

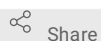


Jul 11, 2021

Understanding the impact of sole soled footwear on toddler spatial, temporal and kinetic gait parameters.

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dx.doi.org/10.17504/protocols.io.bq6dmza6

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ABSTRACT

A quasi-experimental pre-post study design will be used to assess whether spatiotemporal parameters of gait, and in-shoe foot and lower limb kinematics, differ when walking barefoot and in soft-soled footwear in newly walking toddlers.

The Vicon camera system will collect kinematic data. The testing conditions include barefoot and footwear. Footwear undergoing testing are a commercially available soft soled shoe (Bobux XPLOERER). Data will be extracted directly from the GAITRite system for analysis.

Differences between barefoot and footwear conditions will be analysed with linear regression analysis clustered by individual participant and robust variances reported. Effect sizes will also be calculated.

DOI

dx.doi.org/10.17504/protocols.io.bq6dmza6

PROTOCOL CITATION

Cylie Williams, Jessica Kolic, Wen Wu, Kade Paterson 2021. Understanding the impact of sole soled footwear on toddler spatial, temporal and kinetic gait parameters.. **protocols.io**
<https://dx.doi.org/10.17504/protocols.io.bq6dmza6>

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CREATED

Jan 04, 2021

LAST MODIFIED

Jul 11, 2021

PROTOCOL INTEGER ID

45989

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Aim:

To assess whether spatiotemporal parameters of gait, and in-shoe foot and lower limb kinematics differ when walking barefoot and in soft-soled footwear in newly walking toddlers.

Hypothesis:

Soft soled footwear would result in similar differences in gait variables as those observed in older children (ages 2-4).

2 Study design:

A quasi-experimental pre-post design.

3 Data:

Data will be collected in a single testing session at the gait laboratory.

Anthropometric data will include:

- age
- sex
- height
- weight.

Spatial, temporal and kinematic data will be collected with:

- GAITRite® Electronic Walkway 4.3 meter mat
- 12-camera Vicon MX system

4 Marker selection and placement:

- 14mm sized markers will be used all pre-determined body locations except the feet, and 9.5mm sized markers at the feet.

- Pre-determined markers locations are on both sides of the body in the following locations:

- posterior calcaneus
- dorsal aspect of the midfoot
- medial aspect of the navicular
- lateral aspect of the cuboid
- medial and lateral malleoli
- medial and lateral knee joint
- anterior and posterior superior iliac spines
- mid-lateral thigh
- mid-lateral lower leg shank
- anterior aspect of each shoulder
- C7 at the back of the neck

- Markers will be placed by an experienced paediatric health professional and double checked by gait laboratory staff, visualised on recording software.

5 Footwear description:

Footwear will be described by the brand, weight, sole thickness, longitudinal and torsional bending, upper material and fixtures.

Footwear will be modified to accommodate the reflective markers with small holes cut in to the posterior aspect of the heel, medially over the navicular region, laterally over the cuboid region and dorsally in the midfoot region. No fixtures (i.e. Straps or elastic) will be modified when cutting holes in the footwear used during data collection.

6 Pre-testing/gait laboratory habituation:

- Toddlers will be encouraged to explore the testing environment to familiarise themselves with the setting.
- Footwear sizing will be checked to ensure appropriate footwear fit under the ankle, the adjustable strap and length being approximately 1cm from the longest toe.

- During this time, the toddler's legs and clothing will be semi-permanently marked for marker placement to ensure any markers that come loose or are removed by the toddler will be replaced in the identical position.
- The reflective markers will be adhered to the skin over the semi-permanent mark using double sided tape.

7 Testing randomisation:

Testing order will be randomised between toddlers. This will alternate between barefoot or footwear depending on the day and the testing session. This alternating process will be recorded in an excel spreadsheet.

8 Gait data collection procedure:

Gait will be encouraged within the laboratory with the following:

- Parent approximately 1 meter from the end of the GAITRite mat with favourite toy or food reward.
- Post box approximately 1 meter from the end of the GAITRite mat and toddler provided with a small token or toy to post
- Uncontrolled speed with post-hoc matching during analysis
- Minimum three mat passes during testing to ensure adequate steps.
- Each toddler was also encouraged to stand still with all markers exposed to motion cameras to capture a static trial used for calibration.

9 Primary outcome measure:

- Stride length (cm).

Secondary gait outcome measures (No hierarchical value):

- Stride time (seconds)
- Velocity (cm/seconds)
- Swing %
- Stance %
- Double support time (sec)
- Cadence (steps/min)
- Steps (count)
- Peak hip flexion and extension (degrees)
- Total hip flexion and extension range (degrees)
- Peak hip adduction and abduction (degrees)
- Total hip adduction and adduction (degrees)
- Peak hip internal and external rotation (degrees)
- Total hip internal and external rotation (degrees)
- Peak knee flexion and extension (degrees)
- Total knee flexion and extension range (degrees)
- Peak ankle flexion and extension (degrees)
- Total ankle flexion and extension (degrees)
- Peak subtalar inversion and eversion (degrees)
- Total subtalar invasion and eversion (degrees)

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Data processing:

Markers will be used to create a custom foot and lower limb kinematic model in Opensim

All foot prints will be visualized within the software, and any partial foot prints removed prior to extraction.

Measured marker trajectories will be cleaned, labelled, and then extracted from the Vicon Nexus software and imported into OpenSim software.

We plan to match within-participant walking speed between trials by excluding data collected during slow walking or running trials.

The segment lengths of a generic model (built-in model 'Gait2392-Simbody' of OpenSim software) will be scaled to each toddler using the markers captured during the static trial.

We plan to use inverse kinematics analysis to minimise the difference between the measured markers and those of the scaled models were used to obtain the kinematics of the toddlers. We are using this approach because it has been shown to reduce soft tissue artefacts and inter-tester variations

11 Data analysis:

We will collect data from both limbs and assess for differences between limbs. If there are no differences, we will report data from the right limb only.

Gait variables will be initially described in frequencies (%), means and standard deviations. The maximum and minimum joint angles for the right hip, knee, ankle, and subtalar joint during the stance phase were reported for each walking condition.

Differences between conditions will be analysed with linear regression clustered by individual participant. Robust variance estimates will be used to account for the within-subject nature of the data.

The mean difference, 95% confidence intervals, p-values and effects will be calculated.

Statistical significance will be considered as $p < 0.05$.

Mean differences and effect sizes will be calculated using the mean difference between the footwear and barefoot conditions and dividing this by the pooled standard deviation.

Due to the novel nature of this work, no sample size calculation is possible.

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