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Gait spatio-temporal characteristics during obstacle crossing as predictors of fall risk in stroke patients



Zihao Zhu^{1,2}, Feng Xu³, Qiujie Li^{1,2} and Xianglin Wan^{1,2*}

Abstract

Background Spatio-temporal parameters provide reference information for the gait variations of stroke patients during obstacle crossing. Analyzing these gait spatio-temporal characteristics of patients during obstacle crossing can assist in assessing the risk of falls. The aim of this study was to analyze the variances in gait spatio-temporal characteristics during obstacle crossing between stroke patients with and without a history of falls, to explore spatio-temporal parameters for assessing fall risk, and to construct a regression model for predicting patients' fall risk.

Methods Thirty-three patients with unilateral brain injury from stroke who were discharged from rehabilitation were included. These patients were categorized into a falls group (with a history of falls) and a non-falls group (without a history of falls) based on whether they had experienced a fall in the previous six months. A Qualisys motion capture system was used to record the marker positions when crossing an obstacle 4 cm in height with the affected leg as the leading limb, and gait spatio-temporal parameters were calculated and obtained. Univariate analysis and logistic regression models were used to compare the gait spatio-temporal parameters of the two groups.

Results 17 participants were categorised into the falls group and 16 into the non-falls group. The single support phase of leading limb, post-obstacle swing phase of trailing limb, obstacle-heel distance of leading limb, and obstacle-heel distance of trailing limb were significantly smaller in the fall group compared to the non-fall group (P < 0.05). The gait spatio-temporal parameter ultimately included in the fall risk prediction model was the obstacle-heel distance of leading limb (OR=0.819, 95%CI=0.688-0.973, P=0.023). The overall correct classification rate from this model was 69.7%, and the area under the curve (AUC) was 0.750 (P=0.014).

Conclusion Abnormalities in gait spatio-temporal parameters during obstacle crossing in stroke patients can contribute to an increased risk of falls. The fall risk prediction model developed in this study demonstrated excellent predictive performance, indicating its potential utility in clinical settings.

Keywords Stroke, Crossing Obstacles, Falls, Risk factors, Regression model, Gait analysis

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Introduction

Stroke is a major disease that poses a serious threat to the health of the global population, characterized by high incidence rates and mortality rates [1-2]. According to the 2021 Global Burden of Disease Study (GBD) data, the global incidence rate of stroke is 1099.3 per 100,000 population, with a mortality rate of 87.4 per 100,000 population, making it the leading cause of Disability Adjusted Life Years (DALYs) worldwide [2]. Falls are one of the most common complications of stroke, with up to 73% of patients experiencing a fall within 6 months after hospital-discharge [3–4]. These falls often result in severe physical and psychological consequences, such as fractures and depression, which substantially impact patient quality of life [5-6]. Consequently, effectively assessing fall risk, designing targeted interventions, and reducing fall incidence are crucial for alleviating the burden on both stroke patients and society.

Obstacle crossing represents one of the most common scenario for falls among stroke patients, accounting for approximately 24% of all fall incidents [7]. Understanding the movement characteristics linked to the typical fall scenarios can enhance the prediction and prevention of falls [8]. Due to neurological and functional impairments, stroke patients frequently need to make a series of gait adjustments to maintain balance and cross obstacles [9]. Comparative studies with healthy individuals have revealed that patients exhibit longer crossing stride time [10], increased post-obstacle swing phase of leading limb [11], higher center of mass (COM) medio-lateral velocity [12], and shorter obstacle-heel distances [10–11, 13, 14, 15] during obstacle crossing. Although these alterations in gait spatio-temporal parameters may elucidate the abnormalities or adjustments in patients' gait strategies when crossing obstacles, they may not necessarily function as reliable predictors of fall risk, given the absence of direct correlation with actual fall events.

A prospective cohort study [16] identified significant differences in the gait spatio-temporal parameters during obstacle crossing, such as pre-obstacle step length coefficient of variation, pre-obstacle step length, and crossing gait speed, between patients who experienced falls and those who did not. However, there remains limited clarity regarding which specific gait spatio-temporal parameters can effectively predict fall risk in stroke patients, with due to the lack of systematic regression analyses of these parameters and the incidence of falls.

The aim of this study was to analyze the variances in gait spatio-temporal characteristics during obstacle crossing between stroke patients with and without a history of falls, and to construct a regression model for predicting patients' fall risk based on gait parameters associated with fall experiences, in order to provide a valuable reference for fall risk assessment and guiding the design of targeted rehabilitation interventions for stroke patients.

Methods

Participants

Inclusion criteria: (1) The patients were diagnosed with cerebral hemorrhage or infarction through computed tomography or magnetic resonance imaging; (2) Unilateral brain injury; (3) Non-acute stroke patients; (4) Age range: 40-75 years old; (5) Completion of rehabilitation and discharge from the hospital post-stroke; (6) Medically stable; (7) Ability to ambulate independently with or without orthosis and/or walking aids; (8) Berg Balance Scale (BBS) score ≥ 45 [17]; (9) Ability to independently cross an obstacle with a height of 4 cm using their affected leg as the leading limb; (10) Ability to follow and respond to verbal instructions.

Exclusion criteria: (1) Cerebellar or bilateral brain damage; (2) Presence of other neurological disorders; (3) Presence of severe hypertension or cardiorespiratory disease; (4) Presence of other conditions affecting balance, walking, and/or cognition; (5) Current participation in any other clinical study or instructor-led exercise program.

A priori sample size estimation was conducted using G*Power 3.1.9.2 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany). Odds ratios (OR) estimated from the number of stroke fallers and non-fallers identified in previous obstacle-crossing test were 6.93 [18]. With an assumed OR of 6.93, 95% power, and an alpha of 0.05, a minimum of 30 participants were required for this study. A total of 33 recovered stroke patients with unilateral hemiparesis discharged from hospital were eventually recruited. This study was approved by the Ethics Committee of Beijing Sport University (approval document NO. 2023152 H), and all participants provided prior written informed consent. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Participant recruitment and screening were completed between June and September 2023. All data collection was finalized in September 2023.

The participants were categorized into a falls group (with a history of falls) and a non-falls group (without a history of falls) based on whether they had experienced a fall in the previous six months. Falls were defined as unintentionally coming to rest on the ground, floor, or lower level that is not a result of a seizure, stroke/myocardial infarction, or a major displacing force [19]. All the collected fall data in this study occurred after the onset of stroke in patients.

Obtaining fundamental participant information

Demographic characteristics, including age, sex, height, weight, and disease duration, were gathered from the hospital's electronic medical record system and standardized questionnaires. Additionally, all subjects underwent assessment by an experienced clinician using the BBS [17].

Crossing obstacle tests

Participants wore tight-fitting clothing and trousers, and retroreflective markers were attached to their whole body in accordance with the Helen Hayes protocol [20]. Participants walked at their self-selected speed on a 10-m walkway and used the affected leg as the leading limb to cross an obstacle placed in the center of the walkway at a height of 4 cm. The obstacle consisted of a wooden crossbar (1 m long, 1 cm wide, 1 cm high) and two supporting wooden blocks (5 cm long, 5 cm wide, 3 cm high) located at each end. The crossbar was placed unsecured on the blocks, making it prone to falling off when the foot touched it, thereby reducing the risk of the participants tripping over the crossbar. A retroreflective marker is attached to each end of the wooden crossbar to identify the position of the obstacle. An 8-camera motion capture system (Oqus 700, Qualisys, Switzerland, 200 Hz) and a force plate (Kistler 9286 B, Switzerland, 1000 Hz) were used to record the marker positions and the ground reaction forces during the obstacle-crossing process. The data from the motion capture system and the force plate were synchronized. Each participant first performed three trial crossings to familiarize themselves with the experimental environment and movements. While crossing the obstacle, a therapist accompanied the participants at a distance of 1 m to protect them from falling. If the participants touched the obstacle, lost their balance, or required the therapist's assistance, the trial was considered a failure and was excluded from the analysis. Valid data were obtained for two successful obstacle crossings for each participant.

Data analysis

The raw marker data were filtered with a low-pass Butterworth filter with a cut-off frequency of 13.3 Hz [21]. Spatial parameters such as step length, step width, and limb-obstacle distance were calculated based on the three-dimensional coordinate data of the heel, toe, and obstacle markers [11, 22–23]. The whole-body segments were defined using the marker coordinates [20], and the position of the body's COM was computed from the weighted sum of the COM from each body segment [20]. The instantaneous COM acceleration was determined by the second-order derivatives of the COM positions with respect to time [24]. The human inertia parameters were adopted from DeLeva's modified Zatsiorsky-Seluyanov's human inertia parameters [25]. Kinetic data were used for phase division only, and foot contact or toe-off was determined based on a vertical ground reaction force greater or less than 20 N.

In this study, the leading limb is defined as the limb that crosses the obstacle first, and the trailing limb is defined as the limb that crosses the obstacle later [26]. The gait cycle of crossing the obstacle is defined as the period beginning with the trailing limb's heel-contact just before crossing the obstacle to the next heel-contact just after crossing the obstacle [27]. The other main phases are divided as follows: the pre-obstacle double support phase is defined as the trailing limb's heel-contact just before crossing the obstacle to the leading limb's toe-off just before crossing the obstacle; single support phase of trailing limb is defined as the leading limb's toe-off just before crossing the obstacle to the leading limb's heel-contact just after crossing the obstacle; obstacle-crossing double support phase is defined as the leading limb's heel-contact just after crossing the obstacle to the trailing limb's toe-off just before crossing the obstacle; single support phase of leading limb is defined as the trailing limb's toeoff just before crossing the obstacle to the trailing limb's heel-contact just after crossing the obstacle; pre-obstacle swing phase is defined as the swing limb's toe-off just before crossing the obstacle to the swing limb's toe just vertically above the obstacle; post-obstacle swing phase is defined as the swing limb's toe just vertically above the obstacle to swing limb's heel-contact just after crossing the obstacle.

Three distances between the lower limb and obstacle were defined (Fig. 1). The toe-obstacle distance was defined as the shortest horizontal distance between the leading or trailing limb's toe marker and the obstacle before the obstacle. The toe-clearance was defined as the vertical distances between the swing limb's toe (leading or trailing limb) markers and the obstacle when swing limb's toe is above the obstacle. The obstacle-heel distance was defined as the shortest horizontal distance between the obstacle and the leading or trailing limb's heel marker after the obstacle. Other gait spatio-temporal parameters include crossing stride length, crossing step length, pre-obstacle step length, post-obstacle step length, crossing step width, pre-obstacle step width, post-obstacle step width, percentage of gait cycle time for each phase, instantaneous anterior-posterior (AP) COM acceleration when swing limb's toe is above the obstacle, and instantaneous medio-lateral (ML) COM acceleration when swing limb's toe is above the obstacle.

Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics version 25.0. Continuous variables were statistically described using the mean±standard deviation

Walking direction



Fig. 1 Illustration of the distances between lower limb and obstacle. The solid line represents the leading limb, the dashed line represents the trailing limb, **A** represents toe-obstacle distance of leading limb, **B** represents toe-obstacle distance of trailing limb, **C** represents toe-clearance of leading limb, **B** represents toe-obstacle distance of trailing limb, **C** represents toe-clearance of leading limb, **B** represents toe-obstacle-heel distance of trailing limb, **F** represents obstacle-heel distance of leading limb, **T** represents the moment of leading limb's toe is above the obstacle, T2 represents the moment of trailing limb's toe is above the obstacle

if they exhibited a normal distribution, and intergroup comparisons were analyzed by independent t-tests. Skewed distribution variables were described using median and interquartile range, and intergroup comparisons were analyzed by the Wilcoxon signed-rank test. Categorical variables were statistically described using frequencies, and intergroup comparisons were analyzed by the Fisher's exact test. According to Cohen's method for calculating effect size differences, the classification criteria for effect size are as follows: Cohen's d between 0.2~0.5 were regarded as small, between 0.5~0.8 as medium and above 0.8 as large effect sizes [28]. The definition of statistical significance is that the probability of a Type I error is not greater than 0.05.

To investigate the relationship between fall occurrence and gait spatio-temporal parameters, a binary logistic regression model was established. The history of falls among stroke patients (no history of falls = 0, history of falls = 1) was used as the dependent variable, and gait spatio-temporal parameters that were significantly different in univariate analyses and excluded multicollinearity were used as independent variables. Independent variable selection was performed using stepwise backward elimination. Multicollinearity among independent variables was assessed using the variance inflation factor (VIF). The receiver operating characteristic curve (ROC) for the regression model was developed, and the predictive value of the model for falls was evaluated by calculating the

Table 1 Basic characteristics of study participants

Characteristic	falls group	non-falls group	<i>p</i> -value
Age (years)	60.9±10.1	56.8±7.2	0.183
Sex (males / females)	10/7	13/3	0.259
Height (cm)	164.4±7.8	168.6±6.3	0.098
Weight (kg)	66.3 ± 9.6	72.6±8.7	0.056
BBS score (ranges)	47.9 ± 1.2	49.7±1.9	0.005*
Disease duration (months)	10.4 ± 5.7	8.5 ± 4.4	0.301

Abbreviations: BBS, Berg Balance Scale

Asterisks indicate differences between groups *P<0.05

area under the curve (AUC). The goodness-of-fit of the model was assessed using Hosmer-Lemeshow test.

Results

Baseline characteristics of the participants

A total of 33 participants met the criteria and were included in the study. Among the participants, 17 had experienced a fall in the previous six months and were categorized into the falls group, and 16 had not experienced a fall and were categorized into the non-falls group. There were no statistically significant differences between the two groups in terms of demographic and clinical characteristics, such as age, gender, height, weight, and disease duration (P > 0.05). However, participants in the falls group had a lower BBS score compared to the non-falls group (P < 0.05) (Table 1).



Fig. 2 Percentage of gait cycle time for each phase (Mean and SD). Abbreviations: Pre_DSP, pre-obstacle double support phase; T_SSP, single support phase of trailing limb; Cross_DSP, obstacle-crossing double support phase; L_SSP, single support phase of leading limb; L_Pre_SW, pre-obstacle swing phase of leading limb; L_Post_SW, post-obstacle swing phase of leading limb; T_Pre_SW, pre-obstacle swing phase of trailing limb; T_Post_SW, post-obstacle swing phase of trailing limb; Asterisks indicate differences between groups **P* < 0.05



Fig. 3 Stride length, step length, and step width (Mean and SD). Abbreviations: Cross_stride, Crossing stride length; Cross_step, Crossing step length; Pre_step, Pre-obstacle step length; Post_step, Post-obstacle step length; Cross_width, Crossing step width; Pre_width, Pre-obstacle step width; Post_width, Post-obstacle step width

Comparison of gait spatio-temporal parameters between the two groups

Single support phase of leading limb (P = 0.031, t=-2.257, Cohen d = 0.786), post-obstacle swing phase of trailing limb (P = 0.026, t=-2.338, Cohen d = 0.815), obstacle-heel distance of leading limb (P = 0.012, t=-2.674, Cohen d = 0.932), and obstacle-heel distance of trailing limb(P = 0.028, t=-2.302, Cohen d = 0.802) were smaller in

the falls group than in the non-falls group. Other parameters showed no significant difference between the two groups (P > 0.05) (Figs. 2, 3 and 4, and 5).

Establishment and validation of binary logistic regression model

Multicollinearity diagnostic results indicate that there is no multicollinearity among the indicators that are



Fig. 4 Limb-obstacle distance (Mean and SD). Abbreviations: L_TO , Toe-obstacle distance of leading limb; L_TC , Toe-clearance of leading limb; L_OH ; Obstacle-heel distance of leading limb; T_TO, Toe-obstacle distance of trailing limb; T_TC, Toe-clearance of trailing limb; T_OH; Obstacle-heel distance of trailing limb; Asterisks indicate differences between groups *P < 0.05



Fig. 5 Instantaneous COM acceleration (Mean and SD). Abbreviations: T1, the moment of leading limb's toe is above the obstacle; T2, the moment of trailing limb's toe is above the obstacle; AP, anterior-posterior direction; ML, medio-lateral direction

significantly associated in univariate analysis (VIF < 10), allowing them to be included in binary logistic regression analysis.

Binary logistic regression analysis results (Table 2) showed that the only gait spatio-temporal parameter

included in the final regression model is the obstacle-heel distance of leading limb (OR = 0.819, 95% CI = 0.688– 0.973, P = 0.023). The assessment of fall risk in stroke patients can be represented by the following regression equation: logit (incidence of falls) = 2.888– $0.200 \times$





Fig. 6 ROC curve in the binary logistic regression analysis

obstacle-heel distance of leading limb. The Hosmer-Lemeshow test demonstrated well-fit of the model (P = 0.214).

The receiver operating characteristic curve in the binary logistic regression analysis is shown in Fig. 6, and the AUC for this model was 0.750 (95% CI = 0.578–0.922, P=0.014). The overall correct classification rate from the model was 69.7%, with a sensitivity of 76.5% (the

proportion of patients with a history of falls correctly classified as fallers) and a specificity of 62.5% (the proportion of patients with no history of falls correctly classified as non-fallers).

Discussion

Crossing obstacles requires a higher level of neuromuscular function, attention, and visual control in stroke patients [29-31], and is a more intricate and challenging movement than walking on flat ground. Due to impaired neuromuscular function, patients demonstrate an abnormal gait pattern when crossing obstacles [32], leading to a greater rate of falls compared to walking on flat ground, as well as crossing obstacles in healthy individuals [7, 33]. Several studies have demonstrated that analyzing the gait of patients while crossing obstacles allows for the effective classification of actual fallers and non-fallers [16, 34–36]. In this study, stroke patients with a history of falls exhibited smaller single support phase of leading limb and post-obstacle swing phase of trailing limb, as well as shorter obstacle-heel distance of leading limb and trailing limb. These gait spatio-temporal parameters reflect abnormal swing limb control, insufficient postural stability, and asymmetrical lower limb muscle strength in patients with a history of falls, providing reference information for the gait variations of patients when crossing obstacles. Analyzing the gait spatio-temporal characteristics of patients when crossing obstacles can assist in identifying abnormal gait when crossing obstacles, and thus assessing the risk of falls in patients.

In this study, we established a fall risk prediction model for stroke patients based on the gait spatio-temporal parameters during obstacle crossing, and the final model incorporated the parameter of the obstacle-heel distance of leading limb. The model achieved an overall correct classification rate of 69.7%, correctly classifying 76.5% of fallers and 62.5% of non-fallers. The AUC for the model was 0.750. According to the diagnostic value classification based on the AUC, values between 0.5 and 0.7 indicate low diagnostic value, between 0.7 and 0.9 indicate moderate diagnostic value, and above 0.9 indicate high diagnostic value [37]. This suggests that the model has moderate diagnostic value in identifying fall risk among stroke patients. Additionally, the *P*-value of the Hosmer-Lemeshow test was 0.214, significantly exceeding 0.05. This demonstrates that the model's probability of predicting fall occurrences in patients is close to the actual incidence, indicating a well-fitted predictive model. Consequently, clinicians can employ the model to assess the fall risk of patients at different stages of their rehabilitation process, identify high fall risk groups, and implement targeted prevention and intervention measures for early prediction, prevention, and intervention. This can help reduce the incidence of falls and enhance the quality of life for patients.

The limb-obstacle distance directly reflects the risk of contact between the limb and the obstacle, making it one of the most commonly used indicators for assessing fall risk in obstacle crossing gait analysis. In this study, logistic regression analysis revealed that the obstacle-heel distance of leading limb can effectively assess fall risk. For every unit decrease in this distance, the fall risk increases by 18.1%. These findings provide a theoretical basis for developing appropriate rehabilitation programs.

Previous studies have revealed that, compared to healthy individuals, stroke patients exhibit a reduced the obstacle-heel distance of leading limb [10, 14, 32, 38]. Researchers have concluded that a smaller obstacle-heel distance of leading limb may increase the risk of actual contact with the obstacle, and the fall risk due to heel contact is greater than that of falling due to toe contact. Further prospective cohort studies have also found that stroke fallers have a significantly smaller limb-obstacle distance, particularly the obstacle-heel distance of leading limb, during the process of crossing virtual obstacles [39]. We found that the obstacle-heel distance of leading limb can serve as an indicator for assessing fall risk in stroke patients, thereby further validating previous research findings. Regarding the impact of the obstacleheel distance of leading limb on fall risk during obstacle crossing, some studies have explained that patients, due to fear of obstacles, tend to adopt a gait strategy of lifting their feet higher to avoid toe contact with the obstacle [11, 15]. Although this strategy increases the toe-clearance, it leads to abnormal limb swing trajectories and a posterior shift in the COM. The foot lands closer to the obstacle after it, thereby increasing the risk of tripping due to heel contact with the obstacle.

Figures 1 and 3 demonstrate that in patients with a history of falls, a decrease in the obstacle-heel distance of leading limb during obstacle crossing is accompanied by reductions in the obstacle-heel distance of trailing limb, the single support phase of leading limb, and the postobstacle swing phase of trailing limb. Some studies suggest that a shorter obstacle-heel distance of leading limb not only directly increases the risk of contact between the leading limb and the obstacle but may also affect the swing of the trailing limb [32]. They note that due to weaker muscle strength and motor control capabilities in the affected limb, the stability of the single support phase is compromised. If the obstacle-heel distance of the affected leading limb is close, it may become difficult to control the swing trajectory of the unaffected trailing limb, leaving insufficient time and space for adjustment to complete the crossing action, thereby increasing the risk of contact with the obstacle during obstacle crossing. Therefore, clinicians should develop targeted rehabilitation programs during the patient's recovery process to enhance lower limb strength, improve the ability to control the posture of the swing limb and the position of the COM, overcome fear of obstacles, and train patients to adopt strategies that appropriately increase the obstacleheel distance of leading limb to prevent falls.

Limitations

This study is retrospective in design, with the determination of fall history predicated on the self-reported fall events by the participants. It is acknowledged that selfreported fall events may be fraught with inconsistencies, inaccuracies, or omissions, which could lead to the introduction of information bias within the data collection. In terms of model validation, although this study employed a rigorous internal validation method, the sample of participants was limited to stroke patients from the hospital where the study was conducted, and the sample size included in the analysis was relatively small. This may be a key factor leading to suboptimal overall accuracy of the model and thereby restricting its wide generalization and application. Conducting prospective studies and generating synthetic data for external validation will significantly improve the model's credibility [40–41]. Therefore, a future direction of research is to introduce the fall risk prediction model into clinical practice settings, promote its application in multiple regions and hospitals, expand the sample size of participants with a history of falls, include prospective fall data from patients, improve external validation, and generate synthetic data to further refine and optimize the model, thereby further enhancing its accuracy and clinical applicability.

The obstacle crossing tests conducted in this study were carried out under laboratory conditions, with a relatively simplistic setup for obstacle height. However, real-life scenarios of obstacle crossing are complex and variable. Patients are not only constrained by environmental factors but also influenced by various psychological and other factors. These factors impose limitations on the comprehensive evaluation of fall risk by the model established in this study. Therefore, it is recommended that future research consider changing the mode of obstacle crossing tests, such as adjusting the height, shape, and placement of obstacles. Additionally, the utilization of wearable devices to establish real-time monitoring models for continuous fall risk assessment and timely interventions is suggested. These measures will enhance the model's value in practical applications.

Conclusion

Abnormalities in gait spatio-temporal parameters during obstacle crossing in stroke patients, such as reduced obstacle-heel distance of leading limb, can contribute to an increased risk of falls. The fall risk prediction model developed in this study demonstrated excellent predictive performance, indicating its potential utility in clinical settings. This model can assist clinicians in effectively identifying stroke patients at high risk of falls and implementing early preventive measures, thereby improving patient outcomes and reducing the incidence of falls. The findings of this study provide a foundation for the development of targeted rehabilitation strategies aimed at mitigating fall risk in stroke patients.

Abbreviations

- COM Center of mass
- AP Anterior-posterior direction
- ML Medio-lateral direction
- T1 The moment of leading limb's toe is above the obstacle
- T2 The moment of trailing limb's toe is above the obstacle

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Author contributions

Z.Z: Writing - original draft, Software, Project administration, Data curation. FX: Writing – review & editing, Resources, Methodology, Investigation. Q.L: Supervision, Resources. X.W: Writing – review & editing, Supervision, Resources, Funding acquisition, Conceptualization. All authors contributed to the article, reviewed, and approved the final version of the manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Beijing Sport University (approval document NO. 2023152 H). All persons gave their informed consent prior to their inclusion in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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