

Functional Electrical Stimulation (FES) in the home: Compliance measurements

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Abstract

Functional electrical stimulation (FES) is an assistive technology shown to improve muscle condition when used appropriately and can also help patients with paralyzed or weak muscles to move. As such it has been explored as a form of exercise in the home environment. One parameter of this exploration which must be considered when interpreting the effectiveness of a device is patient compliance; that is, actual patient usage of a FES device in the home. In this short report, we discuss how the literature has historically reported compliance and propose, upon the premise of the literature, that compliance may be measured in three ways: anecdotally, externally, or procedurally. In emphasizing these methods, we stress that for clinicians or engineers to truly elucidate patient device usage, they must measure compliance by using a number of these measures.

Introduction

The ability for the human body to perform exercise is made possible by the coordinated actions of muscles and bones in conjunction with other structures such as tendons, ligaments, and in more recent times, fascia [1], all working in a synergistic fashion. Irrespective of any degree of cohesiveness this system may possess, it can be rendered inactive or weakened by a variety of both inherited and congenital diseases, as well as traumatic injury. Paralysis, a major feature of these conditions, causes an inability of this system to function properly and thus interferes with or prevents movement. Functional Electrical Stimulation (FES), the use of an external electrical current to stimulate this system, offers a practical manner by which a variety of populations may exercise [2]. While there are several FES devices available for patients, it is rare that these devices are used at home. However, in light of recent initiatives such as EU-RISE and Rise2-Italy, it is clear that the use of FES technology in the home can offer patients a variety of physiological and anatomical benefits to muscle and skin, such as improved muscle bulk and ultrastructural organization, and skin thickness [3]. The health benefits include improved comfort while sitting in wheelchairs [4] and fewer skin issues [5-7].

Therefore, it is no surprise that recent research efforts have focused upon the translation of this work into the home. Researchers in Sydney, for example, conducted a study examining what stakeholders consider to be important issues surrounding translation of this technology into the home, and put forward the “Vienna Schema” which outlines a model designed to guide clinical practice with concepts that are important to consider if a patient is to continue using FES in the home [2]. One concept outlined in their model is the idea that patients would be more likely to participate in FES at home if they are seeing results; however, at best patient usage is unpredictable

in the home. Therefore, it is essential that people who provide FES devices to patients have a method for measuring how often patients use devices once these are provided. Hence, we have chosen to focus this short paper on the concept of compliance to use of FES as reported in the literature.

Defining compliance

Given its suggested benefits, FES is undoubtedly a good candidate for use in an exercise program aimed at restoring health and livelihood to those with SCI, or other conditions. Dolbow *et al.* [8] indeed stress the importance of researching other methods for increasing exercise, and reducing secondary diseases associated with the sedentary nature of a patient with a spinal cord injury. While FES is one such method, whether or not the technology is adopted by those who for whom it is designed, needs to be taken into serious consideration. Otherwise device design is pointless. A metric by which this may be measured is known as compliance, or “exercise adherence” [e.g., 8]. Formally, compliance, was defined by Blackwell [9]:

“Compliance has been defined as the extent to which a person’s behaviour in terms of taking medications following diets or executing lifestyle changes coincides with medical or health advice”

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Compliance is an important consideration as it relates to how well a home study has proceeded [10].

Measuring compliance

There have been multiple methods by which compliance has been measured within the literature on home FES use. For the purposes of discussion, we propose these methods may be considered to be of three classes: 1) anecdotal-referring to user-reported compliance; 2) external-referring to reporting by an individual (e.g., physiotherapist) who conducts research into participant compliance; and 3) procedural-referring to an intrinsic component of an FES system which reports how often the system is used. There have been several studies on home FES which implement such methods.

Measurement of compliance is essential to see how often a system is used in the home environment in concordance with a stipulated protocol from a study or a suggested clinical regimen. In essence, 100% compliance is desirable as it means the effect of a certain FES exercise protocol can be entirely deduced over the period of exercise. Authors such as Dolbow and colleagues [8], for example, use compliance rates to stipulate success of an exercise program. Another example is the work of Baker and colleagues [11]. In their study, compliance was defined as an individual completing 1.5 hours per day of treatment. Semi-compliance was defined as 45 mins per day. Hence, compliance was assessed in a stimulator-measured fashion, with it being examined when subjects visited the physical therapist. However, measuring compliance or usage of a FES device in the home has associated with it a variety of reasons to which one may attribute its inaccuracy.

Measuring compliance by multiple methods may be useful in confirming whether or not patients have high or low compliance to a suggested FES exercise schedule. In a study by Walls *et al.* [12], for example, the authors noted that compliance was 99.4% as noted by participants (anecdotal), and 99.0% as noted by stimulators

(procedural) [12]. These similar figures suggest that the stimulation therapy they used had very good compliance. In addition, the very fact that they measured it by both anecdotal and procedural means could be interpreted as confirming this observation.

In a study by Talbot *et al.* [13], compliance as reported by ES users was indeed less than the time recorded on the stimulation apparatus. The authors argue that this could be attributed either to the fact that users did not document every time they used stimulation, or the stimulator could have been on but not actively utilized [13].

We put forward that for a truly accurate measurement of compliance, it is ideal to use two or all of the three measures proposed (Table 1). To illustrate the practicality of this framework, the literature examined (Table 1) has been stratified on a basis of how compliance is reported. The “theorem” (also discussed in the table) suggests that studies would be well inclined to measure compliance in each of these three areas where possible. Some studies such as Walls *et al.* [12] [anecdotal, procedural] and Talbot *et al.* [13] [anecdotal, procedural] are examples of studies that have used multiple means to measure compliance. By measuring compliance in multiple ways, the truth regarding actual stimulator usage is more likely to be ascertained.

There are several reasons why compliance measures may be less than 100%, and these are important to understand from a researcher’s perspective. Compliance is influenced by the environment, obviously with that changing from lab or clinic to home, and this was also examined in Taylor *et al.* [2]. Compliance is influenced also by the motivation of one to report exercise accurately, but also by the accuracy of the stimulation equipment. It has been suggested by a FES researcher for example, that stimulators often do not deliver what they specify they do (unpublished observations). An appreciation of these issues is important for home FES exercise so that it is researched with precision and marketed as a practical way of exercising for the wider patient population.

Table 1. The compliance theorem and methods adopted in literature

COMPLIANCE THEOREM
In order to maximize the accuracy of compliance measures, in a FES exercise program there should be measures made involving one or more of each of anecdotal, external and procedural means.
LITERATURE EXAMPLES
<p>Anecdotal: Compliance as reported by the patient.</p> <ul style="list-style-type: none"> • Bily <i>et al.</i> [15] requested that their subjects with PFPS take note of when they partook in a stimulation exercise, but compliance data were not reported. • Coote <i>et al.</i> [16] requested that individuals kept a training diary, so they could write down how many training sessions they did. • Donaldson <i>et al.</i> [17] reported a case study of an individual who carried out three different types of exercise over 6 months, recording a “log” [exact method unspecified] of what was done. • Stevens-Lapsley <i>et al.</i> [18] ensured that participants were given logs in paper format. • Talbot <i>et al.</i> [13] also had participants keep logs, once a week. Had to write down date/time stimulation occurred. <p>External: Compliance as reported by an external person in healthcare, research or who is responsible for overseeing provision of the FES device.</p> <ul style="list-style-type: none"> • Chan <i>et al.</i> [19] checked if subjects were compliant, by two methods of approach during a six-week training: six home visits, and six phone calls. • Moynahan <i>et al.</i> [20] gave adolescents who used FES a phone interview everyone to four weeks to ask about how often they used the system. They also discussed differences between what they reported, and “usage logging information”. <p>Procedural: Compliance as reported by a technological mechanism.</p> <ul style="list-style-type: none"> • Burch <i>et al.</i> [14] compared the number of days stimulation was used, against what was specified by study [exact method unspecified]. • Dolbow <i>et al.</i> [21,22]: Measured compliance: how many exercise sessions were performed relative to what was the suggested number which should be performed. • Hendling <i>et al.</i> [10]: Conducted a study to examine compliance in a home FES exercise program for the elderly. Looked at voltage and current using a program made in Visual Studio C#. • Prenton <i>et al.</i> [23]: Used a ShefStim system which registered how many times heel lifted. • Sipski <i>et al.</i> [24] used an Ergys system which requires reprogramming of cartridges, how often they were re-programmed indicated usage. • Stevens-Lapsley <i>et al.</i> [18] utilized an EMPI 300PV stimulator which had an “adherence meter”. • Talbot <i>et al.</i> [13] used a Respond Select stimulator that logged how many hours had been spent doing exercise with the stimulator.

While these issues could be regarded as “internal” to the intervention, study, or implementation, there are external factors involved that also impact device use in the home. In their study of veterans with spinal cord injury, for example, Dolbow *et al.* [8] noted a decreased compliance between the first (71.7%) and second (62.9%) periods of their study. They argue that this decrease may be due to the fact that participants were confirmed to have access to bicycles in the second phase, so may have been less concerned about maintaining exercise. Other than being explanatory of reduced compliance, this observation also illustrates the importance of measuring device usage to determine the provision of resources. Indeed, compliance may be used to determine whether a second party will continue to lend a device to a patient for home usage. For example, a study by Burch *et al.* [14] examining electrical stimulation for osteoarthritis, individuals who didn't have a compliance of 50% were prompted to leave the study after the first two weeks.

Concluding remarks

Should any technology or therapy, for that matter be used to treat or alleviate a condition, it is important that device innovators and clinicians understand how often patients adhere to such tasks [25–28]. Obviously, if they do not adhere to the prescribed program, then they will not reap the potential benefits. In the context of FES, compliance has been measured by a multitude of methods by different research groups. We hope that an understanding of anecdotal, external and procedural compliance measurements may help these groups to obtain precise figures specifying patient usage in the future.

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Ethical publication statement

Authors have confirmed that they have read the Journal's position on issues involved in ethical publication and affirms that this report is consistent with those guidelines.

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