Measurement of hind foot stiffness in children with clubfeet

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Abstract

Clubfoot is a deformation of the foot characterized by equinus, cavus, varus and adductus. The deformity has an incidence of 0.1% and is treated nowadays with the Ponseti method. This includes a casting and bracing phase in order to correct the foot for all deformations, leading to a fully functional foot after four years. Unfortunately, 15% of the treated clubfoot experience a relapse.

According to surgeons, clubfeet are stiffer than healthy feet. Additionally they claim that stiffer clubfeet have a higher tendency to relapse, and are harder to treat. Earlier research showed no increased stiffness in clubfeet when moving the feet over a limited angle. However, the stiffness and amount of work needed to move the clubfeet over the whole range of motion has not been quantified yet in a clinical environment.

In the first part of this research a new measurement device is developed in order to measure stiffness and amount of work with the use of the abduction dorsiflexion mechanism (ADM) brace, which is the brace used in clinical practice for treatment. The measuring device was validated whereafter the precision and reliability of the measurements in clinical setting were determined. The stiffness and amount of work of healthy feet (n = 11, age = 6.5 ± 1.2) and clubfeet (n = 11, age = 6.5 ± 1.3) were compared for dorsiflexion and plantar flexion and abduction. In the second part, a finite element model (FEM) was created to investigate the influence of the talus morphology on the ankle stiffness.

Results show that the developed measurement device is reliable and precise. A significant difference in stiffness was found between healthy and clubfeet. For the amount of work no significant difference was found.

The developed FEM was not suitable yet to investigate the influence of the talus morphology on the stiffness. Further improvement of the model is needed.
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1. Introduction on clubfoot

In the first chapter a general overview upon clubfoot will be given. The deformity and its characteristics will be explained after which the existing treatment methods will be mentioned and the gold standard will be described. This includes the assessing of clubfoot and the capturing of relapses. Finally the importance of research on capturing various parameters on the hind foot, like stiffness, is explained.

1.1 The human foot

The human foot is a complex structure which has two main functions: Supporting the body weight, and acting as a lever to push the body forward while walking or running. It consists of 33 joints and 26 bones which are subdivided by the tarsus, metatarsus and the phalanges. The foot can be split in three parts: The forefoot, which consists of five metatarsals and 14 phalanges, the midfoot which consists of three cuneiforms, the cuboid and the navicular, and the hind foot which is formed by the talus and calcaneus (see Figure 1).1–4.

Figure 1, an overview of the bones in the human foot subdivided in the forefoot, midfoot and hind foot.

The foot can perform a series of complex movements which can be separated into a set of simple movements that include dorsi- and plantar flexion, ab- and adduction and in- and eversion (Figure 2). During dorsiflexion the heel is pushed down and the toes are elevated, whereas during plantar flexion the heel is lifted and the toes are pushed down. Normal range of motion (ROM) of dorsiflexion vary between 20 and 30 degrees, and for plantarflexion between 30 and 50 degrees1,5. Abduction, which literally means “moving away” is when the foot is moved away from de medial plane, while during adduction the
foot is moved towards the medial plane. When the sole of the foot is rotated towards the midline of the body it is called inversion, whereas when the sole is rotated away it is called eversion. These are movements of the footplate, which is the part of the foot that lays below the talus. A normal ROM for inversion and eversion is respectively 30 and 20 degrees.

Dorsi- and plantarflexion are facilitated by both tibio- and subtalar joint, whereas ab- and adduction and in- and eversion are conducted by the subtalar joint. The tibiotalar (or talocrural) joint connects the talus with the tibia and fibula. The subtalar joint is the joint between the talus and calcaneus. Both tibio- and subtalar joints are part of the ankle, see Figure 3.

![Figure 3, schematic view of the Sub- and tibiotalar joints including the connecting bones.](image)

Movement of the subtalar joint is often described as supination (“turning backward”) and pronation (“turning forward”). Supination is a movement which is combined of plantarflexion, adduction and inversion, whereas pronation is a combination of dorsiflexion, abduction and eversion.
1.2 Clubfoot

Paediatric clubfoot, also known as *talipes equino varus* in anatomical terminology, is one of the most occurring congenital orthopaedic deformities. It is a complex 3-dimensional deformity with an incidence of 1 in 1000 births (Figure 4). According to literature clubfoot have been described up to 400 BC.

![Normal Clubfoot](image1)

Figure 4, a normal foot compared to a clubfoot.

The deformation is commonly defined as a combination of varus and equinus of the hind foot, cavus of the midfoot and adduction of the forefoot which is depicted in Figure 5.

![Clubfoot Deformities](image2)

Figure 5, the clubfoot deformities sub divided by hind foot varus, hind foot equinus, midfoot carus and forefoot adductus, respectively from left to right.

Hind foot varus can be described as the calcaneus which is adducted and rotated (inversion) under the talus, whilst hind foot equinus is an abnormal plantarflexion of the hind foot. Midfoot cavus is an elevated longitudinal arch of the midfoot, and forefoot adductus is when the front of the foot is bent of angled towards the median body plane.

In clubfoot, the calcaneus, navicular and cuboid are medially rotated with respect to the talus (see Figure 6) and held in adduction and inversion by ligaments and tendons.

![Clubfoot Diagram](image3)

Figure 6, The calcaneus, navicular, and cuboid, are medially rotated in relation to the talus.
In 50% of the cases both feet are affected by the deformity (bilateral), whereas in the other 50% only 1 foot is affected (unilateral). The affected foot is often found to be smaller and the calf muscle thinner compared to the unaffected side. Studies have also shown that within unilateral cases the healthy foot (contralateral) has a different pressure field during gait analysis compared to healthy children and thus cannot be used as a control. Moreover, there seems to be an association between unilateral cases and limb length discrepancy. Some studies also claim that clubfoot patients may have soft tissue abnormalities in the affected limbs.13–17.

Clubfoot mostly appear idiopathic, but it can also be associated with other medical syndromes.18,19 The exact cause of clubfoot is still unknown, however it is believed that several environmental and genetic factors play an important role, including varying chromosomes and transcription factors. Another indication that genetic factors clearly play an important role is the fact that there is a 33% concordance of identical twins and nearly 25% of all clubfoot cases are familial. According to literature males have a two times higher chance of developing clubfeet than females.9,21 Other proposed risk factors are maternal smoking, maternal age, and diabetes.18,22

Several etiology theories for clubfoot have been proposed over the past. The proposed mechanisms include uterine restriction, abnormalities of bone and joint formation, connective tissue, distal limb vasculature, neurological development and muscle migration. However, the different studies are in disagreement and no single theory adequately explains the unpredictable response of clubfoot to treatment. The fact that it is becoming more clear that clubfoot is multifactorial in origin is the only consensus which seemed to be formed and thus more research is still needed to understand the etiology of clubfoot.20,22–24

1.3 Treatment of clubfoot

Proposed treatment methods for clubfoot date back up to 400 BC. Many techniques have been developed since, and even the statement: “There are as many techniques for manipulative treatment of congenital clubfoot as there are authors who write about clubfoot” has been made. Because of this, International Clubfoot Study Group, established in 2003, has approved Ponseti’s, Kite’s, and Bensahel's techniques as the worldwide standardized conservative techniques for the treatment of clubfoot. The Ponseti method was developed and refined in the late 1940s by Ignacio Ponseti. He observed that patients treated with extensive surgeries for clubfoot frequently ended up with painful feet and residual deformities. Therefore he investigated the functional and pathological anatomy of both healthy and clubfoot which led to the current Ponseti method of clubfoot correction.

For over a decade, a large number of publications worldwide have reported successful outcomes using the Ponseti method with success rates varying from 90% up to 98%. The Netherlands Orthopaedic Association accepted in 2014 the ‘Guideline Clubfoot’, which
implies the Ponseti method as the standard treatment method concerning clubfoot\textsuperscript{27}. In Norway, the Ponseti method was found to be superior and preferable to the previous treatment method in terms of number and severity of operations, flexibility of the foot and ankle and parent/patient reported outcome\textsuperscript{28}. Currently, the Ponseti method is accepted as the gold standard in the USA and in many other countries worldwide\textsuperscript{29,30}.

The aim of the Ponseti method is to start as early as possible with treatment, while using none or minimalized surgical intervention. Ponseti claims to avoid in 89\% of the cases open surgery by using his technique\textsuperscript{31}. The method can be divided into two phases: Firstly the treatment phase, where the deformity is corrected. Secondly the maintenance phase, where a brace is utilized to prevent recurrence. The treatment phase starts as soon as the skin of the patients permits the use of plaster casts, which is usually within 48 hours. Until this point, regular corrective manipulation is performed in order to stretch the structures and to get a feeling for the flexibility and amount of correction which can be achieved with the cast. Usually up to 10 casts are needed to correct the foot in the desired position (see Figure 7), where casts are changed every 5 to 7 days\textsuperscript{32}.

Figure 7, The progression (left to right) of serial casting using the Ponseti method.

First the cavus and hind foot varus are manipulated simultaneously and thus the foot adduction and heel varus are corrected, where after the equinus of the fully abducted foot is corrected. In 80\% to 90\% there is some equinus deformity at the ankle which persists\textsuperscript{33,34}. Therefore, before the last cast is applied a Percutaneous Achilles tenotomy (pAT) is performed where the Achilles tendon is cut and the foot is able to move towards dorsiflexion (see Figure 8).
pAT should only be performed when the foot has been adducted to at least 60 degrees, and when there is less than 15-20 degrees of dorsiflexion\(^{34}\). After the pAT, the last cast is applied for three weeks in order for the tendon to heal. This is the end of the treatment phase, next the maintenance phase begins. The clubfoot is in the desired position now but has a major tendency to relapse, hence an orthosis is used. The orthosis should be worn 23 hours a day the first three months, where after 14 hours a day until the age of four\(^{35}\). The brace should be set up 10 degrees of dorsiflexion and 60-70 degrees of abduction for the clubfoot, while the unaffected foot is set up 30 degrees of abduction\(^{35}\). The Mitchell brace is the most common, where the feet are fixed in this position by means of a bar (see Figure 9, left). However, new braces are on their way where the feet are fixed using springs and thus no bar is needed. The abduction dorsiflexion mechanism (ADM) is an example of such a brace (Figure 9, right), where the correction of the foot can be adjusted by modifying the spring strength\(^{36}\).

Figure 8, foot stance before (upper) pAT and after (bottom) pAT. It can be seen that the foot is able to move more towards dorsiflexion after the pAT.

Figure 9 left: The Mitchell brace where the feet are fixed in the correct position by using a bar, whereas in the ADM brace (right) springs are used instead of a bar.
After a bracing period of approximately four years the child should have a healthy, fully functional foot.

1.4 Clubfoot evaluation

Each clubfoot is unique in its way, which makes classification hard. Nowadays, the severity of the clubfoot is determined by the orthopaedic surgeon by examining the stance of the foot, the range of motion (ROM) and the stiffness of the ankle joint. This is however a subjective process. By evaluating the deformity objectively and making an initial classification, an estimate of the treatment success rate can be obtained. Studies have shown that the treatment result depend on the initial deformation degree\textsuperscript{37}. Different protocols have been developed which standardize the classification of the clubfoot. These protocols can be used to compare treatment results\textsuperscript{37} and as a guideline for the surgeon in an additional follow-up procedure. The proposed standardization protocols are the Pirani and Dimeglio questionnaire, and the Clubfoot Assessment Protocol (CAP).

The Pirani’s classification system uses six contracture clinical indications which define the clubfoot. These are subdivided into three signs related to the hind foot (posterior crease, emptiness of the heel and rigidity of the equinus), and three to the midfoot (curvature of the lateral border of the foot, medial crease and position of the lateral part of the head of the talus). Each sign receives the score 0, 0.5 or 1, which respectively stand for no abnormality, moderate abnormality and severe abnormality. Hence, each midfoot and hind foot receives a score between 0 and 3 which sums up to a score between 0 and 6 for each foot. The Pirani score stands in relation with the number of casts which is needed\textsuperscript{38}, which also relates to the chance whether a pAT is needed\textsuperscript{39}. It has been shown that a Pirani score of 2.5 or 3 equals a chance of 72\% of a pAT\textsuperscript{40}, and a Pirani score of 5, 5.5 or 6 equals a 85.2\% chance of a pAT\textsuperscript{39}. The need of a pAT however does not predict whether more invasive procedure will be needed for correction\textsuperscript{38}. One still must always be careful not to give the impression that no surgery will be needed when a low Pirani score is assessed.

The Dimeglio score has a scale of 0-16 based on the following essential parameters: Equinus in the sagittal plane, varus deviation in the frontal plane, derotation around the talus of the calcaneo-forefoot block and adduction of forefoot on hind foot in the horizontal plane\textsuperscript{41,42}. These parameters are classified by the reproducibility angles, where each parameter is graded 1-4\textsuperscript{43} as can be seen in Figure 10.
Besides these parameters, there are four more possible scores: Posterior crease, medial crease, cavus and deviant muscle function. Each of these can be awarded one extra point, which makes the maximum Dimeglio score 20. Here a score of 1-5 represents benign feet so-called "soft-soft feet". Moderate feet, so-called "soft > stiff feet", with a score of 5-10. Severe feet, so-called "stiff > soft feet", with a score of 10-15 and very severe, pseudoarthrogryposic feet, so-called "stiff-stiff feet", with a score of 15-20\(^4\).

The idea behind the CAP is that firstly the mobility is of major interest. Secondly the muscle function for control over the foot which influences its development. Thirdly the exterior of the foot which plays an important role for patient satisfaction and finally, activity which is a combination of mobility, muscle function and neuro-motoric development. Mobility, muscle function, morphology and motion quality are subdivided into 22 items which form the CAP\(^4\). The CAP can be used in short- and long term follow-up procedures within daily clinical decision making during growth. Unlike the Pirani and Dimeglio questionnaire, the CAP does not add up to an overall outcome. Each item has a scoring interval which is determined by the expected impact on activity, clinical experience and normal variation. The score for each item ranges from 0-4 where 0 is best and 4 is worst\(^4\).

The precise and reliable classification of the severity of the clubfoot remains a challenging task. While some studies\(^3\) show that the number of plaster casts can be predicted by scoring the clubfoot, other studies\(^4\) claim to find a low correlation between the Pirani/Dimeglio score and the number of casts. One suggested method is the use of the Pirani and Dimeglio score simultaneously, since it was found these scores were good correlated\(^3\).
however more complicated since two different methods are used, and on top of that it will take more time. Taken all together, the current classification system for the analysis of clubfoot are not satisfactory yet\textsuperscript{48}.

1.5 Relapse

Every clubfoot has a strong tendency to rotate back to its original deformities, regardless of the mode of treatment\textsuperscript{49}. This is called a relapse and is a major problem in the treatment of clubfoot. Numbers of clubfoot which have been treated by the Ponseti technique and experience relapse range from 10\% to 15\%\textsuperscript{8,49,50} till the age of 11. A relapse is harder to treat as the child is older due to more rigid deformities. A common misunderstanding is that relapses occur because the deformity has not been completely corrected. Relapses are however caused by the same etiology that initiated the deformity. Hence, the causes of relapse will become clear if the pathogenesis is understood\textsuperscript{49}.

Relapses tend to occur in premature infants. The intensity of collagen synthesis as the foot grows appears to be related to the occurrence of a relapse, which makes a relapse after the age of four rare\textsuperscript{51}. They seem to be less common and severe in mild clubfoot and in children with loose ligaments\textsuperscript{49}. They will however almost always occur if appropriate bracing is not used\textsuperscript{51}, and thus noncompliance in the bracing period is the number one cause for developing a relapse\textsuperscript{25}. A pattern is observed in clubfoot treated by the Ponseti technique which have relapsed: The initial relapses are supple, as the muscle imbalance causes dynamic deformities which, if not addressed in time, can lead to static or rigid deformities. Early recognition of a relapse is of extreme importance since it can prevent major soft tissue surgery. The Pirani and Dimeglio score are nowadays used as a risk factor for a relapse since they are able to monitor the progress\textsuperscript{52}. It is also reported that a poor evertor muscle activity is statistically associated with a relapse\textsuperscript{53}. Nevertheless it is still not possible to monitor the compliance with the braces, which makes predicting relapses a challenging task.

Once a relapse is captured, the treatment is the same as the initial treatment which was done to correct the initial deformity. This means four to six weeks of manipulation and casting, where after a pAT is performed if the dorsiflexion of the ankle is less than 15 degrees. Unfortunately, minimum surgery does not always provide a solution for a relapse. In some cases more surgical interventions are needed to correct for the varus or equinus. In children over two-and-a-half years of age, the tendon of the tibialis anterior muscle can be transferred to the third cuneiform. This maintains the correction of the heel varus and improves the anteroposterior talocalcaneal angle\textsuperscript{49,51}. If the pAT does not give a correct equinus stance, a metal plate can be placed over the epiphysis on the anterior side of the Tibia. Hence, the talus and calcaneus are pushed down to reach a higher angle in dorsiflexion since the tibia growth is limited and can only grow posterior\textsuperscript{54}.

Unfortunately there is no solution for all relapses. Studies claim that the use of anterior distal tibial epiphysiodesis does not seem to give a clinically significant improvement in
dorsiflexion of the ankle\textsuperscript{54}, and performing an intervention with tibialis anterior tendon transfer may not be the definitive treatment for clubfoot relapses as neuromuscular deficits may be involved\textsuperscript{55}. In conclusion, relapses remain a major risk and challenge within the treatment of clubfoot.

\subsection*{1.6 Stiffness in clubfeet}

Orthopaedic surgeons claim that clubfeet feel stiffer than healthy feet, and that severer clubfeet also somehow feel stiffer. They believe that this is due to the deformity of the flattened talus head of the clubfoot. Additionally they claim that stiffer clubfeet are harder to treat and have more tendency to relapse\textsuperscript{48,49}. Interestingly severer clubfeet are marked as stiff by the Dimeglio scoring system, less flexible according to the CAP score and have a decreased ROM in the Pirani score. Taken this together, it is plausible severity of the clubfoot is related to the stiffness of the ankle joint, which may be linked to the risk of relapse.

Despite the great amount of literature and research on the subject, little consensus exists on the definition of stiffness. A given definition of stiffness is the mechanical property that determines to which extend external forces delivered to the skeletal system are absorbed and/or transmitted by the articular soft tissue\textsuperscript{56}. Other literature defines stiffness in the most general sense as a property which takes into account the displacement or angle onto the force or torque\textsuperscript{57}. Considering the different existing definitions of stiffness, it seems that the exact definition depends on the context in which it is used, and moreover can be measured in passive or active conditions. So is muscle stiffness defined as the stiffness which describes the stiffness properties exhibited by the tenomuscular tissues, and does joint stiffness enclose all contributions from structures located within and over the joint which includes ligaments, muscles, tendons, joint capsules, skin, subcutaneous tissue, fascia and cartilage\textsuperscript{56}.

In this study, only passive stiffness will be considered. Passive stiffness can be defined as the resistance to elongation or shortening. In biological context passive stiffness is provided by the combination of the joint, tendon and connective tissue, whilst all muscles are relaxed\textsuperscript{57}. The more the amplitude of motion is increased, the more the ligaments will contribute to the total stiffness of the joint. In this research, stiffness will be defined as the flexibility to move the foot between reachable ROM through the joint of the child while the foot is fully relaxed. By measuring the torque at a certain angular displacement, the joint stiffness can be determined\textsuperscript{58}. Such direct measurements, in which external load is applied to a body link and the angular joint displacement is measured, have been used since 1896\textsuperscript{59}. The slope of the graph of the external load/torque and the angular displacement is defined as the stiffness. The passive joint stiffness measured in a narrow ROM (close to the neutral position) are
usually very low. These values increase sharply near the limits of the ROM. However, the joint cannot be considered completely passive anymore due to the stretched muscles which are typically activated in this range\textsuperscript{59}.

\textit{Chessworth and Vandervoort (1989)}\textsuperscript{60} did a study where passive joint stiffness was investigated in healthy women. The resisting torque through the ROM of the joint was determined, where after the passive ankle stiffness was found by calculating the slope for different degrees of dorsiflexion. \textit{Hufschmidt and Mauritz (1985)}\textsuperscript{61} compared ankle stiffness of patients who suffered from long-standing spasticity with a group of healthy subjects. The torque and angular displacement was tracked simultaneously as the foot was moved through its ROM which resulted in a displacement-torque curve, see Figure 11.

![Displacement-torque curve](image)

Figure 11, displacement-torque curve of an ankle which is moved to dorsi- and plantarflexion. The ankle stiffness is defined as the slope of the curve, and the amount of work as the area within the curve.

The ankle stiffness was defined as the slope of that curve. Additionally, the amount of work which was needed to prescribe the angular displacement was obtained by calculating the area within the displacement-torque curve.

In a recent study, \textit{Koopmans et al. (2016)}\textsuperscript{62} performed ankle stiffness measurements, where hind foot stiffness measurements were performed on a group of children with clubfoot and on a healthy control group. The subjects were between two and seven years of age. The stiffness was obtained by looking at the amount of torque which was needed to move the foot 15 degrees in dorsiflexion and abduction. No difference was found between the two groups. A limitation of this study was that 15 degrees might have been a too small angle to measure these differences in maximum torque, and that a difference would be detected if a bigger angle was prescribed. Another limitation was that only the maximum torque was recorded, and no information about non-linearity of the torque-displacement curve was
available. It thus is possible that differences in stiffness between clubfoot and healthy controls do exists, but that these can only be detected when performing measurements over the full ROM.

Hence, the first aim of this study is to determine passive ankle stiffness and the amount of work as the foot is moved through the ROM in dorsiflexion, plantarflexion, abduction and adduction for clubfeet and healthy feet. To investigate this, a new torque-rotation measurement device is developed. It is hypothesized that clubfoot are stiffer compared to healthy feet and more work is needed to move the foot through its ROM. A second aim was to investigate if an increased stiffness can be the results of a flattened talus head of the clubfoot. To investigate this, a finite element model (FEM) of a healthy and clubfoot talus is developed.
2. Validation stiffness measuring device

2.1 Introduction

In order to measure the hind foot stiffness over the whole ROM, a new device had to be developed. As mentioned earlier, joint stiffness can be obtained by measuring the amount of torque which is needed to prescribe an angular displacement. Hence, a device was developed which could measure torque and angular displacement simultaneously as the foot was moved through its ROM in dorsiflexion/plantarflexion and abduction/adduction. This device was combined with the ADM brace (Figure 9, right).

The ADM brace has an upper and lower rotation point. The upper rotation point allows the foot to move into dorsiflexion/plantarflexion, which is guided by the tibio-talar joint (TTJ). The lower rotation point allows the foot to move in abduction/adduction and is conducted by the subtalar joint (STJ). In the current study, the springs in the ADM brace were removed, and the brace was adjusted so it could be externally rotated by means of the developed device. Since the device is able to apply and measure a torque, which is initiated manually by the user, simultaneously with the displacement, it is named the torque-displacement-handpiece (TDH).

In this chapter first the mechanism of the TDH will be described, where after the device will be validated. In the final part of this chapter, the experimental set-up and data processing, which will be used in the clinical setting, will be described.

2.2 Mechanism TDH

A schematic representation of the TDH is shown in Figure 12.

Figure 12, schematic illustration of the TDH. The different compartments are indicated by the arrows. The blue arrow shows the pin of the potentiometer which fits at the STJ or TTJ rotating point of the ADM. It is able to measure the angular displacement as the ADM moves in dorsiflexion/plantarflexion or abduction/adduction. The purple arrow indicates the outer pin which fits the ADM as well. It engages the torque applied by the researcher, which is depicted by the black arrow,
to the ADM. The torque is translated into a force, shown by the red arrows, which can be captured by the force cell, indicated by the green arrow.

The TDH contains a force cell (A.S.T., KAP-S, KAP-E Force Transducer) and a potentiometer (POT meter) (Honeywell 392 Series, 3.17 mm diameter shaft, 10kΩ, 0.5W) which are respectively shown by the green and blue arrow in Figure 12. The TDH is attached to the ADM brace via a headpiece, shown in Figure 12 as the yellow compartment, which consists of a pin which is shown by the purple arrow, and the pin of the potentiometer. The pin of the potentiometer fits on the ADM exactly at the STJ or TTJ rotating point. The outer pin clicks in a specially drilled whole of the arm of the ADM brace, which is the adjustment of the brace mentioned in the introduction. By means of the latter connection the movement which is initiated by the manually applied torque is transferred to the ADM. This mechanism is illustrated in Figure 13.

![Figure 13](image)

The applied torque is translated in a pulling or pushing force (red arrows in Figure 12). The force cell measures these pulling or pushing forces and the POT meter measures the angular displacement which is achieved due to the applied torque. Both signals are sent to a computer in real time via an interface and are registered as a voltage. For the force cell a voltage of 1V corresponds with 10N, whereas for the POT meter a voltage of 1V corresponds with an angular displacement of 36 degrees. Since all measures of the TDH are known (Figure 14), the initial applied torque can be calculated from the registered force:

\[
Torque = C F_{FC} * V_{FC} * 0.080
\]
Here, $CF_{FC}$ is the conversion factor of the force cell [N/V] which equaled 10 N/V, $V_{FC}$ is the output voltage which is measured by the TDH, and 0.080 is the lever of the TDH [m], Figure 14. The validation of the conversion factor will be described later this chapter.

![Figure 14. Schematic representation of the device which was used to measure the force which was generated due to the applied torque. By using the law of the lever, the applied torque could by derived. All measures are expressed in mm.](image)

### 2.3 Validation TDH

The TDH had to be validated before it could be used in a clinical setting. To test whether the mechanism which translates the applied torque into a measured force was working properly, multiple experiments were performed. Precision was tested by adjusting the experimental set-up in between experiments and comparing results. Additionally, reliability was assessed by looking at the repeated measures within each experiment. Accuracy was tested by comparing the experimental values with known true values.

The torque meter was installed in a clamping device. In order to simulate different angles in which the TDH will be used during the clinical experiments, it was fixed in the clamping device horizontally, as well as under a 45° angle (Figure 15a,b). From this position, eight weights with a known mass were applied to the torque meter one by one. The mass of each weight was 500 gram, which sums up to a total of 4000 gram. For each new weight, the voltage output of the force sensor was recorded and the corresponding torque could be derived using the measures in Figure 14. The variation of mass was chosen to simulate a range of torques from 0.1 up to 0.7 Nm, which corresponds to the torque assumed for clubfoot in literature\(^63\). The measured voltage was plotted against the added mass, this relation was expected to be linear.

To simulate a torque in both directions, the weights were fixed both on the left and right side of the turning point (Figure 15c,e). During the conversion of the manually applied...
torque to the angular displacement of the ADM, it is not known at which position of the outer pin of the TDH this conversion exactly happens. To find out whether the position on the outer pin where it engages to the ADM matters, the weights were fixated close to the rotating plane, as well as far away, Figure 15c,d. The combination of adjusted parameters resulted in eight experiments (Table 1). Each measurement within all experiments was performed three times.

Figure 15a-e. In (a,b) the set-up for 0 and 45 degrees respectively is depicted. (c) and (d) represent a set-up in which the masses are fixed far away from and close to the rotating plane respectively. (e) illustrates an experiment where the mass is fixed on the other side with respect to (a-d) of the rotating point.
In order to validate the POT meter, the TDH was attached to an ADM brace and rotated over a known angle of 15, 30, 45 and 180 degrees, in both directions. The angular displacement according to the POT meter could be derived from the output voltage since it was known that 1V corresponded with 36 degrees. Each measurement was performed three times.

### 2.4 Results

Figure 16 displays the results of the eight torque experiments, represented as different colored lines which correspond to the colors of Table 1. Each line is extrapolated up to a mass of zero grams. Pairs of lines, which differed only in the parameter setting distance between the mass and rotating plane, overlap. This is depicted by the red, blue, orange and green dot in Figure 16 which correspond with the colors used in Table 1. This indicates that the position over the outer pin of the TDH where it will engage to the ADM does not influence the measured torque. Changing the side of the mass with respect to the rotating point, resulted in a new line which is reflected in the x-axis. In Figure 16, the pair of lines of the orange dot is a reflection in the x-axis of the pair of the red dot, and the same holds for the green and blue dot. The largest found deviation between the absolute value of the slopes of the reflected lines was 1.95%, which suggest that the measured voltage does not depend on the side where the mass is fixed.

Fixing the TDH under an angle of 45 degrees with respect to the horizontal, shortens the lever between the mass and the rotating point with the cosine of the angle (0.5\sqrt{2}). The multiplication factor between the slope of the lines of the red and blue dot, and between the lines of the orange and green dot deviated up to a maximum of 5% from 0.5\sqrt{2}. This
indicates that the angle in which the force (and thus torque) is applied with respect to the horizontal influences the measured voltage by a multiplication factor of its cosine, as expected.

Figure 16, each line represents one experiment. Eight lines are depicted, however four pairs of lines seem to overlay in such a way that they become indistinguishable. These pairs are indicated with a red, blue, green and orange dot. In the upper four lines (red and blue dot) the mass was fixed on the right side of the rotating wheel, while in the bottom four lines (green and orange dot) the mass was fixed on the left side. The lines which overlay are the ones which represent the difference of fixing the mass far from the rotating plane (at the end of the outer pin) or close to the rotating plane. The lines of the red and orange dot are the ones where the TDH was fixed horizontally in the clamp, while the lines of the green and blue dot are the ones where the TDH was fixed under an angle of 45 degrees with respect to the horizontal.

The slope of each line was calculated by looking at the increase of the voltage as each new weight was added. By dividing this voltage difference to the added mass, a slope could be found [mV/g] which could be converted to [N/V]. By taking the mean of all slopes which have been derived for each new weight, a mean slope was found which was regarded as the slope of each line. Due to the lever system of the TDH, the slope of the lines which corresponded with experiments 1&2 and 3&4 were expected to be a factor $\frac{80}{17.5}$ smaller than the conversion factor of 10 N/V of the force cell. The slope of experiments 1&2 and 3&4 were found to be 45.84 and -46.49 N/V respectively. This corresponds with 10.028 N/V and -10.17 N/V respectively if the factor $\frac{80}{17.5}$ is applied. Hence, the maximal deviation in the slope was 1.70%. This indicates that the TDH is accurate in measuring torque. The biggest difference within the repeated measures was 26 mV, which corresponded with a mass of 26.50 g and a torque of 46.4*10^{-6} Nm. This suggests excellent reliability since this is 0.05% of the torques which will be dealt with in clinical setting.

The POT meter also was found to be accurate and precise. The angular displacement found by the POT meter deviated up to a maximum of 2% from the true angle, and the biggest difference within the repeated measures was 1%.
2.5 Experimental setting

In order to test the TDH, measurements were performed on a healthy, 20 years old volunteer with a body length of 1.65 meter. The experimental set-up and methods, which will also be used in the clinical setting, are described here.

TDH & ADM brace

The springs and movements limitation were removed from the ADM brace so that a neutral foot stance could be achieved and the foot would freely move in dorsi- and plantarflexion and ab- and adduction. These movements could be induced through the TDH by attaching it to the STJ or TTJ rotating point and applying a torque, see Figure 17.

Figure 17, the ADM brace was moved in plantar- and dorsiflexion (a,b) and in ab-adduction (c,d), by attaching the TDH to the TTJ or STJ rotating point and applying a torque.

Experimental setting

For the ADM measurement the subject was seated with the knees at an angle of approximately 90 degrees, with the lower leg in a vertical position while not touching the
ground (Figure 18). The subject was instructed to fully relax the foot and calf during the measurements. Measurements started from each participant’s own neutral position with the foot in the brace.

Figure 18, sitting position for the experiment. Knees at an angle of approximately 90 degrees, lower leg in a vertical position while the feet are not touching the ground.

The TDH was attached to the TTJ rotating point, and a torque was applied which made the foot move in dorsiflexion. The angular displacement and torque were only measured by the TDH if the angular displacement overcame a threshold value of approximately 10 degrees. Hence, first a small torque was applied which made the foot move beyond the threshold value. After the foot returned to its neutral position, and an increasing torque that would move the foot through the full ROM for which a child would not experience any pain or discomfort, was applied. The torque and displacement signal from the TDH were transmitted to an interface and processed. Subsequently the foot was moved in plantarflexion. By attaching the TDH to the STJ rotating point the foot could be rotated in ab-adduction. Next, the measurements were done for the other foot. Each measurement was repeated three times and took approximately 10 seconds. Thus, the whole experiment consisted of three dorsiflexion measurements, and three ab- and three adduction measurements for the left and right foot.
In between each measurement it was checked whether the foot was still relaxed, the seating position of the subject was correct and the brace and TDH were still fixed well, this typically took 1 minute. In total, one experiment took 20-25 minutes.

**Analysis of the displacement torque data**

From each experiment, three displacement torque graphs were obtained for dorsi- and plantarflexion, ab- and adduction. Prior to further analysis, the graphs were adjusted so that the beginning and ending position (angular displacement) were equal. The ending position is here defined as the position of the foot to which it returns after it reached its maximum displacement, see Figure 19 (one repeated measure of a healthy 5 year old participant). The maximal displacement and torque were noted, and further analysis was performed.

![Figure 19](image)

Figure 19, typical displacement-torque graph for one repeated measure (healthy subject, five years old) in dorsiflexion. Left: Graph without adjustment. Right: Graph after adjustment which will be used for further analysis.

Next, the graph was split into two parts: One where the foot is moving through its ROM due to the applied torque, and one where it moves back towards its initial position, Figure 20 blue and red line respectively.
Figure 20, the blue line represents the part where the foot moves by means of the applied torque (journey out) and the red line represents the part where the foot moves back (journey back).

As described in the introduction, the stiffness can be determined by calculating the slope of the displacement-torque curve. When calculating stiffness, only the blue line was considered. For the stiffness of dorsi- and plantarflexion, a linear fit was performed such that the slope represented the stiffness. For ab- and adduction the blue line was split into two parts since it could not be approximated as one linear part. The line was split at 0.5*Torque\(_{\text{max}}\), which was arbitrary chosen based on empirical evidence obtained by examining the displacement-torque curves of the subjects. This resulted in stiffness 1 and stiffness 2, illustrated in Figure 21.

Figure 21, Left: Displacement torque graph of dorsiflexion experiment. The first order polynomial is represented by the black line. Right: Graph of an abduction experiment. The red line represents 0.5*torque\(_{\text{max}}\), considered from the beginning position. The slope of the black and green line represent the first and second stiffness respectively.
The amount of work was obtained by taking the integral of the displacement torque curve, which was also done by Hufschmidt and Mauritz (1985). Because the angular displacement was initiated manually, each repeated measure resulted in a different angular displacement. Hence, direct comparison of the amount of work between subjects would not be correct. To compare the amount of work between subjects, it was normalized by dividing it by the total displacement, Figure 22. This resulted in a mean dissipated torque.

Figure 22, Displacement torque curve, the red area represents the amount of work. The mean dissipated torque is obtained by dividing the amount of work by the total displacement.

The data which was obtained for each subject for each repeated measure now consisted of the maximum displacement, maximum torque, stiffness 1 and 2 and the mean dissipated torque. Each parameter was averaged over the three repeated measures, which resulted in one value for each parameter for each foot. This was done for dorsi- and plantarflexion, ab- and adduction, on the left and right foot.

### 2.6 Conclusion

In conclusion, it was found that the TDH is a reliable, precise and accurate device to measure an applied torque and an angular displacement. The measurements can be performed clockwise as well as counterclockwise. Moreover, the TDH is able to measure the applied torque correctly if it is applied under a certain angle. Finally, the location on the outer pin on the TDH where the force is applied does not influence the measured torque.

This makes the TDH a suitable tool to measure the torque and displacement as the ankle joint moves through its ROM. From these parameters the ankle stiffness can be derived.
Additionally, the protocol which was used to test upon the volunteer can be applied in the clinical setting as well.
3. Clinical study

3.1 Introduction

As explained in the introduction, clubfoot patients are expected to have stiffer feet compared to healthy patients. However, in an earlier study of Koopmans et al. (2016) this was not found, possibly because of limitations of the used measurement device that did not allow measuring the full ROM. As described in chapter 2, a new device was developed in this study that overcomes many of the shortcomings of the earlier device.

The first goal of this study was to determine the reliability, precision and reproducibility of the ADM stiffness measure. The second goal was to investigate if differences in stiffness and amount of work can be detected when comparing a group of clubfoot patients and a healthy control group.

In order to analyze reliability, precision and reproducibility, each measurement was performed three times. Using these repeated measurements, the precision and reliability were accessed from the CV$_{\text{rms}}$ and the interclass correlation coefficient (ICC) respectively.

Subsequently, it was tested whether clubfeet are stiffer compared to healthy feet. The stiffness in both the TTJ and STJ was analyzed for a group of clubfoot patients and a healthy control group. For each clubfoot the surgeon also subjectively rated the foot as “stiff” or “not stiff”, which still is the gold standard. Additionally, the amount of work which is needed to move the foot through the ROM was compared between the clubfoot group and the healthy control group.
3.2 Methods

Participants

Clubfoot patients at the age of 5 to 8 years were recruited at a clubfoot treatment center. Both uni- and bilateral affected idiopathic clubfoot patients were included.

In total 11 clubfoot patients with 17 clubfeet and 11 healthy subjects with 22 healthy feet were included in this study. The mean (SD) age of the clubfoot group and healthy group was 6.5 (1.21) and 6.5 (1.29) respectively. Table 2 gives an overview of numbers and specifics of patients and healthy subjects. Additional information which was obtained from every subject can be found in Appendix 3.

Table 2, specifications on clubfoot patients and healthy subjects. N is number of subjects, N_Bi is number of bilateral clubfeet patients, N_Uni is the number of unilateral clubfoot patients, N♂ number of male and N♀ number of female subjects.

<table>
<thead>
<tr>
<th>Specification subjects</th>
<th>N</th>
<th>N_Bi</th>
<th>N_Uni</th>
<th>N♂</th>
<th>N♀</th>
<th>Mean age</th>
<th>Mean shoe size (EU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clubfoot</td>
<td>11</td>
<td>8</td>
<td>3</td>
<td>7</td>
<td>4</td>
<td>6.5</td>
<td>30</td>
</tr>
<tr>
<td>Healthy</td>
<td>11</td>
<td></td>
<td>6</td>
<td>5</td>
<td></td>
<td>6.5</td>
<td>31</td>
</tr>
</tbody>
</table>

Measurements took place after regular consultation by the orthopaedic surgeon. The experiments were performed on each subject as described in paragraph 2.6. In order to maintain a relaxed foot, the subject was distracted during the measurements by letting him/her play a game on an IPad, or by making conversation. All measurements were performed three times to enable the assessment of the reproducibility and reliability of the data. Age-matched participants for the control group were recruited at the orthopaedic department at Máxima Medical Center, Catharina Hospital and a gym class. Additional inclusion criteria for healthy participants were no disorder affecting the lower extremities and no syndromic diseases. The participants for the control group who were recruited at the hospital were visiting the hospital for an affection which had no influence on the foot, and thus matched the inclusion criteria. For the clubfoot patients, each clubfoot was also scored as “stiff” or “not stiff” by the orthopaedic surgeon by filling in Appendix 2.

Participants were excluded from the study if they were unable to cooperate during the measurements or unable to sufficiently relax their foot.

The Medical Research Ethics Committees United (MEC-U) approved the studies on both the clubfoot and healthy children. All parents or guardians of the children gave written informed consent before participation (Appendix 1).
3.3 Data analysis

The data of each patient consisted of the maximum displacement, maximum torque, stiffness 1 and 2 and the mean dissipated torque for each foot. For comparison between patients and controls, data of bilateral clubfoot patients and healthy control subjects of the left and right foot were averaged. For unilateral clubfoot patients, the affected foot was considered as one data point, while the data of the unaffected (contralateral) foot was not used.


Validation ADM stiffness measure

Precision of the ADM torque, displacement, stiffness and mean dissipated torque measurements was determined using the root mean square of the standard deviation \(SD_{\text{rms}}\), which was calculated using equation one:

\[
SD_{\text{rms}} = \sqrt{\frac{\sum_{j=1}^{m} \sum_{i=1}^{n_j} \frac{(x_{ij} - \bar{x}_j)^2}{df}}{m}}
\]

with \(df = \sum_{j=1}^{m} df_j = \sum_{j=1}^{m} (n_j - 1)\) \hspace{1cm} (1)

Here, \(m\) is the number of subjects, \(n\) the number of measurements, \(x\) the measured quantity, \(\bar{x}\) is the mean quantity for subject \(j\) and \(df\) is the total number of degrees of freedom which had to be calculated since a number of exact three repeated measures could not always be achieved.

The degree of variation was tested with the root mean square of the coefficient of variation \((CV_{\text{rms}})\) calculated by equation two, which was expressed in percentages. A \(CV_{\text{rms}} < 10\%\) was stated as a good precision:

\[
CV_{\text{rms}} = \sqrt{\frac{\sum_{j=1}^{m} CV_j^2}{m}}
\]

with \(CV_j = \frac{SD_j}{\bar{x}_j} * 100\%\) \hspace{1cm} (2)

Here \(SD_j\) is the SD over the three measurements calculated separately for each subject using equation 3.

\[
SD_j = \sqrt{\frac{\sum_{i=1}^{n_j} (x_{ij} - \bar{x}_j)^2}{n_j - 1}}
\]  \hspace{1cm} (3)

To investigate the reliability of the data, the intra class correlation coefficient (ICC) was calculated by a two-way mixed model for absolute agreement within one subject. The reliability was considered good if ICC > 0.75.
Comparison data between clubfoot and healthy control group

The difference in maximum displacement and torque, stiffness 1 and 2 and the mean dissipated torque between clubfoot patients and healthy subjects was tested using two-tailed independent t-tests when the data was normally distributed. When the data was not normally distributed, the Mann-Whitney U test was used. A p-value of <0.05 was considered significant.

The mean stiffness of the clubfoot patients was compared with the ratings of the surgeon. This was done by checking whether the feet which were rated as stiff by the surgeon, had a higher stiffness than the measured mean of the group. From the 11 clubfoot patients, 10 were rated by the surgeon.

3.4 Results

Reproducibility ADM stiffness measure

$CV_{rms}$ and the ICC of the maximum displacement, maximum torque, calculated dissipated torque and calculated stiffness were determined based on the 3 repeated measurements for dorsi- and plantarflexion, ab- and adduction for the left and right foot, where all subjects were included. The results of the maximum displacement and maximum applied torque can be seen in Table 3.

Table 3, $CV_{rms}$ and ICC for all subjects. Left: Displacement, Right: Maximum applied torque. The values were calculated by averaging the three repeated measures over all 22 subjects.

<table>
<thead>
<tr>
<th>Maximum displacement within patient specifics (N=22)</th>
<th>CV_rms [%]</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion left</td>
<td>5.82</td>
<td>0.89</td>
</tr>
<tr>
<td>Dorsiflexion right</td>
<td>6.20</td>
<td>0.93</td>
</tr>
<tr>
<td>Plantarflexion left</td>
<td>8.07</td>
<td>0.88</td>
</tr>
<tr>
<td>Plantarflexion right</td>
<td>8.30</td>
<td>0.86</td>
</tr>
<tr>
<td>Abduction left</td>
<td>7.69</td>
<td>0.96</td>
</tr>
<tr>
<td>Abduction right</td>
<td>6.57</td>
<td>0.93</td>
</tr>
<tr>
<td>Adduction left</td>
<td>9.40</td>
<td>0.94</td>
</tr>
<tr>
<td>Adduction right</td>
<td>13.98</td>
<td>0.80</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximum torque within patient specifics (N=22)</th>
<th>CV_rms [%]</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion left</td>
<td>6.81</td>
<td>0.94</td>
</tr>
<tr>
<td>Dorsiflexion right</td>
<td>7.24</td>
<td>0.95</td>
</tr>
<tr>
<td>Plantarflexion left</td>
<td>6.72</td>
<td>0.88</td>
</tr>
<tr>
<td>Plantarflexion right</td>
<td>5.67</td>
<td>0.93</td>
</tr>
<tr>
<td>Abduction left</td>
<td>6.15</td>
<td>0.95</td>
</tr>
<tr>
<td>Abduction right</td>
<td>8.61</td>
<td>0.92</td>
</tr>
<tr>
<td>Adduction left</td>
<td>7.45</td>
<td>0.97</td>
</tr>
<tr>
<td>Adduction right</td>
<td>6.27</td>
<td>0.96</td>
</tr>
</tbody>
</table>

Within the maximum displacement measurements, all $CV_{rms}$ values are < 10.0%, except for the adduction on the right foot, which is 14%. The dorsiflexion on the left foot seems to be the most precise measurement, with a $CV_{rms}$ of 5.82%. Within the torque measurements all $CV_{rms} < 10.0%$. The most precise measurement seems to be the plantarflexion on the right
foot, with a CV\textsubscript{rms} of 5.67%. Overall, the results indicate that the precision of the measurements for the left and right foot is the same within the displacement and torque for all directions.

The dorsi- and plantarflexion measurements seem to be more precise than the ab- and adduction measurements. The ICC values when comparing the three repeated measures conducted by one operator are for the displacement and torque all above 0.80 and 0.88 respectively, which indicates good to excellent reliability.

**Reliability calculation stiffness & mean dissipated torque**

The displacement and torque were used to calculate the stiffness and mean dissipated torque. The ICC and CV\textsubscript{rms} values of these calculations can be seen in Table 4 below.

Table 4, left: ICC and CV\textsubscript{rms} of stiffness calculations for all subjects. Abduction and adduction were split into stiffness 1 and 2. Right: ICC and CV\textsubscript{rms} of mean dissipated torque calculations for all subjects.

<table>
<thead>
<tr>
<th>Stiffness calculation within patient specifics (N=22)</th>
<th>CV\textsubscript{rms} [%]</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion left</td>
<td>11.37</td>
<td>0.92</td>
</tr>
<tr>
<td>Dorsiflexion right</td>
<td>7.90</td>
<td>0.96</td>
</tr>
<tr>
<td>Plantarflexion left</td>
<td>5.22</td>
<td>0.98</td>
</tr>
<tr>
<td>Plantarflexion right</td>
<td>8.20</td>
<td>0.91</td>
</tr>
<tr>
<td>Abduction1 left</td>
<td>11.97</td>
<td>0.86</td>
</tr>
<tr>
<td>Abduction1 right</td>
<td>12.78</td>
<td>0.82</td>
</tr>
<tr>
<td>Abduction2 left</td>
<td>22.55</td>
<td>0.56</td>
</tr>
<tr>
<td>Abduction2 right</td>
<td>15.62</td>
<td>0.89</td>
</tr>
<tr>
<td>Adduction1 left</td>
<td>24.08</td>
<td>0.80</td>
</tr>
<tr>
<td>Adduction1 right</td>
<td>17.00</td>
<td>0.81</td>
</tr>
<tr>
<td>Adduction2 left</td>
<td>22.94</td>
<td>0.59</td>
</tr>
<tr>
<td>Adduction2 right</td>
<td>39.33</td>
<td>0.70</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mean dissipated torque calculation within patient specifics (N=22)</th>
<th>CV\textsubscript{rms} [%]</th>
<th>ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion left</td>
<td>12.68</td>
<td>0.81</td>
</tr>
<tr>
<td>Dorsiflexion right</td>
<td>9.86</td>
<td>0.85</td>
</tr>
<tr>
<td>Plantarflexion left</td>
<td>10.46</td>
<td>0.90</td>
</tr>
<tr>
<td>Plantarflexion right</td>
<td>10.35</td>
<td>0.91</td>
</tr>
<tr>
<td>Abduction left</td>
<td>11.31</td>
<td>0.90</td>
</tr>
<tr>
<td>Abduction right</td>
<td>8.43</td>
<td>0.92</td>
</tr>
<tr>
<td>Adduction left</td>
<td>33.68</td>
<td>0.74</td>
</tr>
<tr>
<td>Adduction right</td>
<td>26.03</td>
<td>0.71</td>
</tr>
</tbody>
</table>

The ICC values of the obtained stiffness and mean dissipated torque of dorsi- and plantarflexion are all > 0.80 which indicates excellent reliability. The corresponding CV\textsubscript{rms} are with the exception of dorsiflexion left all < 10%. Within the stiffness, the abduction2 left, adduction2 left and adduction2 right have an ICC of 0.70 or lower. The corresponding CV\textsubscript{rms} are > 15% which indicates that the precision lessens as the reliability is lower. Within the mean dissipated torque, adduction left and right have an ICC of 0.74 or lower with a CV\textsubscript{rms} over 25%. Taken together, particularly the adduction experiments seem to have lower ICC and CV\textsubscript{rms} values. Since all ICC values for the displacement and torque > 0.80, the lower ICC values for the stiffness and mean dissipated torque are likely due to the high gradient in the slope in this region of the curve.
The results suggest that the method used to calculate the stiffness for dorsi- and plantarflexion, abduction1 and adduction1 are reliable. However, when calculating the stiffness of ab- and adduction2 the method seems to be less reliable. As for the mean dissipated torque the calculation for dorsi- and plantarflexion and abduction seem reliable, the adduction reliability seems less reliable. The fact that particularly each second stiffness in the ab- and adduction experiments has a lower ICC probably is related to the empirical choice of the cutting point between stiffness1 and 2, which is 0.5 * Torque_{max}. The lower ICC values of the mean dissipated torque within the adduction were not expected.

**Clubfoot versus control**

The means of the calculated stiffness, mean dissipated torque, maximal displacement and maximal torque of the healthy subjects and clubfoot patients are depicted in Table 5 below together with the differences between the groups.

Table 5, summarization of the mean stiffness, mean dissipated torque, maximal displacement and maximal torque for the healthy and clubfoot group. *p = 0.05

<table>
<thead>
<tr>
<th>Calculated stiffness values [Nm/degree]</th>
<th>Healthy</th>
<th>Clubfoot</th>
<th>Clubfoot – Healthy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>0.028 ± 0.009</td>
<td>0.034 ± 0.015</td>
<td>0.006 (21%)</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>0.063 ± 0.017</td>
<td>0.070 ± 0.026</td>
<td>0.007 (11%)</td>
</tr>
<tr>
<td>Abduction1</td>
<td>0.028 ± 0.005</td>
<td>0.037 ± 0.01</td>
<td>0.009* (32%)</td>
</tr>
<tr>
<td>Abduction2</td>
<td>0.05 ± 0.033</td>
<td>0.07 ± 0.04</td>
<td>0.02 (40%)</td>
</tr>
<tr>
<td>Adduction1</td>
<td>0.026 ± 0.005</td>
<td>0.036 ± 0.012</td>
<td>0.010* (38%)</td>
</tr>
<tr>
<td>Adduction2</td>
<td>0.10 ± 0.104</td>
<td>0.11 ± 0.058</td>
<td>0.01 (10%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Calculated mean dissipated torque values [Nm]</th>
<th>Healthy</th>
<th>Clubfoot</th>
<th>Clubfoot – Healthy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>0.60 ± 0.15</td>
<td>0.65 ± 0.19</td>
<td>0.05 (8%)</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>0.70 ± 0.43</td>
<td>0.95 ± 0.13</td>
<td>0.25 (36%)</td>
</tr>
<tr>
<td>Abduction</td>
<td>0.43 ± 0.12</td>
<td>0.43 ± 0.14</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Adduction</td>
<td>0.30 ± 0.05</td>
<td>0.27 ± 0.10</td>
<td>-0.03 (10%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximal displacement values [degree]</th>
<th>Healthy</th>
<th>Clubfoot</th>
<th>Clubfoot – Healthy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>50.7 ± 9.6</td>
<td>46.7 ± 10.58</td>
<td>-4.0 (8%)</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>28.7 ± 6.9</td>
<td>26.8 ± 4.44</td>
<td>-1.9 (7%)</td>
</tr>
<tr>
<td>Abduction</td>
<td>38.9 ± 9</td>
<td>30.1 ± 6.80</td>
<td>-8.8* (23%)</td>
</tr>
<tr>
<td>Adduction</td>
<td>27.9 ± 7.4</td>
<td>20.7 ± 3.97</td>
<td>-7.2* (26%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Maximal torque values [Nm]</th>
<th>Healthy</th>
<th>Clubfoot</th>
<th>Clubfoot – Healthy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>1.51 ± 0.41</td>
<td>1.65 ± 0.52</td>
<td>0.14 (9%)</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>1.63 ± 0.295</td>
<td>1.71 ± 0.43</td>
<td>0.08 (5%)</td>
</tr>
</tbody>
</table>
Four significant ($p<0.05$) differences were found between the healthy subjects and the clubfoot patients. Stiffness of ab- and adduction was significantly higher in the clubfoot patients group, while the displacement over ab-and adduction was significantly lower. All linear models which were used to derive the stiffness were significant ($p<0.05$) with $R^2>0.9$ for all subjects, which implicated an excellent fit. For the maximal and mean dissipated torque, no significant differences were found.

**Comparison gold standard & physical features**

The stiffness score by the surgeon was compared to the measured stiffness. The results can be seen in Table 6 below.

Table 6, summary of the number of correct ratings taking the surgeon defined stiffness for dorsi- and plantarflexion and ab- and adduction as the gold standard.

<table>
<thead>
<tr>
<th></th>
<th>Dorsiflexion</th>
<th>Plantarflexion</th>
<th>Abduction</th>
<th>Adduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of ratings</td>
<td>10</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Correct number of ratings</td>
<td>7</td>
<td>4</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>% correct ratings</td>
<td>70</td>
<td>40</td>
<td>70</td>
<td>50</td>
</tr>
</tbody>
</table>

In 70% of the cases of dorsiflexion the surgeon marked the foot as “stiff” while the measured stiffness was higher than the mean within the group. For plantarflexion, ab- and adduction this was 40, 70, and 50% respectively.

These results are also plotted in Figure 23, where the surgeons rating is plotted against the calculated stiffness.

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Abduction</td>
<td>1.39 ± 0.47</td>
<td>1.39 ± 0.29</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Adduction</td>
<td>1.09 ± 0.42</td>
<td>1.10 ± 0.28</td>
<td>0.01 (1%)</td>
</tr>
</tbody>
</table>
Figure 23, plot of the surgeons rating on the x-axis against the calculated stiffness on the y-axis for dorsi- and plantarflexion and ab- and adduction. The black horizontal line represents the mean calculated stiffness within the group, corresponding to the movement direction.

The black horizontal line within each movement represents the mean calculated stiffness of the clubfoot group, which divides each plot into four parts; Q1, Q2, Q3 and Q4. The sensitivity and specificity can be calculated by using these quartiles. Here Q1 represents the false negatives, Q2 the true negatives, Q3 the true positives and Q4 the false negatives. The sensitivity is specified as:

\[
\frac{Q_3}{Q_3 + Q_4}
\]

Which equals the probability of a “stiff” score by the surgeon, given that the foot is stiff.

And the specificity as:

\[
\frac{Q_2}{Q_2 + Q_1}
\]

Which equals the probability of a “not stiff” score by the surgeon given that the foot is not stiff.

The found sensitivity and specificity are shown below in Table 7 for each movement.

<table>
<thead>
<tr>
<th>Sensitivity and specificity for each movement</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dorsiflexion</strong></td>
<td>0.67</td>
<td>0.75</td>
</tr>
<tr>
<td><strong>Plantarflexion</strong></td>
<td>0.33</td>
<td>0.50</td>
</tr>
<tr>
<td><strong>Abduction</strong></td>
<td>0.67</td>
<td>0.75</td>
</tr>
<tr>
<td><strong>Adduction</strong></td>
<td>0.50</td>
<td>0.50</td>
</tr>
</tbody>
</table>
The specificity is for each movement equal or higher than the sensitivity. This suggests that the surgeon is better in detecting not stiff feet than stiff feet.

The low correlations in Table 6 and the results of the sensitivity can be related to the fact that the physical size amongst subjects was not taken into account yet. Age and physical features might have an influence on stiffness, while also age-dependent weight of the foot may have an effect on the measurements. It was observable during the experiments that a subject with large feet will consistently need more torque to prescribe a displacement compared to subjects with small feet. Thus, a large foot which is marked as “not stiff” by the surgeon, will still have a higher stiffness compared to the mean of the group. In Alhusaini et al. 2011⁶⁶ passive muscle stiffness measures were conducted on children with cerebral palsy, the passive stiffness was scaled by dividing by the product of the subjects weight and leg length, to correct for different physical size amongst subjects. In the current study, shoe size is chosen as a measure for physical size. In Figure 24 shoe size is plotted against the stiffness for all experiments.

![Figure 24](image)

Figure 24, left: plot of dorsi- and plantarflexion stiffness against shoe size, right: Plot of ab- and adduction stiffness against shoe size. Both healthy subjects and clubfoot patients are included.

The data suggest a correlation between age and stiffness for dorsi- and plantarflexion, while ab- and adduction does not seem to be correlated. Correlation tests revealed a significant correlation (p<0.05) between the stiffness of dorsi- and plantarflexion and shoe size, with a Pearson correlation coefficient of 0.610 and 0.505 respectively. This was expected since the weight of the foot has a higher influence on the movement within dorsi- and plantarflexion compared to the ab- and adduction due to the direction of the movement. In order to correct for shoe size within the two groups, an analysis of covariance (ANCOVA) was performed for dorsi- and plantarflexion stiffness, where shoe size was taken as the covariance. The results can be seen in table 8 below.
Table 8, mean stiffness in dorsi- and plantarflexion before and after correction for shoe size. Table on top: Before correction. Bottom Table: After correction.

<table>
<thead>
<tr>
<th></th>
<th>Mean stiffness healthy subjects [Nm/degree]</th>
<th>Mean stiffness clubfoot patients [Nm/degree]</th>
<th>Clubfoot - healthy [Nm/degree]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>0.028</td>
<td>0.034</td>
<td>0.006 (21%)</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>0.063</td>
<td>0.070</td>
<td>0.007 (11%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Mean stiffness healthy subjects [Nm/degree]</th>
<th>Mean stiffness clubfoot patients [Nm/degree]</th>
<th>Clubfoot - healthy [Nm/degree]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dorsiflexion</td>
<td>0.026</td>
<td>0.036</td>
<td>0.010 (38%)</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>0.061</td>
<td>0.073</td>
<td>0.012 (20%)</td>
</tr>
</tbody>
</table>

The difference in stiffness for dorsiflexion and plantarflexion has increased by 0.004 and 0.005 Nm/degree respectively. A post-hoc analysis (LSD) revealed a significant (p<0.05) difference in the stiffness of the dorsi- and plantarflexion between the healthy subjects and the clubfoot patients.
4. Discussion

In this study a new method for measuring stiffness of feet is discussed and applied to healthy feet and clubfeet. The aim was to develop a reliable, precise and accurate method to determine the ankle stiffness of children within the age of 5-8 years and compare a healthy group with a clubfoot group. Therefore, the TDH was developed which was able to measure angular displacement and applied torque simultaneously. To do so, the ADM brace was modified to work as a gripping device for the TDH. With the acquired data, the stiffness could be calculated.

The clubfoot population in this study is very diverse. Patients who underwent the Ponseti treatment at our clinic were included, as patients who are experiencing a relapse or patients where the deformity was never fully corrected. Not all patients were initially treated at the Maxima Medical Centre or the Catharina Hospital. All patients, except for one, were treated by the Ponseti method. Despite the population variation, all clubfoot in this study are assumed to behave similar which was also visible in the results. For this reason, no differentiations were made upon pathology or initial treatment of the clubfoot.

4.1 Angular displacement and torque

Prior to the measurements on children, the TDH was validated in measuring torque and angular displacement. It was found that the TDH is capable of measuring the applied torque and angular displacement reliable, precise and accurate within the desired range of the clinical values. The small deviations in the measured torque and displacement were most likely due to read-off errors and shear forces. These were reduced to a minimum by loosening the screws of the TDH, which are indicated by the red arrows in Figure 12.

When the precision and reliability was tested in a clinical setting however, larger deviations were found within the experiments. In clinical practice, the ankle ROM is measured by means of a goniometer. In this study the operator did these ROM measurements, however they were not usable due to a lack of experience of the operator. Hence, the available ROM was determined by the feeling of the examiner for each foot. The purpose was to use as much ROM as possible without causing any discomfort to the patient. Determining the usable ROM by the feeling of the operator resulted in a variation of displacement and thus the maximum applied torque within the repeated measures as in between the feet. Additional variation in the used ROM might be caused by the sitting position of the subject. It is known that the flexion angle of the hip and knee have influence on the ankle ROM. Within the used protocol, each subject was seated in the same position (Figure 18). The question remains however whether the hip and knee angle was the same for every subject. Moreover, the angles might also have changed during the experiments due to movements of the child as a result of distraction caused by the surrounding or curiosity for the measuring equipment.
A better method would be to apply a prescribed displacement or torque to each foot. Multiple experiments could then be performed with different prescribed angles, which was also done by Weiss and Kearney (1986)\(^6\). Additionally, the ROM could be measured of each foot by means of a ROM measurement protocol\(^7\), where after the prescribed displacement could be adjusted so that the same percentage of the ROM was used for each foot. However, the ROM measurements by means of the goniometer have a low reliability\(^7\). Wilken et al. (2011)\(^7\) developed a method to measure the ROM more reliably for dorsiflexion. Unfortunately, no method exists yet which reliably measured the ROM in dorsiflexion and ab- and adduction.

Another important point is the behavior and capability of the child to fully relax their feet. All children were < 9 years old and very curious about the experiment and the used equipment. Measurements frequently had to be repeated due to a not fully relaxed foot. It was hard to always tell whether the foot was fully relaxed or not, which is a limitation in this study. The operator was trained by the surgeon how to determine whether a foot was relaxed or not. Inexperience remained a problem however, and checking for a relaxed foot while using the TDH was even more difficult. A method to check for muscle relaxation would be to use electromyographic (EMG) which was also done by Wilke et al. (1997)\(^7\) and Salsich et al. (2000)\(^7\).

Nevertheless, all displacement and torque measurements had an ICC of >0.80 and a CV\(_{\text{rms}}\) < 10% with the exception of the adduction of the right foot (CV\(_{\text{rms}}\) = 13.98%). Interestingly, this was 9.40% for the adduction of the left foot which is a big difference compared to the other differences between left and right, which varied between 0.23 and 2.46%. An explanation might be that it was harder for the subject to relax the foot during an adduction movement, or it might be the result of coincidence. Since the ICC was 0.80 and the CV\(_{\text{rms}}\) of 13.98% still is acceptable, no significant consequences on the further analysis was expected.

### 4.2 TTJ rotating point

The TTJ rotating point allowed the movement during the dorsiflexion experiments. The foot was however free to move around the STJ as well. Therefore, when reaching a higher torque, the foot could also rotate towards adduction to release the tension in the TTJ which was clearly visible during the experiments. This might explain the high values of the maximal displacement in dorsiflexion which were up to 50 degrees, but theoretically cannot be higher than 20 degrees according to biology studies\(^7\). An alternative could be to fixate the STJ rotating point during the dorsiflexion experiments. The surgeon expected however that this would drastically affect the available ROM and it would make the movement unnatural, since both rotating points are needed in order to realize a dorsiflexion movement\(^7\). Moreover, when the surgeon examines the stiffness of the foot in clinical practice, there is also no restriction in any joint movement. Therefore, when no joint movement is restricted the calculated stiffness may resemble more to the stiffness which the orthopaedic surgeon feels.
4.3 Stiffness calculation

The ICC values of the stiffness and mean dissipated torque indicate whether the used method to obtain them is reliable. All ICC values for the stiffness > 0.90 for dorsi- and plantarflexion. This high reliability is likely due to the high linearity in the displacement-torque graph which is used to calculate the stiffness. For the ab- and adduction stiffness, the graph was split into two parts. Interestingly, the ICC’s for stiffness1 of ab- and adduction are all > 0.80 (Table 4). However, the stiffness of abduction2 left, adduction2 left and adduction2 right have an ICC value of 0.70 or lower. Because the displacement-torque graph was split at 0.5*Torque\(_{max}\), which was an arbitrary point. The splitting point was not always chosen optimally which resulted in variation of stiffness2 within and between feet. This can be seen in Figure 25.

In Figure 25, two repeated measures are depicted for an adduction experiment. The horizontal black lines indicate the 0.5*Torque\(_{max}\) which is the point where the graph is split into stiffness1 and 2. It can be seen that within the blue line the splitting point would ideally be at 0.40 Nm which is depicted by the black arrow. The splitting point is now however at 0.58 Nm. This results in a higher stiffness2 compared to the ideal situation. In other subjects, the chosen splitting point could result in a too low stiffness2 as well. Due to this, the calculated stiffness2 is not accurate and causes extra variation within the repeated measures per subject. This was the case for healthy feet as well as for clubfeet. A more advanced algorithm which is able to detect the “belly” of each graph is desirable. A possibility would be to analyze the curve 25% above and under 0.5*Torque\(_{max}\). The curves belly could be detected by finding the point where the curve has its largest gradient, i.e. where the second derivative equals zero. An attempt was made to implement this, however due to noise within the data this did not resulted into the desired detected location of the belly. Applying a smoothing filter or fitting a polynomial curve would be an option for future research.
Figure 25, two repeated measures of an adduction experiment on the same subject with the same foot. The horizontal black lines represent $0.5 \times \text{Torque}_{\text{max}}$ were the stiffness is split. The black arrow represents the “belly” of the blue graph, which would ideally be the splitting point.

4.4 Learning curve experiments

For each measurement, the left and right foot were averaged as one data point. The two-tailed one sample t-test however revealed that within the healthy children there was a significant difference between the left and right foot for stiffness1 in adduction, maximal torque in adduction, mean dissipated torque in abduction and maximal displacement in plantarflexion. Interestingly this only occurs in the healthy group. The healthy group however was the first group which was measured. The clubfoot measurements started by the time the healthy group was almost finished. When taking a closer look at the data for the maximal torque in abduction and adduction (healthy group), it can be seen that the absolute difference between the left and right foot is bigger for the first experiments, and reduces as more experiments have been performed, see Figure 26. This suggests that there might be a learning curve involved and that the absolute difference between the left and right foot will decrease in future experiments.

![Figure 26](image)

Figure 26, Left: absolute difference between left and right foot for the maximal torque in abduction. Right: Adduction. Clearly the absolute difference between the left and right foot reduces as more experiments have been performed.

This was however not the case within the maximal displacement of the plantarflexion, stiffness1 in adduction and mean dissipated torque in abduction. The stiffness and mean dissipated torque are derived from the displacement and torque, which might explain why no learning curve is observed here. No explanation was found however for the absence of the learning curve within the maximal displacement in plantarflexion.

A reason for the found differences between the left and right foot for healthy children might be the dominance of one leg over the other. However, this was not tested and since no based explanation for the difference was found, left and right were in this first attempt to measure stiffness averaged to one data point. In future research the operator should first
gain experience with the measurements before performing the experiments. This way probably no difference between the left and right foot will be found.

4.5 Trueness of stiffness values

It is difficult to get an indication of how close the measured stiffness value is to the true stiffness since there is no “true” value for ankle stiffness. What makes it even more difficult is that in this research six stiffnesses have been measured. It is not known which stiffness resembles “the stiffness” which the surgeon refers to. In Gerald et al. (1978)\textsuperscript{76} stiffness values ranging from 0.25 to 0.96 Nm/degree have been found for dorsiflexion and plantarflexion, while in Rao et al. (2006)\textsuperscript{77} values between 1.042 and 1.50 Nm/degrees were found. This is 10 to 20 times bigger compared to the values found in this study. These experiments however were performed on adults with an age of up to 60 years, and by means of different methods. Hence, those results cannot be directly compared with the found stiffness of this research. In the study of Koopmans et al. (2016)\textsuperscript{62}, stiffness was measured as the amount of torque which was needed to move the foot 15 degree in dorsiflexion or abduction. Values between 0.8 and 0.9 Nm were found for dorsiflexion, and between 0.6 and 0.8 Nm for abduction. In this research, torque values of 0.5 up to 0.8 Nm are found for 15 degrees of dorsiflexion and values of 0.35 to 0.50 Nm for abduction. This also corresponds with Cohen et al. (2013)\textsuperscript{63} where torque values between 0.44 and 0.75 Nm were used to simulate clubfoot stiffness. In Ross et al. 2011\textsuperscript{78} torque-angle measures were conducted, where young healthy subjects (mean age 9.7 years) were included. The torque was measured when increasing the angle with 10°/s with a dynamometer. Values between -1 Nm and 6 Nm were found for the movement of plantarflexion towards dorsiflexion. The mean maximal torque value for the dorsiflexion movement in this study was 1.75 Nm for healthy children, which is almost 4 times bigger compared to our results. Still, the mean age was 9.7 years, but was 6.5 years in this study which makes it hard to compare the values.

4.6 Mean dissipated torque

The amount of work was obtained by calculating the area within the displacement-torque curve. Because the prescribed displacement was different for each experiment, the amount of work was normalized by dividing it by the angular displacement. This resulted in a parameter which was named the mean dissipated torque. Comparing mean dissipated torques would only be fully correct if during the experiment the used ROM is the same part of the total available ROM for each subject. Figure 27 illustrates two abduction experiments on two different subjects. The left graph shows an exponential course. This shape is consistent with previous reports of passive torque-angle relationships where the ankle was moved through the whole ROM\textsuperscript{79}. In the right graph there is no exponential increase in torque. This suggests that there was some ROM left and thus that the operator failed to use
as much ROM as possible. Normalizing the amount of work by dividing it by the total displacement is not entirely correct.

Figure 27, Left: Displacement torque graph for an abduction experiment. Right: Graph of the same experiment on another subject. The left graph shows an exponential increase in torque which is not visible in the right graph.

Considering the results however, this did probably not have a major impact. Besides that, the error can be found within the healthy group as well as in the clubfoot group which compensate each other. Taken together, normalizing the amount of work was an approximation and a limitation in this study which can be overcome by using the same percentage of the ROM for each subject.

4.7 Comparison gold standard

On average, when the orthopaedic surgeon claimed the foot was stiff, the stiffness of the clubfoot turned out to be higher than the mean stiffness in 57% of the patients. This means that there was an overlap in rating a clubfoot as “stiff” of 57% between the gold standard and the measured stiffness. Comparing the calculated stiffness to the mean stiffness of the group is debatable however. During the experiments it was clearly noticeable that big feet were relatively harder to displace in dorsi- and planarflexion compared to small feet, which resulted in a higher torque and a higher stiffness. Big feet are therefore always more likely to be stiff and small feet not stiff according to the calculations, which results into incorrect ratings. Moreover, it was concluded at the end of the experiment that the form which was used to rate each clubfoot (Appendix 2) was not suitable and should be extended in order to rate each clubfoot more accurately. According to the surgeon, this should be done by also rating whether the Achilles tendon feels shortened or not.

4.8 Physical size dependency

In order to correct for the described effect of the physical size on the stiffness, shoe size was chosen as a covariance. Age might seem to be a more logical choice, since it captures not only physical size, but for example also the maturity of the joint. Correlation analysis
however showed no significant correlation between the calculated stiffness in dorsi- and plantarflexion and age. This is not entirely unexpected, since not all young children have small feet, and not all old children have big feet. The observed effect of bigger feet needing more torque to reach a displacement together with the result that age and stiffness are not correlated, suggests that foot weight has a bigger confounding influence on the calculated stiffness than the joint maturity within the investigated age category. As a consequence, shoe size had the highest correlation with stiffness and was therefore chosen as the covariance. The question remains if shoe size is the optimal measure. In future research more parameters such as bone age, status of ligaments and gravity should be taken into account in more detail. It would be beneficial to repeat the experiments on children of the same age and the same shoe size, with a more extensive gold standard measurement as a comparison.

4.9 Comparison stiffness clubfoot and healthy feet

Within ab- and adduction, the stiffness1 for clubfoot was found to be significantly larger than for healthy feet. When taking gravity into account, the stiffness within dorsi- and plantarflexion also was found to be larger for clubfoot, which is in correspondence with the hypothesis. However, no significant difference was found for the stiffness2 of ab- and adduction. This is likely due to the method that was used to calculate stiffness2, which had low ICC values and thus was not reliable. As discussed earlier, a more accurate algorithm that is able to find the optimal splitting point between stiffness1 and 2 is desirable. Moreover, stiffness2 is also dependent on the maximal displacement. The maximal displacement was found to be significantly smaller for the clubfoot group. This was expected, since it is well known that clubfeet have a smaller ROM\textsuperscript{81}. As mentioned before, a ROM measurement should be done prior to the stiffness experiments. When calculating the stiffness, the same percentage of the ROM should be used for every subject where the exponential zone is reached, without discomforting the subject.

4.10 Difference stiffness clubfoot and healthy feet

Considering the finding that a clubfoot is stiffer than a healthy foot, an important question remains what causes this higher stiffness in clubfeet. As explained earlier, joint stiffness enclose all contributions from structures located within and over the joint which includes ligaments, muscles, tendons, joint capsules, skin, subcutaneous tissue, fascia and cartilage\textsuperscript{56}. It is known that clubfeet have morphological abnormalities of vascularity, bone and soft tissue\textsuperscript{16}. Considering the factors which influence joint stiffness, it is likely that the morphologic changes in clubfeet have an effect on the hind foot stiffness. Additionally, research also shows that changes in morphology and severity are highly correlated\textsuperscript{82}, which might suggest that stiffness and severity of the clubfoot deformation are correlated. The orthopaedic surgeon believes that especially the flattened talus deformity has a big impact on the stiffness. Other research however suggests that this deformity might be caused by forced dorsiflexion of the foot, in an attempt to reduce the clubfoot condition\textsuperscript{83}.  

44
Nevertheless, in order to investigate whether the morphological changes in clubfeet influence the stiffness and to what extent, a foot model can be used. In chapter five such a model is introduced.
5. Foot model

5.1 Introduction

As discussed before, the ankle stiffness felt by the orthopedic surgeon may be of great importance to determine severity of clubfeet and the occurrence of relapses. In a biological context, passive stiffness is provided by the combination of the joint, tendon and connective tissue, whilst all muscles are relaxed. In order to determine to what degree each factor has an influence on the clubfoot stiffness, each factor should be analyzed separately. A specified model can be used to determine which parts of the foot characterize the ankle stiffness.

Different models which describe the foot anatomy and function during gait already exist. The Anybody Glasgow-Maastricht foot model is an example of a fully detailed model which includes all bones of the human foot and its corresponding joints together with all intrinsic and extrinsic muscles and ligaments. The problem with the already existing models is that they all are designed for an adult foot. Scaling down to a children’s foot is not straightforward due to different bone shapes and calcification status.

A Surrogate Biomodel was developed by Dimeo et al. 2012 which simulates biomechanical characteristics in the lower extremities of five-year-old clubfoot patients. However, Dimeo focuses on research regarding clubfoot bracing, where this model potentially can be used for the fine-tuning of the brace parameters. Franci et al. 2009 demonstrated that the passive motion in the ankle joint is determined by the articular surfaces and ligaments. It is well known that for young children with clubfeet bone deformations occur. Ippolito et al. 2003 showed that also for older subjects, who have been treated for clubfoot in the past, multiple deformations still exist. A decrease in length of the talus and calcaneus, together with a decrease in distance between the medial malleolus and the navicular and a decrease in height of the trochlea of the talus were found. An important feature which was found by Swann et al. 1969 is the flattening of the superior surface of the talus, which was also noticed by the orthopaedic surgeon and confirmed by Koopmans et al. (2016). This leads to restriction of the movements towards dorsiflexion and plantarflexion and may cause difference in ankle stiffness.

A dorsiflexion movement can be considered as the talus head which rolls over the tibia. A certain torque is needed in order to engage this angular rotating of the talus. When the talus is flattened however, the joint between the talus and tibia is no longer congruent. Hence, more torque would be needed in order to achieve the same angular displacement of the talus, compared to a normal talus of a healthy foot. It is hypothesized that a flattened talus needs more torque to achieve a certain angular displacement compared to a healthy round talus. In this chapter, the aim was to take a first step in developing a finite element model (FEM) of the talus and tibia in which angular displacements could be prescribed to the talus.
Additionally, the reaction torque needed for the rotation could be calculated and compared between a healthy and flattened talus.

5.2 Methods

Model development

CT images of one healthy subject were obtained from hospital archives. The only inclusion criterion was a normal skeletal structure meaning that there were no bone deformities, and a congruent upper and lower ankle joint. The CT images were analyzed using software packages Mimics Research 18.0.0.525 and 3-matic research (Materialise software n.v., manufactured in 2015).

In order to distinguish the bone region, a threshold value of 226 Hounsfield units (HU) was used which was predefined. A 3D mask was then created to visualize the shape of the bones which resulted in Figure 28 below.

Figure 28, the bone region is distinguished due to the threshold value. All bones are visible now, and some are still connected to each other.

All bones were visible now, but holes were still present and some bones were still connected to each other. By using Region Growing and Subtraction algorithms, each bone was individually marked. The small holes that were still visible in the bones were closed by using the Wrap function with a closing distance of 1 mm. This resulted in Figure 29, left. Since only the talus and tibia were of interest, the other bones were left out, Figure 29 right.
Meshing & material properties

The segmented bones were exported to Marc Mentat (MSC SimCompanion Software Marc Mentat 2014). Linear tetrahedron elements with four element nodes (QUAD(4)) were used to create a volume mesh, see Figure 30.

A mesh was created of the talus and the bottom part of the tibia. In order to simulate the cartilage, the existing mesh was dilated with an additional surface of 1 mm thickness from which the original mesh was subtracted. Four contact bodies were defined: Talus, tibia, tibial cartilage and talus cartilage. Using the Contact Properties in Marc Mentat, the cartilage surface was glued to its bone. Additionally, contact was also defined between the cartilage of the tibia and talus. The talus and tibia were held together by modeling two ligaments as a
spring with a Young’s modulus of 0.26 GPa\(^{88}\) (red line, Figure 30). A linear elastic material model is assigned to bone and cartilage. For bone a Young’s modulus of 12 GPa and Poisson ratio 0.4 was used, for the cartilage these were 0.5 MPa and 0.25 respectively\(^{89}\).

**Simulation**

Rotation and translation in x, y and z direction was restricted for the nodes of the upper surface of the tibia, see Figure 31.

![FE mesh of the lower part of the tibia. The nodes of the upper surface, colored in green, are restricted to rotate and translate in x, y and z direction.](image)

Next, a rotation was applied to a node which was located in the center of the talus, Figure 32. This was considered as the reference node. In order to rotate the whole talus, eight other nodes spread over the talus were linked to the reference node by using rigid body elements. A rotation of 0.15 rad around the x-axis was applied over 10 increments, using an updated Lagrangian analysis.

![Rotation node](image)
5.3 Results

Applying a rotation of 0.15 rad led to shear strains which can be seen in Figure 33 below.

![Figure 33](image)

In Figure 33 it can be seen that the talus experiences a peak shear strain in a couple of areas. The shear strain found on top of the talus is likely due to the contact which the talus experiences with the tibia in that area. The locations of the shear strains in the bottom of the talus seem to match the locations of the nodes which were linked to the reference node that was set to rotate.

5.4 Discussion

In this chapter the first step was taken to develop a FEM of the talus and tibia in order to simulate a dorsiflexion movement which is approximated as a rotation of the talus head over the tibia. By prescribing a rotation, the reaction moment can be calculated. The hypothesis was that a flattened talus head leads to a bigger reaction moment compared to a round, healthy talus head. In this study, simulations have only been performed on a healthy talus head and only results of shear strain were obtained.

When looking at Figure 33, it is noticeable that shear strains were present in several areas within the talus. Since contact was defined between the talus and tibia, the shear strains on top of the talus were expected. While the talus rotates it touches the tibia which causes stress and thus may result in strain. The shear strains in the middle and bottom of the talus were likely due to the rigid body elements which were used to link nodes from the talus to
the reference node. These results suggest that defining contact between the talus and tibia, and linking nodes from the talus to the rotating reference node succeeded.

The developed FEM was the first step to a more realistic model of the talus and tibia. However, the used model in this chapter has some limitations and thus it is not suitable yet to test the hypothesis. Firstly, the linkage between the rotating center point of the talus and the other nodes should be optimized. Additionally, when the talus head is rotating, the only contact which it experienced in this model was the contact with the cartilage of the tibia and two ligaments. The location of these attachment sites of the ligaments was arbitrarily chosen in this study. It would be more realistic to implement the anatomical location of these attachment sites. These can be obtained by looking at MRI images or using a commercial human data base. Moreover, the cartilage was now modeled as a 1 mm thick surface over the whole talus and tibia. A next step would be obtain the cartilage from MRI images.

In this model, both the bone and cartilage were modelled as a linear elastic material. Cartilage however shows viscoelastic behavior which can be divided into flow dependent and flow independent behavior. More complex material models, like the biphasic material model, can take this viscoelastic behavior into account.

By optimizing the model, a more accurate simulation can be done in order to obtain the reaction moment of the talus. Once this is achieved, the next step would be to repeat the simulation on an artificially flattened talus head and compare the obtained reaction moments between the healthy and flattened talus head. Hereafter, real CT images of a flattened talus could be used and the model can then be made more realistic by adding joint capsules, skin and flesh elements to it.

5.5 Conclusion

A first step has been made towards a foot model where a rotation of the talus is prescribed where after the reaction moment can be calculated. The developed FEM was not suitable yet to test the hypothesis, and it is clear that the model needs further improvement.
Acknowledgements

I would like to thank the people from the hospital and university who helped me to do this research.

First I would like to thank Marieke van der Steen from the Catharina Hospital Eindhoven who supervised me. Marieke always thought along whenever problems came up, kept me up to date on patients for the experiments, provided METC approval and was always in for a chat. I also would like to thank Bert van Rietbergen who supervised me on behalf of the Eindhoven University of Technology. His critical thinking helped me a lot within the development of the TDH and the FEM. I would like to thank Arnold Besselaar for sharing his knowledge on clubfoot(treatment) and letting me perform the clinical measures. Arnold has also a good sense of humor, he even took the time to email me in the weekend while he was in Germany to report that he saw me on television. Additionally I like to thank Max Reijman who sometimes was present in the meetings with Marieke as well, Max called al my ideas and results in question which forced me to stay alert.

The staff of the CZE and MMC for keeping me up to date on new patients.

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And lost but definitely not least, I would like to thank my friends for supporting me, my brother and parents encouraging me and my colleagues at the university for the good and bad times at the working space.
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Appendices
A1. Validation experiments

Experiment 1

Adjusted parameters:

Slope TDH: 0 degrees, Attachment weights: close, 
side with respect rotating point: left

Reference voltage without weights 
V ref = -180 mV

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<th>Voltage difference [mV]</th>
<th>Slope [mV/g]</th>
<th>Mean Slope [mV/g]</th>
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Biggest difference within repeated measures: 2 mV
**Experiment 2**

*Adjusted parameters:*

Slope TDH: 0 degrees, Attachment weights: far, side with respect rotating point: left

Reference voltage without weights

\[ V_{\text{ref}} = 180 \text{ mV} \]

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*Biggest difference within repeated measures:* 2 mV
Experiment 3

Adjusted parameters:

Slope TDH: 0 degrees, Attachment weights: Close, side with respect rotating point: right

Reference voltage without weights

$V_{\text{ref}} = -326 \text{ mV}$

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Biggest difference within repeated measures: 26 mV
Experiment 4

Adjusted parameters:

Slope TDH: 0 degrees, Attachment weights: far, side with respect rotating point: right

Reference voltage without weights

\( V_{\text{ref}} = -327 \text{ mV} \)

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<th>#2 [mV]</th>
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Biggest difference within repeated measures: 12 mV
Experiment 5

Adjusted parameters:

Slope TDH: 45 degrees, Attachment weights: close, side with respect rotating point: left

Reference voltage without weights
V ref = 216 mV

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<th>Slope [mV/g]</th>
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Biggest difference within repeated measures: 2 mV
**Experiment 6**

*Adjusted parameters:*

Slope TDH: 45 degrees, Attachment weights: far, side with respect rotating point: left

Reference voltage without weights

\[ V_{\text{ref}} = -215 \text{ mV} \]

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*Biggest difference within repeated measures: 7 mV*
Experiment 7
Adjusted parameters:

Slope TDH: 45 degrees, Attachment weights: close, side with respect rotating point: right

Reference voltage without weights
V ref = -326 mV

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Biggest difference within repeated measures: 4 mV
**Experiment 8**

*Adjusted parameters:*

Slope TDH: 45 degrees, Attachment weights: far, side with respect rotating point: right

Reference voltage without weights

\[ V_{\text{ref}} = -326 \text{ mV} \]

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<td>-644</td>
<td>-76.0</td>
<td>-0.152</td>
<td>0.152</td>
</tr>
</tbody>
</table>

*Biggest difference within repeated measures: 4 mV*
A2. Information letter

Betreft: Informatiebrief stijfheidsmeting (klomp)voet
Geachte heer/mevrouw,

Doel van het onderzoek

De klompvoet is een bekende aangeboren orthopedische aandoening. Het Catharina Ziekenhuis Eindhoven en het Maxima Medisch Centrum in Veldhoven zijn voor de klompvoet centra van expertise (klompvoetcentrum). Klompvoeten worden behandeld volgens de Ponseti methode, onderdeel van deze methode is een brace-periode tot het 4e levensjaar van het kind (zie figuur 1 voor een voorbeeld van brace die gebruikt wordt). Ondanks dat deze behandeling erg effectief is, is er nog maar weinig bekend over de ernst van de klompvoet en het ontstaan van eventuele relapse klompvoeten. Bij een relapse klompvoet is er sprake van een terugval, er zijn aanwijzingen dat dit te maken kan hebben met de ernst van de klompvoet en therapietrouw tijdens de brace-periode. Tijdens deze studie gaan we kijken of de stijfheid van de klompvoet een belangrijke rol speelt voor de behandeling van klompvoetjes, de uitkomst van de behandeling en het ontstaan van eventuele relapse klompvoeten.

Figuur 1: ADM brace gebruikt voor klompvoet bracing.

Waarom wordt u gevraagd om deel te nemen?

U ontvangt deze brief omdat u ouder/verzorger bent van een kind tussen de 5 en 8 jaar oud met klompvoeten of gezonde voeten. U bent gevraagd of u kind mee wilt werken aan een onderzoek betreffende de stijfheid/flexibiliteit van klompvoetjes. Om meer inzicht te krijgen in deze stijfheid/flexibiliteit is het van belang dat we de stijfheid van klompvoeten maar ook van gezonde voeten meten. Uiteindelijk zullen we de gegevens van de gezonde voeten kunnen vergelijken met de gegevens van de klompvoeten. Met de volgende meting kunnen wij meer inzicht verschaffen in de behandeling en het ontstaan van eventuele relapse klompvoetjes.

Hoe ziet de meting eruit?

Eerst zal er een aantal algemene gegevens verzameld worden zoals de lengte, het gewicht en de schoenmaat van uw kind. Dan zullen er een paar metingen aan de voeten en
onderbenen verricht worden. De omtrek van het onderbeen wordt opgemeten, en de lengte
van de voet. Ook wordt er gekeken naar de kromming van de voet.

Vervolgens wordt er opgemeten hoe bewegelijk de voet van uw kind is door op te meten
hoeveel graden de voet in elke richting kan bewegen. Uw kind krijgt dan een ADM brace aan
die bestaat uit een sandaaltje en een brace gedeelte, welke gebruikt wordt bij de
behandeling van klompvoetjes (figuur 1). De brace is echter zo aangepast dat deze
gebruikt kan worden voor de stijfheidsmeting. Nadat uw kind de ADM brace aan heeft
zal met behulp van een moment schroevendraaier het voetje van het kind
gedraaid worden over de twee vrijheidsgraden in de brace. Deze meting is niet pijnlijk
en valt binnen de bewegingsvrijheid van de voet van uw kind. De meting zal 3x herhaald
worden voor beide voeten in 4 verschillende richtingen. De voetenmoment
schroevendraaier geeft aan hoeveel kracht nodig is om het voetje te draaien. Deze kracht
staat dan als een maat voor de stijfheid van de (klomp)voet. Tijdens de meting is het de
bedoeling dat uw kind zich niet focust op zijn/haar voeten. De duur van de meting zal in
totaal 20-30 minuten zijn, waarbij het draaien van de voetjes enkele seconden per
herhaling duurt.

Wij vragen u voor toestemming bovenstaande stijfheidsmeting te mogen uitvoeren bij beide
voeten van uw kind en de gegevens van uw kind geanonimiseerd te gebruiken.

Indien u nog vragen heeft, kunt u deze natuurlijk stellen aan de aanwezige onderzoeker
en/of behandeld arts. Mocht u in een later stadium nog vragen hebben of nadere informatie
in willen winnen kunt u contact met ons opnemen via het telefoonnummer onderaan deze
brief. Bent u niet tevreden over het verloop van het onderzoek dan kunt u contact opnemen
met het onafhankelijke Bureau Patiënten belangen van het Catharina Ziekenhuis Eindhoven,
route 16, bereikbaar via telefoonnummer: 040-239 8410.

Met vriendelijke groeten,

P.A. Andrei
Stagiair onderzoek, afd. Orthopedie

A.T. Besselaar
Orthopedisch chirurg

M. Reijman
Senior onderzoeker

M.C. van der Steen
Wetenschappelijk onderzoeker
040-239 6527
A3. Stiffness score form surgeon

Soort klompvoet: Primair / Residu / Recidief

Stugge posterieure structuren: Ja / Nee

Ab/adductie: Stug / Soepel

Knie gebogen

Eindgevoel dorsaalflexie: Hard / Verend: beperkt / Niet beperkt

Knie gestrekt

Eindgevoel dorsaalflexie: Hard / Verend: beperkt / Niet beperkt

Opmerkingen:

Soort klompvoet: Primair / Residu / Recidief

Stugge posterieure structuren: Ja / Nee

Ab/adductie: Stug / Soepel

Knie gebogen

Eindgevoel dorsaalflexie: Hard / Verend: beperkt / Niet beperkt

Knie gestrekt

Eindgevoel dorsaalflexie: Hard / Verend: beperkt / Niet beperkt

Opmerkingen:
Case Rapport Form, stijfheidsmeting bij klompvoetjes

Datum van invullen: ______________ (DD/MM/JJ)

Leeftijd: ______________ jr

Geslacht: □ Man □ Vrouw

Gewicht: ___________ Kg

Lengte: ___________ Cm

Schoenmaat ___________

Links

Lengte Voet ___________ Cm

Lengte onderste extremiteit ___________ Cm

Omtrek onderste extremiteit 1 ___________ Cm

Omtrek onderste extremiteit 2 ___________ Cm

Omtrek onderste extremiteit 3 ___________ Cm

Gemiddelde omtrek onderste extremiteit ___________ Cm

Rechts

Lengte Voet ___________ Cm

Lengte onderste extremiteit ___________ Cm

Omtrek onderste extremiteit 1 ___________ Cm

Omtrek onderste extremiteit 2 ___________ Cm

Omtrek onderste extremiteit 3 ___________ Cm

Gemiddelde omtrek onderste extremiteit ___________ Cm

Klompvoet: □ Links □ Rechts □ Bilateraal □ n.v.t.

Studienummer prospectief cohort: ___________
**Sandaal keuze:** Omcirkelen wat van toepassing is.

<table>
<thead>
<tr>
<th>Lengte voet (mm)</th>
<th>80-85</th>
<th>86-90</th>
<th>91-100</th>
<th>101-110</th>
<th>111-120</th>
<th>121-130</th>
<th>131-140</th>
<th>141-150</th>
<th>151-160</th>
<th>161-170</th>
<th>171-180</th>
<th>181-190</th>
<th>191-200</th>
<th>&gt;200</th>
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<tbody>
<tr>
<td>Links</td>
<td>x</td>
<td>x</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
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<td>11</td>
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<td>x</td>
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<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
<td>x</td>
</tr>
</tbody>
</table>

**ADM keuze:** Omcirkelen wat van toepassing is.

<table>
<thead>
<tr>
<th>Sandaal</th>
<th>2-3</th>
<th>4-6</th>
<th>6-8</th>
<th>9-12</th>
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</thead>
<tbody>
<tr>
<td>Onderbeen Lengte</td>
<td>&gt;140</td>
<td>&gt;180</td>
<td>&gt;210</td>
<td>&gt;240</td>
</tr>
<tr>
<td>ADM Links</td>
<td>x-small</td>
<td>small</td>
<td>medium</td>
<td>large</td>
</tr>
<tr>
<td>ADM Rechts</td>
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<td>medium</td>
<td>large</td>
</tr>
</tbody>
</table>

**ROM meting (zonder brace)**

<table>
<thead>
<tr>
<th></th>
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<th>Rechts</th>
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</thead>
<tbody>
<tr>
<td>Dorsiflexie (°)</td>
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<td></td>
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<tr>
<td>Plantairflexie (°)</td>
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</tr>
</tbody>
</table>

**Bocht van laterale voetrand volgens Pirani (zonder brace) Omcirkelen wat van toepassing is**

0  0.5  1

**Neutrale stand meting (met brace)**

<table>
<thead>
<tr>
<th></th>
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<tr>
<td>Neutrale stand TTJ (°)</td>
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</tr>
<tr>
<td>Neutrale stand STJ (°)</td>
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</tbody>
</table>

**Bijzonderheden/opmerkingen:** ________________________________________________________