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Perspective

A new paradigm is needed to guide the utility of functional electrical stimulation in rehabilitation medicine

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Abstract

Back in 2006, an invited commentary raised the question "are we asking clinically relevant questions"? The commentary referenced an application of electrical stimulation in a clinical trial [1]. This question regarding Neuromuscular Electrical Stimulation (NMES) and Functional Electrical Stimulation (FES) is as relevant in 2020. Based on the premise and presumption that the aim of applying NMES/FES is to enable each patient achieve the most effective and efficient recovery of functional independence, one must wonder if we are asking the most critical, yet clinically relevant questions? This perspective focuses on locomotion and upper extremity function following a Cerebrovascular Accident (CVA) and non-neurological damage to the knee joint. It delineates several questions elaborating on the issue of meaningful outcomes to the patients versus the focus of clinician and researchers on measurable outcomes. It offers pathways that should hopefully lead to considerably more effective and efficient utilization of NMES and FES in rehabilitation medicine.

Perspective

This perspective is written to highlight a concern that current physical rehabilitation treatment options offered to patients recovering from damage to the brain, do not meet many patients' expectations. The paper is limited in scope to stroke survivors using only selected references, but the readers are encouraged to extrapolate and extend the perspective to other patients needing physical rehabilitation including but not limited to cerebral palsy, multiple sclerosis, and musculo-skeletal degenerative joint disease.

Locomotion

The question of clinical relevance has been addressed in the rehabilitation literature numerous times including by asking patients how they perceive the effects of an intervention [2]. But the issue of who determines whether an outcome is relevant to the patient remains unresolved. Clinical researchers focusing on locomotion typically select, if available, objective, measurable, and previously validated outcome measures. Among them are walking distance and speed [3], timed-Up and go (TUG) [4], or five-times stand up and sit down [5,6] tests, representing recovery of basic locomotion ability. Yet the question remains: are objective, statistically significant improvement of 35-50 meters of walking distance, or improved walking speed by 0.15-0.2 meter/sec [7-9] are also perceived by the study's patients as improved locomotion ability? The answer is frequently not, according to several scientific publications [10-12].

Whether researchers measure impairments or functional outcomes associated with locomotion or upper extremity use in daily activities, prediction models such as reported by Wand, et al. [4] were limited to identifying responders and non-responders based on motivation and functional status prior to stroke. Models that predict which patient will recover independence in daily function could not be found in peer-reviewed publications. The inevitable question is therefore: what outcome measures are critical to the patient, not to the researchers-clinicians? [13]. To answer this question there is a need to re-examine what happen to a person that suddenly loses control over the ability to move one or more body parts.

One governing foundation of physical rehabilitation is that human beings hope to remain independent of any form of

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assistance in executing daily functions. These include but are not limited to walking, standing up and sitting down, as well as negotiating uneven terrain. Becoming depended on technology driven assistive devices, and worse on human assistance, reflect successive and sometimes abrupt loss of locomotion independence. Accordingly, a patient who became dependent on human assistance to ambulate or stand up, and following physical rehabilitation no longer need human assistance is likely to perceive the therapy as yielding meaningful improvement. Similarly, a patient who ambulate with hand support using a walker, quad-cane or a cane and after training no longer needs hand support to walk is likely to report a treatment-enhanced meaningful achievement. The same is true for a patient who depends of FES to walk better and after 6-12 months no longer need the FES during ambulation. These are examples of objective, measurable outcomes that are likely to be perceived a success by most patients but unfortunately are rarely, if ever, reported in published clinical investigations. Moreover, these patients' reported changes in outcomes should be primary not secondary or tertiary outcomes in future clinical trials.

To focus on the contribution of FES in the attempt to help patients become independent in locomotion, the primary muscle groups that are likely to benefit from stimulation during standing up and sitting down are the plantar flexors, the quadriceps, and to a lesser extent the hamstrings and dorsiflexors. The need to stimulate these muscles is implied based on well-established biomechanical data that these muscles are the prime physiological torque generators of transitioning from sitting to standing and back to sitting [14]. When the damage is not to the brain but to the musculo-skeletal system such as following repair of the torn anterior cruciate ligament (ACL) or following total knee joint replacement (TKA), the primary loss of strength and motor control are in the quadriceps and hamstrings [15]. Following brain damage, these muscles become weak and atrophied and the patient loses cortical and sub-cortical control over the magnitude and timing of contraction during locomotion [16]. Ambulation is somewhat different than standing up and sitting down. When the damage is to the brain, the likely muscles to benefit from FES during walking are the dorsiflexors, plantarflexors, and hamstring [17]. Following repair of the knee's ligaments or post knee joint replacement, stimulation the quadriceps and hamstring during walking should be considered [18].

The long-term goal of the locomotion training post stroke should be to initiate FES as early as possible and continue using it daily until independent locomotion is achieved so that the patient no longer needs the support of FES to stand-sit and walk. Considering patients without damage to the brain, some 35-40% of patients recovering from reconstructive knee surgeries are expected to benefit from FES/NMES from 4 to 12 months to reach the long-term goal [19,20]. Regrettably, there is no current documented evidence how many stroke survivors are expected to reach the goal of no longer depending on FES to ambulate. One study from 1997 reported that only 3 of 50 patients post-stroke have reached this goal [21]. The critically relevant clinical question is why so few? One plausible hypothesis implicates the "open-loop" design of commercially available FES systems [22]. For example, having pre-determined stimulation intensities to induce contraction of the dorsiflexors may result in "over-stimulation", thus reducing the need for the brain's motor drive to control the activation of these muscles. To transfer control from the FES to the brain, closed-loop designs have been suggested where the stimulation is only added to complete the desired joint range of motion that the patient is unable to complete without stimulation [23]. However, such closed-loop control FES systems are only available to few research groups. Whether it will lead to more patients reaching the goal of becoming FES independent remain unknown until these systems become commercially available.

Upper extremity functions

Typical functions of the upper extremities include the ability to unimanually or bimanually grasp, hold, move, release, and manipulate objects. Numerous clinical researchers favor validated scales to asses recovery of daily use of the paretic upper extremity. Among these scales are the Fugl-Meyer assessment (FMA) [24,25], the Wolf Motor Assessment (WMA) [26,27] or the Action Research Arm Test (ARAT) [28-33]. Unfortunately, statistically significant improvement of these scales did not translate to actual daily functional use of the paretic upper extremity, once the studies were completed [34,35]. Furthermore, one study of stroke survivors calculated the residual deficit (RD) of some of these measures as a mean of identifying the limit of recovery after 12 weeks of intensive training of the upper extremity. The data confirmed that for many, the recovery was very limited [36].

Similar to locomotion, a critically relevant clinical question facing researchers and clinicians is what constitute recovery of hand function following damage to the brain? Depending on the definition, about 80-85% of stroke survivors will not recover sufficient upper extremity movements and dexterity to resume independent use of the paretic extremity in daily activity. This reality hold true even after completing training that include bimanual activities and extended treatment dose [37,29]. Moreover, improvement in the above mentioned scales is typically measured as time (sec) of task completion, not the ability to regain use the paretic hand in unimanual or bimanual daily functions once the study is over. As a result, these patients' realistic goal should be to use the paretic extremity as an assisting, not primary hand in daily functions and the training program should be restructured accordingly. Clinical data confirm that while using the FES many patients can achieve such a goal provided they have a self-administered FES used in the home environment [38,39]. The anecdotal patients seen on the web video media using FES applied to the paretic upper extremity appear to depend on the FES to perform different tasks. But the critical and clinically relevant question is therefore: can FES be used to train the patient so eventually they will use the paretic hand to assist in carrying objects, and helping in bimanual daily functions without FES? Currently, answer to this question could not be found in peer-reviewed publications.

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Few published studies where FES was used in a clinical setting to train the upper extremity, did not report how many, or if any patient who completed training was able to use the paretic upper extremity as assistive hand in her/his home environment without FES [40-42]. Thus, the relevant question is: what technological advancements and training programs are needed so patients become independent using the upper extremity at home? Unlike the lower extremity [43], wearable wireless FES systems are not commercially available for the upper extremity. Moreover, deciding which muscle groups require FES to be able to reach, open the hand, grasp, move and release an object is less predictive than in the lower extremity for several reasons. Variability in patients paresis/paralysis presentation and upper extremity position as well as distance from the object, are some of the reasons [44]. In addition, there is a breakdown in the continuum of care of upper extremity rehabilitation where FES training is only offered for 4-6 weeks and at most for 12 weeks [42]. Considered collectively, it appears that a paradigm shift should be considered if the aim is to maximize the recovery of upper extremity function following damage to the brain.

Summary

This perspective focus on achieving successful outcomes as perceived by patients recovering from damage to the brain or the musculo-skeletal system of the knee joint and contrast them with successful outcomes recommended by clinicians and researchers. The emphasis is on the contribution of non-invasive Functional Electrical Stimulation (FES) to the recovery of independence in locomotion and upper extremity functions. Embedded in the perspective is the suggestion that re-examining both technological and clinical training paradigms will be needed if the goal is to achieve independence in activities of daily living. The suggested paradigms include reprioritization of clinical outcome measures to reflect progress toward recovering independence and the use of closed-loop FES systems to minimize "over stimulation". The closed-loop FES is projected to help transfer of control from the FES induced muscle activation to the brain's motor drive controlling these muscles.

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