

PARTICIPANT INFORMATION SHEET

For parents/guardians of typically developed children

Project title: A new motion capture technique using body surface scanners and wearable sensors for 3D Gait Analysis on children and young adults

Research team

Julie Choisne (Principal Investigator, Senior Research Fellow)
Thor Besier (Co-investigator, Associate Professor)
Enzo Allevard (Co-investigator, PhD student)

Project

Your child is invited to take part in a study to first, understand how well cheap body scanner can create a full body scan of a child compared to a state-of-the-art military grade body scan and second, validate a new method to capture and analyse how children walk. We are trying to develop new workflows using commercial technologies to capture movement such as walking that can be used for clinical assessments. This research project is undertaken by researchers at the Auckland Bioengineering Institute (ABI) for a period of 36 months. The study will be overseen by Dr Julie Choisne, a senior research fellow and primary investigator in the ABI musculoskeletal modelling group, Prof. Thor Besier, a specialist in musculoskeletal systems and orthopaedics and Mr Enzo Allevard PhD student at the ABI.

This Parent/Guardian Information Sheet will help you decide if you and your child would like to take part of our study. It sets out why we are doing the study, what is involved, what the benefits and risks to you might be, and what would happen after the study ends. There is also a separate information sheet for your child. We will go through this information with you and answer any questions you both may have. You may also want to talk about the study with other people, such as family/ whānau, friends, or healthcare providers. Feel free to do this. Whether or not your child take part in this study is your choice. If you do not want your child to take part, you do not have to give a reason, and it will not affect the care they receive. If you do want your child to take part now, but change your mind later, you can pull out of the study at any time without giving a reason.

Your child has the right to consent to participate in research when they are capable of understanding what the study involves and the risks. If your child is able to fully understand, their assent must be obtained.

If you agree for your child to take part in this study, you will be asked to complete and sign a Consent Form. You will be given a copy of both the Parent/Guardian Information Sheet and the Consent Form to keep.

This document is 9 pages long; please make sure you have all the pages.

Description

Understanding how children walk is a key assessment for children who walk differently due to cerebral palsy or other bone deformities in the hip, knee and ankle. To determine which treatment is the best option for each child, clinicians observe how they walk differently than typically developed children. To do so, they would normally rely on an expensive equipment, optical motion capture, which is time-consuming, require a large room and expert technician to run it. We came up with new workflows that integrates commercially available technologies that we believe can provide the same analysis but cheaper, more portable and fully automatic. The first workflow involves the use of wearable sensors and a body scan to register where the wearable sensors are on the child. The second workflow involves video recordings from 2 iPads set at different angles and uses Artificial Intelligence to reconstruct movement. However, we don't know if these new workflows can provide the same accuracy compared to the optical motion capture system (current clinical gold standard). Therefore, the aim of this study is to test and validate these 2 new workflows versus the current clinical standard. In New Zealand, only one optical motion capture system exists for clinical assessment requiring children and families to travel to Auckland annually to get assessed. Having a system who can do the same analysis but be deployed rurally at a lesser cost would be a great advancement for healthcare.

A 3D body scan can be used in various applications. This study will evaluate the accuracy of affordable scanning devices, such as an iPad, compared to a state-of-the-art laser scanner. By doing so, we aim to determine whether an iPad or a time-of-flight camera can accurately reconstruct a participant's body shape and capture the location and orientation of the wearable sensors on the body. The other goal is to assess the performance of a less expansive and more versatile set-up to perform gait analysis.

Selection of volunteers

We are recruiting up to a total of 50 healthy children for the study aged between 6-16 years old able to understand English. We are excluding participant with musculoskeletal injury or gait disorders.

What would your child's participation involve?

Your child participation consists of 2 visits. Your child can either take part of one or both visits. Your child will also have the option to combine both visits into a single 2.5-hour visit performed at AUT, instead of a 1-hour visit at AUT and a 2-hour visit at the Department of Exercise Science.

First session:

The first session consists of scanning the body of your child with a 3D laser scan, an iPad with an integrated LiDAR sensor and a Time-to-Flight camera. Your child will need to bring tight-fitting clothes such as swimwear or any tight shorts and T-shirts like the picture below. A changing room will be available for your child to change prior to the scan. Your child will be accompanied into the scanner room and set up in standing position. Three different positions will be scanned two times by the iPad and time of flight camera devices. The first position will be standing with arms forming a T (90° between arms and trunk), the second position will be standing with arms forming an inverse V (45° between arms and trunk) and the third position will be sitting on a stool (not done for the laser scan condition). Your child comfort will be ensured and verbally confirmed. Your child will be asked to remain motionless (as much as they can) during the scans. Each scanning time should not be longer than 2 minutes. You or your child can request to terminate the scan at any moment without giving a reason.

Duration: This session will not take an hour.

Location: AUT Millenium 17 Antares Place, Rosedale, Auckland 0632

What to bring: Tight fitting clothes such as swimwear. Can be a fitted top and short as the picture below.

Materials: Laser scan (compliant with the U.S. Food and Drug administration regulation pertaining to laser safety), an iPad (Apple, US) and a time of flight camera (Chronoptics, NZ)

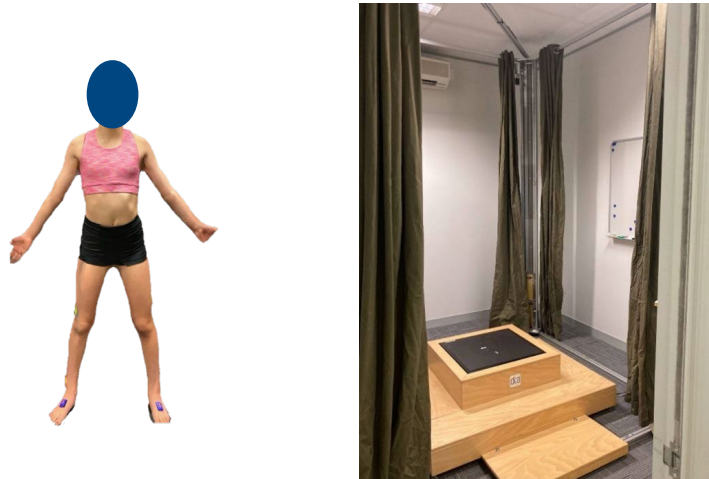


Figure 1: 3D body scan example (Left) and 3D laser scan (Right)

Second session:

The second visit will consist of a motion capture session where we can record how much rotation is happening at each joint during walking. Your child will need to bring tight-fitting clothes such as swimwear or tight clothes as per figure 1. A changing room will be available for your child to change just before the data collection. We will place 7 small wearable sensors; inertial measurement units (Figure 2) on your child's skin (one on each foot, lower leg, thigh and 1 in their lower back). The inertial measurement unit will measure your child's movement. We will also place small reflective markers onto your child's skin (little grey balls of 14 mm diameter), which will be tracked by several infrared cameras. These cameras can only detect reflective surfaces and will only be able to track the reflective markers in space. The sensors and markers placed on the skin will be attached using double-sided hypoallergenic tape. Your child might experience some mild discomfort when removing the tape at the end of the experiment. **Optionally**, two iPad will be placed in the room to record video of your child walking. These videos will then be processed through the OpenCap algorithm. The OpenCap algorithm uses artificial intelligence to compute joint rotation from two 2D videos. It is a very promising tool which works well on adult, but its accuracy has never been tested on children.

When all the sensors are placed your child will be scanned with the iPad with LiDAR sensor or/and Time-to-Flight cameras. After the scanning process, we will ask your child to walk several times across the room, and perform some static and specific movement (squat, jump) trials.

Duration: The entire session will last no longer than two (2) hours.

Location: AUT Millenium 17 Antares Place, Rosedale, Auckland 0632 or Exercise Science department, Building 907, Suiter Street, Newmarket, Auckland 1023

What to bring: Tight fitting clothes such as swimwear. Can be a fitted top and short such as in figure 1.

Materials: Inertial Measurement Units (Vicon Blue trident, Oxford, UK), reflective markers who will be captured by 16 cameras who tracked markers position (Vicon, Oxford, UK), two iPads (Apple, US), time of flight camera (Chronoptics, NZ)



Figure 2: Inertial Measurement Unit (Left) and reflective marker (Right).

What are the possible benefits and risks to your child of participating?

The two sessions do not involve any risk.

Every session is closely monitored, and safety precautions will be in place.

There may be no direct benefit to you or your child from being part of the study. However, the information gained in the study will help validating our new workflows, which will enhance clinical care for patients and families from rural New Zealand.

The study involves non-invasive procedures like body scanning and gait analysis. The motion analysis has been designed to be safe and non-obstructive. There should

be no discomfort when wearing the sensor. However, your child might face some minor discomfort when removing the reflective markers and inertial measurement units.

You can request a researcher of the same sex to handle sensor placement. Please let us know when we book the first session.

Incidental findings will not happen during this study, as no medical imaging will be conducted. However, if issues such as mental distress arise, the caregiver (you) will be present along with two researchers. One of the researchers is specifically trained in conducting studies with children, ensuring that any concerns are addressed appropriately and with care.

What are the rights of participants in the study?

Participation is completely voluntary. Individuals are free to decline to participate, or to withdraw from the research at any time, without experiencing any disadvantage and without giving a reason.

Tight fitting clothes are mentioned in the experiment description. We asked your children to wear swimwear because it is a common example of tight-fitting clothes that they should feel comfortable to wear around others. However, it is not restricted to swimwear. If your children feel more comfortable wearing other types of tight-fitting clothing, such as leggings and a fitted top, they are welcome to do so. The primary requirement is that the clothing should be form-fitting to avoid interference with the scanning.

If your children do not feel comfortable wearing any form of tight-fitting clothing, they are free to withdraw from the study at any time.

Data storage/retention/destruction

Optionally, we plan to use the OpenCap algorithm to evaluate its capabilities in capturing children's movements using two 2D videos recorded from iPad. However, please note that the recorded video (identifiable) will be sent to a U.S. server for post-processing. The privacy protections in the US may be different to those offered in New Zealand, however, the use of OpenCap has been approved by the IT security team of the University of Auckland. The research team has chosen the option to not share the data at all. Nevertheless, the OpenCap development team and the Stanford Neuromuscular Biomechanics Lab will require access to the data for processing. Participation in this part of the data collection is entirely optional and at your discretion.

Your decision will not affect your involvement in the rest of the experiment, which can proceed regardless of your choice. If you need further information about this process, please don't hesitate to ask us.

All participants have the right to access information about them collected as part of the study. Participants will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on their health.

You will be able to request any data held by the project as well as ask for its exclusion and deletion. This will include processed data via the participant's ID number. You will also be able to ask for the access and correction of personal information recorded by the study.

Confidentiality

Information will be reported / published in a way that does not identify you as a participant. Privacy will be ensured in the collection, storage and publication of this research material. Data generated by the study will become property of the University of Auckland. Data that is created in the course of the research will be kept securely for a period of 10 years after the completion of this research project.

We can send to you the 3D body scan at the end of the experiment if you want it. Additionally, we can send you a summary of the research at the end of the study if you want it. It will be sent to you by e-mail if you have ticked the corresponding box in the consent form.

Conflict of Interest

Participation in this study is entirely voluntary and will have no impact on my (parent) current work situation. There is no pressure or expectation from relative, supervision team, or work collaborator to take part in this study. The Principal and Board of Trustees of the school gave the assurance that teachers/parents/students participation or non-participation will have no impact on their employment, relationship or grades with the school.

What will happen after the study ends, or if your child pulls out?

Participants are allowed to pull out of the study at any time without giving a reason and to withdraw any data traceable to them up to 13 months after signing the consent form.

Where can you go for more information about the study, or to raise concerns or complaints?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

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For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 ext. 83711,

or at Auckland Health Research Ethics Committee, The University of Auckland,
Private Bag 92019, Auckland 1142.

Statement of Approval

Approved by the Auckland Health Research Ethics Committee on 20/12/2024
for three years. Reference number AH28362.