Plain Language Statement

Melbourne School of Engineering
Department of Mechanical Engineering

ANALYSIS OF GAIT BIOMECHANICS IN HEALTHY ADULTS DURING NORMAL AND CONSTRAINED WALKING

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Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about. You can do this by contacting the responsible researcher via the provided email, and/or during the meeting that will be scheduled should you express interest to participate in the study.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time with no consequences.

What is this research about?

The main goal of this study is to collect walking data in a sample of healthy young adults. The data can be separated into four main categories, namely lower limbs' joint kinematics (e.g., knee joint angle in time), lower limbs' joint kinetics (e.g., forces exerted by the ankle joint), lower limb muscle activity (e.g., the activity of quadriceps muscle

group), and overall body energetics (i.e., the energy needed to walk). The collected data will be used to better our understanding of the underlying walking mechanisms under different walking conditions and if/how these mechanisms change due to the presence of external constraints (i.e., reduced range of motion of the knee joint). The outcomes of this study will also complement the outcomes of the study with neurologically impaired persons (e.g., stroke survivors), planned within our research group in the near future, allowing us to draw parallels between the two participants' groups and identify unique compensatory tactics of impaired walking.

What will I be asked to do?

Should you agree to participate, you will only be asked to walk on a treadmill on **three different occasions** (**days**), wearing either no equipment on day 1 or data-collection equipment and knee orthosis on days 2 and 3. The equipment includes a metabolic analyser worn on the chest/back (to measure walking energetics), retro-reflective markers worn around the pelvis and on both legs (to measure joint kinematics), and muscle activity wireless sensors placed on your skip on up to eight muscles per leg. Additionally, you might also wear portable motion sensors (inertial measurement units, IMUs) on your legs/pelvis as a redundant measurement of joint kinematics. Joint kinetics will be measured using force plates integrated into a treadmill.

The **first session** (day 1) will take **about 1h45min** to complete. The purpose of this session is for you to familiarise yourself with treadmill walking and for us to collect some baseline data for later analyses. You will wear no data-collection equipment during this first session. The **second and third sessions** (days 2 and 3) will **take about 2h30min-3h each** to complete. These two sessions are what we call data-collection sessions, and you will wear the full data-collection equipment arsenal. Over the two sessions, you will repeat twice the same 17 5-minute walking trials, grouped in three 25-minute bouts (5x5 minutes) plus two independent 5-minute trials. The order of these trials will be randomised. The reason to repeat the same trials twice is to compare your typical (natural) and constrained walking. During the 'natural mode', you will walk freely, with no constraints to your legs. During the 'impaired mode', you will have your knee joint constrained, which will require you to compensate using some strategy (which and how it differs from other participants is exactly what we are interested in). Thus, the purpose of constraining your lower limb joint(s) is to somewhat simulate the walking pattern of neurologically impaired persons, which will allow us to compare such an impaired walking to that of a healthy person. The knee orthosis you will wear is shown in Fig. 2.

During each session and in between different trials, you will be given enough time to rest to avoid the effects of fatigue influencing results. We will minimise any potential risks by securing you with a harness above your head in case you start falling, an emergency button to stop the treadmill should you feel the need to do so, and by routinely asking you how you feel and whether it is ok to continue with the experiment. We can pause/terminate the experiment at any time should you wish so.

Fig. 1 The equipment worn by the study participants. Metabolic analyser consists of a face mask and small device worn on the back. Retroreflective markers (grey spheres) are placed on both bare legs, shoes, and in the pelvic area. EMG sensors are placed on eight muscles of each leg. The knee orthosis is worn always on the left leg.

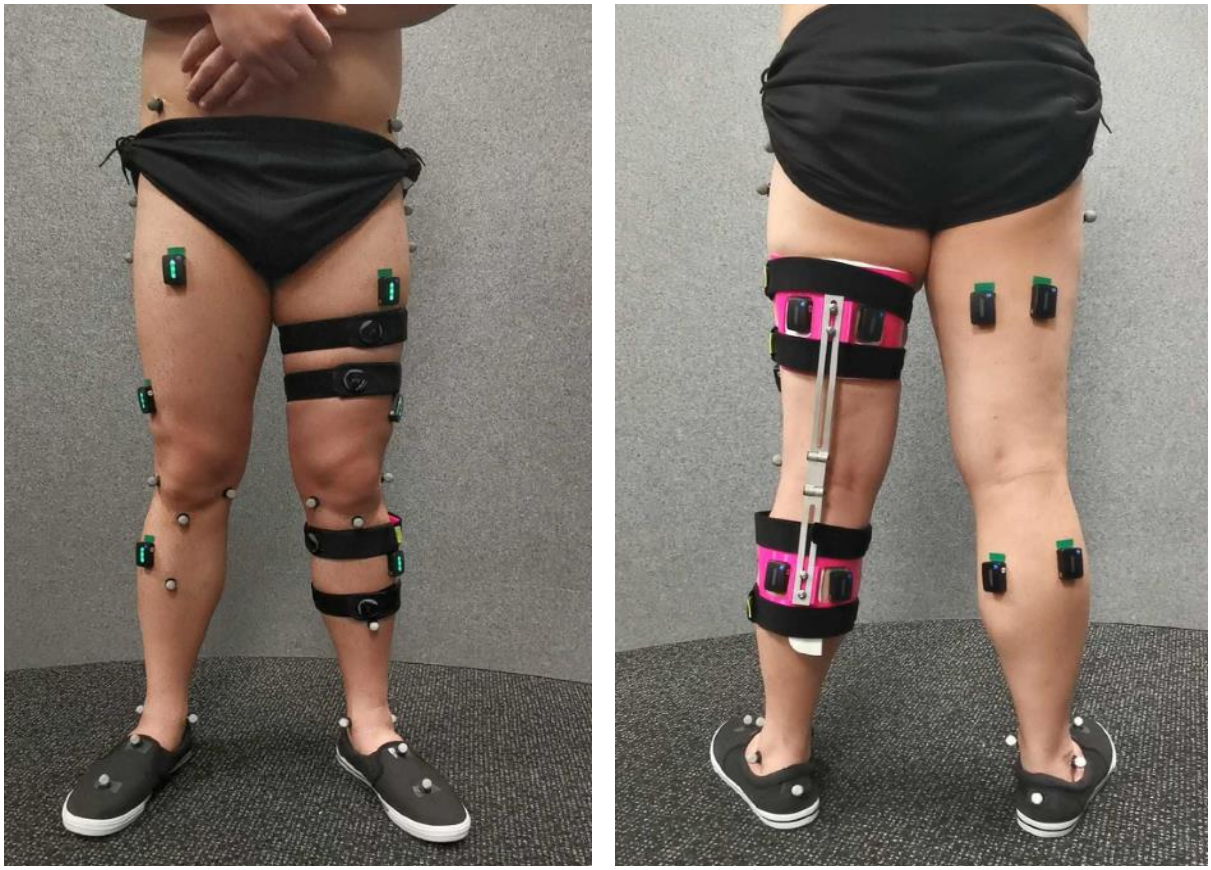

Fig. 2 A close-up of the retroreflective markers (grey spheres), EMG sensors (black devices) and a knee joint orthosis. The markers are worn on both legs, shoes, and in the pelvic area (two at the front and two at the back), requiring tying up pants as shown in the picture. The EMG sensors are worn on both legs in the same positions (symmetric) and require skin to be cleaned and shaved before the sensors are placed. The knee orthosis is always worn on the left leg and is attached to the leg using four BOA straps (similar to Velcro).

We will follow-up with you the following day after each session (experimental day) and a week after your participation ends to ensure there are no consequences (pain, rash, discomfort, etc.) arising from your participation. Finally, **we encourage you to inform us should there be any consequences from your participation** so that we can assist you in resolving potential issues.

The sessions will be carried out by 2-3 researchers, including Dr. Tomislav Bacek as a responsible researcher and 1-2 students (see Additional researchers on page 1 of this statement). We will make sure that **your gender is represented during each session by at least one researcher** to avoid potential gender-related discomfort (e.g., being alone in a room with a group of the opposite gender persons or being touched by a person of the opposite gender while placing the equipment). You will, however, be asked to wear clothes that bare your legs and lower trunk to allow us to place retroreflective markers to the relevant places on your body (legs, shoes, pelvic area – see Fig. 1). Should you agree, we will also put a few extra markers on your torso (e.g., shoulders) and arms, but this will require you to walk in essentially a sleeveless top (as opposed to the participant in Fig. 1, which shows the case without torso and arms markers). Unlike other equipment used in the study as outlined above, baring your shoulders and wearing extra torso markers is not predefined and will depend on whether or not you feel comfortable walking in a sleeveless top.

What are the possible benefits?

This research will have several important benefits for the scientific community. First of all, it will make a significant contribution to our knowledge about the mechanisms underlying walking in different conditions, which is crucial in understanding the human body and its adaptability to the environment we live in. Knowledge about these mechanisms already exists in the field, but it's incomplete, and our study aims to fill some of the existing gaps. Second of all, it will provide an important reference for making comparisons between the walking patterns of healthy and neurologically impaired individuals, which will help us better understand the ways the human body adapts to impairment-induced constraints. Such comparisons are not straightforward, which is why our study requires you to come three days to the lab. Finally, it will guide the development of new rehabilitation techniques and robot-assisted gait therapy approaches to help neurologically impaired individuals regain their mobility and participation in society. This is the ultimate goal of the project this study is a part of.

What are the possible risks?

There are no psychological, emotional, social, legal, economic, or any other risks other than minimal physical risks associated with this study. Before data collection sessions, you will be given at least one hour of walking on a treadmill under different conditions (day 1) to familiarise yourself with treadmill walking and experimental conditions. The treadmill is equipped with a harness safety system above your head (see Fig. 1), which will protect you in case you trip and start falling over. You will also have an emergency button at your hands' reach, and so will the principal investigator. Potential risks coming from unilaterally constraining your knee joint are minimised by

low-to-normal walking speed, sufficient familiarisation period, and harness/emergency stop buttons.

The **sessions will not be open to the public** and will involve wearing your comfortable shoes and clothing. However, you will be required to bare your legs and lower trunk to place data-collection equipment on your body (and shoulders, provided you are comfortable with it). You will not interact with any active mechanical device or a system other than a treadmill and (passive) data collection equipment. As already mentioned, the data collection equipment that you will wear involves retroreflective markers that attach to the skin via double-sided tape and a skin-friendly metabolic analyser worn on the face. While the tape and mask can create some discomfort, this is considered to be minimal and poses no real risk. Due to the current promising and positively evolving situation with covid19, the risk of getting infected is low, but it does exist due to the sharing of the data-collection equipment. To minimise the potential risk of getting infected, we will adhere to all the relevant covid19-related instructions provided by the University and Victorian government. These include wearing masks if you wish us to do so, avoiding physical contact unless donning data-collection equipment, thoroughly cleaning all the equipment and frequently touched surfaces (between two adjacent participants), ventilating the lab where experiments will take place, and regular hand hygiene (hand sanitisers will be available in the lab).

During each session and in between different trials, you will be given a sufficient amount of time to rest to avoid the effects of fatigue/pain influencing results and affecting your safety. Apart from providing you with harness above your head and an emergency button to stop the treadmill should you feel the need to do so, we will further minimise any potential risks by routinely asking you how you feel and whether it is ok to continue with the experiment. **We can pause/terminate the experiment at any time should you wish to do so**. We will also follow-up with you the following day after each session (experimental day) and a week after your participation ends to make sure there are no consequences (pain, rash, discomfort, etc.) due to your participation. We also encourage you to inform us should there be any consequences of your participation so that we can assist you in resolving potential issues. Finally, we will minimise the potential negative effects of underlying health conditions (if any) by discussing in detail your physical condition and fit for the study.

Do I have to take part?

No. Participation is completely voluntary. You are able to withdraw at any time.

Should you wish to withdraw at any stage, i.e., in the beginning, in the middle, or towards the end of the study, we will only use your data if you agree that we do so. If you do not agree and wish to withdraw your data, processed or unprocessed, you can do so without any prejudice or implications.

Will I hear about the results of this project?

The results of this project will be published in scientific journals and/or presented in conferences related to robotics and biomedical engineering, thus being available for

anyone interested in the study outcomes. However, if you prefer, we can also provide you directly with the results upon your request.

What will happen to information about me?

The information that we collect about you in the form of raw data and personal details (name, email, age, gender, etc.) will be stored in two separate folders – on the principal investigator's work laptop and the University's OneDrive cloud folder. The principal investigator will be the only one having access to the locally stored data, while the data stored on the cloud will also be accessible to other researchers involved in the study. The reason for this is the information that can be used to identify you (your name and email), which will not be stored on the cloud. This will make the principal investigator the only person with access to data that can reveal your identity. The data stored online will be anonymised from the moment it was collected so that all post-processing and analysis done by the researchers involved in the study will be using anonymous data.

The data we collect and analyse will be made freely available to the public in the form of an anonymous dataset for use by the scientific community (and wider). They will have no way of identifying you since your performance will be stored as a performance of a *Subject X*. Seeing that this data will be publicly available on a website such as GitHub (public academic repository), the public will have indefinite access to it. On the other hand, the data on the principal investigator's laptop, that will contain information that can reveal your identity, will be stored in a password-protected folder for three (3) years, after which it will be destroyed. This will also include videos recorded and photos taken during experiments (you can opt-out of this while still being able to participate), which will never be shared with the public and will only be used by the researchers in our research group (e.g., for conferences and lectures). Even when used by our group, videos and photos will not reveal your identity (i.e., your face will be blurred).

Who is funding this project?

This study is part of the project funded by the Australian Research Council (ARC) under the Discovery Program (DP) scheme.

Will I be reimbursed for participating in this project?

If you are affiliated with the University of Melbourne and work/study at the University's Parkville campus, where the experiments are taking place, and you are attending campus regularly at the time of experiments, we will not reimburse your participation.

If, on the other hand, you are not affiliated with the University and do not work/study at the Parkville campus, or you are affiliated with the University of Melbourne but you are not regularly attending campus at the time of experiments, we will reimburse your participation.

Where can I get further information?

If you would like more information about the project or the study, please contact the responsible researcher, Dr. Tomislav Bacek (tomislav.bacek@unimelb.edu.au), and he will organise a meeting to discuss this with you. If you would like to participate, please

indicate that you have read and understood this information by signing the accompanying consent form and return it to the researchers. The researchers will then contact you to arrange a mutually convenient time for you to participate in the different sessions.

Who can I contact if I have any concerns about the project?

This research project has been approved by the Human Research Ethics Committee of The University of Melbourne (2021-20623-15928-5; on 11/01/2021). If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Manager, Human Research Ethics, Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 2073 or Email: HumanEthics-complaints@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence please provide the name of the research team or the name or ethics ID number of the research project.