

Carryover Effect after Functional Electrical Stimulation Treatment

Pilot Study for a Quantitative Approach

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Abstract: Functional Electrical Stimulation (FES) has been reported to be an effective treatment for neurological patients, e.g. post-stroke patients. Besides beneficial effects at muscles themselves, a re-learning process named carryover effect has been observed in some patients. This work aims at defining a quantitative method to assess the carryover effect in a group of patients, starting from a set of outcome measures that are specific to the considered treatment. Fifteen post-stroke chronic subjects have been recruited for 20 half an hour sessions of FES-based treatment for Foot Drop correction during ambulation. Gait velocity, a spatial asymmetry index, a temporal asymmetry index, endurance velocity and tibialis anterior activation index during gait have been selected as outcome measures. After the analysis performed with the proposed method based on principal component analysis, 50% of patients presented the carryover effect. The proposed approach is a quantitative method that can be applied to any set of outcome measures of interest. The results could inform further studies aimed at identifying the carryover effect mechanism of action.

1 INTRODUCTION

The aging of society and the continuously improved ability to face acute clinical interventions are enhancing the social impact of the neuro-motor disabilities, and consequently, the relevance of rehabilitation. Foot Drop (FD) is one of the common gait impairments associated with hemiplegia; an estimated 20% of all stroke survivors suffer from FD (Heart Disease and Stroke Statistics—2007 Update). FD is caused by total or partial paresis of ankle dorsiflexor muscles (Kottink et al., 2004); it makes ground clearance difficult during swing, and can lead to inefficient gait compensations such as circumduction and hip hiking (Olney and Richards, 1996; Richards et al., 1999). Residual gait deficits such as FD contribute to increased energy expenditure during gait, decreased endurance, and an increased incidence of falls (Kesar et al., 2010).

The conventional approach to address FD is the prescription of an ankle-foot orthosis, but this has significant drawbacks as discussed by Ring and

colleagues (Ring et al., 2009). An alternative FD treatment was introduced by Liberson and colleagues (Liberson et al., 1961) and consisted in externally induced ankle dorsiflexion through peripheral neuromuscular Functional Electrical Stimulation (FES) during the swing phase of gait. Nowadays, FES rehabilitation treatment is a well-known procedure in clinic rehabilitation (Sabut et al., 2010; Pomeroy et al., 2006). FES has several specific advantages as recently pointed out by Kesar and colleagues (Kesar et al., 2010). Indeed, FES promotes active muscle contractions, can help to improve muscle strength, prevents disuse and atrophy, reduces spasticity and spasms, produces a more energy efficient use of proximal limb muscles, and aids in motor relearning. FES has also been shown to reduce the energy cost of walking post-stroke.

Besides the peripheral effect on muscles themselves, possible mechanisms about central therapeutic benefits of FES have been hypothesized (Rushton, 2003; Sheffler and Chae, 2007; Everaert

et al., 2010). Liberson and colleagues reported the following: “On several occasions, after training with the brace, patients acquired the ability of dorsiflexing the foot by themselves, although the periods of spontaneous activity reported were only transitory” (Liberson et al., 1961). This phenomenon, introduced in literature under the name of carryover effect, was further observed in subsequent studies (Waters et al., 1985, Burridge et al., 1997, Merletti et al., 1979, Ambrosini et al., 2011). If the aim of a rehabilitation treatment is to restore a lost motor function, the carryover effect could be seen as a marker of the therapeutic efficacy. However, a comprehensive quantitative definition of carryover is yet not clear in literature in distinguishing patients in those who report a “carryover effect” after the treatment and those who do not, based on selected outcome measures. This work proposes a quantitative method to combine different outcome measures to define an overall outcome score. The overall outcome score could be useful to inform about the carryover effect. Indeed, it could inform further studies that directly measure brain activity and plasticity (e.g., fMRI or TMS studies) in order to directly address the reason why an FES-based treatment is effective only for a pool of patients.

2 METHODS

2.1 Participants

Patients were recruited from the outpatient and inpatient services at the Villa Beretta Rehabilitation Centre (Costamasnaga, LC, Italy). All patients had suffered from first-ever stroke > 6 months previously, resulting in weakness of at least the tibialis anterior muscle (to <4+ on the Medical Research Council (MRC) scale). Exclusion criteria consisted of (i) responsiveness of less than 10° in FES-induced ankle dorsiflexion; (ii) language or cognitive deficits sufficient to impair cooperation in the study; (iii) inability to walk even if assisted; (iv) high spasticity at ankle joint plantar flexor as measured by the modified Ashworth scale index, MAS > 2 (Ashworth 1964).

Experiments were conducted with approval from the Villa Beretta Rehabilitation Centre ethics committee and all subjects gave informed written consent.

Fifteen patients were recruited for the study and 10 completed the 20 sessions of training. The carryover effect index was therefore possible to be

calculated only for the 10 participants that had all measures.

2.2 Training

All patients were recruited for a specific FES-based treatment for FD correction. Along with post-stroke rehabilitation therapy appropriate to their clinical needs, the patients were trained 5 times per week for 4 weeks, receiving a total of 20 sessions lasting 30 minutes of walking supported by a commercial electrical stimulator. Two commercial devices were available at the Villa Beretta Rehabilitation Centre: Bioness L300 (Bioness Inc.) and WalkAide (Innovative Neurotronics). The more suitable commercial device was selected for each patient depending on his/her best responsiveness to stimulation and best wearability. Current threshold was selected for each participant at the beginning of each session so as to be able to elicit ankle dorsiflexion during gait, but at the same time to remain within the tolerance level. Two stimulating electrodes were placed superficially along the peroneal nerve to elicit tibialis anterior muscle contraction during the swing phase of gait.

2.3 Clinical and Instrumental Measures

Patients impairment at the time of recruitment for this study (t_1) and after the intervention (t_2) was evaluated using a battery of clinical and instrumental tests. In particular, they were evaluated through (i) a gait analysis test performed following the standard Davis evaluation protocol (Davis et al., 1991) in the “Gait Lab” at Villa Beretta Rehabilitation Centre along with (ii) the correspondent dynamic electromyography test; and (iii) the 6-minute walking test. Moreover they were scored by the clinician on the (iv) MRC scale index at tibialis anterior muscle.

A set of outcome measures (N=5) was designed to assess different aspects of patients’ functional current condition. All patients were therefore scored on the following outcome measures within 5 days before the beginning of the intervention (t_1) and within 5 days after the end of the treatment (t_2): (i) gait velocity (Vonschroeder et al., 1995; Perry et al., 1995); (ii) a spatial asymmetry index – SA defined as the absolute value of 1 minus the ratio between paretic leg step length and non-paretic leg step length (Lin et al., 2006); and (iii) a temporal asymmetry index – TA defined as the absolute value of 1 minus the ratio between paretic single support time and non-paretic single support time (Lin et al.,

2006), as measured during the gait analysis test; (iv) endurance velocity, as calculated during the 6-minute walking test; (v) the tibialis anterior activation index during gait - TAAI index defined as the ratio between the activity of the tibialis anterior muscle between toe off and toe strike and during the whole gait cycle (Burridge et al., 2001).

2.4 Carryover Effect Definition

In order to define the carryover effect, we proposed to obtain one representative vector of improvement (overall outcome score) that included all outcome measures assessing different aspects of recovery, with respect to a reference population of control subjects. So as to perform a correct analysis in comparing these scores, all considered outcome measures were converted such that increasing score reflected minor residual disability. Therefore, TA and SA indices were converted such that an increasing score reflected improvement. In particular they have been computed as following:

$$TA = 1 - \left| 1 - \frac{\text{single support time}_a}{\text{single support time}_{na}} \right| \quad (1)$$

$$SA = 1 - \left| 1 - \frac{\text{step length}_a}{\text{step length}_{na}} \right| \quad (2)$$

Where “a” means that measure refers to the “affected leg” and “na” means the measure refers to the “non-affected leg”.

The values of the outcome measures for the control population were derived from literature. The controls dataset was created as 50 points randomly sampled from a normal distribution having mean and standard deviation as reported in literature (Table 1).

The overall outcome score was calculated following the hereby outlined steps.

Let c_j be the outcome measures sampled from the normal distribution for the control group. j ranges from 1 to 5 (i.e. N) and indicates the outcome measure considered. Moreover, let x_{1j} be the outcome measures acquired at t_1 and x_{2j} the same outcome measures acquired at t_2 for the patients group.

Firstly, a transformed space defined on control subjects data is defined:

1) *normalisation* – let μ_j and σ_j be the mean and the standard deviation of c_j outcome measures (i.e., $j=1,2,\dots,5$, number of outcome measures considered) defined on control subjects population. A novel set of standardised variables z_c_j (i.e. zero mean and unit standard deviation) can be defined as follows (Figure 1, panel A):

Table 1: Means and standard deviations of the selected outcome measures for the control population as derived from literature.

| # | Outcome measure | Mean | Standard deviation | Reference |
|-----|--------------------|------------|--------------------|---------------------------|
| i | Gait velocity | 1.07 [m/s] | 0.17 [m/s] | Vonschroeder et al., 1995 |
| ii | TA | 1 | 10%*1 | -- |
| iii | SA | 1 | 10%*1 | -- |
| iv | Endurance velocity | 1.4 [m/s] | 0.2 [m/s] | Ilgin et al., 2011 |
| v | TAAI | 0.70 | 0.12 | Burridge et al., 2001 |

$$z_c_j = \frac{c_j - \mu_j}{\sigma_j}; \quad j = 1, 2, \dots, 5 \quad (3)$$

The standardisation is useful so that the different outcome measures units do not skew the results (Shutte et al., 2000).

2) *definition of principal components* – define a set of N independent/uncorrelated outcome measures (i.e. $y_z_c_j$) called principal components, that are linear combination of the original N discrete variables (Figure 1, panel B). Note that performing principal component decomposition over normalised variables corresponds to perform principal component analysis on correlation matrix (Abdi and Williams, 2010).

3) *scaling of principal components* – define a new set of scaled principal components such that each q_j variable has equal variance over the control group (Shutte et al., 2000). This is accomplished through division by the standard deviation of each principal component. Let s_j be the standard deviation of $y_z_c_j$ principal components (i.e., $j=1,2,\dots,5$, number of principal components), the scaled principal components are defined as follows (Figure 1, panel C):

$$q_j = \frac{y_z_c_j}{s_j}; \quad j = 1, 2, \dots, 5 \quad (4)$$

At this stage we defined the transformed space on scaled independent/uncorrelated variables (i.e. scaled principal components) as defined on control subjects outcome measures.

Secondly, all outcome measures as measured at t_1 and t_2 for patients population are projected in the transformed space defined at steps 1-3.

4) *normalisation of t_1 and t_2 outcome measures* – consider now the same outcome measures as acquired at t_1 and t_2 (i.e. x_{1j} , x_{2j}) and standardise them as follows:

$$z_{x_{1j}} = \frac{x_{1j} - \mu_j}{\sigma_j}; \quad j = 1, 2, \dots, 5 \quad (5)$$

$$z_{x_{2j}} = \frac{x_{2j} - \mu_j}{\sigma_j}; \quad j = 1, 2, \dots, 5$$

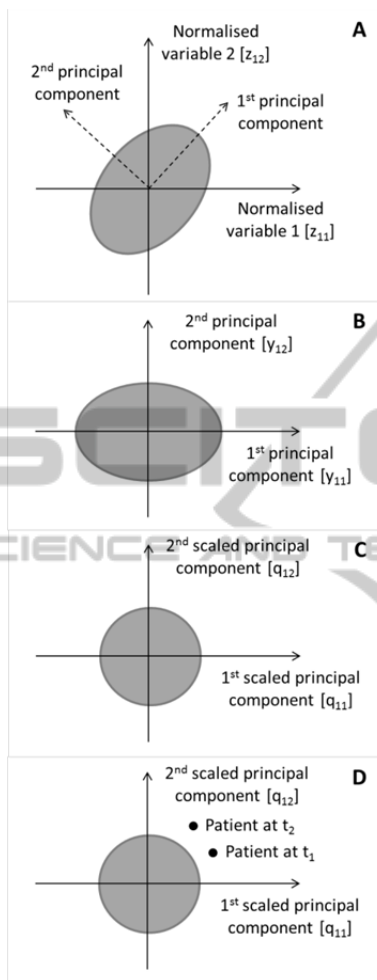


Figure 1: Graphical display of the proposed method with two hypothetical variables represented by the grey shaded ellipse. Only two hypothetical variables are represented for the sake of graphical representation clarity. A) graphical representation of the standardised two hypothetical variables – each control subject is represented by a combination of the two variables, i.e. he/she is a point in the grey ellipse. Since the variables have been standardised the mean of each outcome measure is 0. The principal components axes can be seen as a rotated coordinates system; B) projection of the original data on the principal components axes; C) scaling of the principal components, i.e. the ellipse representing the data becomes a circle; D) an hypothetical patient represented as two points in the transformed space.

Where μ_j and σ_j are the mean and the standard deviation as calculated on outcome measures of control subjects (see step 1).

5) *projection of patients' normalised outcome measures in the principal component plane* – i.e., project the t_1 and t_2 standardized outcome measures in the principal component space defined at step 2 (i.e. define $y_{z_{x_{1j}}}$ and $y_{z_{x_{2j}}}$).

6) *scaling of patients' principal components* – scale the t_1 and t_2 principal component as follows:

$$q_{1j} = \frac{y_{z_{x_{1j}}}}{s_j}; \quad j = 1, 2, \dots, 5 \quad (6)$$

$$q_{2j} = \frac{y_{z_{x_{2j}}}}{s_j}; \quad j = 1, 2, \dots, 5$$

Where s_j are the standard deviation of $y_{z_{x_{cj}}}$ principal components defined at step 3.

At this stage all patients are represented by two points in the transformed space (Figure 1, panel D) where the origin of the reference system represents the controls mean.

7) *patients' distance from control group* – In accord with clinicians, in order to define a threshold for significant improvement, a threshold point was added to the dataset defined as the Minimum Detectable Change (MDC) for each outcome measure. The MDC for each outcome measure was again derived from literature and in particular it was considered equal to 0.3 m/s for gait velocity (Fulk and Echternach, 2008), 0.1 m/s for endurance speed (Eng et al., 2004), 0.12 for TAAI index (i.e., two times the interquartile interval for a group of health subjects - Burrige et al., 2001), 0.032 and 2% for the SA index and TA index respectively (Kesar et al., 2011). This threshold point (i.e. x_{MDCj}) was projected and scaled on the transformed plane defined by controls following steps 4 to 6 as for patients outcome measures (i.e., q_{MDCj}) in order to get a minimum significant threshold for all the scaled uncorrelated variables. Moreover, it has to be taken into account that for some outcome measures it might be possible that the patients value passes the control mean, but this has not to be considered as an impairment. For example gait velocity might be higher than the controls mean, but this would have to be considered as improvement and not as impairment. Therefore, in this study gait and endurance velocity are set to the respective controls mean if the value passes the controls mean itself.

For each patient the overall outcome score (*oos*) was defined as follows:

$$if |q_{2j} - q_{1j}|^2 < q_{MDCj}^2 \quad q_{2j} = q_{1j};$$

$$oos = \sqrt{\sum_{j=1}^5 (q_{2j})^2} - \sqrt{\sum_{j=1}^5 (q_{1j})^2} \quad (7)$$

8) *definition of carryover effect* – If $oos > 0$, the patient overall worsened, whereas if $oos < 0$ the patient overall improved beyond the predefined threshold. The carryover effect would therefore be achieved by those patients whose overall outcome score is negative, i.e. they present an overall functional improvement based on selected outcome measures.

Table 2: Participant characteristics. Part = participant; age = age of the participant at the time of t_1 acquisition in years; M = male; F = female; R = right; L = left; MCA = middle cerebral artery; ACA = anterior cerebral artery; parac = paracentral; type = type of stroke; H = haemorrhagic; I = ischemic; time = time since stroke at the time of t_1 acquisition in months.

| Part | Age | Sex | Site of lesion | Type | Time |
|------|-----|-----|-------------------|------|------|
| PP | 37 | F | R ACA | H | 10 |
| AF | 23 | M | R MCA | TCE | 23 |
| SF | 38 | F | R globus pallidus | I | 23 |
| EM | 64 | F | L MCA | H+I | 13 |
| MT | 19 | M | L MCA | H | 44 |
| RM | 47 | F | L Globus pallidus | H | 44 |
| MF | 25 | F | R MCA | I | 30 |
| SB | 46 | M | R globus pallidus | I | 13 |
| DB | 33 | M | L parac. lobule | I | 6 |
| LF | 61 | F | R MCA | H | 158 |
| LL | 57 | M | L Caudate nucleus | I | 6 |
| GR | 53 | M | L globus pallidus | H | 37 |
| PR | 49 | M | R MCA | I | 89 |

3 RESULTS

3.1 Participants

Table 2 outlines participants characteristics.

3.2 Carryover Effect Definition

The means (\pm standard deviations) reported for each outcome measure at t_1 and t_2 acquisitions are the following: (i) gait velocity - t_1 : 0.45 (\pm 0.17) [m/s]; t_2 : 0.55 (\pm 0.17) [m/s]; (ii) 1-SA - t_1 : 0.81 (\pm 0.14); t_2 : 0.81 (\pm 0.12); (iii) 1 - TA - t_1 : 0.71 (\pm 0.20); t_2 : 0.72 (\pm 0.13); (iv) endurance velocity - t_1 : 0.72 (\pm 0.29)

[m/s]; t_2 : 0.82 (\pm 0.35) [m/s]; (v) TAAI index - t_1 : 0.64 (\pm 0.16); t_2 : 0.57 (\pm 0.21).

The overall outcome score and the relative achieved/non achieved carryover effect for each participant is outlined in Table 3. Five patients out of ten (i.e., 50%) reported a carryover effect as defined by the outlined procedure.

Table 3: Overall outcome score calculated for each participant, along with his/her definition of carryover effect.

| Participant | Overall outcome score | Carryover effect [yes/no] |
|-------------|-----------------------|---------------------------|
| PP | -4.86 | Yes |
| AF | -2.12 | Yes |
| SF | 0.98 | No |
| EM | 0.89 | No |
| MT | -1.01 | Yes |
| RM | 0.07 | No |
| MF | 0.14 | No |
| SB | -0.81 | Yes |
| DB | -0.65 | Yes |
| LF | 0.52 | No |

4 DISCUSSION

This work proposes a quantitative method to distinguish patients undergoing a specific FES treatment in those who report a carryover effect and those who do not. This is an useful approach, since it is common in literature to perform statistical analysis between pre and post treatment sessions looking at the patients as a group that statistically improves or not, possibly with respect to a reference group that does not get the treatment (e.g., Burridge et al., 1997). However the clinical use of FES demonstrated that patients differ in the responsiveness to a FES based treatment (e.g., Merletti et al., 1979). Merletti and colleagues approached the same issue, and demonstrated in 50 post-stroke patients that 34% reported a carryover effect. However they based their results principally on clinical considerations, whereas a rigorous method could be of help when quantitative evaluation is needed. In our study, 50% of patients reported a carryover effect, even if assessed for a smaller group of patients (i.e., 10 subjects). There are contradictory conclusions in literature about the validity of an FES treatments for FD (i.e., Schuhfrie et al., 2012). The proposed step forward of this work is about putting forward that the treatment could be differentially effective for different patients, even with the same functional baseline. This could have

its bases in a central effect of FES that responds to differences in the lesion and consequent recovery at the central nervous system level. Further studies are required to investigate the relationship between the carryover effect and what is happening in terms of plasticity and/or connectivity between the involved areas at central nervous system level.

This work is preliminary and in particular two further issues would be of interest. Firstly the treatment only lasts 20 sessions, and it has been proposed that the longer the treatment the better the results (Schuhfried et al., 2012). It could therefore be interesting to follow up the evolutions of the carryover effect along a longitudinal study. Moreover, a validation of the carryover effect quantitative definition by a group of clinicians that separately assess the presence/absence of carryover would be an interesting further development.

It is interesting to note that this quantitative method could be applied to any other group of outcome measures in order to define the carryover effect on any other particular district (e.g. upper limbs)

5 CONCLUSIONS

The proposed method allows to quantitatively distinguish patients that report a carryover effect following an FES-based treatment for FD. The two groups are easily identified thanks to clear mathematical steps based on principal component analysis that starts from a battery of outcome measures. In our group of post-stroke chronic patients, 50% reported a carryover effect after 20 sessions of FES-based treatment. This could inform further studies aimed at identifying the carryover effect mechanism of action.

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