



MASTER THESIS

THE NEED FOR A STANDARDIZED ACQUISITION PROTOCOL FOR WHOLE LEG RADIOGRAPHY

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THE NEED FOR A STANDARDIZED AQCUISITION PROTOCOL FOR WHOLE LEG RADIOGRAPHY

Several affecters of the measured Hip Knee Ankle Angle and how to optimize the consistency of the Whole Leg Radiograph.

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1 PREFACE

After one year of hard work I can acknowledge one thing, there are still a lot of uncertainties regarding knee osteoarthritis and leg malalignments. What is certain, is that I am grateful to be a part of this research group. The past year was a very pleasant and instructive experience. Thank you Roel, Nienke, Willem-Paul and Kees to be a part of my mentor group. My thesis will enclosure our hard work with an end result which I am proud of.

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2 ABSTRACT

2.1 Objective

The purpose of this project is to find the effect of knee flexion, leg rotation and position of the X-ray source on the measured hip knee ankle angle (HKAA). Also, goniometric measurements are performed on the human leg regarding the angular relations between the feet and the knee. These results are used to create a standard whole leg radiograph (WLR) acquisition protocol in favour of the reproducibility.

2.2 Design

An *in vitro* experiment was designed using sawbones of the whole leg and foot, which were fixated with an Ilizarov frameset in different knee flexion angles and HKAA's. This model was placed on a rotary table, which induced leg rotation accurate to the degree. The X-ray source position was varied between three different heights when making the WLR's.

Geometrical measurements of the lower limb were performed on 67 CT scans. Angles between the Akagi line and the transmalleolar line, the 1st metatarsal line and the 5th metatarsal line were measured.

2.3 Results

The HKAA is underestimated with approximately 1 degree per 20 degrees of external leg rotation when the leg is in full extension (p = 0.000). However, when 5 degrees of flexion is added, the HKAA is overestimated with 0.8 degree per 20 degrees of external rotation (p = 0.000). When the leg is in 15 degrees flexion, the HKAA is overestimated with 4 degrees per 20 degrees of external rotation (p = 0.000). Leg rotation alone (P = 0.001) shows a significant effect on the measured HKAA however, flexion alone does not (P = 0.348). The height of the X-ray beam source does not affect the measured HKAA.

The geometrical measurements on the CT scans were conducted on 134 legs and resulted in the mean angles of 25.69° between the Akagi line and the transmalleolar line, -1.17° between the Akagi line and the 1^{st} metatarsal line and 16.06° between the Akagi line and the 5th metatarsal line.

2.4 Conclusion

In conclusion, with this project aimed on researching different possible affecters of the measured HKAA on a WLR. On top of that geometrical measurements were performed on human legs using CT scans and a feasibility research was conducted in the radiography room among the X-ray technicians. The results were used to design a WLR acquisition protocol with the aim on standardized radiographs. This protocol is implemented and steps are taken for future research studying the reproducibility of the protocol.

3 INTRODUCTION

Osteoarthritis (OA) is the most common knee joint disorder in the Netherlands [1]. Among adults of 60 years of age or older the prevalence of symptomatic OA is 10% in men and 13% in women [2]. It has a high incidence of 47,400 patients in 2017 in the Netherlands [3]. The estimated direct and indirect economic burden in the Netherlands is €10k per patient per year [4]. OA is a progressive joint disease marked by cartilage and bone breakdown. Thereby, associated with changes to all tissue in the knee joint, causing pain, stiffness, deformity and disability in many patients [5]. OA is a multifactorial joint disorder and strongly correlated with: increasing age, presence of other joint diseases, lifestyle variables (e.g. obesity, a history of manual labour, sports activities, cigarette smoking), comorbidities, gender and ethnicity [6].

Recently, there is an increasing interest in defining different phenotypes of OA. This seems important, as each phenotype requires a different treatment approach. Malalignment of the lower extremity (varus or valgus) is an important phenotypic trait of OA, where a varus malalignment is more common compared to a valgus malalignment [5]. Figure 1 illustrates a varus and a valgus malalignment. In most normal knees, approximately 60% of the weight-bearing force is transmitted through the medial compartment and 40% through the lateral compartment [7]. When there is a malalignment is relatively overloaded and one compartment is underloaded. This disbalance in mechanical forces might cause degenerative changes/OA in one compartment, while the contralateral compartment is well-preserved [6]. The opposite is also possible, where unicompartmental OA causes a malalignment due to tissue loss (cartilage and meniscus) in the medial or lateral compartment [6].



Figure 1: Illustration of three different human stances. The most left illustrates the normal stance, the middle a varus deformity and the left illustrates a valgus deformity [8].

The gold standard for determining alignment of the lower extremity is the weight bearing whole leg radiograph (WLR), from which the hip knee ankle angle (HKAA) can be calculated [9]. The HKAA represents the angle between the mechanical axes running from the centre of the femoral head and the centre of the talus to the centre of the tibial spines [5]. A WLR with the measured HKAA is illustrated in figure 2. Pathological varus or valgus HKAA is commonly defined as a deviation of more than 3° from the natural alignment, which is 180° [5], [10]. However, this straight alignment of 180° only occurs in 2.2% of the population [11]. Normal alignment in adults is generally considered to be between 1° and 3° varus [5].



Figure 2: A whole leg radiograph (WLR) with the measured hip knee angle (HKAA), which is the angle between two lines; one between the centre of the centre of the femoral head to the middle of the tibial spines. The other runs from the middle of the talus to the middle of the tibial spines.

When conservative treatment fails in the young and active patient with unicompartmental knee OA and a malalignment, a correction osteotomy is the best treatment option [12]. An osteotomy restores the healthy alignment and biomechanics of the knee joint, which preserves the joint and the anatomy of the knee. It is performed to stop or reduce the progression of OA in the knee joint and postpone or in some cases even avoid a total knee arthroplasty (TKA) [6]. With an optimal planning and accurate osteotomy, the performance of the osteotomy could set the TKA back for at least 10 years [12]. This means that young and active patients will be able to keep their lifestyle with work and/or sport much longer. Figure 3 illustrates a high tibial osteotomy and the shifting of the weight bearing axis.

An accurate WLR is actually also important when a TKA is inevitable. An optimal alignment with the weight bearing line through the centre of the knee favours the long term success of the TKA in terms of wear [13].





The tibia can be scaled into percentages as described by Fujisawa, with 0% at the medial side and 100% at the lateral side of the tibia [15], [16]. Current practice of a high tibial open wedge osteotomy aims on overcorrecting the mechanical load-bearing axis towards the lateral compartment, instead of restoring the natural alignment [15], [16]. Overcorrections are aimed between 60% and 70% on the Fujisawa scale, where Fujisawa recommends a range between 62% and 67% [15]–[17]. The range as recommended by Fujisawa corresponds with a precision of 0.45° wedge angle of the correction osteotomy [17]. This precision is needed for long term survival of the osteotomy and can only be achieved with an accurate pre-operative planning on available imaging techniques [18]. The WLR as illustrated in Figure is widely used for the pre-operative planning due to the weight-bearing position of the patient, which gives the most accurate HKAA [19].

From literature we know many positioning problems of patients during a WLR, which may affect the measured HKAA on a WLR. Known pitfalls are: knee flexion and extension, leg rotation, foot rotation, hip rotation, weight-bearing and foot positioning [5], [9], [27]–[32], [19]–[26]. It appears that there is a difference in foot positioning between a single or double legged WLR. However, no standard limb positioning protocol for the WLR is widely known or is being used [5], [13], [25], [28], [31], [33]. Sheehy and Cooke proposed a

standard protocol, but to the best of our knowledge it is not widely implemented or validated [5], [25].



Figure 4: Pre-operative planning on a WLR in 2D. On image A the red line represents the desired mechanical axis. The yellow line marks the cutting plane of the wedge. The green line runs from the hinge point of the osteotomy cut to the middle of the talus [34].

Pre-operative planning is prone to errors if patients are not positioned correctly, resulting in under- or overcorrection when performing a correction osteotomy. Differences in positioning pre- and post-operative will result in wrong interpretation of results. For instant postoperative pain affects the weight-bearing and therefore the HKAA. [19], [32]. Sanfridsson et al. conducted a research including 24 patients who underwent a correction osteotomy. These participants all got radiographs before and after the surgery, including their non-operated limb. They concluded with this test-retest study that there exists a mean error of 1.2° between the two measurements on different time points [35], [36]. This is illustrated in figure 5, where two WLR's (one before surgery, one after surgery) with the measured HKAA can be found. The non-operated leg shows a discrepancy of 0.9° over time. As said earlier, Jones et al. described a preferred osteotomy precision of 0.45° [17]. This means that currently with no standard protocol for making a WLR, the planned correction can fall outside the desired accuracy.



Figure 5: Whole leg radiographs taken from the same patient on different time points. The left image, before an osteotomy in the left leg, shows a measured HKAA of 6.6° in the right leg. The right image, after an osteotomy in the left leg, shows a measured HKAA of 7.5° in the right leg.

The positioning of the X-ray beam may also have consequences on the HKAA. Different projection angles may result in different HKAA's when beam positions are not standardized [37]. Katsui et al describe the changing angles within the ankle joint on a WLR, due to changing angles of the X-ray beam [38]. This could also be the effect when using the radiography system as in the UMC Utrecht, a Philips DigitalDiagnost v4.0 (Koninklijke Philips N.V., Best, the Netherlands), which uses a fixed X-ray beam height during acquisition where it rotates towards the upper and lower part of the limb. Each system with a similar rotating mechanism as illustrated in Figure 6 could face the same problem.



Figure 6: Graphical representation of the radiography system, with the tilting X-ray beam source, X-ray ruler and moving detector.

Many factors may have an effect on the measured HKAA and a validated standardized WLR acquisition protocol is required to improve patient diagnostics and treatments. The purpose of this study is to find the relations between the measured HKAA and leg rotation, knee flexion and X-ray beam height using sawbones of the lower limb in a sawbone study. Here after a standardized WLR acquisition protocol is created to improve the reproducibility of the measured HKAA. This acquisition protocol will be implemented in the current care in the UMC Utrecht, followed by a clinical study testing its reproducibility.

4 OBJECTIVES

In the current clinical practice, there exists no widely implemented acquisition protocol for a WLR. This results in positional varieties on radiographs, resulting in measurement errors of the HKAA. Non-reproducible HKAA measurements will lead to wrong diagnoses and failing treatments such as osteotomies. Jones et al. reported a desired precision of 0.45° for an osteotomy [17]. At the same time, Sanfridsson et al. reported a mean error of 1.2° in a test-retest reproducibility study for the measured HKAA on a WLR [39].

The main purpose of this project is to study several patient positional influences (leg rotation and knee flexion) and the influence of altering X-ray beam heights on the measured HKAA on a WLR. With a sawbone study the effects of these three parameters will be investigated.

Next to the results of the sawbone study, a CT study will be performed with the aim on mapping the angular relations between several bony landmarks in the lower limb. The angles between the Akagi line and the first metatarsal line, fifth metatarsal line and anteroposterior (AP) malleoli are included in this project. These landmarks will be described in the section "Development". The measured angles will be compared and combined with available literature.

After this an acquisition protocol will be developed, which eliminates inconsistencies between different WLR's. Our aim is to achieve a consistency of 0.45° with the developed acquisition protocol in a test-retest study. The acquisition protocol will be implemented as standard care.

A clinical study afterwards is designed to test the reproducibility of the implemented protocol. This study is eligible for the Medical Ethical Review Committee (METC), which means that it needs permittance of the same committee. Therefore, an application is submitted to the METC Utrecht.

The overall goal of this research is implementing a standard WLR acquisition protocol on behalf of the reproducibility of the measured HKAA.

5 DEVELOPMENT

5.1.1 Measurement setup of the sawbone study

It is important that the measured HKAA's of the measurement setup are reproducible and accurate. The interpretation of results relies on these angles with the first decimal place. This is based on the fact that osteotomy corrections need to be precise within the range of 0.45°. To achieve this precision, our measurement setup needs to be: angle stable, stable on the floor and angle adjustable. Measurements of the HKAA needs to be done in a reproducible manner. Also, human test subjects are not suitable for this study due to the radiation dosage of multiple X-rays. It is above all difficult for human participants to stand still for such a period of time.

An Ilizarov frameset (Smith & Nephew Nederland, Hoofddorp, the Netherlands) is chosen to keep the sawbones in a stable, but adjustable angle for the knee flexion and varus or valgus alignment [39]. The sawbones are strongly fixated to the Ilizarov frameset using Kirschner-wires (k-wires). A rotary table with adjustable rotation to the degree, holds the frameset and sawbones stable on a specific rotation angle. Metal spheres of 4 mm are put into the sawbones in the femoral head, tibial spines and talus, representing the measurement landmarks for the HKAA for an accurate measurement.

Solid foam sawbones (Sawbones Europe AB, Malmoe, Sweden) representing a left leg, including a femur, tibia, fibula, talus, calcaneus and forefoot were used. The sawbone model includes ligaments of the knee and ankle joint. The Ilizarov frameset fixated the sawbones in a predetermined position, in such a way that the HKAA was 5° varus or valgus and the knee flexion range from 0° to 15° [39]. The hinges had 2 degrees of freedom and were attached to the extractors of the Ilizarov frame. These extractors increased 1 mm per rotation. The whole measurement setup in the projection radiography room is shown in figure 7.



Figure 7: Measurement setup in the projection radiography room, with the Bucky system Philips DigitalDiagnost v4.0.

To determine the true AP plane, two Kirschner wires were implanted in the tibia and femur representing the Akagi line and the transepicondylar line. This Akagi line described by Akagi et al. is a marker for the rotation of the tibial plateau relatively to the femoral condyles, where 90° perpendicular to the epicondylar line represents a straightforward pointing tibia plateau and knee-joint [40]–[42]. This means that a knee joint with a straightforward Akagi line is in a AP position [40]–[42].

5.1.2 Measurement protocol for sawbone study

The changing positional parameters have to include enough alterations for the detection of measurement of errors, but also be representative for the current practice. The possible combinations of the parameters varus/valgus, leg rotation, knee flexion and X-ray beam height are listed in table 1.

5° varus and valgus was chosen as these are commonly seen and treated deformities [43]. In the current practice at the UMC Utrecht we noticed that the X-ray beam height varied between the knee joint and approximately 10 cm above the knee joint. For this reason, the X-ray beam height in the experiment varied between knee joint height, 5 cm above the knee joint and 10 cm above the knee joint.

Patients eligible for a high tibial osteotomy cannot present a flexion contracture of more than 15°. If this is the case, the surgery should be carefully reconsidered [15]. Our experiment includes the exclusion criteria of 15° knee flexion and the desired 0° of knee flexion. Also, a small flexion contracture of 5° knee flexion is implemented in our protocol to test whether it affects the measured HKAA on a significant scale.

The objective is to describe both the effects of internal and external rotation on the measured HKAA. A similar study using a cadaver leg performed by Radtke et al. used internal and external rotation up to 20° [13]. Brouwer et al. even rotated the leg up to 30° internally and externally [44]. Both found a linear effect of leg rotation on the measured

HKAA, but only Radtke et al. proved significance [13], [44]. This means that the measured effect should be predictable and it doesn't matter how much leg rotation is induced. Based on these studies our decision was to rotate the leg minimally with 10° internally and externally, and a step in between of 5°. This means potentially a smaller effect on the measured HKAA with less increment when interpolating to the neutral stance.

Table 1: The different parameters, varus or valgus, leg rotation, knee flexion and X-ray beam height.

Varus/Valgus	Leg rotation	Knee flexion	X-ray beam	heigh	nt	
5° varus	0°, 5°, 10°, -5°, -10°	0°, 5°, 15°	Knee-joint, above	5cm	above,	10cm
5° valgus	0°, 5°, 10°, -5°, -10°	0°	Knee-joint, above	5cm	above,	10cm

Protocol

The protocol developed for the sawbone study can be found in supplement 2. The most important parameter is keeping a steady and quick workflow, hence the short time available in the radiography room for the amount of WLR's. This means optimizing the workflow by choosing logical steps for adjusting the angles. Adjusting the knee flexion and varus/valgus angles are most time consuming due to the Ilizarov system and the needed control radiographs afterwards.

Before making the radiographs, we need to be certain that the stitching algorithm is performing properly. This can be tested by making an empty radiograph, where there is no object between the source and the detector. Only the standard measurement tape is present, which aids the stitching algorithm. Due to the exposure of only noise to the detector, the system only can use the measurement tape as a reference. When this is straight on the radiograph, we know that the system creates straight radiographs. The result can be found in figure 8.

The WLR's in figure 9 served as reference radiographs, where the model was set to 5° varus in 0° of rotation and flexion. From this reference position, different rotations of the sawbone model with different X-ray beam heights were applied for the WLR.



Figure 8: Empty radiograph with only the standard measurement tape.

Figure 9: Whole leg radiographs exported from PACS image viewer.

External rotation of the leg is described as positive and internal rotation of the leg as negative values. The same method was performed with the sawbones in 5° valgus with 0° flexion, 5° varus with 5° flexion and 5° varus with 15° flexion. The different parameters are listed in table 1. Figure 10 shows the model in flexed and extended position, also the sagittal and coronal plane are illustrated.



Figure 10: Different positions of the sawbone model. The left image shows a flexed position. The centre image shows a fully extended position. The right image shows the antero-posterior plane of the model, leg rotation means rotating from this plane and position.

5.1.3 Measurements of angular relations on CT

For the development of the WLR acquisition protocol we want to measure certain angles in the human leg. Using literature, we determined that a neutral stance of the knee joint with 0° rotation is found when the Akagi line points in the AP direction. This project aims on finding the angular relations between the Akagi line, the AP malleoli and the feet. The first metatarsus and fifth metatarsus were included to describe the angular relation between the Akagi line and the feet. This is only possible when using 3D scans of patients, where these anatomical structures can be related to each other. In the transversal plane each angle can be determined relatively to the Akagi line, which is illustrated in figure 11 on the following page.



Figure 11: Angular relations between the Akagi line (light blue) and the AP malleoli (dark blue), the 1st metatarsus (grey dotted) and the 5th metatarsus (green dotted).

6 METHODS

6.1.1 Sawbone study

The radiographs of the sawbone model were created in the radiography room following the protocol as described in supplement 2. Knee flexion and varus/valgus changes were executed with the help of a digital level. After each positional change of the model the angles were measured in PACS image viewer in the sagittal and coronal plane. This was achieved by turning the rotary table to 0° and 90°. The Illizarov frame was fixated on the rotary table using bolts. Each image was labelled with the amount of leg rotation, flexion, varus/valgus and X-ray beam height. Afterwards, the images were imported into PACS image viewer.

The images were analysed twice by one observer on independent time points with an hour in between. The angle measurement tool was provided by Sectra (Sectra AB, Linköping, Sweden) and integrated in PACS IDS7 19.3. With this tool the rater can set a point on the middle of the femoral head, the middle of the tibial spines and the middle of the talus. When these points are selected, the tool automatically provides the HKAA angle.

Radiography system

The used diagnostic radiography system is a Philips DigitalDiagnost v4.0, which uses a predetermined X-ray beam height during acquisition where it rotates towards the upper, middle and lower part of the limb. The fixed distance between the detector plate and X-ray beam source was set to 265 cm. The X-ray settings were equal to the protocol for scanning patients with kV set at 81 and modulating mAs. The rotary table was placed on the ground plateau in front of the detector, where a screen containing a radio translucent measurement tape was attached to. We made sure that the rotary table was placed in a straightforward position on the ground plateau using a measurement tape. This means that the rotary table is positioned parallel to the screen and detector plate on the ground plateau. The distance between both ends of the rotary table and the screen were respectively 7.5 cm.

The lead measurement tape served as a scale to determine the X-ray beam height. From the X-ray source, a laser beam points towards the measurement tape matching the X-ray beam height. The measurement tape aids the stitching algorithm of the radiography system, where 3 separate radiographs are combined and stitched to each other. The measurement tape also serves as a calibration method afterwards.

Statistical analyses

One observer rated the images twice on independent moments with one hour in between, where HKAA's were calculated in PACS IDS7 19.3 (Sectra AB, Linköping, Sweden) using the metal spheres as markers. The mean of the two measurements were analysed in SPSS version 25.0 software (SPSS, Inc., Chicago, IL, USA) with multivariable and univariable linear regression analyses. Correlations were tested on significance using a Pearson Correlation test. The intra-rater reliability between the two separate measurements was tested for agreement using a two-way mixed Intraclass Correlation (ICC) for absolute agreement.

6.1.2 Measurements of angular relations on CT

For this part of the project 67 patient CT scans from two different CT cohorts were included. The CT protocol of the first cohort did not focus on the positioning of the feet of the patients. The CT protocol of the second cohort fixated the feet in endo-rotation of 15°. 47 CT scans of the database with free ranging feet position and 20 CT scans with the feet in endo-rotation were included.

Measurements

Each angle was measured in the axial plane of the CT scan using PACS image viewer and an on-screen marker tool MB-Ruler (Markus-Bader, Iffezheim, Germany). The observer scrolled distally through the slices beginning at the tibial plateau determining the positions of the landmarks. Each landmark on the scan was marked with a point as can be seen in figure 12. The landmarks in sequence from proximally to distally are:

- 1. Tibial insertion of the posterior cruciate ligament
- 2. Medial border of the tuberosity
- 3. Medial malleolus
- 4. Lateral malleolus
- 5. Centre of calcaneus
- 6. First metatarsus
- 7. Fifth metatarsus

Angles were determined using the angle measurement tool in PACS image viewer, provided by Sectra (Sectra AB, Linköping, Sweden). Each measurement was performed once by one observer. The measured angles were formed between the following lines:

- 1. Akagi line: line from the tibial insertion of the posterior cruciate ligament to the medial border of the tuberosity.
- 2. Intermalleolar line: line from the medial malleolus to the lateral malleolus.
- 3. First metatarsal line: line from the centre of the calcaneus to the first metatarsus.
- 4. Fifth metatarsal line: line from the centre of the calcaneus to the fifth metatarsus.

Using the intermalleolar line, the AP malleoli was determined, which is the line perpendicular on this axis with the origin in the centre of the talus in the transversal plane.



Figure 12: Pointset of the landmarks on a CT scan of the right leg of a patient, representing: 1st metatarsus, 5th metatarsus, centre calcaneus, medial malleolus, lateral malleolus, medial border tuberositas and tibial insertion posterior cruciate ligament.

Population

For the cohort with no control of the feet positions, clinical data of adult patients with confirmed Pseudoxanthoma elasticum, who visited the UMC Utrecht the Netherlands, were studied. Scans were made with low-dose (<3 mSv) full-body CT scan without contrast, performed on CT-scanner Brilliance 64 (Philips, Cleveland, Ohio. Pseudoxanthoma elasticum is a monogenetic disorder with progressive calcifications of the skin, the Bruch's membrane in the eyes and the arterial wall. The control patients of this cohort consisted out of patients who underwent a similar low-dose full-body protocol.

For the cohort with the feet in 15° fixed endo-rotation the study included patients with predominantly tibiofemoral knee osteoarthritis and satisfy the clinical classification criteria of the American College of Rheumatology (ACR): Knee pain and three of the following criteria: over 50 years age, less than 30 minutes of morning stiffness, crepitus on active motion, bony tenderness, bony enlargement, or no palpable warmth. Patients with planned operations of the knee and hip were excluded. Also, patients with Osteosynthesis material near the knee joint were excluded.

7 RESULTS

7.1.1 Sawbone study

Intra-rater reliability

The intra-rater reliability has a correlation of 1.000 for the average measures and is significant with a *P*-value <0.05. The ICC is tested for measured HKAA's with one decimal place.

Effects of changing X-ray beam height and leg positions

X-ray beam height combined with knee flexion or leg rotation alone does not affect the measured HKAA on a significant level (table 2). Rotation alone influences the measured HKAA. Flexion interacts with leg rotation, making the measured HKAA unpredictable. The B value or gradient of 0.260 is highest when there is 15° of knee flexion combined with leg rotation. This means that the measured error is 0.260 with every degree of rotation when the knee is flexed in 15°.

Table 2: Multiple linear regression analyses of the effects of the parameters, leg rotation, X-ray beam height and knee flexion on the measured HKA. Knee flexion and leg rotation are tested on significant interaction. In the multiple linear regression models the parameters, 0° knee flexion & leg rotation and beam height knee joint, were considered as baseline (BL).

	95% Profile Likelihood Confidence Interval			
Parameter	В	Lower	Upper	Significance
Constant	5.157°	5.114°	5.201°	0.000
0° knee flexion & leg rotation	BL	BL	BL	BL
5° knee flexion & leg rotation	0.088°	0.082°	0.095°	0.000
15° knee flexion & leg rotation	0.260°	0.253°	0.267°	0.000
Leg rotation	-0.049°	-0.053°	-0.044°	0.000
Beam height knee joint	BL	BL	BL	BL
Beam height 5cm above knee joint	0.010°	-0.040°	0.059°	0.695
Beam height 10cm above knee joint	0.020°	-0.030°	0.069°	0.424

The results of the multivariable linear regression for the effects of rotation and knee-flexion angle on the measured HKAA showed excellent significant correlations. Knee flexion and leg rotation showed a significant interaction, meaning that the effect of leg rotation on the measured HKAA is affected by the amount of flexion. External rotation in combination with flexion caused the HKAA to be overestimated with larger errors under higher flexion. This is plotted in figure 13.



Scatterplot showing the measured HKA for different values of external leg rotation and knee flexion

Figure 13: Scatterplot of the measured HKAA for knee flexion angles and leg rotation angles. As the beam height had no effect on the measured HKAA, measurements with different beam heights were pooled. Trend lines described the relation between leg rotation and knee flexion, with the R-squared value and linear equation.



Boxplot of the measured angle between the Akagi line and AP malleoli & metatarsi

Figure 14: Boxplot of the measured angles between the Akagi line and the AP-axis of the malleoli, the 1st metatarsus and the 5th metatarsus. Blue box represents 75% of the angles, the lines gives the deviation without the outliers, which are presented as points.

7.1.2 Measurements of angular relations on CT

The angles between the Akagi line and the AP axis of the malleoli, the 1st and 5th metatarsus of the feet were measured. 67 CT scans of patients were included, which were measured bilaterally. The results are based on measurements of 134 legs and are presented in figure 14. The mean angle between the Akagi line and AP malleoli is 25.69° with a 95% confidence interval (CI) between 24.25° and 27.17°. The mean angle between the Akagi line and the first metatarsus is -1.17° with a 95% CI between -3.85° and 1.51°. The mean angle between the Akagi line and the first metatarsus is 16.06° with a 95% CI between 12.64° and 19.49°. The standard deviation (SD) of the mean angle between the Akagi line and AP malleoli is 8.414°, the 1st metatarsus is 15.211° and the 5th metatarsus is 19.411° (Table 3).

Table 3: Table with the measured mean angles and their the standard deviations between the Akagi line and the AP malleoli, 1st metatarsus and 5th metatarsus.

Parameter	AP malleoli	1 st Metatarsus	5 th Metatarsus
Mean Angle	25.69°	-1.17°	16.06°
Standard Deviation	8.414°	15.211°	19.411°

8 IMPLEMENTATION

8.1.1 Sawbone study

The findings of our sawbone study, suggest that leg rotation alone does influence the measured HKAA significantly. Also, when adding knee flexion, the measured HKAA becomes very unpredictable. We found that the HKAA is underestimated with approximately 1 degree per 20 degrees of external leg rotation when the leg is in full extension. However, when 5 degrees flexion is added, the HKAA is overestimated with 0.8 degree per 20 degrees of external rotation. When the leg is in 15 degrees flexion, the HKAA is overestimated with 4 degrees per 20 degrees of external rotation. The same results showed no significant effects when different X-ray beam heights were combined with leg rotation or knee flexion on the measured HKAA. These measurement errors exceed the desired osteotomy accuracy of 0.45 degrees of wedge opening [17].

Maybe more important, when the knee is in full extension, the leg can rotate 10° before exceeding the desired accuracy of 0.45°. Also, we can focus on eliminating the leg rotation when designing the WLR acquisition protocol, hence knee flexion and X-ray beam height does not influence the measured HKAA in a straightforward leg.

8.1.2 Angular relations on CT

From the results of this project we can conclude that the mean angle between the Akagi line and AP malleoli is around 25° with a SD of 8°. Also, when the Akagi line is straightforward, the line from the calcaneus to the 1st metatarsus is somewhat straightforward and the line from the calcaneus to the 5th metatarsus is in 15° external rotation. An important remark is the SD of the measured angles, where this can be up to 19° for the foot and 8° for the malleoli.

8.1.3 **Literature**

We used literature to compare our results regarding the position and angles in the lower limb. The tibial rotation between the Akagi line and AP malleoli is very comparable to our result, with 25° [41], [45]–[50]. Direct measurements between the Akagi line and foot angles are to the best of our knowledge not described yet. But we can combine several studies and conclude that the angle between the longitudinal axis of the foot and the Akagi line is somewhat 10°[51]–[58]. We eventually chose the longitudinal axis of the feet, as it is more described in literature and used as foot positional marker in the axial plane. Thereby, this landmark less prone to alterations due to deformities [59].

8.1.4 **Experiences radiology**

The experiences of the X-ray technicians in the radiography room are of great importance. To gather this information, we have monitored several days were WLR's were taken of patients.

There were three major problems affecting the consistency of WLR's. The first problem was the workload. The new acquisition protocol cannot add too much time to the workflow of X-ray technicians. This will eventually result in incoherence to the new protocol. The extra step should be minimal or can be performed within a minute and is preferably ready to use each time.

The second problem is caused by the fact that there are many X-ray technicians. Each X-ray technician had his or her own interpretation of a straightforward leg. Thereby there was no strict protocol which resulted in interpretational errors. The protocol should eliminate interpretational errors by making the instructions straightforward and easy to follow. Also, the protocol should be durable and robust, hence when something breaks the protocol cannot be followed.

The last problem was caused by the lack of understanding the importance of consistent WLR's. Two teaching moments were organised to explain the whole process of treating a malalignment and the importance of consistent radiographs. The first moment was at the beginning before the sawbone study. The second teaching moment was organised to explain the results of this project when the project was finished.

During all these sessions, we noticed that time and workload is of great importance. Clear and simple instructions, which are not time consuming will eventually result in more reproducible radiographs.

8.1.5 **Implementation phase**

We propose a more standardized and uniform approach for the positioning of the patients, which is easy to implement in the current care. We believe that the Akagi line is a good representation of the AP alignment of the knee-joint, described by Akagi et al. as the line between the centre of insertion of the posterior cruciate ligament to the medial border of the tuberosity [41], [42], [60], [61]. When using literature describing the tibial rotation, the mean is about 25 degrees external, where there is no difference between OA patients and healthy population [47], [49], [62]–[65]. This angle was between the Akagi line and the AP malleoli, which is perpendicular to the talocrural joint axis [42], [48], [49], [62]–[64], [66], [67]. The angle between the Akagi line and longitudinal axes of the feet in neutral stance is around 10 degrees, and 0 degrees with the first metatarsus [48], [49], [51], [52], [54], [55], [57]. Our results showed that there is a significant difference in measured HKAA when aligning to the Akagi line or the malleoli, with a difference of 0.5 degrees which is more than the desired precision of 0.45 degrees [17]. Therefore, we strongly advise against aligning the leg for a WLR using the ankle fork.

The new standardized WLR protocol should focus on eliminating leg rotation and account for the mean tibial rotation. We propose that patients are positioned in full extension with a distance of 10 cm between the feet. Rotation of the leg is controlled using the feet, hence using the ankle is more prone for interpretational errors. The feet are pointed outwards with 10 degrees of rotation. This is achieved by placing two feet on the ground with an angle of 20 degrees between the two. The angle of 20 degrees is situated between the longitudinal axes of the feet, which run from the centre of the heels to the second distal phalanges, so that the foot is rotated 10 degrees externally from the AP plane. The patients can easily place their feet onto the template on the floor, a graphical representation can be found in figure 15. X-ray technicians thereby control the hip rotation, by placing the upper body in a straightforward position. No handlebars or support are allowed, to ensure full weight-bearing. The X-ray technicians additionally instruct the patient to distribute the weight equally over both legs.



Figure 15: Template of the foot position, which is printed and placed on the floor. The lines on the feet represent the longitudinal axes with 20 degrees between them.

Afterwards a testing phase was introduced. During this phase we have introduced the new protocol to the working X-ray technicians. After working with the new protocol, occurring problems were assessed. For instance, a group of patients were unable to put their feet against each other, which resulted in the choice to put them 10 cm apart. We also checked the radiographs on any standouts, like rotational errors or missing anatomical landmarks. A patient WLR taken using the new acquisition protocol is presented in figure 16. After finishing the test phase, a training moment is organised to explain the new protocol including the findings of the testing phase.



Figure 16: A whole leg radiograph taken from a patient, after the implementation of the acquisition protocol.

9 DISCUSSION

With this project we aimed to develop a standard acquisition protocol for a WLR, that produces reproducible radiographs. The protocol takes the most important parameters affecting the measured HKAA and the spatial position of the knee joint into account in a user-friendly way. The results of the sawbone study showed that leg rotation is the most important positioning parameter, where knee flexion only affects the measured HKAA in combination with leg rotation. The X-ray beam height does not influence the measured HKAA. The main result of the CT study shows us that the longitudinal axes of the feet should be pointed in 10° exo-rotation, in favour of the straightforward positioning of the knee joint. The experiences when monitoring the radiographers shows us that a new protocol should be user-friendly and have little impact on the workflow.



Figure 17: Developed setup of the positioning protocol for a Whole Leg Radiograph. On the ground the board with feet templates, the moving detector and the measurement tape.

Our developed protocol uses a feet template printed on a board, which can be placed on the floor in front of the detector. This aid puts the feet in 10° exo-rotation between the longitudinal axes. The setup of the developed protocol can be seen in figure 17. The X-ray beam source can be placed on any height between the knee joint and 10 cm above

the knee joint. This height depends on the limb length of the patient, which determines the desired field of view and therefore the X-ray beam height.

Subsequently, our next objective is to test the reproducibility of this newly developed protocol using a test-retest principle. Since this research requires an extra radiograph, the study is eligible for the METC commission. An application is submitted and after approval participants can be included.

Besides the need for a standardised protocol, it is still uncertain what the true AP position of the knee-joint is. Another point of discussion concerns if the correction should be measured on standing static radiographs or dynamic gait analyses. Imai et al. did report the orientation of the Akagi line in neutral stance in relationship to the anterior pelvic plane, which is indeed 0° and straightforward [40]. Still, it might be that patients are better off with corrections based on kinetic gait analyses, where varus/valugs angles are based on the maximum peak force moment during the terminal stance phase [7].

Measurements of angular relations leg on CT

Currently in our practice the desired osteotomy correction is calculated based on standing WLR's, as in most hospitals. This translates into the fact that not much is known regarding the true AP position of the knee joint, or even which landmark to use. Therefore, a straightforward Akagi line was chosen as true AP alignment of the knee-joint based on literature [42]. We concluded that the angle between the longitudinal axes of the feet have to be 20° in favour of a straightforward Akagi line. However, there are deviations in these angles between patients and even patients can present differences between their left and right limbs.

When interpreting the results of the sawbone study, leg rotation up to 10° is acceptable. Hence this will result in an error of 0.5° in the measured HKAA, which is nearly the same as the described and desired osteotomy accuracy of 0.45° [17]. In other words, rotational deviations up to 10° are for now acceptable.

When combining these findings with the results of the CT study, it can be concluded that the deviations of 15° and 19° between the Akagi line and feet are too high. This means that positioning the feet using our template will not be representative for the whole patient population. When comparing the deviations of the CT study with literature it can be concluded that, the deviation of the angle between the longitudinal axis of the feet and the Akagi line is less than 10° [54], [55], [68], [69]. This difference can be explained by the fact that scans of patients were included originating from two different databases. One database contained scans of patients which are made with a fixed feet position of 10 degrees endo-rotation, and the other database contained scans of patients with free feet using only the cohort with fixed feet position it resulted in 10° for the 1st metatarsus and 11° for the 5th metatarsus. Both deviations lie around the 10° acceptable rotational deviation.

The rotational angle of the legs of patients with knee OA seems to differ from healthy legs, with a decrease in external rotation which can be up to almost 10° [70], [71]. Also, there is a difference between lateral and medial OA patients in femoral and tibial rotation [70]. This means that measuring the angles between the Akagi line and the feet using healthy patients is possibly not representative and there should be a distinction between medial and lateral compartmental OA patients.

From the results of the CT study a comparison can be made between OA patients and healthy patients regarding the tibial rotation, using the angle formed by the AP malleoli and the Akagi line. Hence this study includes two separate cohorts, where one cohort exists out of 20 OA patients. There is a significant difference between the two groups with a *P*-value < 0.05. The mean tibial rotation of the OA cohort was 21° and the cohort with healthy limbs was 28°. Our results are comparable to the current literature with a decreased tibial external rotation in OA patients [70], [71].

For the CT study the angles of the lower limbs are measured in supine position which lacks weight bearing. At the same time it is known that lower limb shapes and angles can differ with weight bearing compared to non-weight bearing [19], [23], [24], [27], [29], [32], [38], [72]. Unfortunately, there is no other way to precisely measure the angular relations between the feet and Akagi line. These measurements require an axial viewing direction of the whole tibia and foot. For this reason, the results were compared and combined with available literature. Lamm et al. conducted a study investigating the biomechanics of the foot and ankle, using weight bearing radiographs [54]. However, they did not report the angle between the transmalleolar axis and the Akagi line. Interesting fact is that the angle between the first metatarsal line and the longitudinal axis of the feet is around 8° [54]. This is comparable to our results.

Chang et al. studied the relationship between the longitudinal axes of the feet and the progression of OA during gait. They reported an average angle of 21.3° between the longitudinal axis of the feet and the direction of forward progression [53]. This means that the reported longitudinal axes of the feet by Chang et al. are larger than our measured results [53]. However, we think that this can be explained by the included research population, which are OA patients. On the contrary, the patient population from this research consisted mainly out of control patients with presumably healthy cartilage. Gait analysis studies prove that there is a relationship between medial or lateral OA and toe angle [53], [73]. Thereby, the Akagi line was not described by Chang et al. and to the best of our knowledge, no study describes the angle between the Akagi line and longitudinal axis of the foot [53]. It is possible that the Akagi line differs in orientation when the patient is standing or walking.

It would be useful to study the relationship between the Akagi line and the feet positions during gait, to get more information about the correct plane for goniometric measurements of the lower limb. Also, only OA patients should be included, hence there is a difference in the lower limb rotation between healthy and OA limbs.

Sawbone study

During the sawbone study only leg rotation and knee flexion were chosen as variable positioning parameters, as these parameters affect the measured HKAA most significantly [25]. Also we hypothesize that the effect of altering X-ray beam heights are most prominent with great valgus or varus 'deformities', which are mimicked when knee flexion and leg rotation are combined [44]. Our results proved otherwise, where larger varus or valgus deformities showed no evidence that an altering X-ray beam height affects the measured HKAA. This can be concluded from figure 13, where larger measured HKAA angles did not present differences caused by altering beam heights.

Further, it is debatable if larger alterations of X-ray beam height can affect the measured HKAA. Only three beam heights were included with a range of 10 cm. It is possible that a larger range can cause significant measurement errors. However, the expectation is that this will not be the case since the distance from the X-ray source to the detector is sufficient. The same is applicable to knee flexion. This parameter without leg rotation is only tested in three different angles, 0°, 5° and 15°. It is possible that larger flexion angles create significant measurement errors. But at the same time, these patients are not eligible for osteotomy and therefore not in the scope of this project.

Significant effects of leg rotation on the measured HKAA were expected and our results correspond with literature [5], [13], [25], [44]. Radtke et al. conducted a similar study with sawbones and found a linear regression model for leg rotation of $y = 5.9822 + 0.0558x_1$ for a valgus alignment, which is very similar to our found model [13]. However, they did not study the relations between knee flexion, leg rotation and X-ray beam height.

Also, Brouwer et al. conducted a comparable study investigating the relationship between leg rotation and knee flexion and their effect on the measured HKAA, where flexion and rotation were manipulated to a cadaver leg [44]. They concluded that the measured HKAA is only significantly affected when leg rotation and knee-flexion are combined [44]. In contrary, our research resulted in significant effects of leg rotation alone, where knee flexion combined with leg rotation changes the amount measurement error. The difference could be explained by the fact that Brouwer et al. only described the HKAA in whole degrees, where we aimed to be precise on a tenth of a degree. This is needed due to the described preferred accuracy of 0.45° by Jones et al. for an osteotomy treatment [17]. When interpolating the results of Brouwer et al., the slope of the measurement error as a result of leg rotation is similar to our results [44].

Brouwer et al. presents an formula describing the how the measured HKAA is altered as a result of changes in leg rotation and knee flexion [44]. When we use this formula to calculate or predict the measured HKAA, the results are very similar. This means that faulty leg positions can be corrected using this formula described by Brouwer et al. or the regression formula as the result of our study, when knowing the leg rotation and knee flexion.

To the best of our knowledge only two studies describes the test-retest reproducibility of the measured HKAA. Odenbringh et al. performed two WLR's in eight patients in the AP direction with 10 degrees flexion and rounded the measured HKAA's to whole degrees. They found a mean error of 1.3 degrees between the first and second WLR [74]. We believe that the protocol for the WLR should avoid flexion, as flexion is difficult to standardize within patients without a 3D imaging system and varying flexion may bring large uncertainties in the measured HKAA. Sanfridsson et al. performed a test-retest reliability study with both knees in full extension of 24 patients and found a mean difference of 1.2 degrees [35]. From both studies we can conclude that the current practice does not produce reproducible radiographs within the error margin of 0.45 degrees as described by Jones et al. [17].

Cooke and Sheehy proposed a protocol with the purpose of eliminating leg rotation, at the same time accounting for each torsional deformity of the tibia [5], [25]. They proposed that X-ray technicians align each leg using a rotating platform for the feet. Each rotating platform with a foot would be fixed to a certain amount of rotation, determined by flexing the knee and observe the frontal plane while making sure that the flexion plane is in line

with the X-ray beam [5], [25]. Or in other words, when the knee flexion plane is in a straightforward position. However, we are not convinced that this method is sensitive enough. It is also more time-consuming and heavily relies on the skillset of each X-ray technician.

Our sawbone study had some limitations. First, the position of the hinge points of the Ilizarov frame are not parallel to the knee-joint, but 10 cm above the knee-joint. This means that adding varus and valgus to the sawbones, will also result in some translation of the femur. The same accounts for adding flexion and extension. However, this movement corresponds with the anatomical flexion of a human knee, where the rotation point is situated above the knee-joint [75], [76]. We checked every position with a frontal antero-posterior and lateral sagittal radiograph. Second, the foot of the sawbones was secured to the model with the ankle joint ligaments, which is not a rigid fixation. If force is applied to the foot with the metal sphere in the talus, the foot might be displaced. During measurements, we made sure that the foot stayed on the rotary table on the exact same location. Third, our research included only one observer, but achieved an excellent intraobserver reliability of 1.000 for measured HKAA's with one decimal place. We considered the fact that the most important results will be the relationship between a rotated leg, flexed leg or beam height and the reference position. This means that an excellent intraobserver reproducibility would be sufficient for this research. Thereby, the sawbones included metal spheres as marker points, which minimizes the possibility of interpretational error.

Our implemented protocol is an important step towards more consistent HKAA measurements. However, there are still some uncertainties regarding the true AP position of the knee joint. During this project, we realised that OA limbs can differ from healthy limbs and that the deviation between patients can be quite large. Thereby, an accuracy of 0.45° is difficult to achieve when operating with only the human eye as feedback. Our group focusses on the next step, which is developing 3D technology capable of analysing and treating the lower limb geometry. In the meantime, our protocol should keep the measured HKAA consistent, which we are planning to validate with a test-retest study.

10 CONCLUSION

In conclusion, this project describes different affecters of the measured HKAA on a WLR. On top of that geometrical measurements were conducted on the human leg using CT scans and a feasibility research was performed in the radiography room among the X-ray technicians. These results were used to design a WLR acquisition protocol with the aim on standardized radiographs. This protocol is implemented and steps are taken for future research studying the reproducibility of the protocol.

SUPPLEMENTS

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2 SAWBONE STUDY PROTOCOL

1.

Make reference sagittal radiograph with 0 flexion (a) Make reference AP radiograph with 0 flexion and 5 degrees varus (b) 2.

Place sawbones in a HKAA of 5 degrees VARUS and 15 degrees flexion and no 3. rotation make a saggital reference radiograph (c)

4. The following radiographs will be taken in an AP coronal plane, with the sawbones in 5 degrees varus and 15 degrees flexion

a.		Scan sawbones with beam height parallel to the knee-joint (d)
b.		Scan sawbones with beam height 5 cm above the knee-joint (e)
С.		Scan sawbones with beam height 10 cm above the knee (f)
	i.	Rotate sawbones into 5 degrees exorotation
a.		Scan sawbones with beam height parallel to the knee-joint (g)
b.		Scan sawbones with beam height 5 cm above the knee-joint (h)
C.		Scan sawbones with beam height 10 cm above the knee-joint
		(i)
	i.	Rotate sawbones into 10 degrees exorotation
а.		Scan sawbones with beam height parallel to the knee-joint (j)
b.		Scan sawbones with beam height 5 cm above the knee-joint (k)
С.		Scan sawbones with beam height 10 cm above the knee-joint
		(I)
	i.	Rotate sawbones into 5 degrees endorotation
а.		Scan sawbones with beam height parallel to the knee-joint (m)
b.		Scan sawbones with beam height 5 cm above the knee-joint (n)
С.		Scan sawbones with beam height 10 cm above the knee-joint
		(0)
	i.	Rotate sawbones into 10 degrees endorotation
а.		Scan sawbones with beam height parallel to the knee-joint (p)
b.		Scan sawbones with beam height 5 cm above the knee-joint (q)
С.		Scan sawbones with beam height 10 cm above the knee-joint
		(r)
5. Place	sawb	pones in a HKAA of 5 degrees VARUS with 5 degrees flexion and no
rotation make	e a sa	iggital reference radiograph (s)
6. The fo	ollowii	ng radiographs will be taken in an AP coronal plane, with the sawbones
in 5 degrees	varus	and 5 degrees flexion
а.		Scan sawbones with beam height parallel to the knee-joint (t)
b.		Scan sawbones with beam height 5 cm above the knee-joint (u)
С.		Scan sawbones with beam height 10 cm above the knee-joint
		(V)
	i.	Rotate sawbones into 5 degrees exorotation
а.		Scan sawbones with beam height parallel to the knee-joint (w)
b.		Scan sawbones with beam height 5 cm above the knee-joint (x)
С.		Scan sawbones with beam height 10 cm above the knee-joint
		(y)
	i.	Rotate sawbones into 10 degrees exorotation
а.		Scan sawbones with beam height parallel to the knee-joint (z)
b.		Scan sawbones with beam height 5 cm above the knee-joint
		(ai)

C.		Scan sawbones with beam height 10 cm above the knee-joint (bi)
	i	Rotate sawhones into 5 degrees endorotation
а	1.	Scan sawbones with beam height parallel to the knee-joint (ci)
b.		Scan sawbones with beam height 5 cm above the knee-joint
5.		(di)
C.		Scan sawbones with beam height 10 cm above the knee-joint
		(ei)
	i.	Rotate sawbones into 10 degrees endorotation
a.		Scan sawbones with beam height parallel to the knee-joint (fi)
b.		Scan sawbones with beam height 5 cm above the knee-joint
		(gi)
C.		Scan sawbones with beam height 10 cm above the knee-joint
		(hi)
7. Place	sawb	ones in a HKAA of 5 degrees VARUS with 0 degrees flexion and no
rotation make	a sa	ggital reference radiograph (ii)
8. The fol	llowin	a radiographs will be taken in an AP coronal plane, with the sawbones
in 5 dearees v	/arus	and 0 degrees flexion
a.		Scan sawbones with beam height parallel to the knee-ioint (ii)
b		Scan sawbones with beam height 5 cm above the knee-joint
~		(ki)
C		Scan sawbones with beam height 10 cm above the knee-ioint
0.		(li)
	i	Rotate sawbones into 5 degrees exorotation
а		Scan sawbones with beam height parallel to the knee-joint (mi)
h.		Scan sawbones with beam beight 5 cm above the knee-joint
5.		(ni)
C		Scan sawbones with beam beight 10 cm above the knee-joint
0.		
	i	Rotate sawhones into 10 degrees exorotation
а		Scan sawbones with beam beight parallel to the knee-joint (ni)
h.		Scan sawbones with beam beight 5 cm above the knee-joint
Б.		
C		Scan sawbones with beam beight 10 cm above the knee-joint
0.		(ri)
	i	Rotate sawhones into 5 degrees endorotation
2	1.	Scan sawbones with hear height parallel to the know joint (ci)
a. b		Scan sawbones with beam height 5 cm above the knee joint (si)
D.		Scall sawbones with beam height 10 cm above the knee-joint (ii)
υ.		
	:	(ui) Retate southeress into 10 degreess enderstation
	1.	<u>Rotate sawbones into to degrees endototation</u>
a. h		Scan sawbones with beam beint E am above the knee-joint (VI)
D.		
~		(WI) Seen coulones with been beight 10 cm above the lines is int
C.		
		(XI)

9. Repeat beginning with step 2, but everything in <u>5 degrees VALGUS.</u>