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Short report

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RESEARCH

Instrumented gait analysis of stroke patients after FES-cycling therapy.

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Abstract

Background: Functional electrical stimulation (FES) is a modality of motor rehabilitation that consists of the programmed application of bursts of electrical current to the affected neuromuscular region that aims to improve muscle strength, increase the range of motion, facilitate movement control and decrease spasticity. The present study aimed to measure the changes in gait biomechanics of people with Stroke after a FES-cycling rehabilitation program for the lower extremities.

Methods: 39 subjects with chronic stroke received 24 sessions of multi-channel FES synchronized with a cycle-ergometer for the lower extremities. The gait of all subjects was evaluated before and after the intervention by an instrumented gait analysis.

Results: Significant changes were found in the spatio-temporal parameters of gait, mainly in the speed and stride length when considering the general sample. Additionally, in people under 60 years of age, there were found significant changes in joint kinematics after FES.

Conclusions: The rehabilitation using a multi-channel FES-cycling system for lower extremities improve gait biomechanics in people with Stroke.

Trial registration: This study was registered as *Instrumental Gait Analysis on People With Stroke After Rehabilitation With a Synchronized FES and Cycle-Ergometer System* on July 16, 2020 in Clinical Trials with the identifier No NCT04473391 (available at <https://clinicaltrials.gov/ct2/show/NCT04473391>).

Keywords: Stroke; gait; rehabilitation; functional electrical stimulation; cycling

Background

We denominate stroke a group of neurological disorders that have in common their sudden presentation due to a restriction of the cerebral vascular flow, which can be caused by ischemia or hemorrhage, causing a permanent or transitory alteration of brain function [1]. Stroke is one of the leading causes of morbidity and mortality in adults in the developed world and the leading cause of disability in all industrialized countries. The neurological deficiencies after a stroke depend on the region affected by the vascular problem and, within these deficiencies, gait disorder is one of the main issues that interfere with functional performance after the stroke [2].

Gait problems in stroke are characterized by a marked asymmetry in the movement when compared with healthy people [3]. Stroke survivors generally have a

decreased stance phase and an increased swing phase in the paretic side. Additionally, a decrease in gait speed and a reduction in stride length have been evidenced [4]. Gait disorder is a major problem, as it causes difficulties in the performance of activities of daily life (ADL) and, also, causes a high risk of falling at all stages after the stroke in people who reintegrate into the community [5, 6, 7].

Precise gait assessment is an important indicator for predicting outcome and the degree of improvement in functional capabilities achievable after stroke and is useful for designing rehabilitation or the monitoring of its effects [8, 9]. Instrumented gait analysis has been used to assess the outcome of various treatment modalities for gait recovery for people with neurological diseases [10]. Instrumented gait analysis consists of the capture, processing, and analysis of multiple data obtained from a moving person through specialized capture devices. It provides a great volume of biomechanical data essential for decision making and objective evaluation of the outcome [11]. Due to the volume and complexity of the data from the instrumented gait analysis, the Gait Deviation Index (GDI) was introduced as a summary measurement that provides a global view of the lower extremities joint kinematics during gait [12]. The GDI is a validated outcome measure for gait assessment in individuals after stroke [13]. The rehabilitation of stroke patients can have great variability, even between patients with identical clinical severity in the acute phase. Therefore, the study of the mechanisms that promote recovery is crucial for the design of optimal therapies. During this process, motor activity and sensory feedback are essential [14]. Several studies have associated elements of afferent stimulation with positive changes in brain activity, including repetition, goal-oriented activities, and the use of functional electrical stimulation [15, 16, 17, 18, 19].

Functional electrical stimulation (FES) is a treatment modality for the motor rehabilitation of people with diseases of the musculoskeletal and nervous system. The intervention consists of the programmed application of short bursts of electric current to the neuromuscular region affected by the pathology, either directly to the muscles or the peripheral nerve. Physiological effects associated with FES include muscle strengthening, inhibition of spasticity, correction of contractures, improvements in range of motion, and facilitation of voluntary motor control [20]. Evidence suggests that FES therapy reduces motor deterioration in people with stroke [21]. Both clinical reviews and meta-analysis have supported the use of FES for the recovery of muscle strength and motor recovery after pathologies such as stroke [22]. Popovic et al. used FES to generate movements and exercises similar to those performed during ADL in people with central nervous system injuries, reducing significantly the execution time of the movements after treatment [23]. FES can be used in conjunction with exercise equipment such as muscle strengthening machines and cycle-ergometers. When FES is used with cycle-ergometers, the technique seeks to stimulate muscle contractions in synchrony with the pedaling motion of a cycle-ergometer. In complement with conventional therapies, therapy with cycle-ergometers and FES can increase strength in the lower extremities, which can have positive results on the patient's ability to walk and move. Multiple studies have reported the benefits of FES therapy with cycle-ergometers, including improved strength and muscle volume, increased glucose metabolism, and a reduction of spasticity [24, 25]. Benefits have also been reported for cardiovascular, pulmonary,

and immune system functions and, in some cases, an increase in bone mineral density [25, 26]. However, none of the available studies have objectively measured the changes in the gait biomechanics after FES treatment for lower limbs. The present study aimed to measure the changes in gait biomechanics of people with Stroke after a FES-cycling rehabilitation program for the lower extremities.

Methods

An interventional type study (clinical trial) was developed, through a single group assignment model, applied to 39 subjects with chronic stroke with a duration of 8 weeks per subject.

Participants

The study included all the patients of the FES-cycling program of the Rehabilitation Center Club de Leones Cruz del Sur, Punta Arenas, Chile, who met the established selection criteria between January 2017 and January 2020. The clinical history of each participant was reviewed to obtain the sample description (sex, age, diagnosis, and hemiparetic side of the body).

A Inclusion criteria: The inclusion criteria were: Medical diagnosis of stroke; referral by a physician; ability to walk with or without technical aids; gait disorder evidenced in clinical history, and acceptance of informed consent.

B Exclusion criteria: Exclusion criteria were: botulinum toxin infiltration in the last 6 months; musculoskeletal surgery of the lower extremities in the last 2 years; musculoskeletal pain in the lower extremities or spine; skin problems in the lower extremities, and thermo-algesic sensitivity problems in the lower extremities.

Experimental setup

The intervention consisted of FES treatment sessions on a cycle-ergometer for the lower extremities. Each subject received 24 sessions lasting 45 minutes each, 3 sessions per week. The sessions were applied by a physiotherapist with experience in electrotherapy. A 6-channel FES device (TrainFES, Chile) was used, which consists of a stimulator unit of 95x50x30mm and 100g of weight coupled to the motorized cycle-ergometer (MOTOmed Viva 2, Germany), a remote user interface consisting of an android application for the configuration of the stimulation via Bluetooth 3.1, and an inertial measurement unit (IMU) positioned on the rotation axis of the cycle-ergometer to detect the rotations and trigger the synchronized electrical stimulation according to the muscle activation pattern pre-configured for the pedaling exercise (see Figure 1).

The muscle stimulation sequence used in the treatment was configured for each channel independently according to studies regarding muscle activation patterns in healthy subjects during pedaling [27]. The stimulated muscles were the quadriceps (rectus femoris), hamstrings (biceps femoris), triceps surae, and anterior tibialis for all patients using 5x5cm disposable adhesive electrodes. The stimulation was performed unilaterally, on the paretic limb of each subject. The current configuration was established according to the recommendations of the literature related to FES, applying rectangular biphasic pulses with a pulse width of 300 μ s, at a frequency

of 20 Hz and intensity above 20 and up to 60 mA according to the tolerance of the subjects and their muscular response, looking for a visible contraction with the generation of joint movement against gravity but that does not generate an increase in the rate of muscle fatigue [28]. The waveform used was biphasic, consisting of a cathodic pulse that stimulates axons located near the electrode, followed by a secondary anode pulse that balances the load of the primary pulse, avoiding potential damage to the electrode-skin interface [29].

Biomechanical Analysis

The assessment consisted of the instrumented gait analysis through a ten-camera optoelectronic system (VICON Oxford Metrics, UK) under pre and post-treatment conditions. The data acquisition procedure was developed using the conventional dynamic pipeline on the software VICON NEXUS 2.9 by the laboratory operator, according to the Plug-in-Gait biomechanical model [30]. For the data acquisition, the passive reflective markers were fixed to the skin of the subjects with adhesive tape in the following anatomical structures of each leg: lateral malleolus, second metatarsal head, calcaneus, lateral femoral condyle, anterosuperior iliac spine, posterosuperior iliac spine and lateral aspect of the thigh (see Figure 2). All the kinematic data were collected with a sampling frequency of 120Hz. In each assessment session, ten gait trials of each subject were recorded at a self-determined speed in a space of 8 meters length. The kinematic variables were processed and filtered with a 4th order, zero-delay, butterworth low-pass filter at 6 Hz, and subsequently exported in c3d format for analysis. The data analysis of the c3d files was developed in MATLAB software through the free toolbox Biomechanical Toolkit (BTK) to identify the curves with greater intra-test consistency [31]. The methodology used to select the most consistent curves within a set of curves was as follows:

Considering a set of curves S (several gait cycles of each joint angle):

$$set = S_1, S_2, S_3, \dots, S_n = S_m \quad (1)$$

Where n is the number of curves. Thus, a mean difference vector is calculated for each curve:

$$VD_m = D_{m2}, D_{m3}, \dots, D_{m(n-1)} = D_{mk} \quad (2)$$

For equation 2, m is the current signal and D_{mk} is the mean value of the difference between m curve and k curve, which belong to set S (as shown in equation 3). In which index m must be different to index k .

$$D_{mk} = \overline{(S_m - S_k)} \quad (3)$$

Once, the difference vector VD_m is obtained for each curve, a mean value for each vector is calculated as:

$$\overline{VD_m} = \frac{1}{n} \sum_{k=1}^n D_{mk} \quad (4)$$

In which, n is the number of components of the vector VD_m , and k is the current component that belongs to VD_m vector. Equation 4 is restricted for $m \neq k$.

Afterwards, a new vector VF_m is composed by each $\overline{VD_m}$ value:

$$VF_m = \overline{VD_1}, \overline{VD_2}, \dots, \overline{VD_n} \quad (5)$$

Thus, equation 5 represents a vector which contains the mean value for each VD_m vector, where n is the number of curves and m is the curve associated with VD_m vector.

Since VF_m value is a quantification of the difference between m curve with the others; the lower VF_m values represent the more consistent or uniform curves within the set of curves.

In order to select the most consistent curves, VF_m vector is sorted from the highest to the lowest values. Thus, the first four values of VF_m are extracted to obtain the four most consistent curves. The mentioned algorithm assumed that the number of segmented cycles is greater than four.

Afterward, the most consistent gait cycle for every joint angle was averaged (see Table 1). Thus a mean curve of each joint angle was extracted. The previous process was carried out for each patient data set. Finally, a general kinematic profile were obtained by averaging joint angles from all subjects. Furthermore, kinematic profiles were divided into paretic (P) and non-paretic (N-P) limb. Once the segmentation and the average of all the extracted signals have been carried out, the GDI and the spatio-temporal parameters are calculated. The GDI consists of an indicator of gait normality that synthesizes all the variables of the kinematic examination in a single general result, indicating the global normality percentage and for each leg in comparison to a kinematic reference database of individuals without pathology or mobility disturbances. This index is considered normal between the values of 90 to 110 [12]. The GDI was calculated from a kinematic normality database of 38 healthy subjects. Baker et al. published the profiles of kinematic normality consisting of the angles shown in table 1, of 38 subjects, who did not have a pathological gait [32].

Finally, the average spatio-temporal parameters of the gait of each subject were calculated from the dataset of kinematic curves associated to the greatest consistency. The calculated parameters were stride length, cadence, and walking speed.

Statistical Analysis

The statistical analysis was performed using the software SPSS 17.0 (SPSS.Inc.) comparing the gait variables pre (Baseline) and post-intervention (Post-FES), specifically the cadence, stride length, walking speed, paretic limb GDI and non-paretic limb GDI. Descriptive and inferential statistics were performed on the study variables. The qualitative variables were described through frequencies, while the quantitative ones were described through their median and interquartile ranges. Inferential statistics consisted of paired comparisons between pre and post-treatment conditions. Due to the variables did not meet the normality assumption, the comparisons were made using the Wilcoxon test. The analyzes were carried out in the general sample and the sub-sample divided according to age range (under and over 60 years of age). Statistical significance was considered for those values $p < 0.05$.

Results

General sample

The study group was composed by a total of 39 subjects (13 women and 26 men) with ischemic stroke of all age ranges with an average age of 58.74 years. Of the total sample, 31 subjects had left hemiparesis and 8 subjects had right hemiparesis. Table 2 shows the characterization of the sample (see Table 2).

The variables of the instrumented gait analysis in pre and post-intervention scenarios were calculated and compared in order to identify the effects of FES-cycling therapy in the study group (see Table 3). The results indicate that in the general sample ($n=39$), the paretic GDI, non-paretic GDI, and cadence were not significantly modified with the FES therapy. The variables that did show significant improvements with the therapy were walking speed and stride length, in both cases an increase of 0.67 to 0.74 m/sec and 0.86 to 0.95 meters respectively was shown (see Table 4).

Although the GDI of the non-paretic limb and the paretic limb showed variations when comparing the pre and post-intervention scenarios (see Figure 3) these differences were not statistically significant ($p > 0.05$). Similar results were observed in the cadence. Moreover, statistic results related to speed and stride length (see Table 4) show significant differences ($p < 0.05$).

Group over and under 60 years of age

Variations in the GDI of the paretic limb, walking speed and stride length were observed in the group younger than 60 years of age ($n=22$)(see Table 5). These variations were significant ($p < 0.05$)(see Table 6). Specifically, an increase from 74.46 to 78.83 in the paretic lower limb GDI was observed. The same occurred with the average walking speed, which increased from 0.68 to 0.77 m/sec, while the stride length improved from 0.86 to 0.99 meters (see Figure 4). On the contrary, in patients older than 60 years of age ($n=12$), no significant differences were found in any variable after the FES-cycling therapy (results not shown).

Discussion

The present study showed the instrumented gait analysis in stroke patients after therapy with a synchronized multi-channel FES-cycling system. Gait characteristics were measured with an optoelectronic camera system, obtaining spatio-temporal parameters (walking speed, stride length, and cadence) and kinematic data. At the end of 24 therapy sessions with FES, significant improvements were identified in the spatio-temporal parameters and gait kinematics of the subjects with stroke. Our results are consistent with other studies such as the work of Laufer (2009) and Stein (2010), who demonstrated a therapeutic effect after the use of FES for 3 months in patients with chronic stroke [33]. In our study, the spatio-temporal parameters that presented significant improvements were mainly the speed and stride length when considering the general sample. Regarding the improvements in walking speed, our findings are consistent with similar studies in the stroke population. Peri (2016) developed an intervention with FES on a cycle-ergometer of fifteen 30-minute sessions carried out in 3 weeks. Their patients were evaluated before and after the training, through functional scales, gait analysis, and a voluntary pedaling test. In their

study walking speed increased significantly for both the experimental and control groups by 35.4% and 24.3% respectively [34]. Robbins (2006), in a meta-analysis of a group of studies aimed towards improving the walking speed of patients with stroke through FES, revealed that therapy is effective in improving walking speed [35]. Other studies have also demonstrated that FES improves walking speed in chronic stroke individuals, maintaining the achievements of therapy even in mid-term follow-ups [36].

It is important to emphasize that in our study significant changes in walking speed were identified in subjects younger than 60 years of age after segmenting the sample by age range. Subjects older than 60 years of age showed no significant changes in walking speed. These results are supported by the literature that associates aging with a general decrease in walking speed and disturbances of balance in older people [37]. The changes in walking speed detected in our study are important since speed is one of the most used indicators to assess results after motor rehabilitation, being a reliable and sensitive indicator [38, 39]. Regarding the improvements in stride length, our results indicate a significant improvement after FES therapy in the entire sample group. The increase in stride length after FES therapy has been documented before in the literature. Lee (2013) studied the effects of treadmill training with body-weight support and FES on functional movement and gait in stroke patients, finding within their discoveries a significant increase in walking speed and stride length [40]. Sabut (2010) also found significant changes in stride length when evaluating FES of the tibialis anterior focused towards motor recovery on patients with stroke [41].

In this study, the GDI was used as a synthesis measure of the kinematic data obtained with the gait analysis. The results of our kinematic analysis indicate that stroke subjects younger than 60 years of age present improvements in the gait kinematics evidenced by a tendency towards the normalization of GDI after training. Literature studies show that the GDI is used as an outcome measure of gait disorder in various types of diseases such as muscular dystrophy, Parkinson's disease, rheumatoid arthritis, among others, and has also been shown to be a valid indicator in post-stroke patients [13].

Despite the current availability and affordability of therapeutic technologies such as FES, there is a large percentage of subjects post-stroke that only receive conventional therapy and as consequence maintain their walking difficulties or require the use of external aids. The ability to walk is an important requirement to carry out the ADL and reintegrate into the community. Therefore, improving gait characteristics is a priority objective for people after stroke who receive rehabilitation therapy [42].

Conclusions

Rehabilitation of gait with a synchronized multi-channel FES system and cycle-ergometer for lower extremities for people with chronic stroke causes significant improvements in gait biomechanics, mainly in the spatio-temporal parameters. Joint kinematics shows improvements in the paretic limb after FES therapy in patients younger than 60 years of age. Future studies should continue with FES therapy in patients with stroke, comparing the results between the different stimulation

modalities and incorporating new outcome measures, such as the measurement of metabolic consumption during pathological gait assisted by FES. Additionally, the long-term sustainability of the effects of FES therapy on stroke patients should be evaluated.

List of abbreviations

The following abbreviations are used in this manuscript:

FES	Functional Electrical Stimulation
ADL	Activities of daily life
IMU	Inertial measurement unit
GDI	Gait Deviation Index
BTK	Biomechanical ToolKit
P	Paretic
N-P	Non-Paretic

Declarations

Ethics approval and consent to participate

The study was approved by the Research Ethics Committee of the Rehabilitation center “Club de Leones Cruz del Sur” (No CorporacionRCLCS0004). All study subjects signed the respective informed consent form for participation in the study according to the Helsinki Declaration, before starting the study process.

Consent for publication

Not applicable.

Availability of data and materials

The data that support the findings of this study are openly available in figshare at <https://doi.org/10.6084/m9.figshare.12659933>

Competing interests

The authors declare that they have no competing interests.

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Author’s contributions

Conceptualization, P.B.; methodology, P.B.; software, P.B., D.S.; hardware, P.B., R.A.; validation, P.B., R.A.; resources, A.A., J.M.A.; data curation, P.B., A.M.; writing—original draft preparation, P.B.; writing—review and editing, P.B., J.M.A.; supervision, P.B.; project administration, P.B., A.M.; and funding acquisition, P.B., J.M.A. and A.A.

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Figures

Figure 1 Patient setup for FES-cycling therapy. The figure presents (A) 6-channel electrical stimulator; (B) Adhesive electrodes on lower limb muscle; (C) Inertial measurement unit (IMU) positioned on the rotation axis of the cycle-ergometer, and (D) Motorized cycle-ergometer for lower limbs

Figure 2 Reflective markers positioning of the Plug-in-Gait model. The white circles on the lower limbs and pelvis of the subjects correspond to the spherical reflective markers of the optoelectronic camera system.

Figure 3 FES-cycling therapy effects on biomechanical variables in the total sample. The figure presents the graphs of the averaged values of GDI in the paretic limb (P), GDI in non-paretic limb (N-P), Walking speed, and Stride Length at Baseline and Post-FES conditions.

Figure 4 FES-cycling therapy effects on biomechanical variables in the group under 60 years of age. The figure presents the graphs of the averaged values of GDI in the paretic limb (P), GDI in non-paretic limb (N-P), Walking speed, and Stride Length at Baseline and Post-FES conditions.

Tables

Table 1 Kinematic variables from Instrumented Gait Analysis. Table shows the extracted joint angles from Nexus software.

Joint	Sagittal	Frontal	Transversal
Pelvic	Tilt	Obliquity	Internal-External rotation
Hip	Flexo-Extension	Add-Abduction	Internal-External rotation
Knee	Flexo-Extension	-	-
Ankle	Dorsi-plantarflexion	-	-
Foot	-	-	Foot progression

Table 2 Description of sample subjects. The table presents the sample characteristics in particular number of subjects, gender, age, and hemiparetic side.

Variable	Description
Number of subjects	39
Number of men	26
Number of women	13
Mean age \pm sd (years)	58.7 \pm 9.3
Left hemiparesis	31
Right hemiparesis	8

Table 3 Outcomes measures in Baseline and Post-FES conditions in the total sample. The table presents the averaged GDI values for the paretic (P) and non-paretic (N-P) lower limbs. Walking speed, Stride Length, and Cadence are presented as bilateral average values.

Study condition	N-P GDI	P GDI	Speed m/s	Stride length meters	Cadence steps/m
Baseline	77.34	76.81	0.67 \pm 0.27	0.86 \pm 0.22	90.95 \pm 22.83
Post-FES	77.70	78.36	0.74 \pm 0.28	0.95 \pm 0.23	90.57 \pm 20.09

Table 4 Wilcoxon test results between Baseline and Post-FES conditions in the total sample. The table presents the Wilcoxon test results, considering all study subjects. Statistical significance $p < 0.05$ (*).

Variable	n	Median	Wilcoxon test	
			z	p value
N-P GDI Baseline	39	78.7	-0,0349	0,97696
N-P GDI Post-FES	39	79.3		
P GDI Baseline	39	78.5	-1,0117	0,3125
P GDI Post-FES	39	78.8		
Speed Baseline	39	0.66	-2,3514	0,01878*
Speed Post-FES	39	0.71		
Stride length Baseline	39	0.9	-2,9569	0,00308*
Stride length Post-FES	39	0.95		
Cadence Baseline	39	95.7	-0.4713	0,63836
Cadence Post-FES	39	94.8		

Table 5 Outcomes measures in Baseline and Post-FES conditions in the group under 60 years of age. The table presents the averaged GDI values for the paretic (P) and non-paretic (N-P) lower limbs. Walking Speed, Stride Length, and Cadence are presented as bilateral average values.

Study condition	N-P GDI	P GDI	Speed m/s	Stride length meters	Cadence steps/m
Baseline	76.37 \pm 10.56	74.46 \pm 11.43	0.68 \pm 0.28	0.86 \pm 0.22	93.79 \pm 24.35
Post-FES	77.96 \pm 8.43	78.83 \pm 9.13	0.77 \pm 0.25	0.99 \pm 0.24	93.21 \pm 18.25

Table 6 Wilcoxon test results between Baseline and Post-FES conditions in subjects under 60 years. The table presents the Wilcoxon test results, considering all subjects under 60 years. Statistical significance $p < 0.05$ (*).

Variable	n	Median	Wilcoxon test	
			z	p value
N-P GDI Baseline	22	77.55		
N-P GDI Post-FES	22	80.35	-0.7467	0,45326
P GDI Baseline	22	74.9		
P GDI Post-FES	22	79.75	-2,564	0,02382*
Speed Baseline	22	0.68		
Speed Post-FES	22	0.795	-2,5486	0,01078*
Stride length Baseline	22	0.94		
Stride length Post-FES	22	0.97	-3,5453	0,00038*
Cadence Baseline	22	96.35		
Cadence Post-FES	22	94.25	-0,7125	0,4777

Figures



Figure 1

Patient setup for FES-cycling therapy. The figure presents (A) 6-channel electrical stimulator; (B) Adhesive electrodes on lower limb muscle; (C) Inertial measurement unit (IMU) positioned on the rotation axis of the cycle-ergometer, and (D) Motorized cycle-ergometer for lower limbs



Figure 2

Reflective markers positioning of the Plug-in-Gait model. The white circles on the lower limbs and pelvis of the subjects correspond to the spherical reflective markers of the optoelectronic camera system.

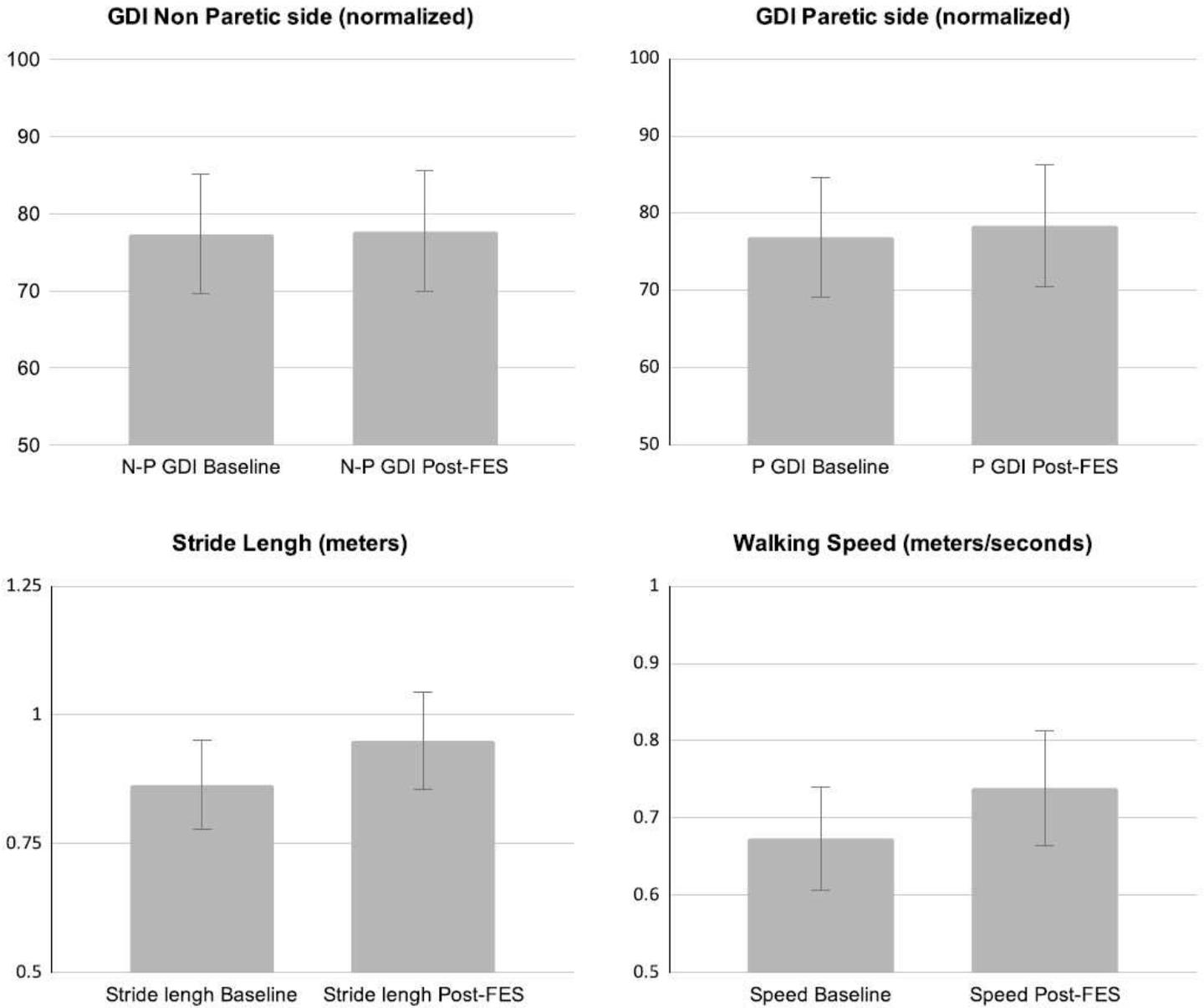


Figure 3

FES-cycling therapy effects on biomechanical variables in the total sample. The figure presents the graphs of the averaged values of GDI in the paretic limb (P), GDI in non-paretic limb (N-P), Walking speed, and Stride Length at Baseline and Post-FES conditions.

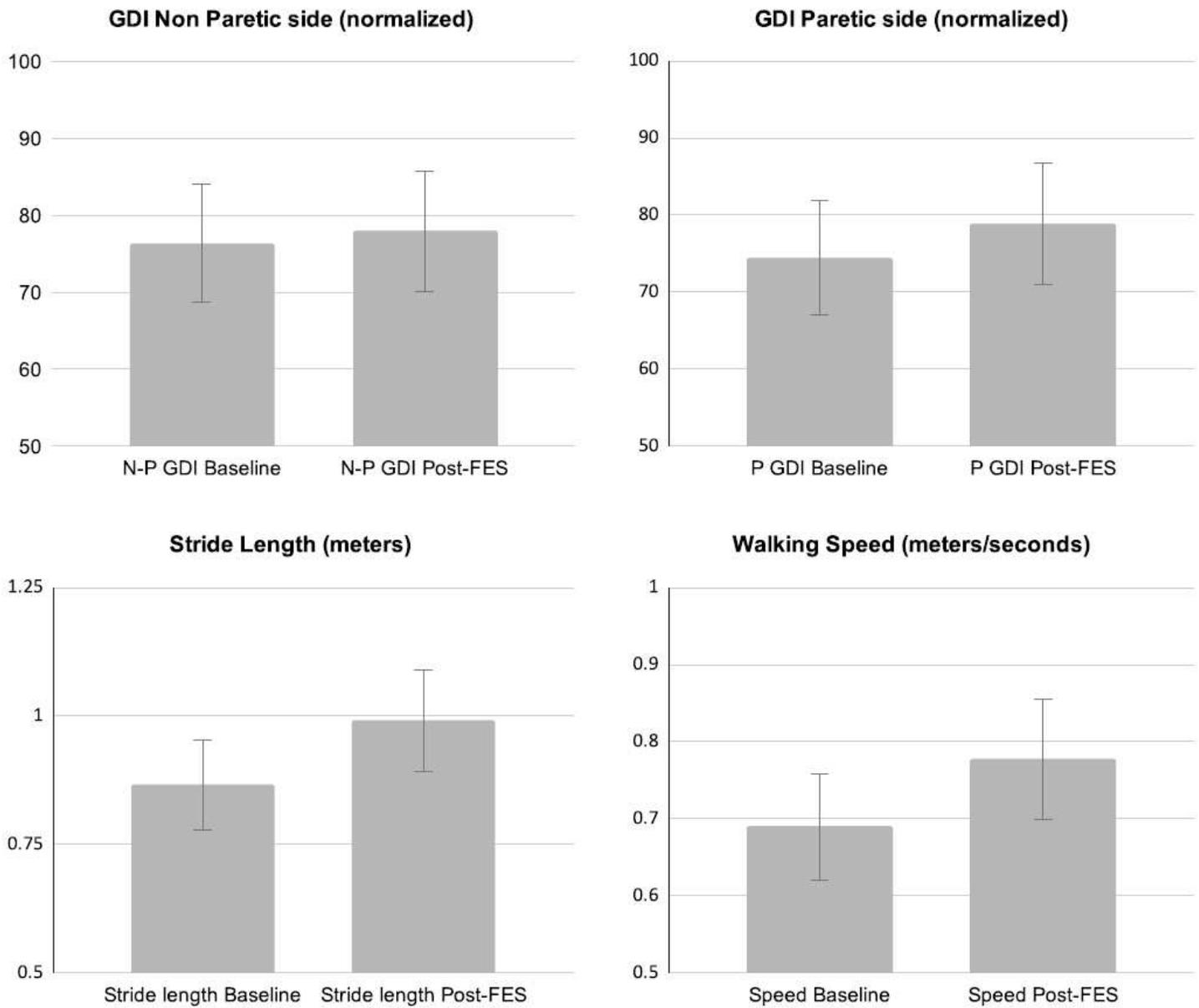


Figure 4

FES-cycling therapy effects on biomechanical variables in the group under 60 years of age. The figure presents the graphs of the averaged values of GDI in the paretic limb (P), GDI in non-paretic limb (N-P), Walking speed, and Stride Length at Baseline and Post-FES conditions.