in order to promote successful regeneration.

Liu, L., Khat, T., et al Electrophysiological Improvement after Co-Implantation of Carbon Filaments and Fetal Tissue in the Contused Rat Spinal Cord , Neuroscience, 1995

In traumatic peripheral nerve injuries, often there is a significant gap between the cut ends of a nerve that presently is repaired with an autograft, but this results in loss of function at the donor site. Investigators at the VA Palo Alto are developing an artificial nerve graft composed of a tubular conduit, a matrix made of the structural protein collagen with linear channels for guidance of axonal regeneration, and cultured Schwann cells obtained from the same patient. Rate of recovery of sensory and motor function are being compared to autografts. Implantation of artificial nerve grafts into damaged spinal cords is planned.

Architectural Design and Accessible Environments

Designed and commercialized Bowel-Care Shower Chair for persons with SCI to reduce bowel care time, promote effective elimination and reduce risk of pressure ulcers.

Modifications to environments or designs of personal technologies are needed to eliminate barriers encountered by wheelchair users.

Bowel care programs for some individuals with spinal cord injury can take up to two hours. Seating posture and comfort during this time are key elements in avoiding the threat of pressure ulcers. The Bowel-Care Shower chair was designed to accommodate seating position, effect safe transfer from another wheelchair, and provide easy access to digital stimulation.

Related studies at the Atlanta Rehabilitation Research and Development Center have produced a Roll-In Shower to allow access to bathing facilities for wheelchair users without the need to transfer from their chairs. The flexible design allows for permanent or temporary installation and has been adopted by hotels to accommodate patrons who use wheelchairs.

Work in Atlanta is also being carried out to determine the usefulness of grab bar configurations for elderly persons in order to design a grab bar standard that will enhance the safety and independence of older persons in toileting.

Wheelchair Design

Multidisciplinary research is addressing high incidence of pain and secondary disability due to over use injuries among veterans who use wheelchairs. This is of particular importance for Korean and Vietnam Era veterans.

Collaborative research and testing to establish standards for safety, durability, measurement, and definitions of terms has led to the development of standards adopted by the American National Standards Institute (ANSI), Rehabilitation Engineering and Assistive Technology Society of North America (RESNA), and International Organization for Standards (ISO).

Wheelchair selection processes and comparative data between diverse and complicated wheelchair products have been published. This work provides a basis for providing greater mobility to veterans and represents the leading edge in wheelchair evaluation.

A growing diversity of style, cost, use, and quality has led to the development of national and international standards for safety, durability, reliability and efficacy of wheelchairs. The VA has funded collaborative research and testing to enable veterans and clinicians to make objective comparisons of available and emerging products in accordance with the veterans needs. The use of these standards also helps to ensure veterans are provided with quality products which meet their needs. The power of the standards comes with being able to evaluate the performance of products with which one is not familiar. The standards which result from this work are referred to as the ANSI/RESNA and ISO Wheelchairs Standards. Standards are an

involving process which has probably had the most profound effect on increasing quality while containing cost. The VA Pittsburgh Health Care System provides testing of products design for use by veterans and publishes the results for comparison with other wheelchairs.

The increasing selection and complexity of wheelchairs is based upon the understanding that wheelchairs must closely match the abilities, desires and needs of the user. There are a wide range of configuration options and accessories which tailor a wheelchair to the individuals giving him/her maximum mobility to perform the functions that s/he desires. The expansion of wheelchair options and the increasing complexity has led to the need for specialized training and assistance in wheelchair and seating selection and configuration. To aid in wheelchair prescription, the VA Pittsburgh Health Care System is developing a computer data base and expert system to provide easy access to products and prescription methodologies. *VanSickle, D., Cooper, R. et al Determination of Wheelchair Dynamic Load Data for Use with Finite Element Analysis, IEEE Transactions on Rehabilitation Engineering, Vol. 4, No. 3, 1996.*

Cooper, R, Trefler, E. et al Wheelchairs and Seating: Issues and Practice, Technology and Disability, Vol. 5, 1996.

Cooper, R., Robertson, R. et al Wheelchair Impact Response to ISO Test Pendulum and ISO Standard Curb, IEEE Transactions on Rehabilitation Engineering, Vol. 2, No. 4, 1994.

Several studies have shown that approximately 80 percent of veterans who use manual wheelchairs greater than five years will go on to develop arm pain. Moreover, studies have shown that physicians have not been very successful in treating this pain. Wheelchair propulsion is accomplished by bilateral simultaneous repetitive motion of the arms which often results in musculoskeletal and/or neurologic injury. The most commonly reported site of pain and injury is the shoulder followed by the wrist and then the elbow. The development of the SMARTWHEEL, a 7 degree-of-freedom force and movement sensing pushrim, by investigators at the VA Pittsburgh Health Care System has provided a valuable tool in the study of wheelchair propulsion biomechanics. This research is providing insight into appropriate set-up and selection of wheelchairs in order to reduce the incidence of upper extremity pain and secondary disability among veterans who use manual wheelchairs. The SMARTWHEEL is being used as a research and assessment tool at five sites within North America.

Boninger, M., Cooper, R. et al Wrist Biomechanics During Two Speeds of Wheelchair Propulsion: An Analysis Using A Local Coordinate System, Archives of Physical Medicine and Rehabilitation, Vol. 78, No. 4, 1997.

Cooper, R., Robertson, R. et al Methods for Determining 3-Dimensional Wheelchair Pushrim Forces and Moments, Journal of Rehabilitation Research and Development, Vol. 34, No. 2, 1997.

Asato, K., Cooper, R. et al SMARTWHEELS: Development and Testing of a System for Measuring Manual Wheelchair Propulsion Dynamices, IEEE Transactions on Biomedical Engineering, Vol. 40, No. 12, 1993.

Low back pain and deformity are common among veterans who use wheelchairs long-term. Many devices have become available to address this issue, but all are based upon static seating posture. Wheelchair driving is a dynamic seating activity. The VA Pittsburgh Health Care System is conducting research to determine if cushions and back support systems are effective in reducing road vibration and shocks. This may lead to fewer spinal deformities and the concomitant secondary disabilities. Moreover, shock loads through the seat may cause internal hematoma leading to pressure sore development. This mechanism of pressure sore development has not been studied here-to-fore.

Through collaborative research, the VA is assisting with the development of several wheelchair products to ease travel, to participate in a wider variety of activities, and to promote standing. The evaluation and cooperative development of products has led to greater mobility and quality of life for veterans.

Fractures/Bone Mass/Osteoporosis

Computer simulation program used to study changes in bone density in both spinal cord injured and fracture castimmobilized subjects.

VA demonstrates the importance of daily physical activity for maintaining bone mass in aging adults.

A sequelae of spinal cord injury is reduced bone mass and the consequent higher risk of fractures. Studies within the VA seek to diminish fracture risk and promote healing.

Investigators within the Palo Alto VA Health Care System are conducting research focused on bone loss that occurs with disuse in patients who have a spinal cord injury and patients treated for ankle fractures with a cast. Using a standard clinical CT imaging system to monitor bone loss in these patient populations, in combination with computer algorithms for bone registration and beam hardening corrections, researchers will be able to gather the most accurate information to date on the rate and extent of bone loss after spinal cord injury or cast immobilization. This work is critical for evaluating outcome measures for therapies aimed at preventing and reversing bone loss in the extremities of these two patient groups. In addition, the developed tools can be readily applied to all patients at risk for or diagnosed with osteoporosis. *Yan, C, Beaupre, G. et al Registration of Serial Skeletal Images for Accurately Measuring Changes in Bone Density, Orthopaedic Research Society 22:206, 1997*

Yan, C., Whalen, R. et al Accurate Single Energy Spectrum Beam Hardening Correction for Quantitative Computed Tomography (QCT), Accepted to the 83rd Annual Meeting of the Radiological Society of North America.

The structure and integrity of the skeleton are a direct reflection of physical activity, diet, hormone status, and genetic factors. Investigators at the VA Palo Alto Health Care system have developed a comprehensive theory for skeletal tissue development, maintenance and adaptation that is being used to explain the changes in bone mass as a result of increases or decreases in the intensity of daily physical activity. These studies show that mechanical function is perhaps the most dominant factor in determining the form and function of the skeletal system. These findings are playing an important role in assessing methods for preventing and treating osteoporosis.

Carter, D., van der Meulen, M. et al Mechanical Factors in Bone Growth and Development, Bone 18, 1996.

Carter, D, van der Meulen, M. et al "Skeletal Development: Mechanical Consequences of Growth, Aging and Disease" In: Osteoporosis, (ed. R. Marcus, D. Feldman, J. Kelsey), Academic Press, 1996.

Cardiovascular Assessment and Training

Clinical trials of VA developed Wheelchair Aerobic Fitness Trainer (WAFT) proved its benefit in assessing cardiovascular conditions of wheelchair users and pointed to potential use as a physical fitness aid and trainer of wheelchair athletes.

Exercise test protocols for early detection of coronary artery disease in persons with lower limb impairments present unique diagnostic challenges for the clinician. To date, alternatives to standard treadmill or cycle ergometers have employed pharmachologically induced stress (e.g. dobutamine, adenosine) in combination with echocardiography or thallium scintigraphy. These procedures are less safe for the patient and more difficult to perform than graded physiologic stress testing. A wheelchair ergometer known as the Wheel-chair Aerobic Fitness Trainer (WAFT) was developed by researchers at Hines VA Hospital and provides a unique and clinically useful noninvasive method for the detection of coronary artery disease in persons with lower limb disabilities. The WAFT is an electro-mechanical treadmill for wheelchairs providing user access with minimal assistance and allowing rapid supine positioning for echocardiographic imaging pre- and post-exercise.

Analysis of accumulating data indicates that the WAFT is appropriate for graded exercise testing. In addition to its use as a diagnostic modality, the WAFT is being used in physical rehabilitation and conditioning of persons with lower extremity impairments who have widely varying levels of strength and cardiovascular fitness.

The WAFT recently was displayed at the National Veterans Wheelchair Games in San Diego and at the Paralympics in Atlanta. Competing athletes used it to warm up and gauge the pace of their performance prior to participating in events.

COMMUNICATIONS, COGNITIVE, AND SENSORY AIDS

Low Vision Enhancement

Clinical trials of Low Vision Enhancement System (LVES) demonstrated improvement in visual acuity over best lens correction in 96% of subjects, all of whom were legally blind.

Initial clinical trials of Liquid Crystal Dark-Adapting Eyeglasses showed better acuity, contrast sensitivity and more assurance in traveling.

Veterans with support and help from someone at home are twice as likely to use their low vision devices as those without such support.

Low Vision is the result of a decrease in visual acuity, visual field, or contrast. It usually precludes reading, independent travel, daily living activities and vocational opportunities. World War II veterans are now in the age-groups with a high prevalence of low vision and Korean and Vietnam veterans are moving into these age-groups. The VA estimates that today there are more than 650,000 veterans with low vision and by the year 2005 that number will increase to almost 850,000.

A number of studies and developments have been funded to assist persons with low vision. Most notable is the development of a Low Vision Enhancement System (LVES), the first low vision assistive device with autofocus, continuous zoom magnification, image brightness constancy, and image enhancement. Unlike most aids which are task specific, this new enabling technology allows severely visually impaired veterans to perform numerous tasks such as reading, writing, sightseeing, or watching TV.

Early prototypes of LVES were fashioned in collaboration with NASA, Polaroid Company, and Johns Hopkins University. In outward appearance, the device resembles an infantryman's night-scope, is head mounted, battery powered, and portable. To the user, the portable system magnifies distant object size from two to nearly nine times. For users, the really exciting aspect of LVES is the user ability to actually make what he sees better and not simply bigger. This is accomplished through user controlled image contrast enhancement. Initial clinical trials at the VA VICTORS and Blind Rehabilitation Centers have demonstrated marked improvements in visual acuity and contrast sensitivity in 96% of the test subjects. Most importantly, LVES represents a platform on which future enhancing and enabling technologies may be added.

Massof, R., Rickman, D. et al Low Vision Enhancement System, APL Tech Digest, 15:2, 1994.

Ballinger, R., Lalle, P. et al Veterans Affairs Low Vision Enhancement System (LVES) Study: Clinical Cases and Preliminary Overview, Optometry and Vision Science Supllement, 72, 1995

COMMUNICATIONS, COGNITIVE, AND SENSORY AIDS

VA Researchers at the Kansas City VICTORS Low Vision Rehabilitation Program have developed software to incorporate the use of the Scanning Laser Ophthalmoscope (SLO) to accurately and precisely measure scotomas and preferred retinal loci for visual tasks in low vision patients. The addition of this instrument to the low vision rehabilitation armamentarium has allowed clinicians to better design therapy and adaptive strategies for the growing population of veterans with severe chronic vision loss. The Kansas City low vision team were recipients of the 1996 Olin E. Teague Award given to an individual or clinical team in VA who has had the most impact on the rehabilitation of veterans.

Ceron, O., Maino, J. et al Validation of Scanning Laser Ophthalmoscope Visual Parameter Scale, Optometry Vision Science Supplement, 73, 1996

Schuchard, R., Fletcher, D. et al A Scanning Laser Ophthalmoscope (SLO) Low Vision Rehabilitation System, Clinical Eye and Vision Care, 6 (3), 1994

Modulation of lighting intensity and shading is another successful way of increasing visual acuity for reading and hand tasks. VA investigator initiated research at the Atlanta Rehabilitation Research and Development Center has resulted in recent design and development of a lightweight, portable, glare free, cool, lighting device for partially sighted veterans. Initial clinical trials of liquid crystal Dark Adapting Eyeglasses showed better acuity, contrast resolution and assurance in traveling.

Investigators at the Atlanta Rehabilitation Research and Development Center followed 200 veterans for up to two years to determine the keys to adjusting successfully to visual impairment. Four variables were studied to predict continued use of prescribed vision aids: age, amount of vision loss, cause of vision loss, and family support. Of the four only one variable made a difference. Veterans with support and help from someone at home were twice as likely to use their low vision devices as those without such support. *Watson, G., De l'Aune, W. et al National Survey of the Impact of Low Vision Device Use Among Veterans, Optometry and Vision Science, Vol. 74, No. 5, May 1997*

Hearing Loss: Augmentation and Prevention

Results of RR&D funded prospective study to determine benefits and provide prescriber information for use of cochlear implants was widely published and findings thereof found general acceptance among audiologists.

Data from VA study formed the basis of American Speech-Language-Hearing Association national guidelines for ototoxity monitoring.

Current hearing aid technology provides new capabilities in terms of both signal processing and the flexibility with which they can be prescribed and fitted. In addition, test instruments for hearing aid evaluation and audiologic assessment have been substantially improved. VA studies have focused on clinical evaluation of these technologies to assist audiologists successfully harness new knowledge in clinical practice.

For the profoundly hearing impaired, approaches for remediation that substitutes for rather than augments lost structure or function of the auditory system is necessary and has proven successful. Cochlear prostheses are electronic devices that can be surgically implanted in suitable candidates to enable them to hear again.

COMMUNICATIONS, COGNITIVE, AND SENSORY AIDS

Cochlear implants consist of two parts, one surgically implanted into the inner ear and an external component that functions as a microphone to detect and process sound waves. What is "heard" by the person varies from alerting sounds, to background environmental sounds, to intelligible speech sound, to telephone conversations.

A VA cooperative study was designed to investigate the safety and usefulness of several advanced cochlear implant devices. Uniform protocols were used in a randomized multi-center trial evaluating effectiveness in eighty two candidate subjects. Three devices were tested. One could process signals from only one sound source electrode and the two other devices channeled up to three electrode sound receptors placed within the hair cell layer of the cochlea. The VA study concluded that both multi-channel implants are more effective than the single-channel device. The extensive network of nationwide VA clinical facilities made this a definitive study determining efficacy and safety.

Cohen, N., Waltzman, S. et al A Prospective, Randomized Study of Cochlear Implants, New England Journal of Medicine, January 28, 1993

VA has also received acclaim for its work in preventing hearing loss as a side effect for patients receiving therapeutic treatment with drugs having ototoxic potential. These drugs commonly include the cancer chemotherapeutic cisplatin and carboplatin and many of the aminoglycoside antibiotics. VA investigators have developed a bedside ototoxity monitoring technique in an effort to promote early detection and implementation of intervention strategies. Data from a study designed to compare the relative efficiency of measuring hearing thresholds in the low- and high-frequency ranges for the purposes of early detection formed the basis of national guidelines for ototoxicity monitoring adopted by the American Speech-Language Hearing Association.

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Fausti, S., Henry, J., et al Ototoxicity in Hearing Disorders, Third Edition, JL Northern, Ed, Boston: Allyn & Bacon, 1996.

Speech/Language Remediation

Developed and successfully transferred into commercial use Lingraphica, a portable, self-contained, computer-based medical device using graphic symbols to allow two way communication for persons with aphasia.

Aphasia is a common consequence of stroke and other diseases treated within the veterans healthcare system. VA studies focus on developing options for patients to regain communication skills through speech rehabilitation or devices designed to augment communication. Recently transferred into commercial use, Lingraphica is a portable, self-contained, computer-based medical device using graphic symbols to allow two way communications for persons with even the severest aphasia. It is the first FDA-regulated medical device for speech-language remediation.

COMMUNICATIONS, COGNITIVE, AND SENSORY AIDS

Lingraphica is yet another example of successful application of emerging computer technology to traditional manual methods. In developing Lingraphica, investigators at the Palo Alto VA Rehab R&D Center built on existing visual communications systems utilizing decks of cards with pictures or symbols manipulated by patients for purposes of communicating. Through development of this concept using personal computers with high resolution graphic displays to replace the cards, researchers produced an integrated computerized system that combines spoken words, printed words, images and text processing to facilitate communication. As a result, language-impaired persons have greatly expanded ability to interact with others in a less cumbersome manner.

Although not yet scientifically tested, clinicians have observed that Lingraphica may also serve not only as an adaptive device, but as a successful rehabilitative method for correcting patient's natural language. Indications are that some patients have improved through the pairing of Lingraphica with speech therapy.

Palo Alto investigators were also recognized in December of 1993 for their success in transferring this technology into commercial use by the Technology Utilization Foundations' National Award of Excellence in Technology Transfer.

Perhaps more importantly, as reported recently in the peer-reviewed literature, the Lingraphica System has emerged as a powerful treatment tool when integrated into carefully constructed and comprehensive therapy programs known as Language Care Center Programs. Even chronic patients previously discharged from traditional therapy respond to Language Care Center therapy with significant additional improvements, as shown by measurements using standardized, valid and reliable assessment tests. *Aftonomos, L., Steele, R. et al Promoting Recovery in Chronic Aphasia with an Interactive Technology, Archives of Physical Medicine and Rehabilitation 78 (8), 1997.*

Harris, V., Shireman, C. et al, Innovative Programming for Adults with Aphasia, Advance for Speech-Language Pathologists and Audiologists, 7 (23), 1997

Steele, R. Lingraphic Methods in Interface Design, Proceedings of International Workshop on Human Interface Technology, University of Aizu (Japan), 1995.

REHABILITATION RESEARCH AND DEVELOPMENT

MEETING THE CHALLENGE Independence in Function

- ... Independence in Vocation
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