## **RECOMMENDATIONS FOR MINIMUM TRIAL NUMBERS DURING WALKING GAIT**

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In a rehabilitation context, athletes may not be able to complete large numbers of trials during testing due to joint edema and pain. The purpose of this research was to determine the minimum number of trials needed to achieve a negligibly fluctuating temporal variance profile during walking gait. The time-series kinematics of the hip, knee and ankle were recorded from 10 participants, completing 11 trials each. The time-series variance of each kinematic variables were calculated for ten trials and used as a reference. Using a two-sample SPM1D {t} ( $\alpha$ =0.05), all variance combinations (9, 8, 7, ... 3 of 11 trials) from the same participants were compared to the reference. Results showed a minimum of 7 trials were needed to achieve '*stable*' kinematic variance during walking gait. This study provides evidence for selecting an appropriate number of walking trials in gait analysis, especially in early-stage rehabilitation for patients with joint pain or edema.

**KEYWORDS:** variance, kinematics, time-series, SPM.

**INTRODUCTION:** To perform an analysis of variance, which is the foundation of all parametric and non-parametric statistics, the variance or randomness of the measurement must be modelled correctly. One factor that can influence the variance of a measurement is the number of observations, trials or participants used to obtain a Gaussian distribution of said measurement. Therein, with a larger number of observations, the standard deviation or variance of a Gaussian distribution becomes narrower, with smaller fluctuations in variance, which in turn can affect the results of the analysis of variance (i.e., significant vs non-significant) (Figure 1). A workaround to this problem



Figure 1: Illustration of changes in 0D variance as a function of trial

is for clinicians and researchers to record large numbers of trials for clinical gait assessments, or recruit large samples of participants for group or time-based comparisons. Though a logical workaround, recording a large number of trials during a clinical gait assessment within a rehabilitation setting may not be feasible as the patients may not be physically capable due to joint edema and/or musculoskeletal pain. Additionally, a large number of trials may over-power analyses, making clinically negligible effects statistically detectable. In clinical settings, the number of trials a patient is allowed to perform during testing is often restricted, which can place practical limitations on a clinical researcher's ability to appropriately perform exploratory statistical analyses on their biomechanical data.

Prior studies have investigated the number of trials required to achieve '*stable*' performance, i.e. negligibly fluctuating temporal variance, variables in lower limb tasks such as walking (Hamill and McNiven, 1990), running (Forrester, 2015), and continuous jumping (Racic et al., 2009). These studies have used either the sequential estimation technique (SET) or intraclass correlation coefficients (ICC). In SET, the average performance variable is computed sequentially by adding one trial at a time until the value reaches a '*stable*' range against a predetermined threshold. Both SET and ICC techniques make use of a zero-dimensional (0D) statistics with means as the dependent variable. One drawback of 0D statistics is that the temporal nature of the movement is not assessed, limiting the application of these findings to

time-varying biomechanical signals. In practice, kinematics and kinetics data are time-series in nature (1-dimensional). To overcome this limitation, researchers need to determine the minimum number of trials required for the assessment of time-varying (1D) biomechanical data. Therefore, the purpose of this research was to determine the minimum number of samples required to achieve a negligibly fluctuating temporal variance profile during a common clinical movement assessment, walking gait.

**METHODS:** Five healthy Asian males and five healthy Asian female participants (height: 1.6  $\pm$  0.11 m, mass: 56  $\pm$  10.1 kg, age: 56 $\pm$ 19.0 yrs.) were collected at the Biomechanics Laboratory in Rehabilitation Research Institute of Singapore. Each participant's lower limb biomechanics were assessed during barefoot walking gait trials at their self-selected pace. Testing was completed when each participant completed a minimum of 11 right limb full strides as only the right limb was used for analyses. Each stride started with right heel contact and ended at the subsequent right heel contract

A Qualisys motion capture system recording at 200 Hz, synchronised with two Kistler force platforms recording at 2,000 Hz were used to record three-dimensional kinematics and 6 DoF ground reaction forces (GRF). A patient-specific lower limb laboratory-specific kinematic marker set and kinematic model similar to the Calibrated Anatomical System Technique (CAST) developed by Cappozzo et al. (1993) was used. Providing a brief overview of these procedures, ankle joint and knee joint centres were defined using anatomical landmarks on the medial and lateral malleoli and epicondyles respectively. A regression model from the pelvis markers was used to define the hip joint centres. All anatomical information was then stored within technical coordinate systems held away from joint axes of rotation. Kinematic marker trajectories and GRF data were both low pass filtered at 10 Hz using a zero-lag fourth-order Butterworth filter. Direct kinematic modelling procedures were used to calculate joint angles as per the standards set by the International Society of Biomechanics (ISB) (Wu and Cavanagh, 1995).

The time-series 3D kinematics of the hip, knee and ankle joint were calculated. The kinematic waveforms were time normalised to 100% stride. Using manual registration, the first 60% was normalised to stance, with the remaining 40% normalised to swing (Pataky et al., 2020). For statistical analysis, time-series 3-component hip kinematics (i.e., flexion/extension, ab/adduction, internal/external rotation), 1-component knee kinematics (i.e., flexion/extension) and 1-component ankle kinematics (i.e., plantar/dorsiflexion) were used since the 5 kinematics variable were commonly analysed in biomechanics studies.

The SPM1D package (spm1d.org), was used for time-series variance analysis (Pataky et al., 2013; 2016). Therein, the variance for all combinations of 10 out of 11 trials was calculated and used as the reference data set (rVar). Thus, the rVar consists of 11 time-series variance. Ten-trial is selected since it is considered sufficient generally and has been adopted in previous study (Racic et al., 2009). Eleven time-series variances for random combinations of 9 out of 11 trials was calculated to form a subset of variance (SubVar) data set. The SubVar was then compared to the rVar using a SPM1D two-sample {t} ( $\alpha = 0.05$ ). The whole process (from forming a subset of data to SPM1D comparison) was iterated 1,000 times to generate a sufficient number of random SubVar. The whole process then was repeated for random combinations of 8, 7, 6, ... 3 trials out of 11 (equation 1).The percentage of difference for a particular trial number n =

$$\frac{1}{mx} \sum_{p=1}^{m} \sum_{i=1}^{x} d_{pi}$$
 (1)

Where *p* denotes the participant number; *i* denotes the iteration number; *m* denotes trial number (n = 10); *x* denotes the number of iteration (n = 1,000); d denote the percentage of stride that the SubVar and rVar showed significant differences in each comparison.

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For all kinematic variables, the cumulative amount of time (percentage stride) the *t*-statistic breached the critical-*t* threshold as defined by SPM was calculated.

**RESULTS:** For all kinematic variables tested, there was a logarithmic decrease in the mean time-series variance deviations relative to the rVar from 3 trials to 6 trials. On average, the percentage of stride variance deviations were between 1.25% and 0.2% stride difference. Between 6 to 8 trials, there was a plateau in time-series variance deviations relative to rVar (0.2% stride). From 8 to 9 trials, another logarithmic decrease in mean-variance deviations were observed (Figure 2).



Figure 2: Mean time-series variance deviation of 3 to 9 trials relative to reference time-series variance dataset (10 of 11 trials). Blueline indicates the mean %Stride difference of the 5 kinematic data. Shaded area indicates 95% CI of the %Stride difference

The violin plots in Figure 3 allow for the visualisation of the time-series variance difference relative to the rVar for each trial combination. Looking across all joints kinematics analysed; when 7 trials were collected, there were zero instances when the trial combinations resulted in >40% stride variance deviations relative to the rVar. When 3 to 6 trials were collected, there were between 1 to 42 instances when the trial combinations resulted in >40% stride variance differences relative to the rVar.



**Figure 3:** Depiction of individual percentage stride time-series variance differences for 3, 4, 5 .... 9 trial combinations.

**DISCUSSION:** The fluctuations in mean temporal variance profiles of the joint kinematic were similar across all three joints of the lower limb, with the hip flexion/extension showing a trend of having a higher percentage of stride difference. As expected, the variance fluctuations

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decreased as more trials were included in the analysis. When looking at the mean and individual % stride difference measures between trials numbers, it is apparent that a minimum of six trials is needed to obtain a negligibly fluctuating temporal variance profiles for SPM statistical analysis. This is an important methodological consideration when assessing an athlete's rehabilitation progression. If an athlete is not able to complete a minimum of six trials during biomechanical testing, it may not then be appropriate to perform exploratory SPM analyses of the data, as the elevated temporal variance profile may affect the statistical test being performed (i.e., SPM1D {t}).

Looking to previous 0D literature, depending on the sample size and the task being performed (i.e., walking, running jumping), different trial numbers have been recommended. Depending on the sample size used, and the task being investigated, the trial number recommendations range between 3 to 19 (Forrester, 2015; Hamill and McNiven, 1990; Racic et al., 2009). From these 0D findings, it is apparent that these 1D temporal variance findings may be task and sample size-dependent. Besides, this method does not require a uniform variability across the time-series because a t statistic value was calculated separately at each time point. It is therefore recommended that future research investigate the sensitivity of task and sample size on the temporal variance profile of continuum biomechanics data (i.e., kinematics, kinetics and EMG) for SPM analysis. Also, future research is recommended to investigate if minimum trial recommendations change if joint kinetics, muscle forces or articular loading are measured.

**CONCLUSION:** SPM1D is a unique and useful analysis platform for assessing the time-series variance of continuum biomechanics signals. For a sample of 10 participants, the minimum number of trials required to obtain a negligibly fluctuating temporal variance profile for the lower limb kinematic variance during walking gait is six. Thus, a minimum of six trials is recommended when performing exploratory SPM analysis on time-series lower limb walking gait kinematics, especially for patients that cannot tolerate a prolonged walking assessment.

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