GUEST EDITORIAL

Functional Electrical Stimulation Systems: What Have We Accomplished, Where Are We Going?

Few fields of rehabilitation research have generated as much excitement and public interest as functional electrical stimulation (FES) by computer control. Early publicity gave the potential users of FES systems hopes that this modern technology could almost normalize their impaired functions. Unfortunately, the great expectations of persons with physical disability (limb paralysis) have been deflated by the lengthy development process of FES systems and their high cost, and ultimately, by their limited clinical applicability and functional significance. No user of any FES system for limb control has performed at a skill level anywhere close to normal or that of the fictional "bionic" characters of movies and television that are so well known to the public. However, when expectations are realistic and match the achievable performance, FES systems have had a positive impact on the lives of many individuals with disability.

Successful clinical application of FES systems depends on several factors: a) simplicity of the desired task, b) total implantation of the device which usually results in improved cosmesis and eases donning and doffing, c) low rate of mechanical failure and medical complications, d) functional improvement greater than can be achieved by other means, and e) relatively low cost.

Expanding briefly on these five criteria, it is generally accepted that, given the current state of the art, stimulation of a single muscle or muscle group without need for sensory feedback in order to complete a relatively simple motor task is more likely to result in acceptable function than synchronized stimulation of multiple muscles for prolonged performance of a complex task that requires continuous sensory feedback to obtain coordination and balance. In contrast to external devices, totally implanted systems, safe and free of mechanical failures, appeal more to the user in chronic applications of FES as they are cosmetic, require no or little donning and doffing time, and are not likely to affect the health and well being of the person. External FES devices will remain the preferred choice for temporary applications for both functional and therapeutic purposes.

Cost is a relative term and includes user evaluation, the device, implantation, training, indirect costs, and maintenance. Ultimately, the cost must be judged by the value of the function gained and improved quality of life over time. In general, the simpler the device and the greater the user population, the lower is the actual monetary cost. One form of FES that meets most of these criteria is cardiac pacing. Diaphragm pacing by electrical stimulation of the phrenic nerve also meets most of the criteria and has become the standard of care for persons with high level

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complete tetraplegia, who are otherwise dependent on mechanical respiration but have intact lower motor neurons for the phrenic nerve.

Application of FES systems for limb control is a particularly complex endeavor. Usually, multiple muscle groups must be stimulated in a correct and accurately timed sequence; sophisticated sensory feedback is required for optimal control, coordination, and balance, and the physiological functions of the musculoskeletal and cardiovascular systems must be adequate and provide enough strength and endurance to complete the desired task, often in a repetitive fashion over a relatively lengthy period of time. Despite these formidable requirements, FES systems have been developed for both upper and lower limb use, and these systems have been applied with some clinical success, providing persons with C5-6 tetraplegia with hand grasp and release, permitting persons with thoracic level paraplegia to stand up and ambulate for limited distances with a walker or pair of crutches, and creating a means for persons both with tetraplegia and paraplegia to exercise their paralyzed limbs on a cycle ergometer for potential health benefits. Recent development of upper limb FES systems has brought them close to the stage of total implantation, and implantable FES systems for standing and limited ambulation may not be very far behind.

Unfortunately, the complex designs of such systems make them subject to mechanical failures. Expense of system components, the limited size of the potential user population, and the extensive training required for successful use, result in a high cost and the functional benefits have not yet been shown to reduce the overall cost of care. Given the current trends in healthcare delivery, where managed care and cost containment rules, it may be questioned whether the development and marketing of expensive high technology devices, such as FES systems, makes any sense. Considering the large financial investments that have already been made in this technology, the current state of development and the well demonstrated small, but significant, functional gains associated with use of FES systems, it currently seems sensible to proceed cautiously, but to set modest and easily achievable goals that swiftly lead to increasing function at a relatively low cost.