

SINGLE TOPIC ISSUE

Functional neuromuscular stimulation (FNS)

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This issue of the *Journal of Rehabilitation Research and Development* provides a snapshot of the progress that has been achieved in the research and application of functional neuromuscular stimulation (FNS) taken at the Fourth International Conference on Motor Prostheses at Deer Creek Conference Center, Mt. Sterling, Ohio, in July 1994. The objective of that conference was to facilitate the development of new neural prosthetic approaches to replace motor function after disease or injury. The chairman of the conference was P. Hunter Peckham, PhD, of Case Western Reserve University and the Veterans Affairs Medical Center, Cleveland, Ohio, and the cochairman was Andy Hoffer, PhD, of Simon Fraser University, Vancouver, British Columbia. The conference program was designed to identify and address the technical and physiological issues that are key to the successful clinical implementation of neural prosthetic devices. Users of neural prostheses participated in the discussions. Sessions were held on the following topics: FNS ambulatory assistance; FNS applications for upper limb control; respiration and micturition; dynamic myoplasty; muscles—the actuators; electrodes, leads, and connectors; neural signals for command control and feedback; feedback control strategies; and technology transfer and multicenter trials.

This conference provided a clear indication that many of the old obstacles to progress in development and deployment of neuroprostheses are falling to the force of knowledge based on recent progress in the basic sciences and the successful applications in the clinical world. The six main articles in this issue on specific aspects of FNS were all presented at this conference, and the Conference Abstracts *Neural Prostheses: Motor Systems* provides summaries of major conference discussions.

Background

Electrical excitation of diseased or damaged neural tissue has been recognized for several decades as a

powerful technique to improve some functions in persons with paralysis. Perhaps no alternative, short of actual regeneration of neural tissue, can elicit the equivalent level of function. This is because the electrical stimulus can be delivered directly to the neural tissue to generate the desired response of the nerve. When properly applied, the energy transfer is both safe and efficient. Low levels of current can be safely injected to neural tissue with a minimal but biologically acceptable response. Furthermore, the energy amplification is substantial, since a small stimulus can generate a considerable action. For example, an electrical stimulus of a few milliwatts generates as much as a hundred newton-meters of torque in the lower limb.

Electrical stimulation may be used to activate motor or sensory nerves, excite or inhibit nerves, and even generate unidirectional impulses. Another use of electrical signals is to use afferent signals from intact structures whose communication links with other body systems have been destroyed or diminished by an injury or disease to provide feedback to guide motor activity. It is conceptually possible, therefore, to obtain “artificial” control with electrical stimulation over virtually all structures which rely upon neural communication for their activation. This encompasses virtually all of the critical motor and sensory pathways involved in paralysis of the central nervous system as a result of, for example, spinal cord injury (SCI), stroke, and cerebral palsy. For these reasons, this technique has received considerable attention from physicians and engineers for nearly 3 decades.

At a recent meeting, “Behavioral Adaptation to the Use of Assistive Technology,” Dr. David Gray set out a conceptual diagram to represent the challenge to developers of assistive technology and other rehabilitative modalities (**Figure 1**). He classified individual performance levels in several life activities for persons who had traumatic injuries into abilities present prior to

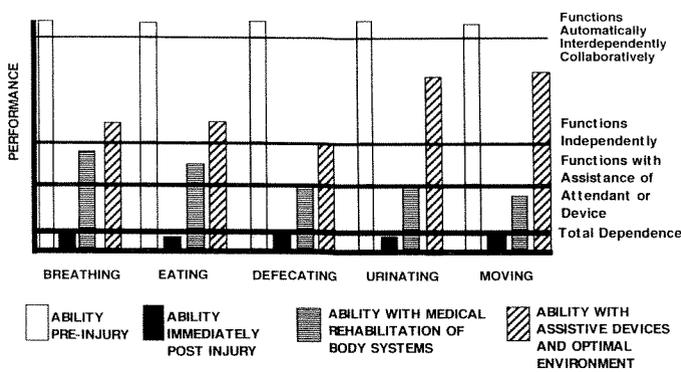


Figure 1.

The potential optimal effects of medical rehabilitation and the use of assistive technologies in improving the lives of people with disabilities.

injury, the period immediately after injury (acute phase), and the postinjury period where different types of treatments may result in dramatic changes in functional capacities. In addition to traditional rehabilitation therapies and provision of personal care attendant services, assistive technologies were featured as an increasingly reliable and affordable means of substituting, replacing, and restoring lost or diminished function. The outcomes of these types of interventions were then characterized in terms of the level of dependence, independence, and interdependence. Enhancing performance of persons with disabilities to reach a level of functioning that allows them to be economically independent and socially interdependent may necessitate using many different types of interventions. While each intervention has strengths and weaknesses, assistive technologies hold great promise when they give more control to the consumer, provide less reliance on social skills of the consumer, and are economically feasible when averaged over the life of the person with a disability.

The development of a new generation of neuroprostheses has played an important role in efforts to improve the lives of people with disabilities. Taking five basic life activities selected by Gray (breathing, eating, defecating, urinating, and moving) as examples of essential activities for independent living, one can illustrate how neuroprostheses can dramatically change the lives of people with SCI. Implanted neuroprostheses for breathing and urinating have been in clinical use for a decade (see Creasey et al, *Electrical stimulation to restore respiration*, and the session chaired by Creasey and Van Kerrebroeck, "Neuroprostheses for control of

micturition," in the Conference Abstract *Neural Prostheses: Motor Systems* in this issue), and those for eating and defecating are presently in clinical trials. One system for moving (stepping) using surface electrodes to deliver stimulation has completed clinical trials, while others using implanted devices are in an earlier stage of clinical research.

As shown in **Figure 1**, each of these neuroprostheses has been demonstrated to provide individuals with the capacity to improve their performance from the level of functioning with assistance to greater than independent function. A survey performed by Creasey (see Peckham et al, *Technology transfer of neuroprosthetic devices*, in this issue) revealed that approximately 3,000 implantable neuroprostheses for these and other functions have been deployed worldwide. Each of these neuroprostheses provides a remarkable story about the impact on a person's life. The vast majority of these systems are reported to function acceptably for the patient for many years with minimal failures. One can thus claim that these efforts have reached a level of clinical acceptance in several of the potential applications of neural prostheses.

This success has been the result of considerable progress in the basic sciences and engineering made possible only through continued commitment of funding agencies. These advances in our basic knowledge of the interface of electrical stimulation and the biology of the human organism need continued nurturing. Yet continuation of this support will, in large part, rest on the shoulders of clinical applications of technologies that have shown utility in improving the lives of people with disabilities. Both the acquisition of basic knowledge necessary to build neuroprostheses and the lessons learned from clinical trials of these devices have been a result of an international effort. In the United States, the National Institutes of Health and the Department of Veterans Affairs are particularly to be credited, and the National Institute on Disability and Rehabilitation Research for their earlier involvement. The knowledge and technology have been the result primarily of the work of scientists and clinicians supported by the Neural Prosthesis Program at the NIH. Without the considerable commitment of the VA Rehabilitation Research and Development Service in supporting research to realize motor system neuroprostheses in a clinically deployable form, the applications to people with disabilities would not have been achieved.

It remains clear, however, that there are significant challenges to overcome in the further development and

deployment of neuroprosthetic systems. We must remember that most of the systems that have been implemented are first generation technologies. In many cases, knowledge currently exists that will enable clinicians to develop more advanced systems to provide additional functions for persons with disabilities. In other cases, we have not yet determined all the knowledge or developed all the technology to achieve the clinical objective. Continued effort by all partners is required in order to sustain both basic and applied research activities to achieve our clinical goals.

To date, the deployment of clinical systems has almost exclusively been a single neuroprosthesis supplying one function to a recipient. However, many (and perhaps most) of the persons with disabilities have multiple organ system involvement. To achieve the goals set by Gray, an alternative design strategy might be to develop a single complex system that integrates all neuroprostheses with the multiple functions being enhanced. Efforts to integrate the neuroprosthetic technology in order to deliver it in an acceptable form to both the clinician and the consumer are necessary to achieve this goal.

There remain many obstacles to overcome. The time and costs to develop and deploy a neuroprosthesis are considerable. The regulatory review is extensive. The cost of the technology must be balanced by the improvement in function and quality that can be realized. Most importantly, the neuroprosthesis must achieve the acceptance by the consumer (the person with the disability), the deployer (the clinician), and the payer. Third party payment agencies, both private and government, need to cost average options for more than 1 to 5 years. For example, while a neuroprosthesis for bowel and bladder control may cost \$25,000 for initial installation and have a modest annual cost, the reduction in cost of attendant care (ranging from \$6,200 to \$9,100 annually¹) would easily be offset if cost accounting were made on a 10-year basis. This type of economic

analysis might provide a rationale for payment for such neuroprostheses as well as provide a market for the development and purchase of such devices. The problem of "dumping" the responsibility for rehabilitation from the health industry to a general fund for the socially disadvantaged needs to be addressed. Some portion of these technologies must, surely, fall within the purview of making human capital investment for long-term social benefits both moral and economic.

Although significant clinical progress has been achieved to date, neuroprostheses are not nearly as widely deployed a rehabilitative tool as anticipated. Why? Are they too complex to implant or to use? Is the technology too intimidating to the clinician unfamiliar with it? Is he or she skeptical of its utility? Has there been a failure to educate the clinicians regarding the technology? Are people with disabilities skeptical of its utility? Have so few been implanted that the disability community is unaware of the possibilities? Are the functional gains in one area offset by inconvenience, loss of function in other activities, fear of medical personnel, and "the medical model" controlling even more of their lives? Are legislators more willing to fund traditional "cure" research than clinical research on improved function? Are they aware of the reduction in healthcare costs such devices could render? Are manufacturers reluctant to consider this a viable "market"? The answers to these questions are likely to be varied and personal. Of course, some clinicians will not accept its use, and neither will some consumers. However, with clinical success and knowledge will come acceptance. Thus, it seems imperative that effort be focused to achieve clinical success.

¹ Berkowitz M. Economic consequences of spinal cord injury. In: Proceedings of the The First National Conference on Economic Consequences of Disabilities, September 1993, Washington, DC: Paralyzed Veterans of America Research and Education Program, 1993:49.