# Biomechanical investigation of the efficacy and perceived performance of a knee brace

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# Abstract

The most prevalent joint disease in adults is osteoarthritis. The knee joint is the joint which is the most affected by osteoarthritis, with mechanical overloading being one of the causes. While no cure exists for osteoarthritis, many different treatment options are available. One alternative is to wear a knee brace on the affected leg. This aims to slow down the progression of osteoarthritis to postpone, or remove the need for, more invasive surgical treatments. Several studies reported that knee braces can lower the perceived pain in patients. However, there is no consensus regarding the biomechanical effect of wearing knee braces, both at the level of the affected knee and in terms of overall effects on gait. The aim of this thesis was to see how the knee brace *OA Nano* (Enovis) affects gait kinematics and the forces associated with gait. Gait analysis was performed on seven healthy subjects when wearing a knee brace, using video recording for retrieving kinematic data and a force plate for kinetic data. In addition, a design investigation was also conducted to evaluate the knee brace and determine any design improvements. Our results indicates that the gait is not affected by the knee brace, as no significant changes was found in neither ground reaction forces nor any of the investigated gait parameters. When wearing a knee brace, the gait speed varied from 0.75 – 1.20 m/s with brace to 0.78-1.21 m/s without brace. The step length differences varied from -8 to +4 cm in both legs when wearing the brace. The range of motion in the brace wearing leg decreased slightly, between 0° and -11° when wearing the brace. The overall appearance of the graph of the knee angle was similar for all subjects and some differences were found, ranging from 4° lower to 8.3° higher during

the gait cycle when wearing the brace. The greatest differences in the ground reaction forces were found to range from -11.6% to 13.9% in the peaks when wearing a knee brace. We conclude that the knee brace does not affect the investigated gait parameters in healthy subjects, as all differences either lie within the standard deviations or are of the same magnitude as the error of the measuring systems. As for the design of the knee brace, the overall design was appreciated by the participants. However, the straps were often fastened in the wrong order and more distinct numbering of the straps was suggested in the design.

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# 1. Introduction

The most common disease to affect the joints is osteoarthritis [1], where the most frequent type is knee osteoarthritis [2]. Amongst the elderly population, osteoarthritis is the most prevalent cause of disability [3]. In Sweden, over one million people suffer from osteoarthritis [4]. It is often characterised by pain during movement, which may become continuous as the disease progresses [2].

It is not possible to cure osteoarthritis. Current treatment methods can include surgery or the use of orthopaedic aids to manage the disease [2]. In those with knee osteoarthritis, different knee braces have changed the user's gait parameters [5]–[9]. One such parameter is range of motion in the knee, which has been shown to both decrease [5]–[7] and increase [8] when wearing different kinds of knee braces. Walking speed [5], [9] has also increased, whereas step and stride length were reported to both increase [5], [7] and decrease [6], respectively. There is therefore no consensus on the biomechanical effects of wearing knee braces. As these studies use different types of braces, there is a possibility that the effects on a person's gait depends on the particular design of the brace itself. Unloader knee braces, like the *OA Nano* from Enovis [10], are often designed to protect the affected compartment of the knee from high loads [11]. Despite its wide adoption (250-300 units sold in Sweden annually), no study has investigated its effects on gait using measurements of ground reaction forces and gait kinematics.

Moreover, in one study, 25 out of 60 participants withdrew from the study, citing lack of effect as the main reason alongside skin irritation and bad fitting [12]. Thus, it could be of interest to investigate if there are any areas of which the design and comfort of a knee brace could be improved.

## 1.1. Aim

This thesis aims to investigate possible alterations in gait biomechanics in healthy subjects when wearing the knee brace *OA Nano* (Enovis). Furthermore, another point of investigation is regarding the design of the knee brace, in which the usability and design aspects will be explored.

## 1.2. Design of the study

The idea for this project was developed in conjunction with the company Enovis. An experimental method for how to investigate gait parameters and design aspects in a knee brace was developed by us with guidance from supervisors. A gait analysis was performed, where the subjects were recorded on video and asked to walk on a runway with an integrated force plate. The experimental set up, see Figure 1, consisted of a runway with an integrated force place and a smartphone camera (C1) placed three metres from the runway. Kinematic data was extracted using the video recordings. The force plate was used to extract ground reaction forces. This data was then compared to literature. In the design investigation, the brace was evaluated in terms of usability and design through a survey distributed to brace users and usability tests conducted with the same subjects as in the gait analysis.

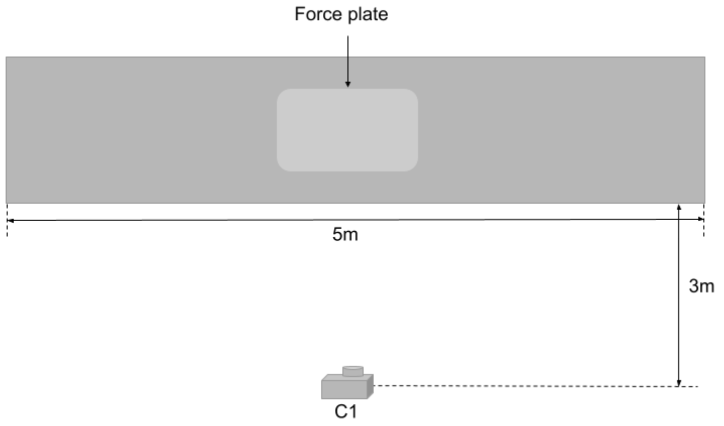


*Figure 1: A schematic image of the experimental set up used in the gait analysis. The runway is pictured at the top of the illustration, with the force plate in the middle. C1 is the smartphone placed three metres from the runway.*

## 1.3. Authors' contributions

The thesis consists of two parts, one larger part consisting of a gait analysis and one smaller part consisting of a design investigation. Both the authors contributed equally to creating the gait analysis and the setup. Alvina Vernersson has focused on the post-processing of data, while Alice Garnheim focused on creating the design investigation. Both authors contributed equally to the discussion of the two investigations and to the report.

# 2. Background

The background will include information regarding anatomical parts and functions of the knee joint as well as osteoarthritis. Moreover, the different gait phases will be explained. Concepts used in the method, such as the software later used in the project, the design and usability concepts, and the knee brace used will also be explained.

## 2.1.Knee joint

The knee is a joint that connects four bones in a complex network of ligaments and muscles [13, p. 365]. It is stabilised by surrounding ligaments, tendons and muscle tissue [13, p. 365]. It is one of the most complex joints in the body and can be distinguished into two different joints, the tibiofemoral joint (between femur and tibia), and the patellofemoral joint (between patella and femur) [14, p. 181]. The latter joint will not be discussed further in this thesis. As a central joint between the two longest lever arms in the body, the tibiofemoral joint (henceforth the knee joint) is exposed to high biomechanical loading and moments. Therefore, it is not uncommon for different kinds of pathological problems to appear in the knee [14, p. 181].

There are three compartments in the knee. There is a patellofemoral compartment, which is located behind the knee cap. The inner part of the knee is referred to as the medial compartment and the outer part of the knee is referred to as the lateral compartment [15].

The knee joint can be described as a modified hinge joint that allows for six degrees of motion, including 3 translations and 3 rotations. The most dominant motion is that of flexion/extension, referring to the rotation of the knee in the sagittal plane [16], see Figure 2. The rotation of the knee in the frontal plane and transverse plane is called varus/valgus and internal/external rotation respectively. The additional three degrees of motion refer to relative movement in space [16].

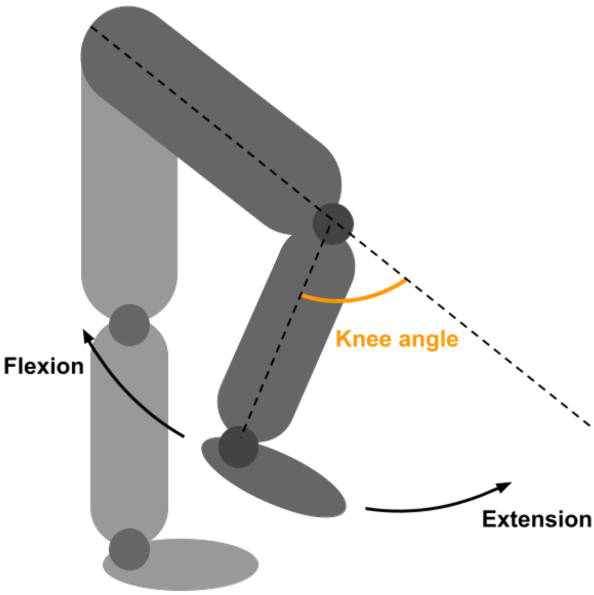


*Figure 2: A schematic image showing the knee angle, as well as the flexion and extension motions in the knee joint.*

The condyles at the distal parts of femur rest on the proximal parts of tibia. As a result of the non-symmetrical shape of the femoral condyles and the tightening of the crucial ligaments (that connects femur and tibia), an internal rotation of femur occurs at the last 0-20° of the extension [17], called the screw home mechanism. When looking at the opposite movement (flexion from hyperextension) the femur will externally rotate back to its original position. The screw home mechanism will unload the muscles and the load is instead carried by bone and ligaments which improves stabilisation as the knee moves towards hyperextension. If knee extension is limited, then the stability of the knee will rely more on the surrounding muscles and ligaments, thus increasing the risk of injury as a result of less stabilisation, over worked muscles and pain [18].

## 2.2. Gait

The way a person walks is defined by their gait [19, p. 49]. When performing a gait analysis kinetic and kinematic data can be obtained to quantify a person’s gait.

### 2.2.1. Phases

There are two different phases to gait, the stance phase and swing phase. During the stance phase for one leg, the foot is placed on the ground. This phase is composed of five different parts; heel contact, foot flat, mid stance, heel off and toe off. During toe off, the swing phase also starts, which is when the leg swings forward. The swing phase consists of an additional two parts, mid swing and heel contact, which is also the point when the stance phase repeats [19, p. 53]. This is illustrated in Figure 3.

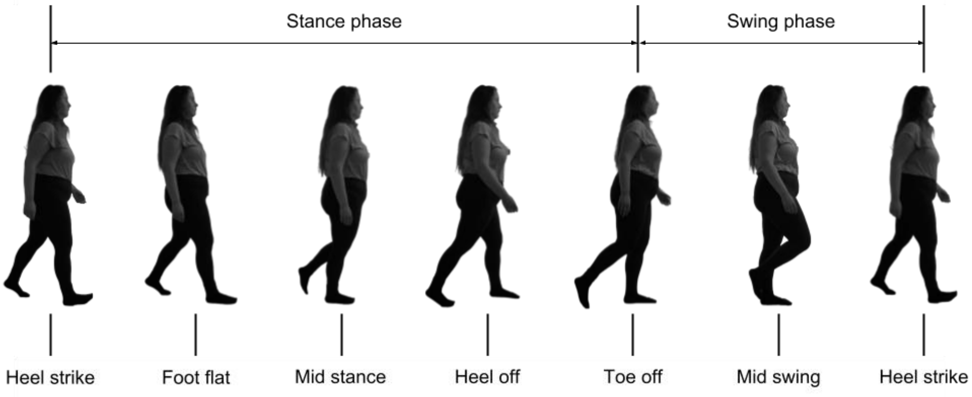


*Figure 3: Phases of a normal gait cycle.*

The heel contact is also commonly known as heel strike and characterises the start of the stance phase. The heel strike generally lasts between 10 and 20 ms [19, p. 61]. The term initial contact can be used in instances when the heel is not the first part of the foot to make contact with the ground, for example in pathological gait. Among individuals, the amount of force applied to the ground during heel strike varies depending on the persons style of walking [19, pp. 60–61].

The swing phase accounts for approximately 40 % of the gait cycle, while the stance phase accounts for 60%. These percentages will depend on the walking speed as the swing phase becomes longer with increasing speed, and the stance phase becomes shorter [19, p. 54].

### 2.2.2. Measurements

Different measurements can be taken to characterise a person's gait. One of them is stride length, which is the length from one heel strike to the next of the same foot. The length difference between two heel strikes by different feet, i.e. of the left and right foot, is known as step length [19, p. 55]. This is illustrated in Figure 4.

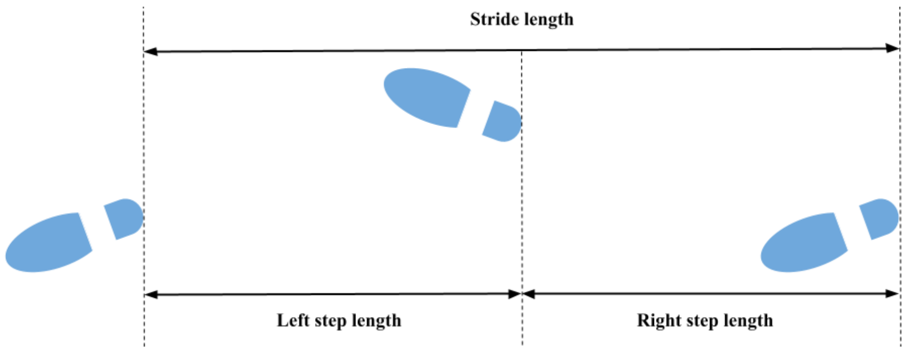


*Figure 4: An illustration showing stride length, left step length and right step length.*

Left and right step lengths are typically equal in physiological gait but can differ in pathological gait. One step length can be zero, or negative, if one foot is not brought in front of the other [19, p. 55]. The average duration of one step (step duration) has been measured at approximately 0.55 seconds for all ages on an even surface [20].

Another possible measurement is gait speed, which is how fast a person covers a certain distance, and is typically expressed in metres per second [19, p. 56].

### 2.2.3. Kinetic data

Kinetic data can be obtained from the ground reaction forces. When the foot touches the ground during walking, the ground applies forces on the foot. These are known as the ground reaction forces and to measure them, a force plate can be used [13, p. 471].

The vertical ground reaction force is the most analysed ground reaction force during gait analysis and is usually shaped like a M [21, p. 82]. This is illustrated in Figure 5, which shows a step from heel strike to toe off, normalised to the person's body weight (BW).

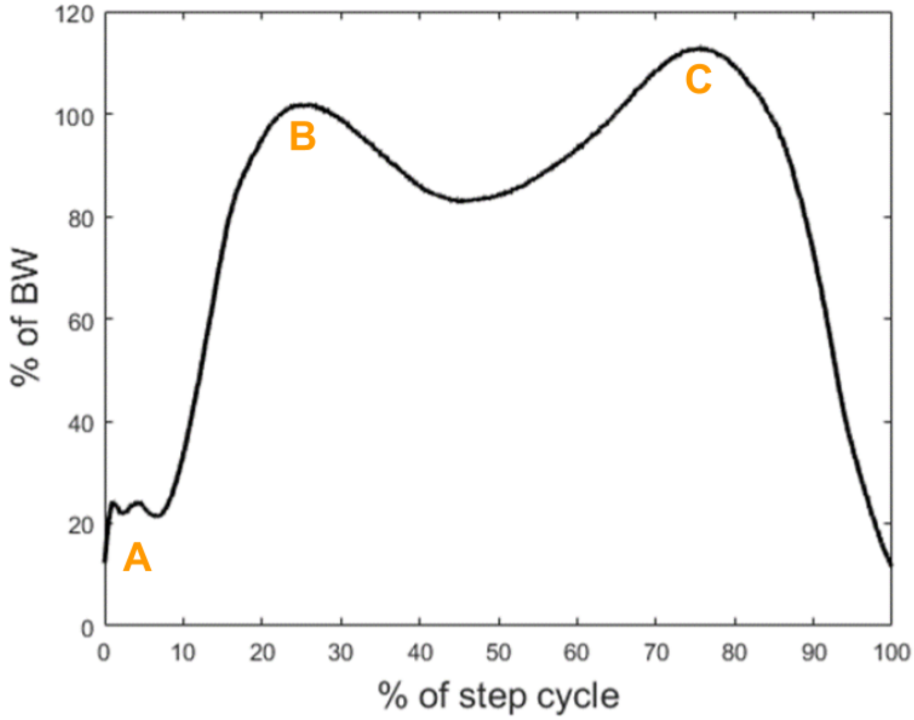


*Figure 5: An illustration of the vertical ground reaction force during one step. The y-axis shows the amount of force normalised to a person's body weight (BW). The x-axis shows one step cycle, from heel strike to toe off.*

As heel strike occurs, there is a small peak in the vertical ground reaction force [19, pp. 60–61], defined by point A in Figure 5. Between heel strike and when the foot is flat on the ground, there is a quick increase in the vertical ground reaction force [19, p. 63], which can be seen between point A-B in the step cycle in Figure 5. It is in the early stance that the first peak of the M-shaped curve occurs [21, p. 82], at point B in Figure 5. During mid-stance, the force decreases (between point B and C in Figure 5), and then increases to a second peak during late stance (at point C in Figure 5), and toe off (from point C to the end of step cycle in Figure 5) [21, p. 83].

There are two horizontal ground reaction forces, which are characterised by the direction of movement. There is the anterior-posterior force, which is in the same direction in which the person is moving and there is the medio-lateral force, which is perpendicular to the direction of movement and the vertical force [21, p. 84].

There are three phases to the anterior-posterior ground reaction force curve, a short backwards phase, a breaking phase, and a propulsion phase. The backwards phase occurs as the foot hits the ground, while the breaking phase occurs during the lead-up to midstance. The final phase, the propulsion phase, accounts for the other half of the stance phase [21, p. 84].

The appearance of the medio-lateral force varies between both individuals and steps when walking straight forward. [21, p. 84].

### 2.2.4. Kinematic data

Kinematic data of a person's gait can be obtained by taking images while walking and then tracking certain locations on that person's body [13, p. 463].

For example, kinematic data can be obtained by looking at the knee angle, i.e., the angle between the femur and tibia. A typical variation in the knee angle during a step cycle can be seen in Figure 6.

In one gait cycle, there are two extension and two flexion peaks in the knee. Full extension occurs during heel strike (0% of gait cycle in Figure 6) and in mid stance (45% of gait cycle in Figure 6). The flexion peaks occur in the beginning of the stance phase (20% of gait cycle in Figure 6), and early swing phase (at 75% of gait cycle in Figure 6) [19, p. 59]. The knee flexion in the early swing phase is between approximately 60° and 70° [19, p. 62]. A larger range of motion in the knee joint is necessary with increasing movement speed. Slow walking has, during the stance phase, a knee flexion range of 0-6 degrees. The equivalent in fast walking is 12-18 degrees [14, pp. 184–185].

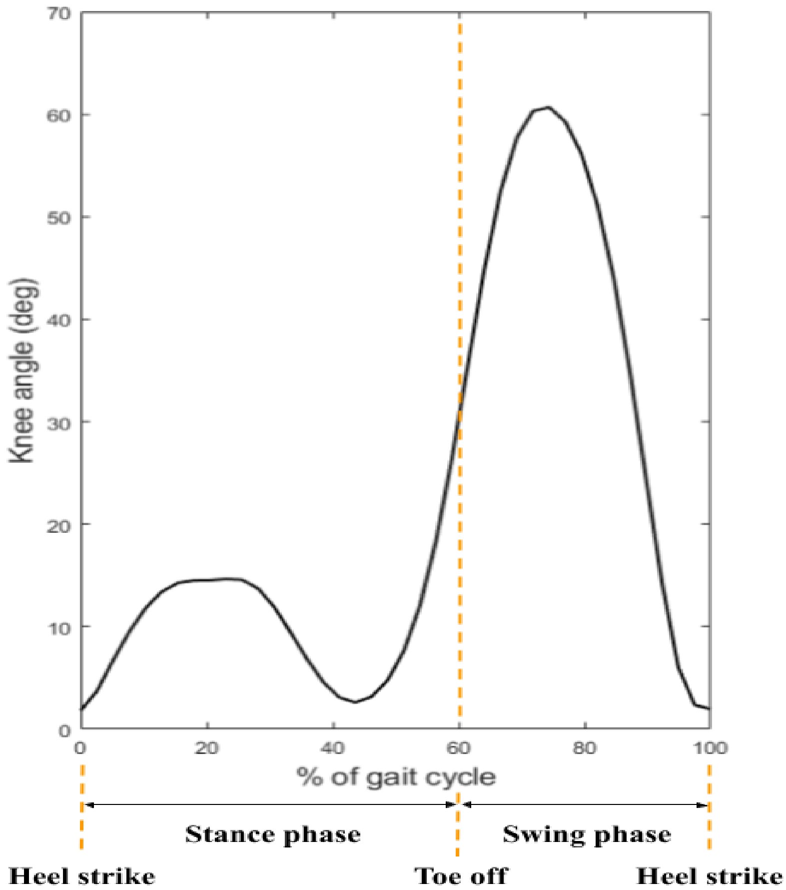


*Figure 6: The stance phase, swing phase, heel strike and toe off are shown in relation to the knee flexion angle.*

## 2.3. Osteoarthritis

Osteoarthritis is the most common chronic disease among those over the age of 65 and affects the joints [4], with the knee being the most commonly affected joint [2]. Risk factors for osteoarthritis include age, gender, obesity, occupation, genetics [22] and joint trauma [23].

Deterioration along with loss of (articular) cartilage and bone remodelling are common physical characteristics of osteoarthritis [24]. Progression of osteoarthritis causes internal changes of the cartilage, altering the mechanical environment. The cartilage in the osteoarthritic joint becomes stiffer and thinner. Therefore, the load transmitted to the bones increases [25].

Knee osteoarthritis can occur in the patellofemoral, lateral tibiofemoral, or medial tibiofemoral compartment of the knee [26, p. 3]. Medial compartment osteoarthritis is the most common type [27]. This is often paired with a varus alignment of the knee, narrowing the medial compartment [28].

To determine whether a patient suffers from osteoarthritis, x-ray imaging can be used, which also makes it possible to determine the stage of progression of osteoarthritis [2]. Osteoarthritis cannot currently be cured; hence, the treatment focuses on reduction of symptoms. Furthermore, the progression of the disease may be slowed down [2]. The treatment options include but are not limited to:

*General measures:* This treatment option includes adjustments to the patient's lifestyle alongside patient education, with the goal of reducing excessive stresses on the cartilage [2].

*Physiotherapeutic measures:* Physiotherapy, which could include walking, stretching and muscle stimulation [2].

*Orthoses and orthopaedic aids:* The use of aids, such as wedges in shoes or braces can be used for knee osteoarthritis. The use of knee braces may lead to better function, and decreased pain [2]. To correct a varus deformity in the knee, which occurs in medial compartment osteoarthritis, a valgus force could be applied [28] (using a three [28] or four [11] point loading system) to shift the contact force in the joint towards the non-osteoarthritic compartment [28]. However, knee braces have been found to be unpleasant among users and so are not used for extended period of time [7].

*Surgery:* Different types of surgery can be conducted, if conservative treatments, such as those mentioned above, are not effective [2].

## 2.4. Effects of knee braces in patients with osteoarthritis

Several studies have been conducted regarding the effects of knee braces in patients with osteoarthritis in terms of pain and gait parameters.

Brouwer et al. [12] found a statistically significant difference in pain severity in those who had used a certain knee brace for 12 months (intervention group) compared with the control group. However, no significant difference was found in terms of quality of life between the control and intervention group. Furthermore, 25 out of 60 participants in the intervention group discontinued their treatment during the 12 month trial, citing no effect of treatment as the main reason [12]. Two other studies found a statistically significant decrease in pain if using a knee brace when walking [6], [9]. A study by Richards et al. investigated two different types of knee braces, where one of the braces decreased the subjects' pain when resting, walking, and climbing stairs [29].

In terms of gait parameters, there are conflicting results regarding the effect of a brace. Gaasbeck et al. found that after six weeks of brace usage, the range of motion decreased on the arthritic limb when wearing the brace [6]. Decreased range of motion caused by wearing knee braces in subjects with osteoarthritis was also found by Fesharaki et al. [5] and Arazpour et al. [7]. However, another study by Arazpour et al. found an increase in average values of range of motion in those who had worn a knee brace for six weeks [8]. When investigating the effect in range of motion that a knee brace has on the non-arthritic leg, Gasbeeck et al. found no differences between the braced and unbraced condition [6].

Schmalz et al. found an increase in step length in the arthritic leg and gait speed in patients with knee osteoarthritis when wearing a brace [9]. An increase in step length was also found by Arazpour et al. [7]. Another study by Arazpour et al. found an increase of both step length and speed of walking in those who had worn a knee brace for six weeks [8]. Conversely, Gaasbeck et al. found a decrease in step length when wearing a knee brace [6].

In terms of ground reaction force, Schmalz et al. found an increase in the first peak of the vertical force when wearing a knee brace. However, the authors of this study theorised that this may be due to the increased walking speed [9]. Another study reported an increase in the ground reaction force during loading and push-off on the leg which had the knee brace [29]. Nagai et al. reported no significant changes in ground reaction force with a brace compared to unbraced condition of the knee [30].

In terms of gait symmetry, it has been found that wearing a brace induced a consistent and instant improvement in gait symmetry for those with osteoarthritis in one knee [31].

In the case of investigating a brace's effect on the non-osteoarthritic leg, this can often be overlooked [5], [7], [8], [29]. However, it can be of interest to also investigate if there are any effects on the non-osteoarthritic leg. Draper et.al [31], looked into the symmetry of gait by comparing the proportion of time spent in stance or swing phase. Their results showed that the proportion of the stance phase (of the osteoarthritic leg) was lower than the swing phase before putting on a knee brace, indicating an antalgic gait. They also showed that the symmetry improved, which is assumed to be an improvement in gait, whilst wearing a knee brace [31]. Thus, it can be of importance to investigate both legs separately, as the changes in gait parameters might differ between the legs, therefore affecting the symmetry of gait.

One study evaluated the effects of knee braces in healthy subjects [11] and showed a statistical significant decrease in range of motion whilst wearing knee brace.

## 2.5.Open Pose

There are different ways to record kinematic data, one being a motion capture system. This consists of several cameras and requires placement of markers on the body within a laboratory environment [32]. The current methods are often time consuming, expensive, requiring specialised expertise and equipment [33]. Some approaches have been developed to obtain kinematic data from video recordings, one example being OpenPose

[34]. It is an open-source pose estimation program based on a central neural network that predicts two-dimensional poses of one or multiple people from an input image (or video) [34]. The two-dimensional poses include multiple keypoints, located for example in the ankle, knee and hip joint [34]. The correlation coefficient found when comparing OpenPose to a motion capture system, has been found to be 0.93 and 0.86 for the knee joint angle closest and furthest away, respectively, from the camera [35]. Moreover, when comparing OpenPose to an optical marker-based motion capture, the mean absolute error in terms of joint positions was <20 mm in 47% of cases, and <30 mm in 80%. 10% of joint positions differed more than 40 mm. The main reason for those higher errors was failed tracking by OpenPose, for example by detecting keypoints in the video that do not correspond to the joint positions of the person or by incorrectly switching keypoints between left and right leg [36].

Instructions for use and the OpenPose installations can be found on GitHub [37], [38].

## 2.6.Design aspects

There are several aspects to the design of objects, a few of them being affordance, signifiers, and constraints.

Affordance describes the relationship and possible interactions between a user and an object. These interactions depend on the actual and apparent properties of the object [39, p. 11]. One example involving knee braces could be that there is a metal frame in the brace. This offers an affordance of giving support to the knee.

Signifiers indicate to the user what behaviour is suitable in regards to objects [39, p. 14]. Signifiers inform the user what possible actions there are and how the action should be completed. The users should be able to identify these signifiers, if not, the signifiers do not serve their purpose [39, p. 19]. In the case of knee braces, a signifier could be numbers on the straps, which would indicate the order of which the straps should be fastened.

To limit the number of potential actions a user can have with an object, constraints can be used. Constraints are divided into four different kinds, one of them being physical constraints, which ensure only certain operations can be done with an object [39, p. 125]. In the case of the knee brace, the hinge cannot be extended above normal flexion range, providing a physical restraint to the movement of the hinge.

## 2.7. Usability

### 2.7.1. What is usability?

Usability is defined by ISO 9241-11:2018(en) in section 3.1.1. as the *"extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"* [40]. This definition defines three important parts of usability; specified users, goals and context of use [41, pp. 11–12]. It is possible to test usability, by letting users perform real tasks with the product and observing them [41, p. 15].

When conducting small studies, it is important to give the participants tasks to complete to ensure that the product is used in the intended way and to facilitate the analysis by standardising the test among test users [41, p. 20]. These tasks should depend on the goals for both the participant, in terms of product use, and the study [42, p. 171].

### 2.7.2. Usability testing

There are different types of tests for testing usability. One of them is summative evaluation, in which users complete their scenarios or tasks without interference [42, p. 145].

Pre-test and post-task questionnaires can be used during the test. Pre-test questionnaires can be used to gain further important information about the participant, which could be relevant to the test [43, pp. 222–223]. Post-task questionnaires can provide quick feedback after each task. The user experience can be determined from questions such as if the task took a longer or shorter time to complete than expected, and how easy or difficult the participants found the task [43, p. 226].

Another way to gain information regarding the user experience is by conducting an interview after the usability testing. By conducting a semi-structured interview, valuable insights can be gained as the interview can go in its own direction [43, pp. 239–240].

In tests, there is only a certain amount of information that can be gained regarding the product that is being tested. The information gained, called findings, will depend on how the test is structured. However, there is a limit to how much can be found. Depending on how much the usability test should uncover in terms of findings, the number of users can vary. However, to ensure that 85% of findings from the test are discovered, five users should be recruited. As the amount of users increase above five, less new discoveries are found [41, pp. 16–17] [44]. However, when conducting small studies, such as studies with five participants, it is important to limit the user group [41, p. 20].

## 2.8.Knee brace

The OA Nano (Enovis) knee brace will be used in this thesis. It is a 4-point bending knee brace designed to shift the loading of the knee and provide general stabilisation of the knee. This to minimise the instability of the knee that occurs among patients with osteoarthritis (as a result of the loss of cartilage). It weighs approximately 400 grams and comes in seven sizes [10]. It consists of a magnesium frame with attached straps which are used to secure the brace [10]. The straps should be fastened in the order indicated in Figure 7. There are brace options for medial and lateral osteoarthritis and the *OA Nano* has been clinically proven to off-load the affected part of the knee [10].


*Figure 7: The OA Nano knee brace with numbering of each strap, indicating the order in which they should be fastened.*

# 3. Material and methods

This chapter will cover the material and methods used for the gait analysis, design investigation and the post processing of data.

## 3.1. Survey

A survey was conducted to obtain information regarding what the end users value most in their product.

To ensure the questions asked during the upcoming usability test (with healthy subjects) were relevant to what the end users find important regarding brace use, a survey was distributed in three Facebook groups relating to those suffering from joint disease. The survey aimed to investigate the general use of braces but was not limited to knee braces or people who suffer from osteoarthritis. The survey consisted of 19 questions. Questions relating to age, type of brace and how often the brace was used were single choice. Questions regarding opinions on the use of the brace were both single choice and multiple choice and there was an option to add an answer in the multiple-choice questions. The questions can be found in Appendix A.

## 3.2. Gait analysis

The aim of the gait analysis was to investigate if there were any differences in healthy subjects' gait when wearing a knee brace on one leg compared to when wearing no brace. This was done by comparing gait parameters such as step length, gait speed, knee angle and ground reaction forces. These parameters were extracted for each leg separately. All subjects wore the knee brace on their right knee. By comparing the gait parameters for a leg while wearing a knee brace to those found when walking without the brace, differences can be determined.

Seven healthy subjects were recruited, five women and two men with the average age of 25 (±2) years. The subjects were instructed to wear tight fitting trousers, as to ensure that the brace would fit over the clothes. Informed consent was obtained for all subjects. To obtain the correct size for the knee brace, the circumference of the subjects' right leg was measured at three locations, 15 cm above the patella, 15 cm below the patella and over the knee. From these measurements, a correct sized brace was chosen for each subject according to the size guide for the OA Nano knee brace, found on the company's website [10]. Five OA Nano knee braces were available for use in sizes XS-XL. If any of the measurements taken did not correlate to the same size, the size which most measurements correlated to was chosen. The same knee brace was used in both the gait analysis and design investigation. All subjects wore knee braces made for lateral osteoarthritis on their right leg. The hinge in the medio-lateral direction was adjusted until reaching a light pressure against the inner part of the knee in all subjects.

### 3.2.1. Data collection

To extract data, a force plate (Kistler 9281B) was placed in the centre of a 5-metre-long runway. The start of the runway and a part along the runway was marked with tape, and the distance between these two points was measured (later used for scaling). The software used to acquire the data from the force plate was BioWare (v. 5.2.1.3). A smartphone (C1) (Samsung S10) was placed 3 m perpendicular to the runway (see Figure 1). C1 filmed in UHD at 60 frames per minute. In the design investigation, C1 was placed to ensure a full view of the participant during the scenario.

The sampling rate of the force plate was set to 1000 Hz. The total measuring time was set to five seconds and was manually started for each step. Each subject was weighed twice on the force plate, with and without brace respectively. These measurements were later used to normalise the collected force data.

The subjects were asked to walk from one side of the runway to the other, while placing the foot closest to the camera on the force plate. This will be referred to as one trial. Each subject completed three trials per leg without the knee brace. An additional three trials per leg was completed when wearing the knee brace on the right leg. Some subjects began the gait analysis whilst wearing the knee brace, while other subjects began without. This order was randomised. A trial was considered successful if the whole foot was placed on the force plate. The subjects were instructed to walk as naturally as possible, looking straight forward (at visual markers on each side of the runway).

### 3.2.2. Post processing

Data from the force plate was processed using MATLAB (Mathworks, Inc.). BioWare (Kistler) was set to record force during a five second span. The step was defined as the parts where the force amplitude reached above a cut-off of 10% of the maximal force detected during each trial. The force data was then filtered using a lowpass filter with a passband frequency of 50 Hz, after which each condition (left/right leg and with/without brace, respectively) was resampled to equal lengths before retrieving the averaged amplitude of the three trails performed during each condition. Lastly, the force data was normalised by the subject's body weight. Recordings of the force that were damaged (when inspecting visually) were deleted.

In terms of the video footage, C1 captured the subjects from a sagittal view. The video was cut into short clips (Clipchamp, Microsoft), where one clip consisted of a subject walking from one end of the runway to the other, i.e., one trial. All videos were analysed with OpenPose (v. 1.6.0).

The extracted gait parameters from OpenPose were:

- **Step length** - the distance in centimetres in the travelling direction between an ankle keypoint at heel-strike to the subsequent ankle keypoint at heel-strike of the opposite leg.
- **Step time** - the time from one heel-strike to the next.
- **Gait speed** - step length divided by step time.
- **Knee angle** - the angle formed between hip-, knee-, ankle- keypoints (where 0˚is full extension of the knee, positive and negative derivatives correspond to flexion and extension respectively).

The output from OpenPose consisted of a video with the joints superimposed on the video as well as the detected poses and their keypoints (e.g., hip joint-, knee joint-, ankle joint- coordinates).

A Matlab script by Stenum et al.[33], [45] was used to extract the gait parameters. Initially all frames were visually inspected so that all detected keypoints referred to the subject, thereby removing falsely positive detected persons. The coordinate system was updated so that the positive vertical direction corresponds to upwards in the video and the positive horizontal direction to that of the travel direction of the subject. The time-series of the horizontal ankle position was inspected for detection and correction for any errors in faulty classifications of left and right leg. Any gaps in the keypoints' trajectories that were less or equal to two video frames were interpolated (using linear interpolation), and trials with bigger gaps then this were excluded in this study. The keypoint trajectories were filtered using a low-pass Butterworth filter with a cut-off frequency at 5Hz. Lastly, the distance in metres between the start and the end of the runway was specified in post processing to determine the scaling factor. The data from each condition (right and left leg whilst using a brace or no brace respectively) were expressed as a function of the percentage of the gait cycle before retrieving the averaged gait parameters of the three trails performed during each condition. A heel-strike was characterised as the point in time of a positive peak in the trajectory of the ankle relative to the mid-hip keypoint.

## 3.3.Design investigation

A part of this thesis covered a usability scenario, which had the aim to investigate the design of the OA Nano, in terms of usability and ease of use. As described earlier, usability relates to having specified users, goals, and context of use. Hence, to evaluate usability, a testing environment in which the specified users may use the product to reach a specific goal is ideal. A design scenario, in which the brace was to be put on was created and test persons which had not previously used a knee brace were recruited. These participants partook in the gait analysis and consisted of two males and three females with the average age of 25 (±2) years.

### 3.3.1. Usability scenario

In the usability scenario, a manuscript was used to ensure each participant received the same information regarding the scenario.

Before the tasks, a pre-test questionnaire was distributed. This to establish the user group and to get information about if the participants have had previous knee injuries or had used a knee brace. Information regarding the participants gender and age was also collected in the questionnaire.

In the scenario, the participants were instructed that they suffered from knee osteoarthritis and had been referred to an orthopaedic clinic to receive a knee brace. Their initial response regarding the design of the orthosis was noted, as one of the aims was to uncover the initial reaction to the knee brace by potential users.

As another aim of the usability test was to establish benchmarking criteria during the scenario, any errors encountered during this time were noted, along with the ease of use of putting the knee brace on. By identifying these factors and combining them with the initial response to the design, the orthosis could be evaluated in terms of affordance, signifiers, and usability.

Osteoarthritis is common in those over 65 years of age, with half the world's population in this age group suffering from osteoarthritis in this age group [3]. Decreased hand strength and dexterity are linked to increased age [46]. As the participants in this project are younger (25±2 years), it can be assumed that their hand strength and dexterity is higher than in those over 65 years of age. In order to simulate the conditions of decreased hand strength and dexterity, the participants also completed the task of putting the knee brace on whilst wearing mittens.

All tasks the participants were instructed to complete were:

1. *Putting on the brace:* During this task, any errors by the participant were noted.
2. *Putting on the brace with instructions:* During this task, any errors by the participant were noted.
3. *Putting on the brace with mittens:* During this task, any errors by the participant were noted.
4. *Standing up, walking around, and doing squats whilst wearing the brace:* These tasks were completed to identify any fit issues with the design.

After task 1-3, a post-task questionnaire was distributed. After the post-task questionnaire was answered, the participants were asked a set of questions, as a semi-structured interview. Any differences seen between task two and three were also noted to investigate if the mittens were a good simulation of a decreased hand dexterity and if this affected how the participants put on the knee brace.

The information gained in the pre- and post-task questionnaires were compiled. The answers to the questions in the interviews were transcribed.

# 4. Results

This section covers the results of the gait analysis and the investigation of the design of the knee brace.

## 4.1. Survey

35 brace users responded to the survey, which included responses regarding all types of braces. Nine of these respondents used a knee brace to help with their osteoarthritis. 29 respondents had used their brace for over six months. When asked what they appreciated the most with their brace, 94,4% of users stated that it decreased their pain.

The users were asked if the occasion affects their decision to wear a brace. They were given multiple options and could also add their own answer, see Figure 8. It was possible to select several options. 40% of users stated that they would not use their brace during formal events and 20% of users would not use their brace when visiting restaurants. However, almost 70% stated that the type of event or activity did not affect their choice to wear a brace, some of which also stated they would not use their brace during formal events or restaurant visits. Because of this, the participants in the design investigation were asked if there were any occasions where they would choose not to wear the brace they were given.

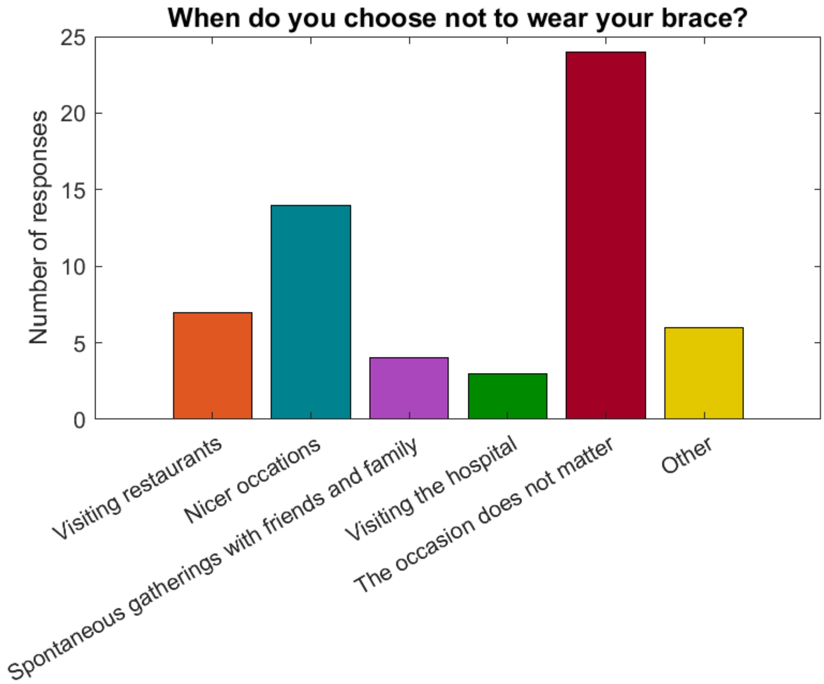


*Figure 8: Question number 10 from the survey and the collected responses.*

11% of users stated that a different coloured brace would increase their use of the brace, thus, a question regarding the colour of the brace was also included in the design investigation. Furthermore, when asked what users disliked with their brace, 23% stated they found their brace ugly.

## 4.2. Gait analysis

This section covers the results from the gait analysis. All results were compared on an intraindividual level (comparing one individual with itself) and the potential changes in the gait parameters when using the brace were explored. The right and left leg were analysed separately, as at times they are affected differently by the brace (when worn on the right leg).

### 4.2.1. Step length

The measured step length obtained during the experiments can be seen in Figure 9. The first two subjects had an increased step length in both legs with the knee brace. Subject 3 increased their step length in the left leg and decreased their step length in right leg when walking with the knee brace. In the last four subjects, the median step length decreased when wearing a knee brace for both the right and left leg.

In the right leg, the step length differences in all subjects ranged from -4 cm to +4 cm when wearing the brace. In the left leg, the step length differences ranged from -8 to +2 cm.

Only the step length ranges in the left leg in subject 6 showed no overlap in the different brace conditions; the remaining subjects showed a distinct overlap of the total step length range in the different trials, see Figure 9.

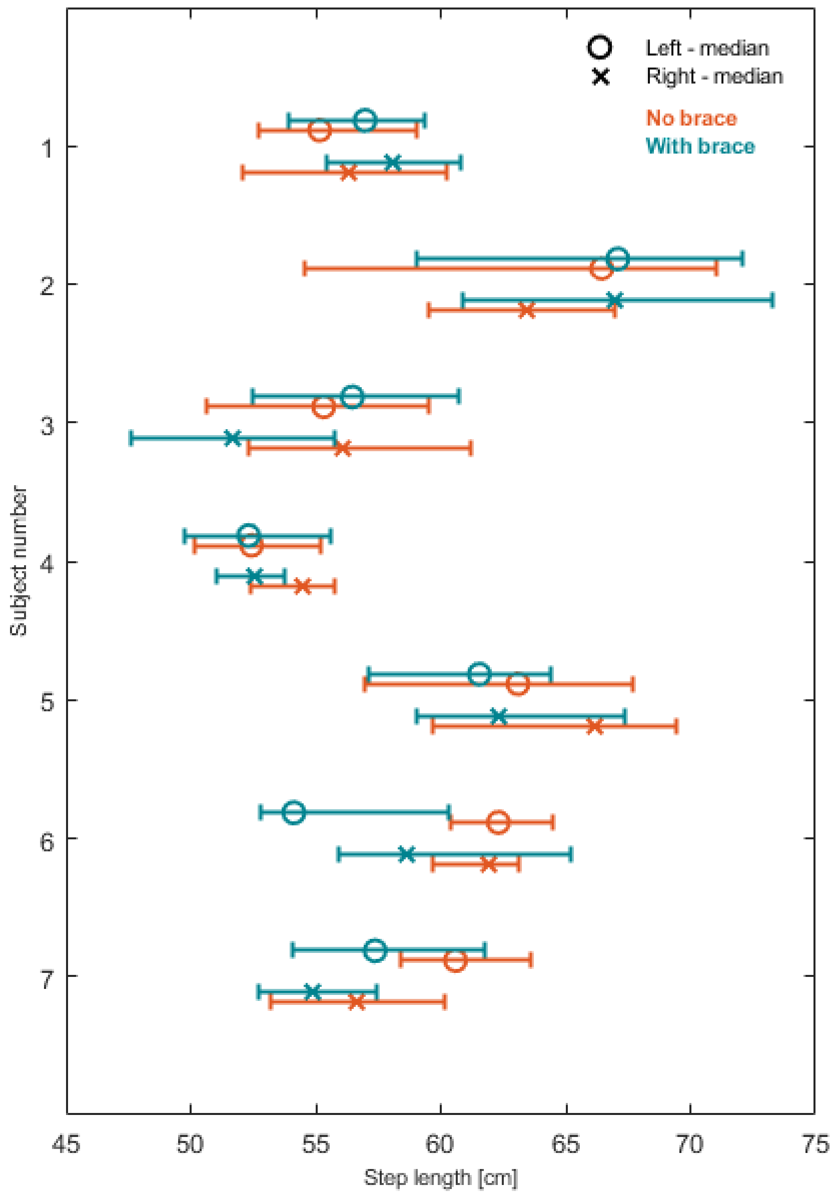


*Figure 9: Step length of the affected and left leg whilst wearing a knee brace or not, respectively. The total range and median from the three trails are presented, where the median is shown with a cross or circle for the affected and left leg respectively.*

### 4.2.2. Ground reaction forces

Figure 10 and Figure 11 show the vertical ground reaction forces normalised to the subjects' body weight. Variations in the order of +/- 10% were observed for the peak vertical ground reaction force in the right leg, when comparing between wearing the brace and not wearing the brace. In the first peak, the differences in force in the right leg between when wearing the brace were between -11.6% to +11.4% of the normalised force compared to not wearing the brace in all subjects. In the second peak, these differences were between -7.4% to +10.3%, when wearing a brace compared to not wearing a brace in all subjects.

In the left leg, small variations of the normalised vertical ground reaction force were observed. In the first peak, these differences were between - 1.6% and +13.9%, when wearing the brace. The maximum difference of 13.9% was seen in subject 7 on the left leg on the first peak. In the second peak, the differences in force between all subjects when wearing the brace were between -6.5% and +6.5%, compared to not wearing a brace.

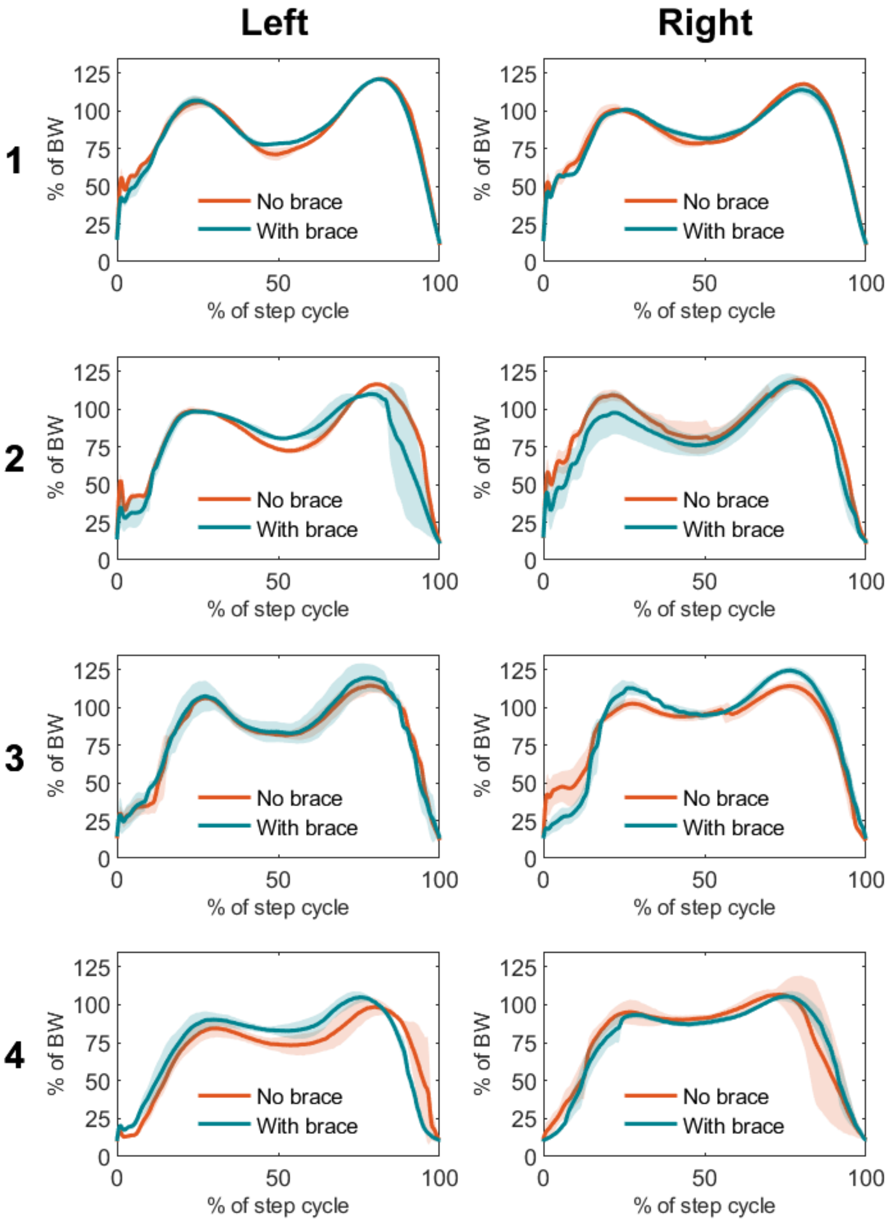


*Figure 10: Ground reaction force in the vertical direction for different subjects (1-4). The left column shows the ground reaction force whilst placing the left leg on the force plate and the right column of the right leg normalized to the subjects' body weight (BW). The average ground reaction force during a step without and with a knee brace are shown in orange and petrol lines, respectively. The standard deviations for each condition are shown in a shaded area in corresponding colours.*

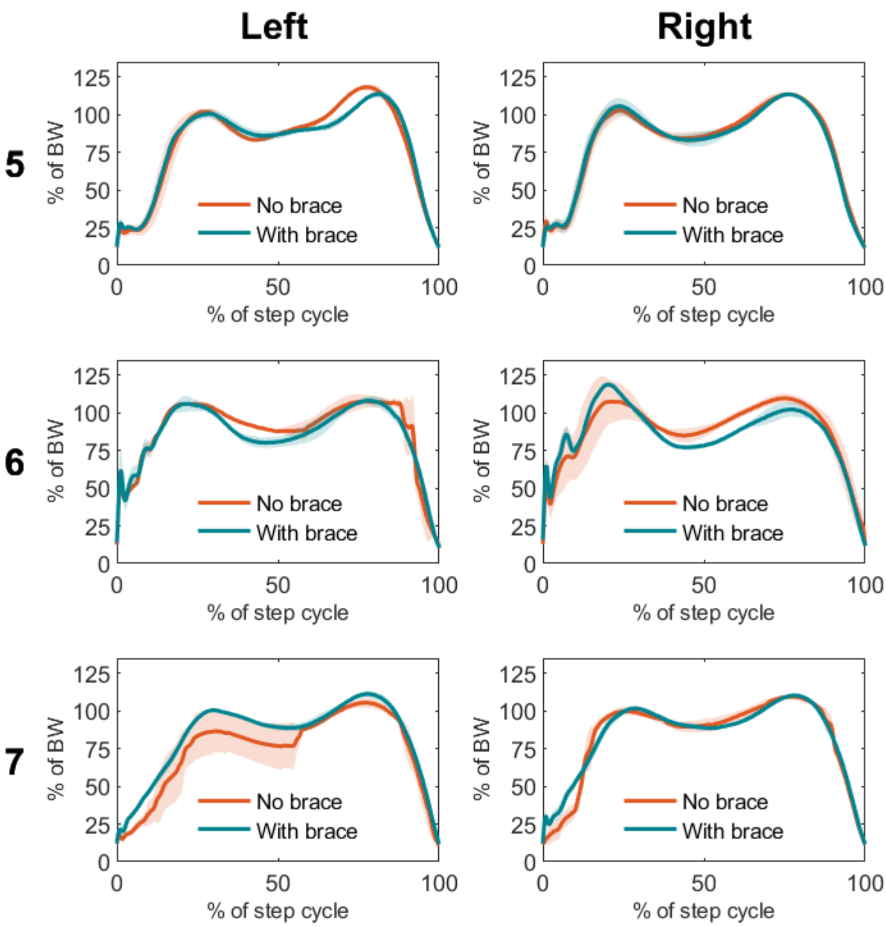


*Figure 11: Ground reaction force in the vertical direction for different subjects (5-7). The left column shows the ground reaction force whilst placing the left leg on the force plate and the right column of the right leg, normalized to the subjects' body weight (BW). The average ground reaction force during a step without and with a knee brace are shown in orange and petrol lines, respectively. The standard deviations for each condition are shown in a shaded area in corresponding colours.*

Figure 12 and Figure 13 show the anterior-posterior (forward-backward) ground reaction forces normalised to the subjects' body weight. Each subject reported similar trends, starting with a negative peak followed by a positive peak in each leg.

In the negative peak of the right leg, the differences in normalised anterior-posterior force were between -1.8% to +2.2%, in the different braced conditions, for all subjects. In the positive peak, these force differences were between -1.6% to +4.35% for the normalised force, when wearing a brace compared to not wearing a brace for all subjects.

In the negative peak of the left leg, the differences in normalised anterior-posterior forces were between -2.6% to +1.3% of the normalised force for all subjects when wearing a brace compared to not wearing a brace. In the positive peak, the force differences were between -6.3% to +2.13% for the normalised force, between the two braced conditions.

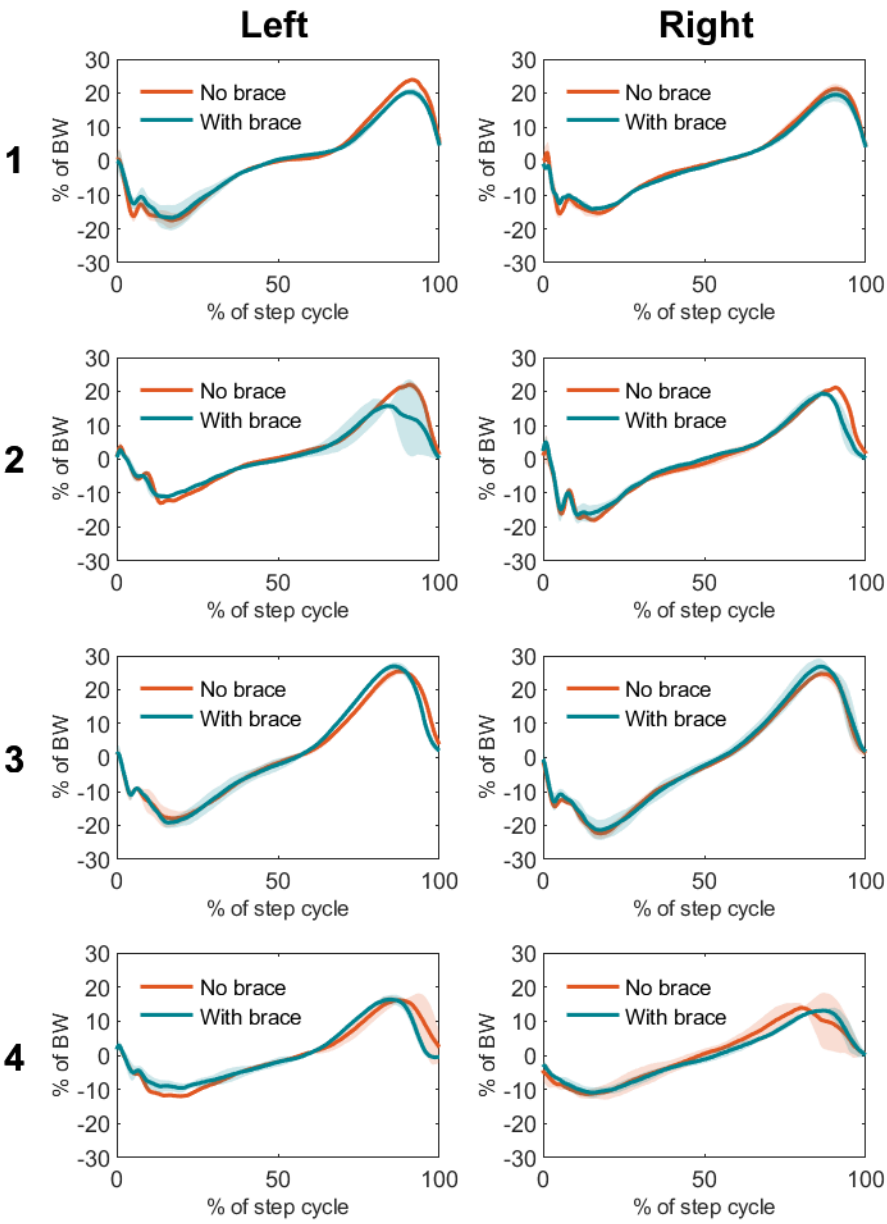


*Figure 12: Ground reaction force in the anterior-posterior direction for different subjects (1-4). The left column shows the ground reaction force whilst placing the left leg on the force plate and the right column of the right leg normalized to the subjects' body weight (BW). The mean ground reaction force during a step without and with a knee brace are shown in orange and petrol lines, respectively. The standard deviations for each condition are shown in a shaded area in corresponding colours. The positive direction of the force is the same as that of traveling.*

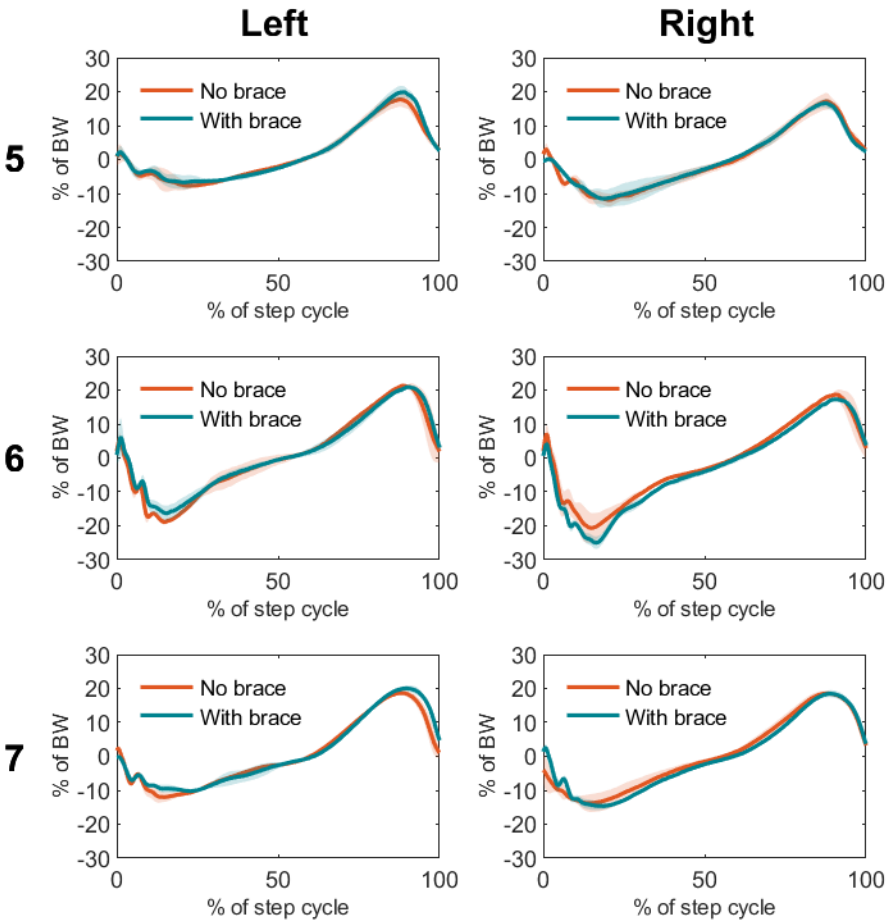


*Figure 13: Ground reaction force in the anterior-posterior direction for different subjects (5-7). The left column shows the ground reaction force whilst placing the left leg on the force plate and the right column of the right leg normalized to the subjects' body weight (BW). The mean ground reaction force during a step without and with a knee brace are shown in orange and petrol lines, respectively. The standard deviations for each condition are shown in a shaded area in corresponding colours. The positive direction of the force is the same as that of traveling.*

The appearance of the ground reaction forces in the medio-lateral direction, see Figure 14 and Figure 15, look alike when comparing the left and right leg of one individual. No significant differences in the graphs could be seen when comparing with and without brace, despite clear differences in the curves between different individuals.

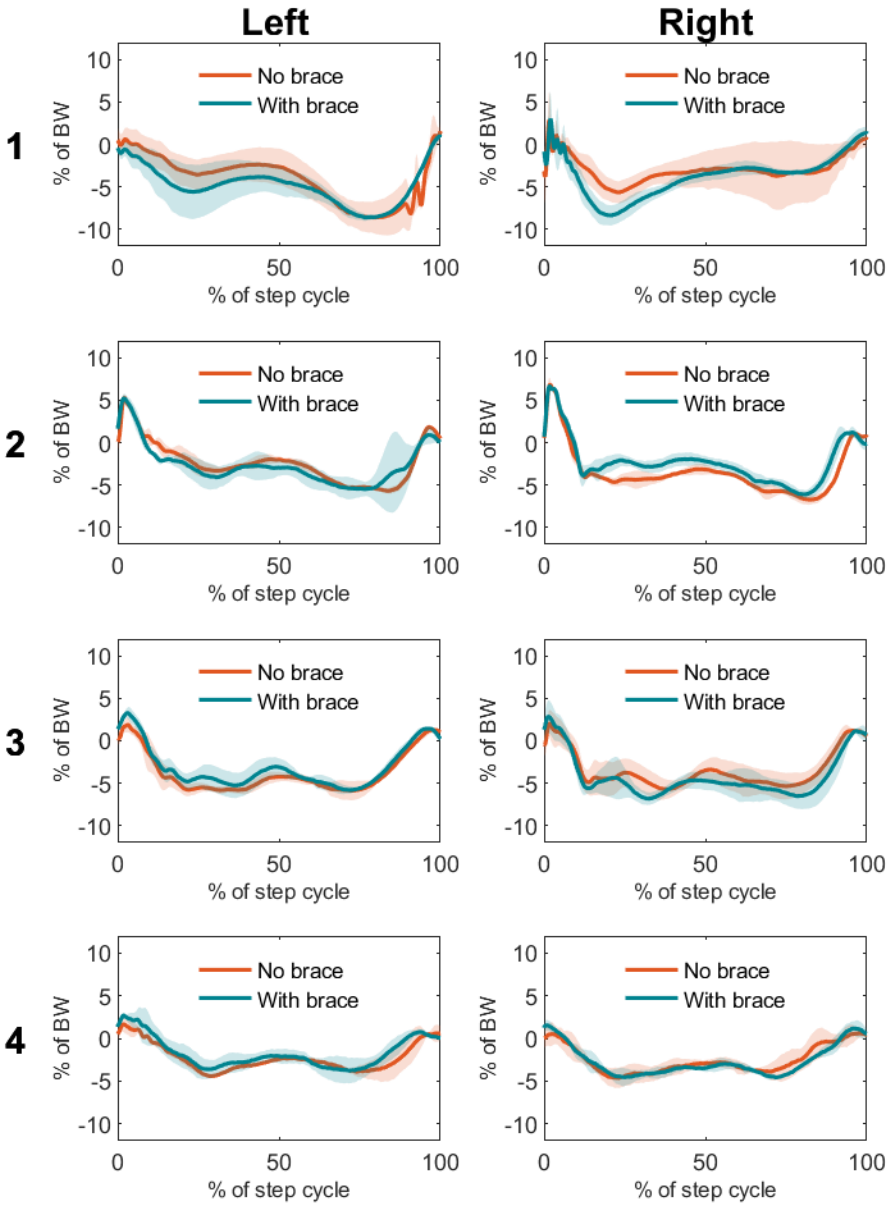


*Figure 14: Ground reaction force in the medio-lateral direction for different subjects (5-7). The left column shows the ground reaction force whilst placing the left leg on the force plate and the right column of the right leg normalized to the subjects' body weight (BW). The mean ground reaction force during a step without and with a knee brace are shown in orange and petrol lines, respectively. The standard deviations for each condition are shown in a shaded area in corresponding colours. Positive values correspond to a force in the lateral direction and negative values to the medial direction.*

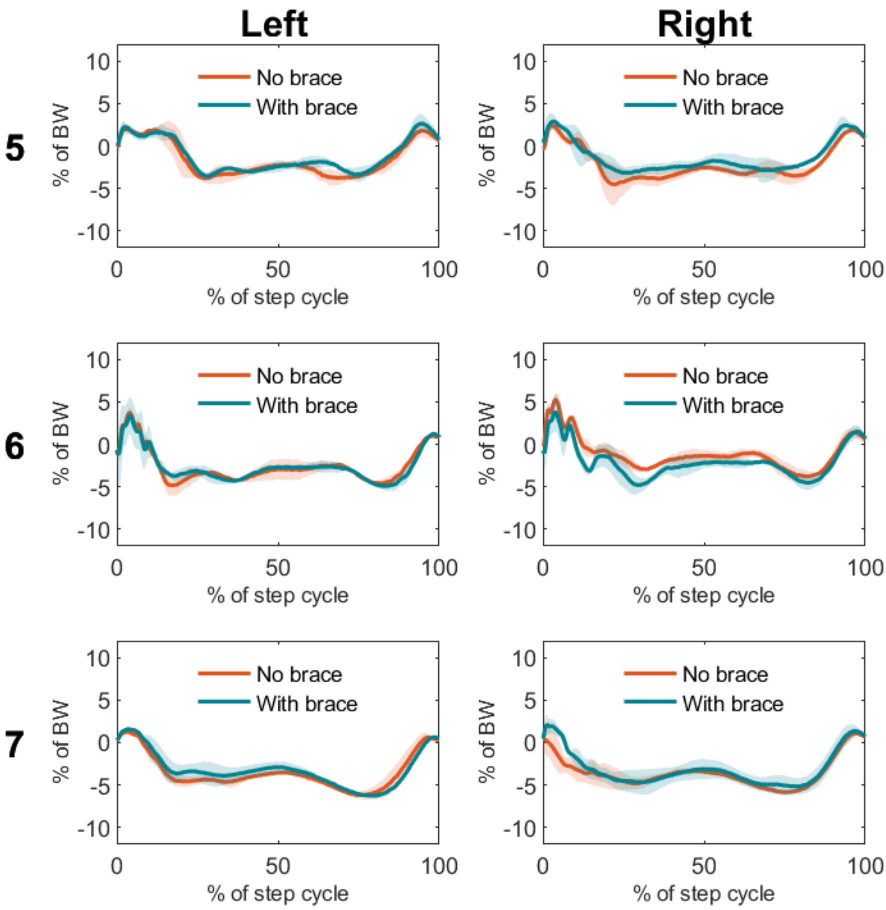


*Figure 15: Ground reaction force in the medio-lateral direction for different subjects (5-7). The left column shows the ground reaction force whilst placing the left leg on the force plate and the right column of the right leg normalized to the subjects' body weight (BW). The mean ground reaction force during a step without and with a knee brace are shown in orange and petrol lines, respectively. The standard deviations for each condition are shown in a shaded area in corresponding colours. Positive values correspond to a force in the lateral direction and negative values to the medial direction.*

### 4.2.3. Knee angle

The knee angle variations over a gait cycle (one stride) and the standard deviation is shown for each condition in Figure 16 and Figure 17. The general trend in the changes of the knee angles were similar for all subjects, starting at about 0° at heel strike followed by two peaks, with a higher amplitude on the second peak.

The initial value refers to the amount of extension in the knee at heel-strike, where 0° corresponds to a full extension of the knee (see Figure 2). This initial value in the knee angle differed for the right leg in all subjects, ranging from -1.5° to +6.6° when wearing a brace. In the left leg, the corresponding values for all subjects when wearing a brace was -2.6° to +1.35°.

At the end of the stance phase a second full extension occurs (at about 45% of the gait cycle). The differences between the braced conditions at this point were between -1.3° to +5.9° in the right leg. In the left leg when wearing a brace, these differences were between 4° lower to 7° higher. In the majority of cases, wearing knee brace resulted in a reduction of extension in both legs at this point.

The high peak (at about 75% of gait cycle) indicates the maximum flexion of the knee during gait (see Figure 2 and Figure 6). This maximum flexion peak decreased for all subjects with an angle between 0.9° and 5.5° in the right leg when wearing a brace. The peak values in the left leg when wearing a brace ranged from -3° to +8.3° in all subjects.

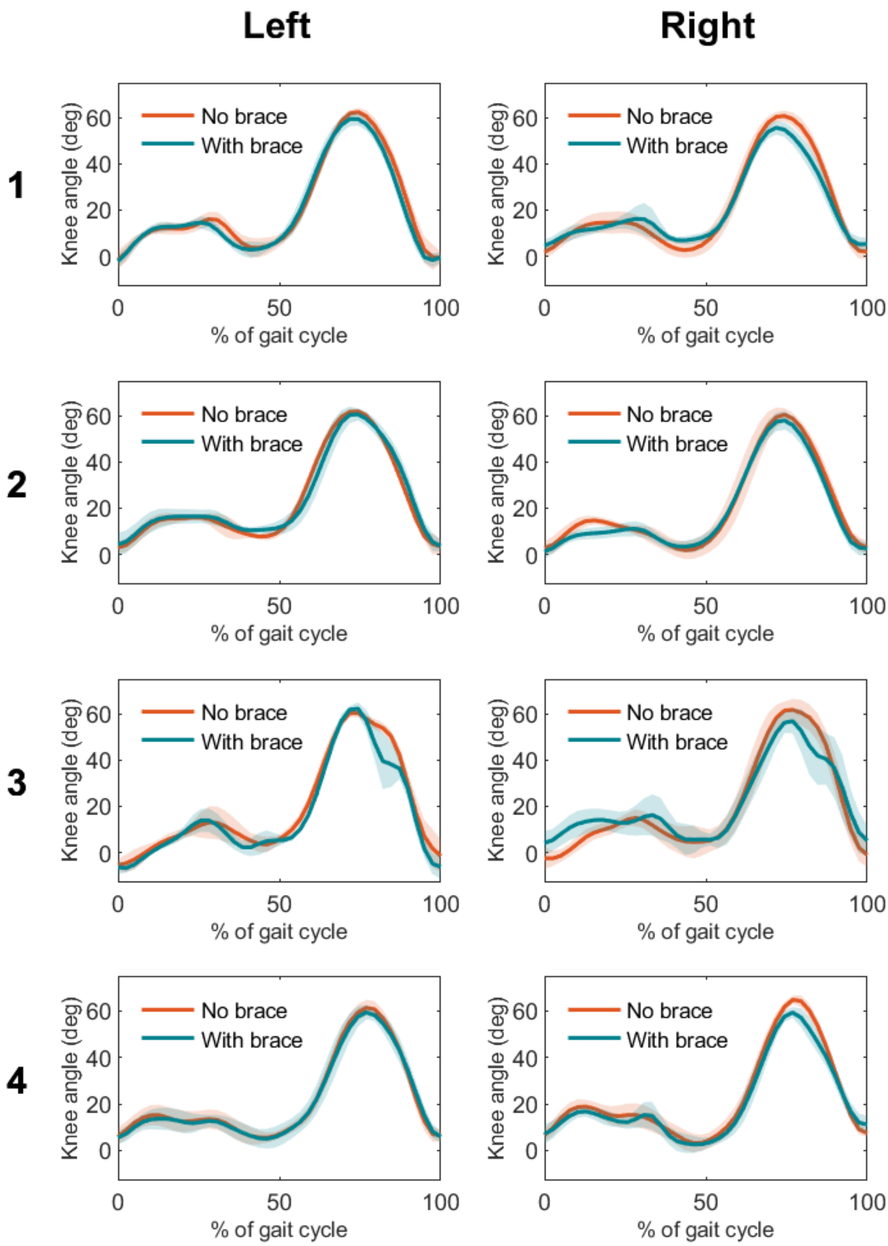


*Figure 16: Knee angle variation during a gait cycle for different subjects (1-4). The left column shows the knee angle of the left leg and the right column of the right leg. The average knee angles when walking without and with a knee brace are shown in orange and petrol lines, respectively. The standard deviations for each condition are shown in a shaded area in corresponding colours.*

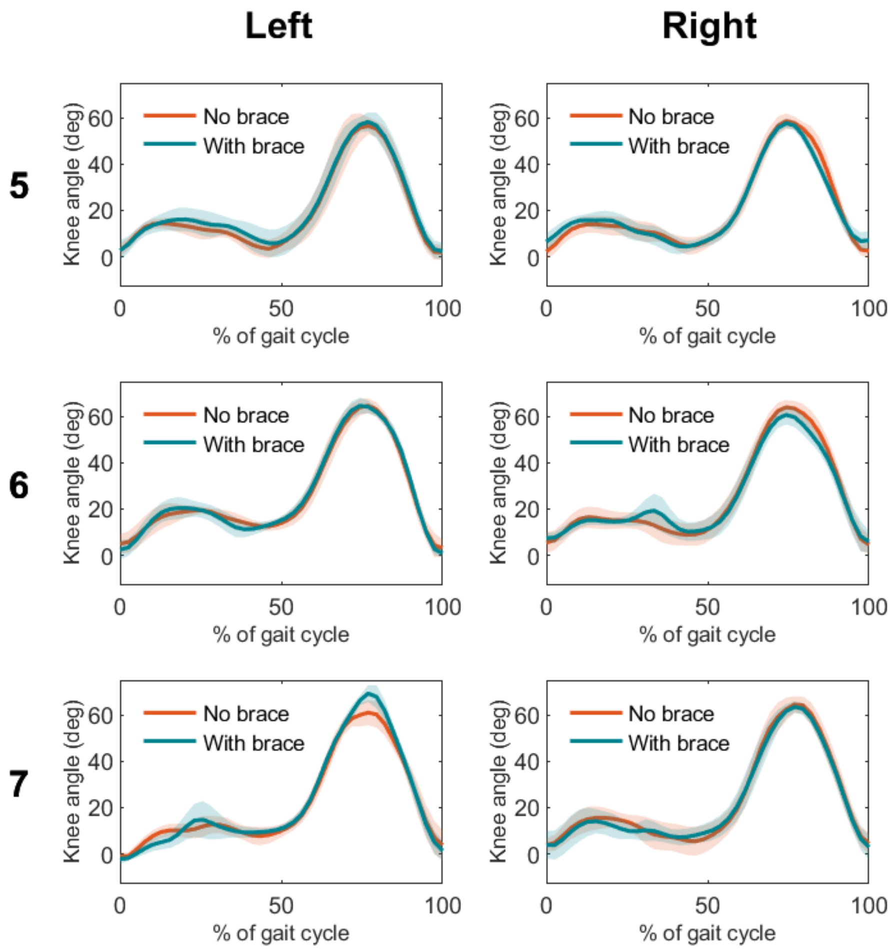


*Figure 17: Knee angle variation during a gait cycle for different subjects (5-7). The left column shows the knee angle of the left leg and the right column of the right leg. The average knee angles when walking without and with a knee brace are shown in orange and petrol lines, respectively. The standard deviations for each condition are shown in a shaded area in corresponding colours.*

### 4.2.4. Range of motion

The measured angle between the maximum flexion and the maximum extension, usually called the range of motion, are shown in Table 1. The range of motion in the right leg decreased (between 2° to 11°) when wearing a knee brace in all subjects but one, see Table 1. No difference in range of motion could be seen in the last subject.

In the left leg the range of motion differed between -3° and +10°, only three subjects had a reduced range of motion in the knee joint. The remaining four subjects had an increased range of motion when using a knee brace in their left leg.

*Table 1. Range of motion in the knee joint in the two braced conditions, for each leg.*

| **Subject number** | **No brace - left (deg)** *mean* | **With brace - left (deg)** *mean (diff)* | **No brace - right (deg)** *mean* | **With brace - right (deg)** *mean (diff)* |
|---|---|---|---|---|
| **1** | 64° | 61° (-3°) | 59° | 51° (-8°) |
| **2** | 59° | 57° (-2°) | 59° | 57° (-2°) |
| **3** | 66° | 69° (+3°) | 64° | 53° (-11°) |
| **4** | 56° | 54° (-2°) | 62° | 57° (-5°) |
| **5** | 55° | 56° (+1°) | 56° | 53° (-3°) |
| **6** | 61° | 64° (+3°) | 59° | 55° (-4°) |
| **7** | 62° | 72° (+10°) | 61° | 61° (0°) |

### 4.2.5. Gait speed

The gait speed differences, in the different braced conditions, can be found in Table 2. Participants one and two had a slight decrease (< 0.17 m/s) in gait speed with brace, whereas participant six had a small increase (< 0.13 m/s). The remaining subjects had no significant differences. When comparing all subjects, the average gait speed ranged from 0.75 – 1.20 m/s with brace and 0.78 – 1.21 m/s without brace.

*Table 2. Gait speed for all participants with and without brace.*

| **Subject** | **No brace (m/s)** *mean± std* | **With brace (m/s)** *mean± std* |
|---|---|---|
| **1** | 1.21 ± 0.01 | 1.07 ± 0.06 |
| **2** | 1.19 ± 0.06 | 1.02 ± 0.03 |
| **3** | 1.04 ± 0.22 | 0.90 ± 0.03 |
| **4** | 0.78 ± 0.03 | 0.75 ± 0.04 |
| **5** | 0.83 ± 0.06 | 0.83 ± 0.09 |
| **6** | 1.07 ± 0.01 | 1.20 ± 0.10 |
| **7** | 0.88 ± 0.03 | 0.91 ± 0.03 |

## 4.3.Design investigation

This section will cover the design investigation.

### 4.3.1. Design scenario

The participants were asked about their first impression of the knee brace. The responses included that the knee brace seemed advanced and sporty. Three participants believed the colour of the knee brace could influence how much they use it. Colours preferred included black or light colours such as white or grey, and having the knee brace in one colour only was also mentioned.

In terms of using the brace as a treatment method, one participant would use the brace if it would lessen the symptoms substantially. Two participants mentioned they would use it in their daily life, where one of them also said they might remove it at home or when sitting. Another participant would use it based on the recommendation of medical staff and the fifth participant would use it for longer walks or when in pain.

Occasions when the knee brace would not be worn included when being dressed up or going out to a club, but it was also mentioned that this would depend on the pain level without the knee brace and that it would be worn if in considerable pain.

Three participants could consider using the knee brace for prevention of an illness, whereas two mentioned they would not remember to use it. It should be noted that the OA Nano is made for individuals with osteoarthritis [10] and not for preventive reasons. However, by asking if the participants are willing to wear it to prevent an illness, this could indicate that they are overall accepting of the design.

#### 4.3.2. Putting on the knee brace without instructions

When putting on the knee brace without instructions, no participant fastened the straps in the correct order and none of the participants noted the numbers written on the inside of each strap indicating which order they should be fastened. One participant mentioned that the numbers could be of a different colour to ensure that they stand out visually. This since the placement of the numbers is on the inside of the strap and a change of colour or size in these would not be detectable when worn.

Four participants did not know how tightly to fasten the brace. All participants put on the knee brace the correct way up, most participants citing the reason for this was that the metal frame was larger on the part meant for the thigh.

Regarding how participants found putting on the knee brace, two participants mentioned that the straps were easy to fasten and appreciated that the straps were made of Velcro. Another participant stated that the straps were of a good size, but that they were too short around the thigh. The two remaining participants thought it was easy to figure out how the knee brace should fit. However, two of the other participants mentioned that it was hard to figure out the height (proximal/distal) at which the knee brace should be placed.

#### 4.3.3. Putting on the knee brace with instructions

When completing the task of putting the knee brace on with the enclosed instructions, three out of the five participants initially tightened the straps in the wrong order. However, the correct order was then realised when reading through the instructions more carefully and the straps were then fastened in the correct order.

Four participants thought the knee brace had an improved fit after putting it on with instructions compared to with no instructions. One of these participants mentioned that the brace felt tighter, and another that it fit well, but felt more uncomfortable. One of the participants also mentioned when putting the brace on fastening the straps in the correct order, the trousers became slightly uncomfortable underneath the brace. One participant felt no difference in brace fit when using the instructions.

### 4.3.4. Putting on the brace when wearing mittens

In this task, all participants mentioned that the mittens got caught on the Velcro during the fitting of the brace. Despite this, the participants stated that the mittens did not make it harder to fit the brace. One participant did mention that the straps stuck to each other.

The participants were asked if there were any changes in the design that they would like to see in order to make the brace easier to put on with mittens. One participant mentioned that the part of the strap which is gripped during the fitting of the brace is smooth and did slip slightly from their grip. Another participant mentioned that the straps could be made longer and have a block at the end of the strap, so that the straps would not be pulled out of their socket.

### 4.3.5. Post-task questionnaires

The participants also filled out a post-task questionnaire regarding each task (found in sections; 4.3.2, 4.3.3 and 4.3.4), where they indicated how easy or difficult they found each task, and if they took longer or shorter time than anticipated.

Four out of the five participants wrote that the brace was easy or very easy to put on without instructions, while the fifth participant found it difficult. All participants found it harder to put the brace on using the instructions.

All participants found that the time it took to fit the brace was less or precisely the time they expected it to take. Furthermore, all participants found that it took longer or much longer to fit the brace while following the instructions.

When fitting the brace with mittens, three participants found that it was easier than expected, and two participants found that it was harder than expected. Four participants indicated that it took shorter or much shorter time than expected, while the fifth stated that it took much longer time than expected.

#### 4.3.6. Exercises when wearing the knee brace

The participants performed certain movements while wearing the brace. The first exercise involved the participants standing up from sitting whilst wearing the brace. One participant mentioned that the brace pushed their lower leg forward. Another mentioned that the front part of the brace was pushed into their thigh. A third participant mentioned that they could feel the support of the brace and that the load on the knee became less. Another participant mentioned that they could feel the presence of the brace, while the fifth participant did not have any views on the matter.

The second exercise involved walking around with the knee brace. One participant stated they felt no change walking with the knee brace. Two mentioned that they felt that the brace limited their movement. A fourth participant mentioned that they walked slower and more carefully, and another participant that it felt like the brace pushed their leg forward (facilitating the swing phase of the gait cycle).

Thirdly, the participants were instructed to do squats whilst wearing the brace and to comment on the experience of it. One participant mentioned no difference, and another two stated that it did not feel strange. One participant mentioned that they were unable to squat as low as they would have been able to without the brace and that it felt like something was holding them down while they were getting back up. Another participant mentioned that they felt that the left leg required more strength to complete the motion compared to the right leg.

# 5. Discussion

The aim of this study was to investigate if wearing a knee brace induced any gait alterations in healthy subjects. To extract this information, a gait analysis was performed using pose estimation and a force plate. No significant differences could be found in kinematic data nor in ground reaction forces when comparing gait performed when wearing the knee brace compared to not wearing the brace.

Furthermore, this study aimed to investigate design aspects of the evaluated knee brace. This was done by reaching out to the end users and have them respond to a survey. Moreover, a usability test was conducted with five participants. Our results showed that opinions of the participants were similar to those of the end user. We identified an issue with the design, which is the low visibility of the signifiers. That resulted in an incorrect strap fastening from the users. Overall, the design of the knee brace was appreciated by the participants.

## 5.1. Gait analysis

Unloader knee braces are designed to shift the loads in the affected knee, so that less load is transferred to the side of the knee that is affected by osteoarthritis. As a consequence, several analyses focus on verifying if the knee brace achieves this effect [5]–[7], [9], [30], [47]–[50]. However, it is also important to assess whether wearing the brace causes any changes in gait, e.g., to the contralateral leg or by altering gait symmetry. This was investigated in this thesis by looking at different gait parameters and comparing any differences in these, caused by the knee brace.

### 5.1.1. Step length

There were differences in median step length in subjects when wearing a knee brace in the range of -8 cm (-11.9%) to +4 cm (+7.1%) in both legs, which can be seen in Figure 9. The ranges of the step length overlap in all cases but one. The mean absolute error in step length in OpenPose when compared to a motion capture system is 5 cm [33], thus, the differences found in step length are in the same order of magnitude as the measurement error of the measuring system.

In previous studies of subjects with osteoarthritis, the overall step length has been found to increase 3 cm and 10 cm when wearing a knee brace[7], [8]. In the osteoarthritic limb, the step length has been found to increase by 2 cm [9] and decrease by 1 cm [6] when wearing a knee brace on the osteoarthritic limb. In the non-arthritic limb, the step length decreased by 2 cm in the same studies [6], [9]. These differences stated are presented on a group level, whereas in this thesis, all differences are analysed on an individual level due to the restricted group size. The differences found in this thesis, -8 cm to +4 cm, are slightly larger than the differences found in the studies mentioned. However, our differences describe the maximum difference in median step length, whereas the studies mentioned only describe the mean group change. These differences we found in the right leg are of a similar scale as the results found in these studies. All studies used different braces; thus, it can be reasonable to assume that the different changes in step length could depend on the brace itself.

In all subjects but one, the changes found in median step length were symmetrical: a decrease/increase in the right leg also resulted in a corresponding change in the left leg. Asymmetrical gait patterns could indicate a pathological gait [51], thus a more symmetrical gait induced by the brace could be beneficial for patients.

#### 5.1.2. Forces

There were variations in the vertical ground reaction force when wearing a brace in all subjects ranging from -11.6% to +13.9%. Thus, there are no clear trends in how the brace affected the vertical ground reaction force. In all but one case (the right leg of subject 3), our standard deviations overlapped in the peaks of the force.

In the first peak in the vertical ground reaction force in the left leg of subject 7, the force is 14% higher with brace than without. However, this subject also showed a standard deviation range of 30.5% at this peak. This could be due to subject 7 having a larger variability between the three trials compared to other subjects, which may explain the magnitude of the differences in the first peak.

Previous studies have found mixed results in terms of knee braces’ effect on the ground reaction forces. No significant difference in ground reaction forces during the gait cycle when wearing a knee brace in subjects with osteoarthritis has been found [30]. Another study found a statistically significant increase in the first peak of the vertical ground reaction force of 5% of the normalised force in the osteoarthritic limb when wearing a knee brace [9]. Richards et al. [29] found increased ground reaction forces when wearing a valgus knee brace in subjects with osteoarthritis in the vertical direction (7.3% and 8.9% of the normalised force in the first and second peak respectively) and the anterior-posterior direction (an increase of 4.3% of the normalised force in the first peak). They theorised that this increase was due to increased confidence when walking with the knee brace [29]. The subjects in this thesis can be seen as having a healthy gait and thus should have the same confidence when walking with the knee brace, as without it. Hence, it is reasonable that this increase in ground reaction force was not found among the healthy subjects in this thesis.

In the anterior-posterior ground reaction forces, the forces during both peaks varied depending on the subject, with a range from – 6.3% to +4.3% with brace. Hence, there were no trends regarding increases or decreases of the anterior-posterior force in the peaks that are dependent on if the brace is worn or not. All standard deviations overlapped in all cases but one (the second peak on the right leg in subject 1). An increase of the force in the first peak has been found to be 4.3% of the normalised force in subjects with osteoarthritis when wearing a brace [29]. Another study found a relative increase on 16.4% of the normalised body weight force in the anterior-posterior ground reaction force in the affected leg of subjects with osteoarthritis when wearing a knee brace [9]. However, Richards et al. theorised that the increase in ground reaction force peaks in the vertical and anterior-posterior ground reactions forces were due to increased confidence when walking [29] and this should not apply to the healthy subjects in this thesis.

When comparing the appearance of the graphs of the medio-lateral forces in the left and right leg of one subject, they have a similar appearance in terms of when and where peaks occur regardless of the brace. However, the appearance of the graphs were different between subjects. There are times when our standard deviation of the forces with and without brace do not overlap, such as in subject 1, in the right leg at 20% of the gait cycle, and in subject 6, in the right leg at approximately 15% and 30% of the gait cycle. However, these differences are in the range of approximately 2-4% of the normalised force.

Few studies that investigate the effect of knee braces on the medio-lateral forces were found. However, one study did find no significant difference in this force in participants with osteoarthritis when wearing a knee brace [9]. This is in line with our results and could indicate that knee braces do not affect the mediolateral forces. However, further investigations in this force could be of interest. In unilateral osteoarthritis, i.e. osteoarthritis affecting one side of the knee, an unloader knee brace would apply a force in the frontal plane to shift the internal forces away from the affected side [50]. Thus, it could be reasonable to assume that this would also affect the gait parameters in the frontal plane (e.g., the medio-lateral ground reaction force). Any changes in the medio-lateral ground reaction forces can currently not be verified, as the results in this thesis and the mentioned study [9] show no induced differences when wearing a knee brace.

### 5.1.3. Knee angle and range of motion

There were differences in the knee angle during one gait cycle among the subjects when wearing a knee brace, see Figure 16 and Figure 17. At the first full extension (at about 0% of the gait cycle), the difference in knee angle between the braced conditions in the right leg was up to 6.6°, and in the left leg up to 2.6°. When the second extension occurred (at about 45% of the gait cycle), the differences in both legs were 7° or less. The mean absolute errors of the knee angle when compared to a motion capture system were found to be 5.6° by Stenum et al. [33]. As our differences in knee angle at extension are 7°, they are in the same order of magnitude as the measurement error of the measuring system. The knee is exposed to its largest loading when close to full knee extension, i.e., during the beginning and end of stance phase. Since people affected by osteoarthritis have impaired cartilage and joint function [2], [25], it is even more important that the loading conditions in the knee joint are optimal to prevent any further impairment of the joint, causing reduced function and potential for pain.

One study found an increase of 1° in the knee extension at heel strike, in subjects with osteoarthritis, when wearing a valgus knee brace compared to no brace, however, this difference was not significant [29]. Another study found a reduction in knee extension in the end of stance phase of approximately 4° and in swing phase, of approximately 8° in subjects with osteoarthritis when wearing a brace after six weeks of use, compared to no brace at the initial zero weeks [6]. These differences are of the same scale as the differences found in this thesis. However, the differences in these other studies vary from the differences in this thesis. These variances in knee angle at extension could be due to different types of braces being used.

During the peak flexion angle (at about 75% of the gait cycle), differences in the braced conditions were found in the right leg of between 0.9° and 5.5°

and in the left leg between -3° to 8.3° when wearing the brace. This knee flexion angle is often between 60° and 70° [19, p. 62]. All participants were in (or close to) this range in both legs, in both braced conditions. As the measurement error of the measurement system is 5.6° [33], the differences found in this thesis are of the same order of magnitude.

One study showed a reduction of the knee flexion in patients with osteoarthritis of 6° during swing phase, when wearing a valgus knee brace ($p < 0.1$) [29]. However, another study found no reduction in knee flexion [6] in subjects with osteoarthritis when wearing a knee brace compared to no knee brace. Different braces were used in these studies and could explain why they vary from each other and the results in this thesis.

The knee angle curve for subject three, during swing phase, for both legs (see Figure 16) does not show the same smooth peak as other subjects. This subject did not have as tight-fitting trousers as the other subjects. The tracking in OpenPose was at times unsuccessful which led to several frames with keypoints being removed from the dataset during postprocessing. This could have had an impact on the detected steps as they are more reliant on the linear interpolation in these gaps. Furthermore, four steps had to be removed due to larger gaps. If OpenPose is to be used in future studies, it is important to ensure the subjects wear tight fitting trousers for a better pose estimation.

Our results showed that the average range of motion in the right knee decreased up to 11° when wearing the brace in all subjects but one (subject 7), see Table 1. A decreased range of motion could be a result of either a decrease in extension or flexion in the knee. A restricted motion in the knee extension can increase the risk of injury and have a negative effect on the stabilisation of the knee [18]. A reduction in flexion could cause an altered gait pattern and difficulty walking up stairs and sitting [52].

From the knee angle figures (Figure 16 and Figure 17), a decreased range of motion trended in the flexion phase of the right leg, the same leg that also had a decreased range of motion. Hence, this decrease in range of motion could be assumed to occur mainly during the swing phase and during knee flexion. However, the differences found in range of motion are up to 11° and are therefore of the same magnitude as the measurement error of the measuring system.

In studies conducted in subjects with osteoarthritis when wearing knee braces compared to not wearing braces, a reduction of knee range of motion of 2°, 5° and 5.3°, respectively, could be found [5]–[7]. Another study found an increase in the range of motion of 4.7° in subjects with osteoarthritis when wearing a knee brace [8]. Furthermore, a study with healthy subjects reported a decreased range of motion of 6.4° when wearing a knee brace [11]. Four out of the five mentioned studies report a similar trend in decreasing range of motion, which could indicate that the decreased range of motion is due to knee braces.

A noteworthy point is that patients with osteoarthritis already have a decreased range of motion when walking [53] compared to a control group. Decreasing the range of motion further could thus affect their ability to climb stairs or sit down, or affect the knee extension, increasing the risk for injury.

This would be an unwanted side effected of knee braces and it is critical to ensure that the full knee flexion is not significantly limited by the brace in patients with osteoarthritis.

Differences can be seen in the left leg in terms of range of motion, ranging from -3° to +10° (see Table 2). These differences lie within the accuracy of the measuring system used. There are not many studies on the effect on the non-arthritic leg when wearing a knee brace on the arthritic leg, nonetheless, one study found that the range of motion in the non-arthritic leg was not affected by the knee brace [6], which correlates with our findings. Thus, it can be assumed that the knee brace does not affect the range of motion in the non-arthritic leg.

#### 5.1.4. Gait speed

Differences were found in the subjects' gait speed (see Table 2) when comparing the braced and unbraced condition. Three subjects had gait speed differences; however, they were less or equal to 0.17 m/s. This equals 14% relative decrease in gait speed. The mean absolute difference when comparing the gait speed extracted from OpenPose and a motion capture system has been found by Stenum et al. to be 0.04 m/s [33]. When combining our standard deviations in gait speed with this measurement error, they are of the same order of magnitude as the differences found.

In subjects with osteoarthritis, the gait speed has been found to increase between 0.05-0.12 m/s when wearing a knee brace in subjects with osteoarthritis [5], [7], [9]. It was theorised that these increases were due to increased confidence when walking [5], [7]. As healthy subjects can be assumed to be confident when walking, similar changes cannot be seen in the subjects in this thesis.

Moreover, gait speed has been reported to decrease with age (above 30 years of age) [54]. Since the observed subjects are in the same age group, this should not affect the results in our study. However, this means that the value of the gait speed that was found cannot be compared directly to studies with older participants. This fact should also be taken into consideration when performing gait analysis in a wider ranged age group.

### 5.1.5. Other possible effects of knee brace

Multiple studies have shown a decrease in perceived pain level whilst using a knee brace [6], [9], [12], [29]. This despite the fact that the effects of the biomechanical intervention of a knee brace are inconclusive. Because of this there is a theory that the importance of the brace does not lie only in its load-shifting properties, but also in the increased proprioception of the knee [7], [55]. The increased proprioception makes the patients more aware of their knee and gait, which might be the cause of the decreased perceived pain level whilst using a knee brace.

## 5.2. Design investigation

### 5.2.1. Response to brace

All participants mentioned they could consider wearing the brace as a treatment method and three participants stated that they would consider wearing it for preventative reasons. This could mean the participants are generally accepting of the design itself and the way the brace looks. None of the participants mentioned that they disliked the design, unlike the survey in which 23% of users found their brace ugly. Similar to the survey in which 40% of users would not wear their brace to formal events, participants in this investigation also mentioned they would not wear this brace when dressed up. Furthermore, it was mentioned by the participants that their use of the brace in certain situations would depend on their pain level. This is similar to the survey answers, where almost 70% stated that the type of event or activity did not influence their brace use. Thus, it can be assumed that the participants have similar views to the end user in terms of brace use. From the results in the survey, it was clear that the questions were sometimes answered ambiguously. The majority of users stated that the occasion did not affect if they wore their brace, but also stated they would not wear their brace to certain events. Overall, the participants in this scenario had a positive view of the brace and it can thus be assumed the end users would have a similar opinion.

### 5.2.2. Fastening of the brace

All participants fastened the knee brace the correct way up. The reason for this is that the upper part has a wider metal frame circumference, suitable for the thigh, compared to the lower part. This part of the design has provided a constraint, to ensure that it is not comfortable to attach the brace upside down. Moreover, the different sized frame for the calf and the thigh also provided a signifier regarding the intended placement.

When fastening the brace without instructions, an error all participants made was fastening the straps in the wrong order. As the brace would come with instructions, it would be possible to eliminate this error. The straps themselves were fastened in the correct way, indicating that the affordance of the straps, as to how they should be used by threading them through a hole and fastening them using Velcro, clearly showed the intended use. However, two out of the five participants also fastened the straps in the wrong order at first, despite being asked to follow instructions. One comment was made by a participant to have the numbers on the straps in a different colour to improve visibility of these numbers. The current design is a black sticker with a small grey number, placed on a black background. Furthermore, the location of these numbers is not in view when fastening the brace. Thus, a different colour to draw attention to it could benefit the correct fastening of the straps without having an impact on the appearance of the brace. As the numbers act as a signifier to let the user know in which order to fasten the straps, the numbers will not serve their purpose if the user is not able to see them.

According to experts in the field, the effects of attaching the straps in the wrong order were considered negligible for patients with osteoarthritis. Hence, the resources required to implement these design changes and reduce the risk of incorrect attachment may be considered too high of a cost for the gained effect. However, if the straps could be fastened in the correct order by changing something as simple as the colour of the numbers or the background to them, it could be beneficial to investigate this design change further.

### 5.2.3. Putting on the brace when wearing mittens

When putting on the brace while wearing mittens, all participants stated that the mittens got caught on the Velcro. Three participants wrote in the post-task questionnaire that it was easier than expected to put on the brace while wearing mittens, while two stated it was harder than expected. However, during the interview, it was said by all participants that the mittens did not influence how easy or hard it was to put the brace on. It seems from discussion with the participants that the apparent difficulty of the task had more to do with the fact that it was their third time putting on the brace, rather than the mittens themselves.

As the mittens did not influence the difficulty of the task, this indicates that the size of the straps and the hole in which they are threaded through are of adequate size for those with lesser grip strength. However, it should be noted that this could also be because mittens are not an adequate alternative to simulate lesser grip strength, as the only effect the mittens seemed to have on the task when looking at the responses of the participants, was getting caught on the Velcro. Thus, to fully ensure the brace can be put on by those with lesser grip strength, it should be tested with the intended user group.

During the scenario, it was also mentioned that the straps caught onto each other when attaching the brace. Furthermore, it was also mentioned that the straps were too short. One user suggested making the straps longer and installing a block to ensure they do not fall out of their hoops. This could be a point of future investigation, as this would eliminate the issues of both the straps being too short and possibly them getting caught on each other.

#### 5.2.4. Exercises when wearing the knee brace

When completing the different exercises, the participants did mention some noticeable effects of the knee brace. For example, when standing up, the knee brace pushed one participant's leg forward and another participant felt the support of the knee brace. During walking, four participants mentioned that their gait felt changed or limited by the brace. However, these changes in gait cannot be seen in the biomechanical investigation. Thus, there is a possibility that the participants felt limited by the brace due to the pressure it exerted on their knee and leg, but that the brace had no effect on their gait.

## 5.3. Limitations

### 5.3.1. Gait analysis

Despite informing the subjects to walk "naturally" and look straight forward, they were still required to ensure the foot closest to the recording side was placed on the force plate. Furthermore, the runway was five metres, which could be argued to be too short to induce a natural gait and could have influenced gait parameters such as step length, as the subjects could have increased or decreased their step to ensure the foot was placed correctly. This could also influence the timing and length of knee flexion/extension. To ensure this does not affect future trials, a force plate which is longer and wider could be used in combination with a longer runway.

Previous studies have found that the gait parameters extracted from OpenPose vary compared to motion capture systems [33], [36]. For example, the mean absolute difference when using OpenPose to calculate step length compared to a motion capture system, has been found to be 5 cm [33]. Furthermore, the mean absolute error of the knee angle has been found to be 5.6° when comparing OpenPose and a motion capture system [33]. However, the main reason for larger errors in pose estimation when using

OpenPose was reported to be due to failed tracking [36]. This was accounted for in this study since every frame was manually inspected. Any incorrect key point placements were corrected to match the joints of the person walking or deleted if not overlapping with the joints. Therefore, it is reasonable to believe that a somewhat smaller error margin could be assumed. However, at this point it cannot be proven, thus, it is reasonable to include these potential errors in the results.

### 5.3.2. Design investigation

One of the limitations in this thesis was that the analyses were conducted on young volunteers. Additionally, while both males and females were represented in the user group, there was only a small age variation among the participants, and all were students. The design investigation could have benefitted from participants with a wider age range that reflects that of the end user and with different occupational backgrounds. However, several responses were similar to those of the end user when compared to the survey distributed, hence, the results found could still be of use for the intended application.

The survey was shared in three closed Facebook groups relating to joint disease. Meaning that only those who are both active on this particular social media platform, and members of any of the three groups, would be able to access the survey. Due to this, the answers in the survey may not be representative of all users who use knee braces and could lead to key findings being missed. Furthermore, some findings may be labelled as key findings due to these being overrepresented in a certain user group, that are active in these types of Facebook groups.

## 5.4. Ethical aspect

When conducting studies that include people, there is always an ethical aspect. Personal data was handled within the scope of this project and required anonymisation before publication. The handling of personal data is restricted due to GDPR and the data obtained and used in this thesis was obtained from the subjects. Informed consent was obtained from all subjects and the participation was on a voluntary basis. It was important to ensure during the thesis that this data was only handled by the authors and supervisors.

It is important to note that this thesis does not investigate how a healthy gait is defined and should not be used as such. It can also not be determined in this thesis if the minor gait changes that occurred in certain subjects were healthy or not.

## 5.5. Future work

Future work could include inviting subjects with osteoarthritis to complete the trials. Furthermore, different knee braces could be used in healthy or osteoarthritic subjects using the same method as in this thesis to investigate if the results are brace dependent. The method that was developed in this thesis has the potential to be easily replicated in a confined space without the need for a motion capture system and enables effortless execution if patients with osteoarthritis become available. One often-used method to perform gait analysis, is the use of reflective markers that are attached to each joint in order track the motion of their joints. The method developed during this thesis is markerless, which enables future trials to be completed rapidly.

In previous studies, the non-osteoarthritic leg is often overlooked. Our results indicate that the contralateral leg is not affected by the knee brace. However, we believe that it is of importance to analyse the behaviour of both legs in future work to ensure that the gait symmetry is not affected by a knee brace.

It could also be possible to create computer models and use the forces acquired in this thesis to investigate inverse dynamics. This could be of interest as the differences found, while not significant, may potentially have a large impact on the dynamics within the knee.

It could also be of interest to investigate the effects on gait if the subjects wear the knee brace on their dominant or non-dominant leg. This was not included in this study, but it could be of interest to investigate if the dominant leg has any impact of how the knee brace may change gait parameters in the different legs.

Furthermore, it could also be of interest to investigate additional gait parameters in the frontal plane by performing a corresponding video analysis with a camera placed in front of the person walking. It is in the frontal plane that one could assume that any biomechanical changes could be seen, as the knee brace induces forces in this direction.

# 6. Conclusion

The findings in this thesis showed that with the method used, no significant differences in any of the investigated gait parameters when wearing an OA Nano knee brace in healthy subjects could be found. Thus, this indicates that the OA Nano does not affect gait in healthy subjects. The clinical relevance of how these findings might affect patients with osteoarthritis are currently unknown. We encourage further studies to solidify the findings in this thesis and to determine its clinical relevance.

This study developed an experimental method to assess kinematic and kinetic data during gait, using a force plate and simple camera recordings. This method could easily be replicated to investigate if the OA Nano has the same effect on patients with knee osteoarthritis.

The design of the brace could possibly be improved by changing the colour of the numbers or background on the straps to ensure patients fasten the straps in the correct order. Furthermore, ensuring the straps cannot fall out of the hooks and making the straps longer was suggested.

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# Appendix A

This appendix includes all the questions from the survey that was distributed in three Facebook groups (in Swedish).

1. Hur gammal är du?
    a. - *Fritext*

2. Vilket/vilka besvär gör att du använder en ortos? (Flerval)
    a. Artros
    b. Korsbandsskada
    c. Muskelsvaghet
    d. Motverka felställningar
    e. Smärta
    f. Annat - *Fritext*

3. Hur länge har du använt en ortos för detta ändamål?
    a. Under en månad
    b. En till sex månader
    c. Över sex månader

4. Hur ofta använder du din ortos en vanlig vecka?
    a. 1-2 dagar
    b. 3-4 dagar
    c. 5-7 dagar

5. Hur mycket använder du din ortos de dagar du använder den?
    a. 0-3 timmar
    b. 3-6 timmar
    c. 6-9 timmar
    d. 9+ timmar

6. Vilken typ av ortos använder du?
    a. Knä-ortos
    b. Handleds-ortos
    c. Fotleds-ortos
    d. Axel-ortos

e. Annat - *Fritext*

*Om svaret var a på fråga 6 ställs frågan;*
Vad motiverar dig till att använda din ortos? (Flerval)

a. Kunna gå till affären
b. Gå i trappor
c. Ta promenader
d. Möjlighet att vara med vid sociala tillställningar
e. Minskad smärta
f. Det underlättar min vardag hemma
g. Min läkares rekommendation
h. Annat: *Fritext*

*Om svaret var a på fråga 6 ställs frågan;*
Har du en DonJoy ortos?

a. Ja
b. Nej
c. Vet inte

7. Vid vilka tillfällen väljer du att inte använda din ortos? (Flerval)
   a. Lunch/middag ute
   b. Finare tillställningar
   c. Spontana möten med nära vänner eller släkt
   d. Besök på sjukhuset
   e. Andra tillfällen: *Fritext*
   f. Det är inte tillfället som avgör när jag har på mig min ortos

*Om svaret var a-e på fråga 7 ställs frågan;*
Vad är anledningen till att du inte har på dig ortosen vid dessa tillfällen? (Markera alla som stämmer in)

a. Den skaver
b. Den passar inte med mina kläder
c. Den är ful
d. Den är krävande att få på
e. Den är klumpig
f. Jag blir för varm
g. Annat: *Fritext*

*Om svaret var a på föregående fråga ställs frågan;*

Varför tror du att din ortos skaver? (Flerval)

a. Den flyttar på sig när jag rör mig
b. Den sitter väldigt tight
c. Kanterna på ortosen gör ont
d. Annat: *Fritext*

8. Upplever du någon märkbar skillnad **direkt** med ortosen jämfört med utan? (Flerval)
    a. Minskad smärta
    b. Extra stöd
    c. Jag vågar belasta mer
    d. Det känns mer stabilt
    e. Annat: *Fritext*

*9.* Upplever du någon skillnad vid användning av ortosen **över längre tid** jämfört med utan? (Flerval)
    a. Mindre smärta
    b. Mer stabil
    c. Mindre svullnad
    d. Mindre öm
    e. Mer svullnad
    f. Mer öm
    g. Får mer ont i andra leder
    h. Annat: *Fritext*

*10.* Hur nöjd är du med din ortos i allmänhet?
    a. Väldigt nöjd
    b. Ganska nöjd
    c. Varken eller
    d. Ganska missnöjd
    e. Väldigt missnöjd

11. Hade en ortos i en annan färg gjort att du använde den mer?
    a. Ja
    b. Nej
    c. Kanske

12. Vad är det du gillar med din ortos? (Flerval)
    a. Den är estetiskt tilltalande
    b. Den tillåter mig att göra fler aktiviteter

c. Den minskar min smärta
d. Annat: *Fritext*

13. Vad tycker du mindre om med din ortos? (Flerval)
    a. Den är ful
    b. Den skaver
    c. Den passar inte med mina kläder
    d. Den är stor
    e. Den är svår att få på
    f. Den är klumpig
    g. Jag blir för varm
    h. Den är svår att rengöra
    i. Annat: *Fritext*

Om svaret på fråga 12 var b ställs frågan;
Varför tror du att din ortos skaver? (Flerval)
    a. Den flyttar på sig när jag rör mig
    b. Den sitter väldigt tight
    c. Kanterna på ortosen gör ont
    d. Annat: *Fritext*