

Gait Evaluation with Bioelectrical Signal Patterns during Cybernic Treatment*

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Abstract— Cybernic treatment with a wearable cyborg Hybrid Assistive Limb for medical use (Medical HAL) improves ambulatory function in patients with progressive neuromuscular diseases. The progress of cybernic treatment is evaluated based on the change in the patient's walking distance and walking speed over a certain treatment period. However, evaluation methods to capture temporal changes in gait functions during each therapy are required for more effective evaluation in clinical practice. Because the patients' muscular activities are measured with each trial of cybernic treatment, bioelectrical signals (BES) of lower limb muscles measured by Medical HAL may aid in evaluating the wearers' gait functions. Thus, this study proposed a method to quantify the BES patterns of patients during cybernic treatment and compared them with the BES patterns of healthy personnel for evaluation, which confirmed the correlation between the BES pattern and the patients' gait abilities. First, we obtained a reference BES pattern from the BES of three healthy personnel during walking using Medical HAL. Second, we calculated the similarity between the reference BES pattern of the healthy personnel and the patient's BES pattern using derivative dynamic time warping (DDTW), which quantified the patients' BES patterns based on their shape. Third, we investigated the correlation between patients' DDTW of BES patterns during cybernic treatment and 2-minute walking distances. The correlation coefficient between the patients was -0.83 ($p < 0.01$) and that within patients was -0.38 ($p < 0.05$), indicating a significant BES pattern relationship between walking with Medical HAL and gait abilities. Conclusively, the similarity between the BES patterns of healthy personnel and patients calculated using DDTW might be applied to the evaluation of patients' gait functions. The ability to assess the gait function with data measured during cybernic treatment would provide understandings of the patient's functional changes over time.

I. INTRODUCTION

Progressive neuromuscular diseases such as amyotrophic lateral sclerosis (ALS) and muscular dystrophy (MD) are caused by damage to nerves and muscles, which gradually result in muscle weakness and motor dysfunction. There exists no radical cure for these diseases, and medication treatments can only suppress the natural progression of symptoms [1]. HAL for Medical Use (Medical HAL) is a wearable cyborg HAL (Hybrid Assistive Limb) developed as a medical device [2-3], and cybernic treatment using Medical HAL is conducted to maintain or improve the gait function of patients with progressive neuromuscular diseases. Medical HAL moves in unison with the wearer based on physiological and motion

information, including bioelectrical signals in muscles of lower limbs, joint angles, and floor reaction forces. Bioelectrical signals (BES) are motor unit potentials on the skin, which correspond to the motor torque required for each joint movement, including hip and knee, in accordance with the wearer's motor intention. The integrated movement of Medical HAL and the wearer allows patients to repeat walking based on their motor intention without overloading the neuromuscular system. Consequently, cybernic treatment encourages the structural development and strengthening of the nervous loop via Medical HAL, wherein the activation of the nervous system results in the maintenance and improvement of the locomotive functions of the patients [3-5].

To monitor the therapeutic results and treatment progress of their motor dysfunctions, the gait functions of patients undergoing cybernic treatment are generally evaluated based on the walking distance or speed. However, conventional walking tests cannot be practically carried out in each treatment trial due to the burden on medical staff involved in measuring data while ensuring patients' safety. It is thereby difficult to grasp the changes in gait functions of the patients associated with cybernic treatment over time. In order to understand the functional status of the patient's gait and quickly construct more effective treatment plans, therefore, evaluation methods that can be used at a higher frequency to capture temporal changes in patient's gait functions are required. Here we consider the utilization of physiological and motion information measured by the Medical HAL during cybernic treatment. Because the patients' muscular activities are measured with each trial of cybernic treatment, for example, BES of lower limb muscles measured by Medical HAL may aid in evaluating the wearers' gait functions. BES reflects the alterations in patients' neuromuscular systems owing to its attribution to the action potential generated during movement control [6].

This study is focused on the BES pattern to utilize it as an index for gait evaluation. The BES pattern on the surface of the skin around the lower limb muscles varies depending on muscle activations during walking [7]. In a healthy personnel's normal gait without Medical HAL, the BES pattern is a characteristic for each measurement site [8]. Similarly, the BES pattern of patients wearing Medical HAL may indicate certain characteristics, and the activities of the neuromuscular system during walking can be recorded by analyzing the BES pattern. Furthermore, the relationship between the patients' gait ability and the BES pattern measured during walking with

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Medical HAL might be applied for evaluating the gait of patients undergoing cybernic treatment.

Therefore, this study proposed a method to quantify the BES patterns of patients during cybernic treatment and compared them with the BES patterns of healthy personnel for evaluation, which confirmed the correlation between the BES pattern and the patients' gait abilities.

Section II outlines our method for data acquisition, quantification of BES patterns, and analyzing the relationship between patients' gait ability and the acquired BES patterns. Section III contains the analysis results, and Section IV discusses the BES patterns obtained from cybernic treatment in the context of gait evaluation.

II. MATERIALS AND METHODS

A. The BES Pattern during Cybernic Treatment

In this study, the Medical HAL recorded the BES in the wearer's right-knee extensor muscles during cybernic treatment. In this instance, the BES patterns of the right-knee extensor muscle for each gait cycle recorded during cybernic treatment of a patient with progressive neuromuscular disease are illustrated in Fig. 1, wherein the BES patterns were normalized with respect to amplitude and time. The BES patterns presented in Fig. 1 (a) and Fig. 1 (b) were measured at the first trial and three months after the first trial, respectively. The two patterns were significantly different, and the difference could be quantified by a comparative analysis with those of healthy personnel. Therefore, this study proposes a method for determining the similarity between BES patterns of patients and healthy personnel as an indicator for gait evaluation.

B. Data on Patients' BES and Walking Test

The cybernic treatment of patients with progressive neuromuscular diseases required patients to walk with Medical HAL for approximately 20–40 min per trial. During this period, the Medical HAL measured the BES in the extensor and flexor muscles of the right and left knee and hip joints, and the floor reaction forces of both legs as time-series data [9]. The patients regularly performed a two-minute walking test (2 MWT) that measured the walking distance for two minutes and performed without wearing Medical HAL to ensure gait evaluation.

This study used time-series data measured during cybernic treatment and the results of 2 MWT, which were a part of the data obtained from the long-term outcome survey of HAL for Medical Use (Lower Limb Type) in Japan. The available data were from seven patients with progressive neuromuscular

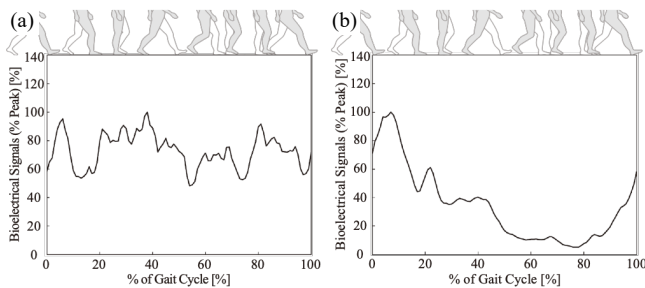


Figure 1. The BES patterns of the right-knee extensor muscle during cybernic treatment of a patient.

(a) First trial, (b) Three months after the first trial.

disease (Patients A–G) treated between August 2018 and July 2020 at a single institution. The number of trials and 2 MWT performed during this study period varied for each patient. The details on disease, sex, height, weight, and the number of 2 MWT results for each patient are listed in Table I, where MD, ALS, IBM, and SBMA denote muscular dystrophy, amyotrophic lateral sclerosis, inclusion body myositis, and spinal and bulbar muscular atrophy, respectively.

C. Measurement of Healthy Personnel's BES

Initially, we measured the BES of healthy personnel during walking with Medical HAL to obtain the reference BES pattern for determining its similarity with that of patients.

The BES in the right-knee extensor muscles of healthy patients were measured during walking on a treadmill with Medical HAL, as presented in Fig. 2. Three healthy adult males, (Participants X–Z) aged 21–23, were selected as participants. The control parameters of the Medical HAL and treadmill speed were adjusted in advance to ensure a comfortable walking speed for each participant. The BES data were measured and signal-processed using Medical HAL [9]. Thereafter, the average of the BES patterns measured in the right-knee extensor muscles of Participants X–Z was derived for 90 gait cycles per participant, i.e., a total of 270 cycles. The average pattern was used as a reference for healthy individuals and obtained as per the following procedure:

- 1) The BES data were divided into gait cycles starting from the moment of right heel contact, which was detected based on the values of the floor reaction force sensors.

TABLE I. PATIENTS' INFORMATION

Patient ID	Disease	Sex	Height [cm]	Weight [kg]	The number of 2MWT results
A	MD	male	163.7	81.3	9
B	ALS	female	162.8	51.4	9
C	IBM	male	159.7	59.4	3
D	MD	male	177.5	91.7	7
E	MD	female	163.3	60.0	4
F	SBMA	male	166.2	64.3	6
G	MD	female	156.6	70.5	4

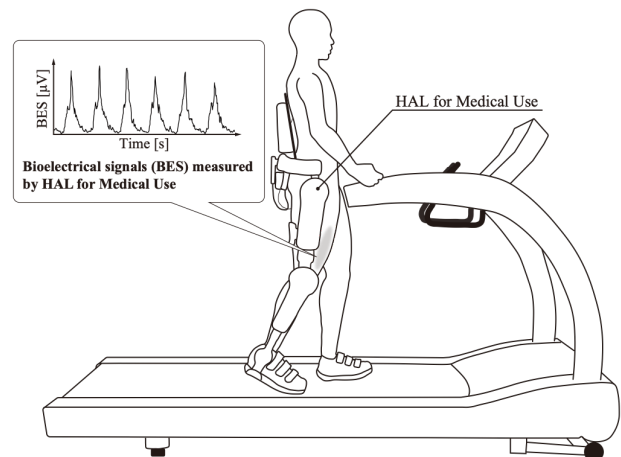


Figure 2. Image of data measurement during walking with Medical HAL.

- 2) The BES data were normalized to the period of each gait cycle by resampling the gait cycle to 101 points at regular intervals from 0 to 100. In addition, the value interpolation was performed using cubic spline interpolation.
- 3) The amplitudes of the BES were normalized for each gait cycle [10-11], and the maximum and base values were set to 100 and 0, respectively.
- 4) The average BES values of 270 cycles as well as the pattern connecting the average values were determined for each sampling point.
- 5) The pattern obtained in the above step was normalized with the amplitude based on the same method used in 3). This pattern was considered as a reference of healthy personnel's gait with Medical HAL.

This experiment was conducted with the ethical approval of the Faculty of Engineering, Information and Systems, Research Ethics Committee, University of Tsukuba (Approval number: 2021R463).

D. Similarity Calculation of the BES Pattern

The similarities between BES patterns of healthy personnel and patients with progressive neuromuscular disease undergoing cybernic treatment with Medical HAL are described in this section.

The similarities between the two time-series data of BES or joint angles during walking can be determined using certain comparison methods such as Pearson's correlation coefficient, root mean square error, and linear fit method [12]. However, these methods do not consider the time deviations or nonlinear relationships between the parameters. Typically, the difference between BES patterns of patients and healthy personnel during walking with Medical HAL becomes prominent upon comparison. Therefore, the similarity calculation methods that are flexible toward time shifts and nonlinear differences are considered appropriate for such scenarios. In this study, we used the derivative dynamic time warping (DDTW) algorithm that satisfies the conditions. This algorithm can calculate the similarity of patterns from the correspondence of rising and falling trends by comparing the two time-series data. Thus, the similarity calculation was conducted based on the original method proposed by Keogh and Pazzani [13].

The BES patterns obtained from the time-series data of patients (S) and healthy personnel (T) were assumed as:

$$S = \{s_1, s_2, \dots, s_i, \dots, s_M\}, \quad (1)$$

$$T = \{t_1, t_2, \dots, t_j, \dots, t_N\}. \quad (2)$$

In addition, the first derivative of the sequences was considered for each time series to consider the shapes of patterns for evaluation. For instance, the derivative estimation of a time series s can be expressed with $D_s[i]$:

$$D_s[i] = \frac{(s_i - s_{i-1}) + ((s_{i+1} - s_{i-1})/2)}{2}, \quad (3)$$

where $1 < i < M$. After transforming all the points of S and T to S' and T' using the derivative estimation equation expressed in (3), the two sequences S' and T' were aligned by considering a matrix, as depicted in Fig. 3. Each matrix element (i, j)

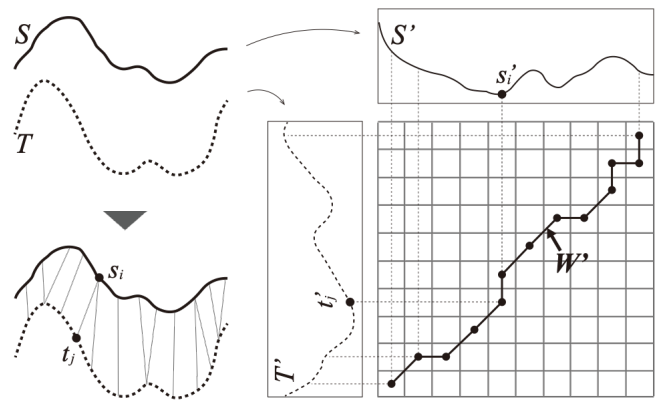


Figure 3. Example of alignment by DDTW.

corresponded to the alignment between the points s'_i and t'_j , which belong to S' and T' and have values of $D_s[i]$ and $D_t[j]$. Moreover, the correspondence between s_i and t_j of S and T inherited the combination (i, j) , which signified the variation in derivative values at s'_i and t'_j , expressed as

$$d(s'_i, t'_j) = |D_s[i] - D_t[j]|. \quad (4)$$

Subsequently, we constructed a warping path W that was a continuous set of matrix elements that defined the mapping between S' and T' , provided that W satisfied the following conditions:

- 1) It started and finished at the diagonally-opposite corner cells of the matrix.
- 2) Its allowable steps were restricted to adjacent cells, including diagonally adjacent cells.
- 3) Its points were placed as monotonically non-decreasing with time.

As there were several warping paths W satisfying the above conditions, the optimal warping path W' was determined by minimizing the sum of $d(s'_i, t'_j)$, which belongs to the matrix element including W . Thereafter, the value of DDTW that was used to evaluate the similarity was calculated as follows:

$$(\text{Value of DDTW}) = \frac{\sum_{l=1}^L d(s'_{m_l}, t'_{n_l})}{L}, \quad (5)$$

where L denotes the length of W' and (s'_{m_l}, t'_{n_l}) represents the l^{th} alignment combination of W' . The value of DDTW represents the average of the differences between the derivatives of two points S' and T' aligned by W' . Thus, a smaller value of DDTW corresponds to a higher similarity between the BES patterns of patients and healthy personnel.

In this study, the average pattern derived in Section II-C was used as the healthy personnel's pattern for determining the similarity between BES patterns of patients and healthy personnel. As discussed earlier in Section II-B, the BES patterns of right-knee extensor muscles measured by Medical HAL during cybernic treatment were used as a reference for patients. The time-series data of the BES in the right-knee extensor muscle were categorized into gait cycles by simultaneously detecting the heel contact from the values of the floor reaction force. Lastly, the similarity for each categorized gait cycle was calculated using the DDTW

algorithm on the BES patterns obtained from patients and healthy personnel.

E. Correlation Analysis

The relationships between patients' gait ability and BES patterns during cybernic treatment were clarified by investigating the correlation between the distances of 2 MWT and DDTW values obtained upon comparing the BES patterns of patients during therapy with those of healthy personnel.

First, we calculated the "DDTW score" for BES patterns obtained from the time-series data of Patients A–G under each trial of the cybernic treatment.

- 1) The time-series data on BES in the right-knee extensor muscle measured during cybernic treatment were categorized based on each gait cycle.
- 2) For each gait cycle, the DDTW value was evaluated by comparing the patients' BES pattern with that of a healthy person.
- 3) The average DDTW value was calculated for each trial, which represented the DDTW score of the trials.

Subsequently, the correlation coefficients were calculated by pairing the distance covered in 2 MWT with the DDTW score for each trial; all pairs of data are listed in Table II. Moreover, the correlation coefficients derived from multiple measurements for each patient could be interpreted as the correlation between patients and that within patients [14]. In this study, the correlation coefficient between patients was evaluated as the weighted correlation coefficient to consider the various observations for each patient. The procedure was performed according to the method described by Bland and Altman [15]. The actual formula can be expressed as

$$\frac{\sum m_i \bar{x}_i \bar{y}_i - \sum m_i \bar{x}_i \sum m_i \bar{y}_i / \sum m_i}{\sqrt{\{\sum m_i \bar{x}_i^2 - (\sum m_i \bar{x}_i)^2 / \sum m_i\} \{\sum m_i \bar{y}_i^2 - (\sum m_i \bar{y}_i)^2 / \sum m_i\}}}, \quad (6)$$

where all summations were from $i = 1$ to 7 (the number of patients), m_i denotes the number of observations for patient i , \bar{x}_i and \bar{y}_i represent the mean values of the 2 MWT distances and DDTW scores for patient i , respectively. Thereafter, the p-value was calculated based on the t-value for the seven samples. Furthermore, the correlation coefficient within patients was determined using multiple regression based on the method described by Bland and Altman [16]. As listed in Table II, the distance covered in the 2 MWT was used as the outcome variable. The DDTW score and the patient treated as a categorical factor using dummy variables with six degrees of freedom were considered as the predictor variables. The analysis of variance (ANOVA) table was used for the regression, and the magnitude of the correlation coefficient within patients can be written as

$$\sqrt{\frac{\text{(Sum of squares for the DDTW score)}}{\text{(Sum of squares for the DDTW score)} + \text{(Residual sum of squares)}}}. \quad (7)$$

The sign of the correlation coefficient corresponded to the sign of the regression coefficient obtained from the DDTW score. The p-value was determined from the F-test.

III. RESULTS

A. Healthy Personnel's BES Patterns

The BES patterns of the right-knee extensor muscles of Participants X–Z walking on a treadmill with a Medical HAL are presented in Fig. 4, wherein Fig. 4 (a)–(c) depict the patterns of 90 gait cycles for each of the three participants. In addition, Fig. 4 (d) portrays the average pattern obtained from the three participants for a total of 270 cycles, where the solid and dashed lines represent the average pattern and the range of standard deviation, respectively. The similarities between the BES patterns of patients and healthy personnel were determined by using the average pattern depicted in Fig. 4 (d) as the reference BES pattern of healthy personnel.

TABLE II. DISTANCES OF 2MWT AND DDTW SCORES

Patient ID – Trial No.	Distance of 2MWT [m]	DDTW score	Patient ID – Trial No.	Distance of 2MWT [m]	DDTW score
A-1	42.6	2.03	D-1	137.4	1.16
A-2	61.0	1.10	D-2	154.1	1.14
A-3	75.5	1.23	D-3	155.2	1.08
A-4	87.7	1.41	D-4	158.4	0.89
A-5	96.4	1.66	D-5	161.6	1.17
A-6	103.9	1.65	D-6	160.0	0.91
A-7	94.6	1.52	D-7	175.0	1.01
A-8	97.2	1.42	E-1	57.8	2.36
A-9	91.3	1.59	E-2	65.7	1.89
B-1	29.2	2.56	E-3	94.8	1.78
B-2	43.8	2.47	E-4	108.9	1.91
B-3	31.3	2.33	F-1	162.1	2.16
B-4	37.6	2.32	F-2	164.5	1.10
B-5	44.0	3.38	F-3	182.0	1.82
B-6	43.4	2.52	F-4	201.6	1.22
B-7	42.5	2.37	F-5	198.7	1.75
B-8	50.1	2.72	F-6	204.5	1.28
B-9	40.0	2.95	G-1	61.6	1.50
C-1	108.0	2.66	G-2	70.5	1.36
C-2	104.0	1.98	G-3	113.0	1.50
C-3	123.0	2.05	G-4	62.5	1.40

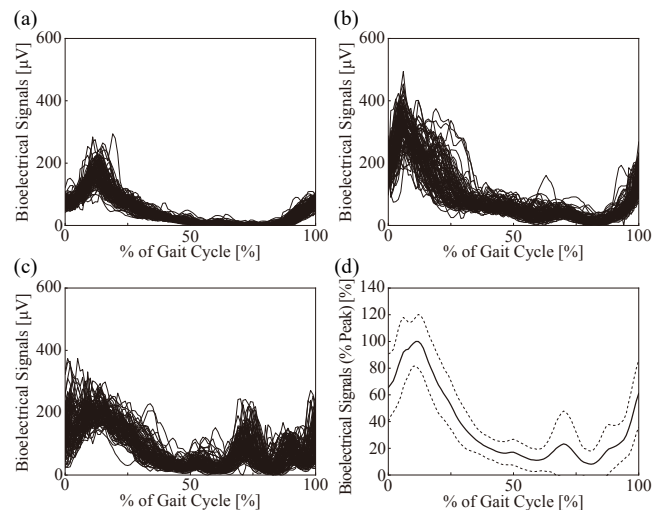


Figure 4. The BES pattern of the right knee extensor muscle of healthy personnel during walking with Medical HAL. (a) Participant X, (b) Participant Y, (c) Participant Z, (d) Average of X–Z.

B. The Similarity of BES Pattern Shapes

As an instance of representing the BES pattern similarities between patients and healthy personnel during walking with Medical HAL based on the DDTW scores, Fig. 5 illustrates the alignment results after applying the DDTW score on the patterns presented in Fig. 1 (a) and (b). The solid line in Fig. 5 denotes the patients' BES pattern during cybernic treatment, which is identical to that displayed in Fig. 1. The dashed line in Fig. 5 represents the BES patterns of healthy personnel during walking with Medical HAL, which is similar to the pattern portrayed in Fig. 4 (d). These results highlighted the significant difference between the BES patterns measured during the first therapy and that after three months. As can be observed from Fig. 1 (b), the BES pattern reached its maximum shortly after the initial contact, decreased toward the swing phase, and increased during the swing phase, which is not highlighted in Fig. 1 (a). Moreover, the tendency of muscle activity patterns depicted in Fig. 1 (b) was similar to that of a healthy person's gait [8]. The lines connecting the graphs of patients and healthy personnel in Fig. 5 were aligned based on the DDTW scores. The variations in the derivatives of every two points connected by the lines were used to determine the similarity. The value of DDTW in Fig. 5 (a) was 2.56 and that in Fig. 5 (b) was 0.96. Therefore, the value of DDTW was smaller in Fig. 5 (b), and the BES pattern observed in Fig. 5 (b) was more similar to that of the healthy personnel. Furthermore, four examples are presented in Fig. 6 as a reference for the DDTW results.

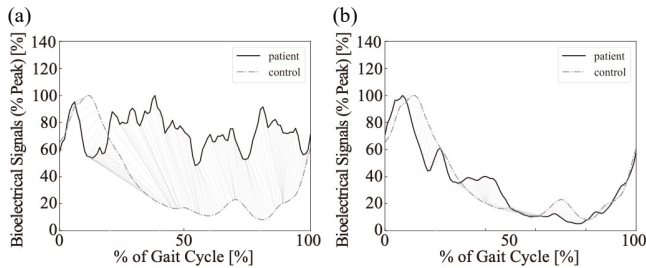


Figure 5. Results of alignment by DDTW. (a) For the pattern in Fig.1 (a); (b) for the pattern in Fig. 1 (b).

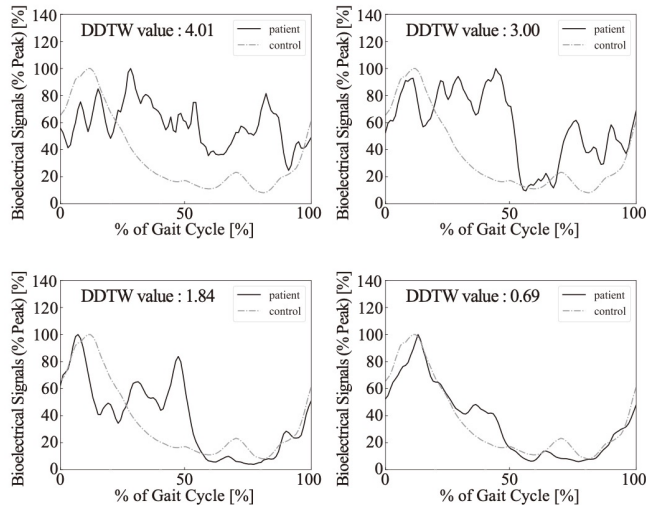


Figure 6. DDTW values.

C. Correlation Coefficients

The investigation of the correlation between the 2 MWT and DDTW scores yielded a correlation coefficient of -0.83 between the patients. At this instant, the t - and p -value were 9.59 and 2.08×10^{-4} , respectively. In addition, we conducted multiple regression analysis to determine the correlation coefficient within patients and obtained the ANOVA table, as listed in Table III. Moreover, the sign of the partial regression coefficient of the DDTW score was negative. Thus, the calculated correlation coefficient within patients was -0.39 , and the corresponding p -value was 1.88×10^{-2} .

In summary, the investigation of the relationship of the data between patients revealed that the distance covered in 2 MWT and the DDTW score exhibited a strong negative correlation coefficient of -0.83 ($p = 2.08 \times 10^{-4}$), as listed in Table IV. Furthermore, investigating the variability of the data within the patients revealed a weak negative correlation of -0.39 ($p = 1.88 \times 10^{-2}$) between the distance covered during 2 MWT and the DDTW score.

IV. DISCUSSION

We obtained the BES pattern for the right-knee extensor muscles of healthy personnel walking with Medical HAL using the average pattern for three participants. Regarding the normal gait of healthy personnel walking with Medical HAL, we determined from Fig. 4 (d) that the exhibited muscle activity specifically increased and decreased during each gait cycle, like that for walking without Medical HAL. In addition, the BES patterns in the right-joint extensor muscles with and without Medical HAL displayed a similar trend in healthy individuals. Therefore, in case the BES patterns of patients with progressive neuromuscular diseases exhibited identical tendencies during walking with and without Medical HAL, the patients' muscle activities during walking without Medical HAL can be estimated based on muscle activities measured during walking with Medical HAL.

The similarities between the BES patterns of patients and healthy personnel were determined by conducting an alignment based on the distribution of the two patterns (Fig. 5). In addition to the results presented in Figs. 5 and 6, the alignment of other pairs of patterns generally corresponded to the rising and falling trends of the values. Although we did not

TABLE III. THE ANALYSIS-OF-VARIANCE TABLE FOR TABLE I

Source of variation	Degrees of freedom	Sum of squares	Mean square	Variance ratio (F)	P-value
DDTW	1	1.49×10^3	1.49×10^3	6.08	1.88×10^{-2}
Patients	6	1.05×10^5	1.75×10^4	71.5	7.72×10^{-18}
Residual	34	8.34×10^3	2.45×10^2		
Total	41	1.15×10^5			

TABLE IV. THE CORRELATION COEFFICIENTS

Type of correlation	Correlation coefficient	P-value
Between patients	-0.83	2.08×10^{-4}
Within patients	-0.39	1.88×10^{-2}

investigate alternative methods for determining the stated similarities of BES patterns between patients and healthy personnel in terms of shape, the DDTW-based method implied suitability owing to its flexibility in handling temporal shifts and nonlinear variations in pattern.

Regarding the relationships between the distances covered in the 2 MWT and the corresponding BES patterns, the correlation coefficient between patients confirmed that patients with smaller DDTW values tended to have superior 2 MWT results (Table IV). In addition, this relationship suggested that patients, whose BES pattern during walking with Medical HAL was similar to that of healthy personnel, could walk a longer distance without using Medical HAL. Thus, the walking distance covered in 2 MWT might be estimated from the patients' BES pattern during cybernic treatment. Therefore, the comparison of patients and healthy personnel can be considered an evaluation criterion for the cybernic treatment. Although this study used only single-center data, to the best of our knowledge, no similar studies have attempted to incorporate the BES pattern measured during therapy into gait evaluation. Thus, we believe that this study presents a deeper understanding in evaluating the patients' gait functions based on the aspect of muscle activity during therapy. However, the variations in walking distance for 2 MWT and those in DDTW value exhibited a weak correlation coefficient within an individual, as presented in Table IV. Therefore, the estimation of variation in gait ability within a patient would require considering the pattern distribution and additional indicators. Although this study instanced only the BES patterns of the right-knee extensor muscle, multiple muscles should be integrated for gait evaluation. Moreover, the utilization of cybernic treatment in patients with progressive neuromuscular disease is increasing, and thus, we will analyze additional data on physiological and motion information during cybernic treatment.

As discussed in the Introduction, analysis of the BES pattern during cybernic treatment and investigation of its relationship with gait ability may be applied for gait evaluation during cybernic treatment. The similarities between the BES patterns determined by DDTW and analysis of the correlation with the distance covered in the 2 MWT would contribute toward the realization of gait evaluation with data acquired under cybernic treatment.

V. CONCLUSIONS

In this study, we proposed a method to quantify the BES patterns obtained from patients during walking with Medical HAL as an indicator for gait evaluation. The method was the evaluation of the similarities between the BES patterns of patients and healthy personnel based on DDTW scores. Moreover, the relationship between patients' BES pattern and gait ability was confirmed, and the results indicated significant BES pattern relationships between walking with the Medical HAL and gait abilities. Thus, the similarity between the BES patterns of healthy personnel and patients calculated using DDTW might be applied to the evaluation of patients' gait functions. The ability to assess the gait function with data measured during cybernic treatment would provide understandings of the patient's functional changes over time.

In future studies, we will integrate the results obtained from multiple muscles to evaluate the patients' gait function.

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