RADIOGRAPHIC ASSESSMENT OF CORONAL ALIGNMENT OF THE LOWER LIMB IN END STAGE OSTEOARTHRITIS OF THE KNEE

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DECLARATION OF ORIGINALITY

This research has been prepared in partial fulfillment of the requirements for award of the degree of Master of Medicine in Orthopaedic Surgery by the University of Nairobi, School of Medicine. It is my original work and all efforts have been made to ensure accuracy of information presented in it. References to other works are made and this has been clearly indicated.

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This is to certify that the study was undertaken under our guidance and supervision and that this book is submitted with our approval as the university supervisors.

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DEDICATION

This work is dedicated to my loving wife Mary, who has not only persevered the distraction of every intellectual pursuit but offered her unwavering support. My siblings who have always demanded a standard and to my parents who were my very first fans.

CERTIFICATE OF AUTHENTICITY

This is to certify that the work identified below is the original work of the author.

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LIST OF ABBREVIATIONS

FAMA – Femoral anatomical mechanical angle

HKAA- Hip Knee Ankle Angle

KNH – Kenyatta National Hospital

TKR – Total Knee Replacement

VCA – Valgus correction angle

ABSTRACT

Background

The position of the femoral component in the coronal plane is one of the determinants of postoperative alignment of the lower limb in the coronal plane which influences the survival of the prosthesis. Ideally the femoral component should be implanted perpendicular to the femoral mechanical axis. To do this, the valgus correction angle used to perform the distal femoral cut should be equal to the angle subtended by the mechanical and distal anatomical axes of the femur in the coronal plane. This angle can be accurately determined using preoperative whole lower limb (hip knee ankle) radiographs. Alternatively a presumptive distal femoral cut can be executed using a valgus correction angle of between 5^0 and 7^0. This assumes an ideal relationship between the mechanical and distal anatomical axes of the femur however this relationship is influenced by variations in femoral anatomy specifically the neck shaft angle and bowing of the femur in the coronal plane. Variation of these determinant factors between populations may make the use of presumptive cuts inaccurate resulting in incorrect positioning of the femoral component which contributes to post-operative malalignment of the limb in the coronal plane. These variations may explain the lack of consensus between authors on the safety of use of presumptive cuts and the need to perform routine preoperative whole lower limb radiographs to accurately determine the valgus correction angle to use when performing the distal femoral cut. The objective of this study was to establish the pattern of variation of the valgus correction angle as well as its determinants,coronal femoral bowing and neck shaft angle, in Kenyan patients with end stage osteoarthritis of the knee. The findings have implications for operative practice including the use of preoperative whole lower limb radiographs in routine total knee replacements as well as the choice of valgus correction angle to use in the event of performing presumptive distal femur cuts in the study population.

Objective:

To determine the pattern of variation of the valgus correction angle, bowing of the femur in the coronal plane and the neck shaft angle in patients with end stage osteoarthritis presenting in four orthopaedic centres for total knee replacement.

Design

Cross-sectional observational study

Setting

The study was conducted at four orthopaedic centres namely Kenyatta national hospital, St. Francis community hospital, PCEA Kikuyu and the Aga Khan hospitals.

Patients and Methods

The patients were screened in the orthopaedic clinics of the respective hospitals and those with end stage osteoarthritis were selected for inclusion in the study. Patients were recruited until the target of 80 lower limbs with end stage osteoarthritis was reached. This resulted in the inclusion of 48 patients into the study. Data on the patient age, height, weight, time up and go and stair climbing test was collected. Weight bearing-whole lower limb radiographs were taken with each patient positioned with the lower limbs in 15^0 of internal rotation. Radiographic land marks described by Mullaji et al(1) were used to draw axes in the coronal plane and measurement of the angles of interest: the valgus correction angle, angle of coronal femoral bowing and the neck shaft angle were made.

Data was keyed into the Statistical Package for Social Scientists and analysed. p values less than 0.05 were taken to be statistically significant.

Results

The valgus correction angle predicted by the whole lower limb radiographs averaged $6.29^0 \pm 1.80^0$ for all limbs regardless of alignment and $6.5^0 \pm 1.95^0$ for patients with varus lower limb alignment. Of the lower limbs studied, 9.8% (8) had a predicted valgus correction angle greater than or equal to 9^0. Bowing of the femur averaged $2.45^0 \pm 3.14^0$ in all lower limbs regardless of alignment and $2.54^0 \pm 3.39^0$ in limbs with varus lower limb alignment. There was a strong positive correlation between bowing of the femur and the valgus correction angle $r = 0.857$ $p <$

0.01 for all lower limbs and $r = 0.907$ $p < 0.01$ for the limbs in varus alignment. Analysis of the impact of the neck shaft angle on the valgus correction angle in patients with varus lower limb alignment demonstrated a significant difference between patients with coxa vara from those with coxa valga $p < 0.05$.

Conclusions

The average valgus correction angle in the population studied is significantly less than that reported by Mullaji et al ,$7.3^0 \pm 1.6^0$, but significantly greater than that reported by Kharwadkar et al, $5.4^0 \pm 0.9^0$. The average bow was lower than that reported by Mullaji et al however this difference was not significant. The demonstration of a significantly lower valgus correction angle in individuals with a coxa valga compared to those with coxa vara corroborated the findings of Bardakos et al. These findings show that coronal femoral bowing and the neck shaft angle affect the relationship between the anatomical and mechanical axes of the femur and given their variation between populations may influence the accuracy of use of presumptive distal femoral cuts and therefore the need to take preoperative whole lower limb radiographs to precisely determine the valgus correction angle.

INTRODUCTION

End stage osteoarthritis of the knee is one of the five top causes of disability in non-institutionalised elderly persons and with the increasing proportion of the elderly population and cost of its treatment is of significant economic burden. Primary total knee replacement (TKR) is of significant economic benefit to society. This benefit however is lost in the event of revision.

Placing the lower limb in neutral postoperative alignment in the coronal plane requires placing femoral and tibial components perpendicular to mechanical axes of the respective bones as well as performing balancing of the soft tissues. Performing the distal femoral cut using contemporary instrumentation requires referencing the distal femoral anatomical axis and making the distal femoral cut using a valgus correction angle equal to the angle subtended by the distal anatomical and mechanical axes of the femur. The surgeon can perform the cut using a presumptive valgus correction angle presupposing an 'ideal' relationship between the anatomical and mechanical axes of the femur.

The relationship between these two axes has been found not to be ideal and is influenced by the NSA and coronal femoral bowing. Studies in Asian and Caucasian races have shown that the two factors (relative coxa vara and coronal femoral bowing) act in concert to increase the valgus correction angle and make the use of presumptive cuts in these populations unsafe in a proportion of patients undergoing TKR.

Studies have demonstrated that the neck shaft angle in black females is in significantly greater valgus than that in other races. This may ameliorate the effect of coronal femoral bowing and make the use of presumptive valgus cuts among black females relatively safer than in other races – i.e. there will be a lower proportion of patients with inaccurate cuts if a presumptive valgus correction angle is used.

Why the distal femoral cut? With the right instrumentation and valgus correction angle this cut can be made by different surgeons with a relatively great degree of accuracy and predictability eliminating its contribution to coronal malalignment. This is important given that alignment in the coronal plane has an influence on the postoperative survival of the prosthesis through wear of the polyethylene insert with resultant aseptic loosening.

After infection, aseptic loosening accounts for the greatest number of revision knee replacements. Furthermore it is a major indication for all component revision which costs more than any other form of revision surgery for knee replacement.

LITERATURE REVIEW

Osteoarthritis of the knee is defined as a degenerative, non-inflammatory disease of the knee joint that inhibits normal synchronous movement of the knee creating abnormal motion and stress concentration that results in changes in articular cartilage (2). Osteoarthritis is a major cause of musculoskeletal pain and the single most important cause of disability and handicap in industrialised nations. Osteoarthritis of the knee is one of the five diseases responsible for the greatest proportion of physical disability in non-institutionalised elderly men and women. Annual individual direct and indirect costs of osteoarthritis of the knee are estimated to be 1099$ and 1452$ respectively(3).

End stage osteoarthritis of the knee is characterised by presence of pain that limits activities of daily living and radiographic changes corresponding to grade three of the Kellgren Lawrence classification(4)(5). The predominant definitive treatment is total knee replacement which is essentially resurfacing the articular surfaces of the knee. It involves the insertion of femoral, tibial and occasionally patella components as well as balancing of the peri-articular soft tissues.

Implantation of the femoral component is one of the constituent steps during TKR. With respect to the coronal plane the objective is to place the femoral component perpendicular to the femoral mechanical axis. Desire to achieve ideal placement of the femoral component has even seen the evolution of the instrumentation that uses computer navigation(6). The cost of the instrumentation required to conduct knee replacements using computer navigation ,however, is expensive and has not been shown to be justifiable particularly in countries with limited resources (7). The use of conventional instrumentation to perform knee replacements is still the predominant means of performing knee replacements in these settings.

During use of conventional instrumentation, the distal femur cut is performed utilising an intramedullary rod that references the anatomical axis of the distal femur. The VCA used to perform the distal femoral cut is predicated on the relationship between the distal anatomical and mechanical axes of the femur. To accurately establish the relationship a whole lower limb weight bearing radiograph of the limb in 15^0 of internal rotation is required.

In the absence of such a radiograph one can make a presumptive cut based on an assumption of an ideal relationship between the two axes.

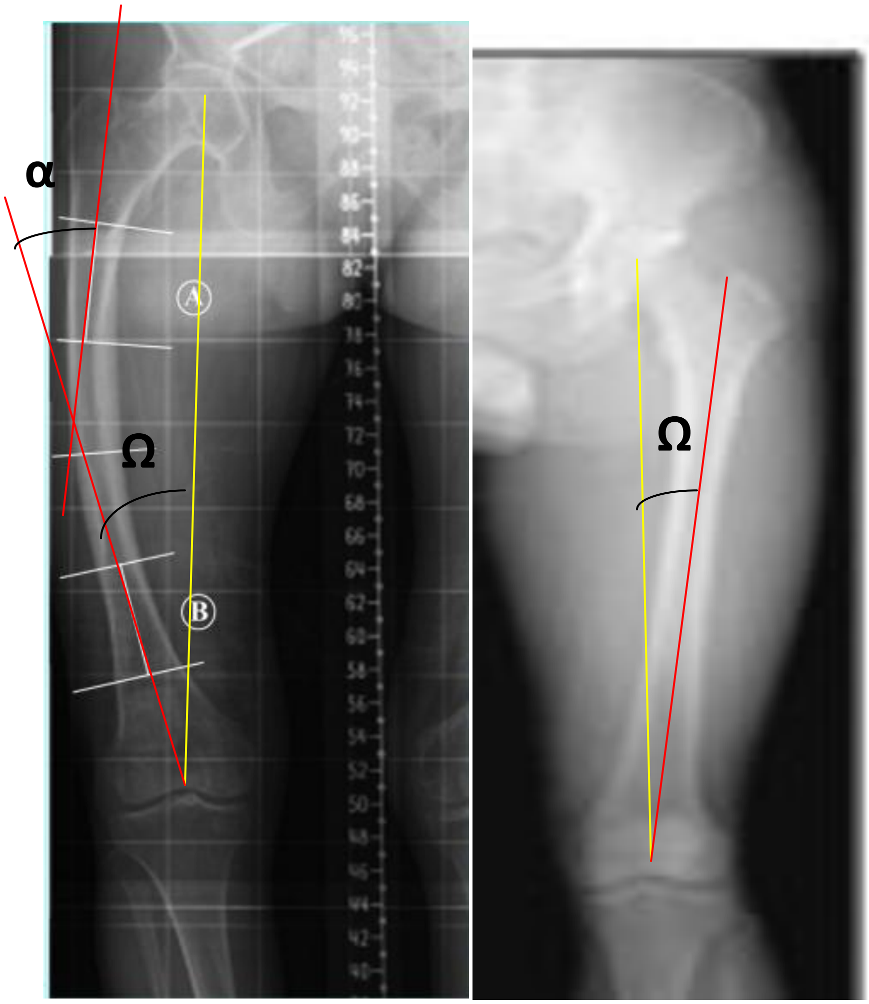
However, there are authors who have argued that the use of presumptive cuts is inaccurate due to variations in the femoral anatomy that affect the relationship between the distal anatomical and mechanical axes of the femur (1,8,9). These variations would potentially make the performance of presumptive cuts erroneous with respect to ideal placement of the femoral component. Variations in the neck shaft angle and coronal femoral bowing influence the relationship between the mechanical and distal anatomical axes of the femur and preclude the assumption of an ideal relationship that would allow the use of presumptive cuts. They argue that accurate performance of the distal femoral cut even in routine TKRs requires use of preoperative weight bearing whole lower limb radiographs to precisely determine the valgus correction angle to use to during performance of the distal femoral cut.

Effect of coronal femoral bowing on valgus correction angle.

Bowing of the femur in the coronal plane is a change in the morphometry of the femur that is not readily detectable clinically or on short antero-posterior radiographs of the knee. Mullaji et al (1) compared several coronal femoral axes between healthy Asians and individuals with varus lower limb alignment and end stage osteoarthritis of the knee. He noted a significant difference between the two groups with respect to the lateral bow of the femur. The angular relationship between the distal anatomical axis and the mechanical axes of the femur (i.e. the valgus correction angle) also differed significantly between the two groups. In individuals with varus alignment the angle averaged $7.3^0 \pm 1.6^0$ (range 4^0 - 12^0). This was significantly higher than that in the healthy individuals for whom the relationship averaged $5.5^0 \pm 0.8^0$ $p < 0.05$. With respect to the femoral bow, this averaged $3.6^0 \pm 2.5^0$ in the patients with osteoarthritis with varus alignment and $0.4^0 \pm 1.2^0$ in the healthy individuals. This too was significantly different between the two groups. There was a high positive correlation in their study between lateral bowing of the femur in the coronal plane and the VCA. This correlation was significant at $p < 0.01$. The VCA was $\geq 9^0$ in 18.8% in the sample they studied (a presumptive distal femoral cut using a VCA of 6^0 in these patients would potentially result in a 3^0 error in the positioning of the femoral component and contribute to the same degree to the error in postoperative coronal alignment).

Yau et al (8) in a study of 93 lower limbs in Chinese patients with arthritis of the knee measured the degree of bowing in the coronal plane. They reported marked bowing of the femur, $>2^0$, in the coronal plane in 62% of the femurs they studied. Of the femurs they studied, 44% had lateral bowing averaging $5.3^0 \pm 3.2^0$ and 18% had a mean medial bowing averaging $4.4^0 \pm 1.9^0$. The mean VCA in the group with coronal femoral bowing averaged $6.1^0 \pm 1.9^0$ compared to that of $5.7^0 \pm 0.7^0$ in patients with straight femora. If presumptive femoral cuts were performed in the two groups with a VCA of 5^0 31% of the cuts in the bowed femora would have an error of $>2^0$ compared to 3% in the straight femora group. A 6^0 valgus correction angle would result in 31% of the distal femoral cuts in the bowed femora group being in error and none of the straight femoral group being in error $p < 0.0001$. A valgus correction angle of 7^0 would result in an error in 34% of the patients with bowing of the femur and an 11% error rate in patients with straight femora. There are studies that have proposed that even computer assisted total knee replacement is sensitive to higher levels of coronal femoral bowing albeit in excess of 5^0 (10).

Figure 1 showing effect of lateral bowing of the femur on the valgus correction angle

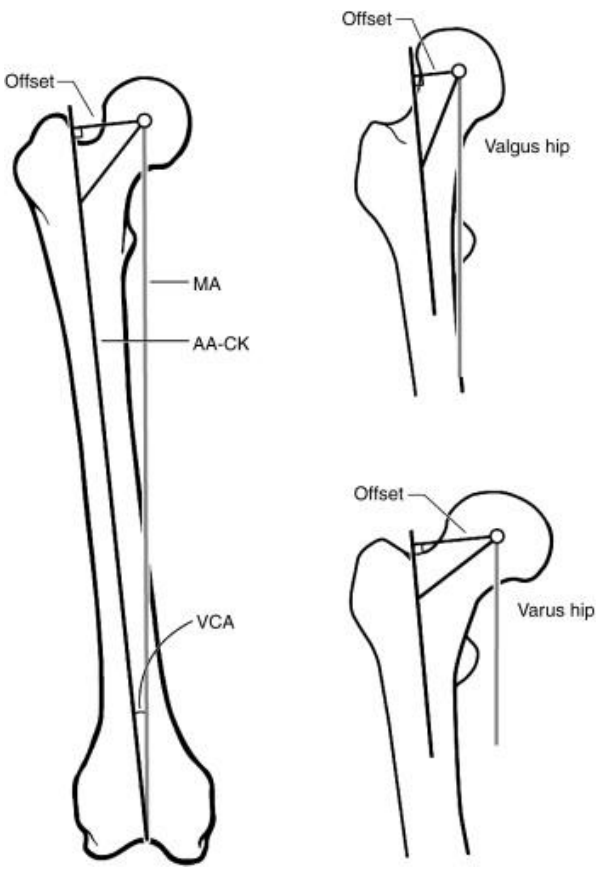


Influence of the femoral coronal bowing on the valgus correction angle	
(yellow line)	Mechanical axis of the femur
(red line)	Distal femoral anatomical axis
σ	femoral coronal bowing angle
Ω	valgus correction angle

Effect of neck shaft angle (NSA) on the valgus correction angle(VCA)

The relationship between the VCA and the NSA is particularly straight forward. Coxa valga results in a reduced offset and consequently a reduction in the valgus correction angle. Coxa vara on the other hand increases the offset and the valgus correction angle. Bardakos et al in a study examining the effect of the NSA on the VCA reported strong negative correlation between the NSA and VCA. The more vertically inclined the neck of the femur the lower the VCA and vice versa (9). They concluded that patients with coxa valga should have a valgus correction angle of 5^0 or less and 6^0 or more in patients with coxa vara.

Figure 2 showing the effect of the NSA on the VCA



Walensky et al (11) in a study to explain the difference in incidence of neck shaft fractures between individuals of different races showed that the neck shaft angle in black women was significantly greater than in white females. In black females the NSA averaged $125.1^0 \pm 0.8^0$ whilst that in white females averaged $121.4^0 \pm 0.97^0$ ($p < 0.001$).

Rickels et al (12) in a study to describe morphology of the NSA for purposes of use of the information in the design of femoral stems for total hip replacements reported that the NSA also varies with age. They reported that the average neck shaft angle in persons aged over 50 years was significantly different from that in individuals aged less than 50 years 127^0 and 122^0 respectively $p < 0.001$.

In a study of femoral geometry in the adult femur of Kenyans Lakati et al studied 70 femora and reported that the NSA averaged 129.21^0 without significant difference between the left and right femora 128.67^0 and 129.03^0 respectively(13).

There are differing opinions on the safety of performing presumptive cuts

Literature on the accuracy of performing presumptive distal femoral cuts using a valgus correction angle of between 5^0 and 6^0 varies. On one hand there are authors who have reported that the influence of coronal femoral bowing or variation of the neck shaft angle makes the use of presumptive cuts relatively unsafe (1,8,10). The studies in literature differ in the reported proportions of patients in whom presumptive cuts would be erroneous. Mullaji reported that 18.8% of the lower limbs he studied would have an error in the distal femoral cut if a presumptive cut were used. Kinzel & co (14) studied 80 patients undergoing TKR and reported that the use of presumptive cuts would result in errors in the distal femoral cut in 10% of patients. 8.5% of the patients studied by Teter & co(15) had an error in the positioning of the femoral component and consequently they suggested the need to perform whole lower limb radiographs preoperatively to accurately determine the relationship between the distal anatomical and mechanical axes to guide performance of the distal femoral cut.

There are however dissenting authors who have reported the routine use of whole lower limb radiographs is not necessary in performance of TKR in patients with primary osteoarthritis without any history of trauma to the limb in question. Kharwadkar & co (16) in a study of 83 patients undergoing total knee replacement analysed the relationship between the distal anatomical and mechanical axes of the femur and reported that it averaged $5.4^0 \pm 0.9^0$. They concluded that a presumptive distal femoral cut based on a valgus correction angle of 5^0 -6^0 for routine uncomplicated total knee replacement was safe.

McGrory and Trousdale(17) randomised 94 patients meant to undergo TKR into two groups, those to have preoperative whole lower limb radiographs to determine the valgus correction angle and those to have presumptive distal femoral cuts. They reported no statistical difference between the groups with respect to the accuracy of obtaining an ideal postoperative mechanical axis. They suggested use of radiographs only in cases of patients with prior fractures, osteotomies or congenital deformities of the lower limb. Jeffrey et al (18) concurred that whole lower limb radiographs are necessary only for patients with bone deformity or previous surgery.

From the foregoing it is evident that there is lack of consensus on the need for performing preoperative hip to ankle radiographs to determine the valgus correction angle to use in performing the distal femoral cut during TKR. It is possible that variations in femoral anatomy that influence the relationship between the distal anatomical and mechanical axes of the femur may result in differences in accuracy of performing the distal femoral cut between populations. Incidence and severity of lateral bowing of the femur may vary between populations. Similarly the neck shaft angle may vary between the studied populations. The interaction of these two factors is also of interest and may vary between the populations studied. For example, the influence of lateral coronal femoral bowing may be vitiated or at the very least ameliorated by the presence of coxa valga. Coxa vara on the other hand may work in concert with lateral femoral bowing to increase the valgus correction angle. This may explain the differences in findings between the authors and hence the differences in opinion regarding the recommendation for the need of preoperative hip knee angle radiographs.

Why the emphasis on accurate performance of the distal femoral cut?

The correct placement of constituent components of the knee prosthesis with respect to the coronal, sagittal and axial axes influences the survival of the prosthesis. The desire to achieve reproducible ideal placement of the components is the subject of research and has even resulted in the development of modalities including the utilisation of computer navigation. Placing the femur component correctly in the coronal plane is a determinant of postoperative alignment of the limb in the coronal plane which has been shown to affect the rate of aseptic loosening and therefore the need for revision of the total knee replacement. Accurate placement of the femur component ensures it does not potentially contribute to an error in alignment of the limb in the coronal plane. It is therefore imperative to establish potential sources of error in the ideal placement of the femoral component and mitigate these including the safety of use of presumptive cuts and the need for the use of preoperative whole lower limb radiographs.

Primary TKR has been shown to be of greater financial benefit to society when compared to conservative management of end stage osteoarthritis of the knee. Direct cost to the individual averages $ 20,000 but this is offset by the benefit to society through reduced number of days off work and acquisition of gainful employment averaging $ 39,000. The net gain to society for the 600,000 total knee replacements done in a calendar year in the United states amounted to $ 12 billion (19). This benefit however is lost in the event of revision of the knee replacement which on average is estimated to cost two and a half times as much as a primary total knee replacement(20).

Mechanical loosening is reported to be responsible for 16.1% of revisions second only to infection which is responsible for 25.2% of revisions and is the predominant indication for tibial insert revision. Mechanical loosening is the most common indication for all component revision, femoral component revision and patella revision. On average all component revision costs $ 56,087(20). Granted that certain factors that influence the rate of revision are non-modifiable, e.g. age of the patient, it is imperative that the surgeon optimises those that are.

Prescription of an ideal coronal alignment following TKR has been a subject of continuing debate in orthopaedic literature. The effect of postoperative alignment in the coronal plane on survival of the contemporary prosthesis has not been conclusively settled(21–23). Coronal alignment in the lower limb is described in reference to a vertical line passing through the pubic symphysis and perpendicular to the horizontal. The mechanical axis of the limb is described by Maquet’s line, a line passing from the centre of the femoral head to the centre of the talar dome. A line that bisects the femoral diaphysis describes the femoral anatomical axis and in turn one that bisects the tibial diaphysis describes the anatomical axis of the tibia.

Ideal post-operative coronal alignment was first described by Denham as $4^0 – 10^0$ of valgus with respect to the anatomical axis and subsequently by Insall as 3^0 of varus to 3^0 of valgus with respect to the mechanical axis. Insall stated that 'at this angle the prosthesis is by design least subject to forces which might loosen or cause excessive wear"(24,25).

Their suggestions were corroborated by studies which showed increased failure in knees that did not achieve coronal alignment within the prescribed range. Jeffery et al in a study of 115 knees demonstrated that the failure rate secondary to aseptic loosening in patients with postoperative alignment within 3^0 varus to 3^0 valgus was 3% whilst those outside this alignment had a rate of aseptic loosening of 24% p=0.001(18). In a similar study assessing the effect of postoperative alignment on failure Tew & co observed significantly greater rates of failure in limbs with postoperative anatomical tibiofemoral angle outside 7^0 of valgus(26). Bargren & co conducted a cadaveric study to establish the load at failure on axial loading of knees with varus and valgus alignment after total knee replacement(27). They demonstrated that knee arthroplasties failed in eccentric loading at 34 – 51% of the load that would cause failure on axial loading if postoperative alignment was ideal. They concluded that their findings demonstrated the importance of achieving proper overall alignment following total knee arthroplasty.

There has been literature that has challenged the need to achieve postoperative alignment in the coronal plane within the prescribed limits. Parratte & co in a follow up study of 280 patients who underwent total knee replacements reported no significant difference in survival between patients with postoperative alignment in the coronal plane within the prescribed limits and those whose alignment was outside this limit at 15 years of follow up(28). His findings were echoed by Bonner et al who followed up 501 total knee replacements in 396 patients and reported a weak tendency towards survival following restoration of a neutral mechanical axis(22). The change has been postulated to be due to the vitiation of the contribution of other factors that act in concert with malalignment to cause aseptic loosening. Such changes include changes in the sterilisation of the polyethylene by irradiation or inert gas which reduced the level of free radicals in the polyethylene insert and hence reduced the embrittlement of the polyethylene and its susceptibility to wear. Introduction of highly polished tibial trays in an effort to reduce backside wear, improvements in locking mechanisms and recognition of the importance of the use of cement to seal the bone implant interface to reduce the access of wear debris were other changes that ushered in the era of the contemporary knee replacement(29). These changes may have ameliorated the effect of postoperative malalignment on the survival of the knee replacement explaining the contemporary studies that have questioned the importance of achieving postoperative alignment within the prescribed range(30,31).

There are contemporary studies that challenge the aspersions cast on the importance of ideal alignment in the coronal plane following TKR. The importance of achieving ideal alignment of the whole lower limb as well as positioning the individual components in relation to the mechanical axes of the respective bones has been shown to influence the rate of survival following cemented cruciate retaining total knee replacement. Ritter et al in a study of 6032 knee replacements reported the rate of failure in knees with a postoperative anatomical tibiofemoral axis within $2.5^0 – 7.4^0$ valgus of 0.6% and a failure rate of 1.4% in knees whose alignment was outside this ideal alignment of the lower limb p=0.0053. Mean time to failure for the lower limbs outside this ideal alignment was 5.2 ± 3.6 years (0.6 – 13.1 years). The pattern of malalignment also influenced the mechanism of failure. Majority of limbs with varus malalignment failed by medial tibial collapse and the majority of limbs with valgus malalignment failed due to ligamentous instability(32).

Findings in studies that detected reduced axial load at failure in knees with eccentric loading are corroborated by anatomical studies that demonstrated that the greatest concentration of trabeculae in the proximal tibia was found in the anterior and central portions of the epiphysis and metaphysis of the tibia. This confers upon the central and anterior portions of the proximal tibial epiphysis the ability to withstand a significantly greater compressive load before failure compared to the peripheral portions of the proximal tibial epiphysis and metaphysis(33,34). These studies would suggest that the concentration of trabeculae decreases in the eccentric portions of the proximal tibia with a resultant decrease in the axial load that these peripheral portions can withstand.

Generation of polyethylene wear debris is an aetiological factor for osteolysis in aseptic loosening. Finite element analysis with modelling of the high conformity polyethylene inserts demonstrated increased contact stress in the event of malalignment in the coronal plane (35,36). In a retrieval analysis of 89 total knee replacements and 89 unicondylar knee replacements wear related loss of height of the polyethylene inserts was influenced by the polyethylene's shelf age, the patient's age and angulation of the knee in the coronal plane following surgery(37). The relationship between wear and postoperative alignment was inferred by a study by Pang et al (38). Retrieval analysis of wear in 83 posterior stabilised contemporary polyethylene inserts from Genysis II knees showed significantly greater wear in patients with postoperative varus alignment greater than 3^0.

In a study of the severity of patella fractures in patients with patella resurfacing Figgie et al reported that for all 36 patients they studied coronal alignment was outside the ideal range of neutral and that the severity of the fractures increased with increasing deviation from ideal alignment in the coronal plane (39). This is conceivable given the effect of coronal alignment on the q angle.

Despite the lack of consensus on the importance of achieving postoperative coronal alignment within a prescribed range, even the dissenting authors suggest that the surgeon should still make every effort to achieve this ideal alignment(28). The demonstration of failure at lower loads with eccentric loading and the reduction in the density of trabeculae in the periphery of the epiphysis and metaphysis of the proximal tibia would suggest that alignment with axial load passing through the centre of the proximal tibia would ensure that the stress passes through the strongest part of the proximal tibia reducing the risk of collapse(36)(35). It would also evenly distribute the stress in the polyethylene insert over a larger area reducing generation of wear debris(33,34).

The use of presumptive cuts in the performance of the distal femoral cut is predicated on assumption of an ideal relationship between the mechanical and distal anatomical axes of the femur. Literature has demonstrated that this relationship is influenced by femoral anatomy features such as the NSA and bowing of the femur in the coronal plane. Given that the accuracy with which the femoral component is inserted is one of the determinants of postoperative lower limb alignment it, is imperative to establish the pattern of this relationship in a population and thus inform the safety of use of presumptive cuts in the performance of the distal femoral cut in the population in question.

Accuracy of use of predetermined individualised valgus correction angle has been demonstrated in the study by Palanisami et al who randomly assigned patients to two groups; one to have presumptive cut of 5^0 and another to have an individualised cut using a valgus correction angle determined preoperatively using a whole lower limb radiograph. They demonstrated significant improvement in both femoral component placement as well as post-operative alignment when individualised valgus correction angles were used(40).

Conclusion of literature review

Despite the aspersions cast on the importance of postoperative alignment in the coronal plane and its influence on the survival of the prosthesis, anatomical studies and retrieval analysis of implants from knee replacements revised for aseptic loosening infer an advantage of achieving ideal alignment within a prescribed limit. Position of the femoral component in the coronal plane is one of the determinants of postoperative alignment of the limb in the coronal plane. With the use of conventional techniques for knee replacement the distal femoral cut is equal to the angle subtended mechanical and anatomical axes of the femur at the knee. This relationship is influenced by variations in femoral anatomy specifically bowing of the femur in the coronal plane and the neck shaft angle which vary between populations. This variation may influence the differences in reported accuracy of presumptive distal femur cuts. It is imperative to establish the pattern of variation of the valgus correction angle and its determinants in a population to inform the accuracy of the use of presumptive cuts and the potential need to perform whole lower limb radiographs during preoperative planning. With the increase in the number of knee replacements this may have an influence on the rate of revision total knee replacements. It is, however, worth mentioning that ideal placement of the components is not the only determinant of survival of the prosthesis and other factors also play a role including but not limited to obesity and the type of implant.

STUDY JUSTIFICATION

Precise placement of the femur component in the coronal plane is one of the determinants of postoperative alignment of the lower limb in the coronal plane. Ideally the femur component is implanted perpendicular to its mechanical axis. In order to achieve this using the instrumentation of conventional total knee replacement the valgus correction angle used to make the distal femoral cut should be equivalent to the angle subtended by the mechanical and distal anatomical axes of the femur. This is because the intramedullary rod used during performance of the distal femoral cut references the distal femur's anatomical axis.

The relationship between the mechanical and distal anatomical axes of the femur in the coronal plane is influenced by the anatomy of the femur particularly bowing of the femur in the coronal plane and the neck shaft angle. These elements of the femoral anatomy vary between populations and may explain the differences reported by various authors on the accuracy or lack thereof using presumptive distal femoral cuts that assume an ideal relationship between the mechanical and distal anatomical axes of the femur.

Authors have emphasised the inaccuracy of using presumptive cuts in populations with wide variation of the valgus correction angle and have advocated the need to use preoperative radiographs to precisely determine the valgus correction angle. There are, however, studies that have reported that use of presumptive cuts in the populations they studied did not result in significant errors in the distal femoral cut. These authors have suggested the use of preoperative whole lower limb radiographs is not necessary to determine the valgus correction angle in routine total knee replacements and should be reserved for use in patients with history of diaphyseal fractures, high tibial osteotomies and fractures of the proximal tibial or distal femoral epiphysis.

The incidence and severity of coronal bowing of the femur in the study population and its effect on the accuracy of performing presumptive distal femoral cuts is unknown. Even in the event of significant coronal femoral bowing, this may be ameliorated or even vitiated by the relative coxa valga reported in blacks and therefore still make the use of presumptive cuts in the performance of the distal femoral cut relatively safe in the study population.

Knowledge of this information has implications for the conduct of TKRs in the population under study. It may inform the utility of whole lower limb radiographs to determine the valgus correction angle in routine primary total knee replacements. The information will also determine the safety of use of presumptive cuts based on a valgus correction angle of 5^0, 6^0 or 7^0 in the population studied.

These decisions could influence the performance of distal femoral cuts in the study population which is of importance. The position of the femur component in the coronal plane is one of the determinants of post-operative coronal alignment which in turn influences the survival of the prosthesis. Significant variation in the valgus correction angle would suggest that patients in the population studied should have preoperative whole lower limb radiographs to establish the VCA for performance of the distal femoral cut even during routine primary total knee replacements. If the variation of the valgus correction angle in the population studied doesn't predict errors in the distal femoral cut with use of presumptive cuts this would suggest that the use of a VCA of 6^0 – 7^0 to perform the distal femoral cut wouldn't result in significant errors in femoral component placement during routine primary TKR.

With increasing number of total knee replacements being performed, this information could have implications on how successfully ideal postoperative alignment is achieved in the coronal plane and therefore potentially improve the survival of knee prosthesis and reduce the rate of revision total knee replacements barring other variables.

Null hypothesis

The pattern of coronal alignment in patients with end stage osteoarthritis does not preclude use of presumptive valgus correction angles for the performance of the distal femoral cut.

Study objectives

Main objective

To study the pattern of coronal alignment in patients with end stage osteoarthritis using whole lower limb radiographs.

Specific objectives

1. Establish the pattern of coronal femoral bowing in patients with end stage osteoarthritis of the knee in the study population.
2. Establish the pattern of the valgus correction angle in patients with end stage osteoarthritis of the knee as predicted by whole lower limb radiographs.
3. Demonstrate the effect of the NSA on the VCA.

Study duration

The study was conducted from February 2018 to July 2018.

MATERIALS AND METHODOLOGY

Study design

Cross – sectional observational study

Study setting

KNH, PCEA Kikuyu, St. Francis community Hospital and the Aga Khan hospital.

Study population

Patients with end stage osteoarthritis of the knee scheduled to have total knee replacements.

Inclusion criteria

Patients with end stage osteoarthritis eligible for total knee replacement. Eligibility for total knee replacement will be determined using the time up and go test, the stair climbing task and activities of living subscale of the knee outcome scale. These have been shown to be predictive of patients who require total knee replacements(5).

Exclusion criteria

1. Patients with history of diaphyseal fractures of the femur or tibia.
2. Patients with history of distal femoral or proximal tibial fractures.
3. Patients with history of corrective surgery for lower limb malalignment including distal femoral cuts or high tibial osteotomies.
4. Patients with fixed flexion contractures greater than 20^0.

Sample size calculation

Sample size was calculated using the formula for determination of the value of a quantitative variable using a cross sectional study. The quantitative variable of interest in this study is the valgus correction angle.

Sample size = $Z_{1-\alpha/2}{}^2 * SD^2/d^2$

Where

$Z_{1-\alpha/2}{}^2$ = the standard normal variate. At 5% type one error it is 1.96^2

SD = standard deviation of the variable from a previous study.

d = absolute error or precision (calculated error of 0.05 of the quantitative variable of a previous study)

Based on a previous study by Mullaji et al:

SD = 1.6 the standard deviation of the valgus correction angle in the study by Mullaji et al.

d = 7.3 * 0.05 = 0.35 magnitude of a 5% error of the quantitative variable of interest from a previous study in this case a valgus correction angle of 7.3

This gave a value of $1.96^2*3.5^2/0.35^2$ = 80 lower limbs. The actual number of patients would be determined by the rate of bilateral osteoarthritis. The rate of bilateral end stage osteoarthritis in the sample studied was 70%. This translated to 48 patients studied.

Sampling method

Convenience sampling was used. Patients were selected as they presented at the orthopaedic clinics for total knee replacements at the study settings.

Data collection

Patients presenting to the clinic with a diagnosis of osteoarthritis scheduled for undergo total knee replacements of the knee were screened for inclusion in the study. Patients with short anteroposterior radiographs demonstrating features of osteoarthritis had their contacts taken and were then called and reviewed by the principal investigator for inclusion in the study. The principal investigator reviewed the radiographs to score patients according to the Kellgren Lawrence classification. The time up and go test and stair climbing tests were used to determine the impairment of movement. Patients with Kellgren Lawrence scores of 3 or 4 and prolonged time up and go as well as stair climbing tests had the affected limbs examined. Patients selected for the whole lower limb radiographs also had to have no fixed flexion deformities greater than or equal to 20^0.

Selected patients had weight bearing whole lower limb- hip to ankle- radiographs with the lower limb positioned in 15^0 of internal rotation with the patella used as the reference as described by Paley & co. Axis of rotation of the knee in the sagittal plane was used to confirm positioning by ensuring it was perpendicular to the x ray beam. This was done by ensuring that the knee points forward on flexion. Leg length discrepancies were also corrected to prevent flexion of the longer limb which beyond 20^0 of flexion causes internal rotation of the tibia on the femur and makes measurements in the coronal plane unreliable(41,42). The radiographs were taken with the knees in maximum extension and the x ray beam centred on the knee and the beam at a fixed distance from the patient.

The lesser trochanter's profile and the patella's position were used to establish ideal rotation of the limb before measurements were made. The landmarks used to make the measurements of interest were established as described by Mullaji et al.

Mose's circles were used to establish the centre of the femoral head. The midpoint of the intercondylar notch was used to establish the lower reference point on the femur. The upper reference point of the tibia T was taken to be halfway between the tips of the tibial spines. The centre of the talar dome was taken as the centre of the ankle A.

Three reference points were marked on the femoral shaft: Fp, a point bisecting the femoral shaft at the lower end of the lesser trochanter; Fd a point bisecting the femoral shaft 10 cm above the knee joint; and Fc a point bisecting the shaft midway between Fp and Fd.

The mechanical axis of the femur was defined by a line between the centre of the femoral head H with the centre of the knee K. A line between Fc and K defined the anatomical axis of the distal femur. This line closely approximates the path followed by the intramedullary rod cutting jig used to perform the distal femoral cut. A line from the centre of the femoral head bisecting the neck and intersecting the anatomical axis of the proximal femur defined the neck shaft angle.

A goniometer was used establish the following angles:

1. The hip knee ankle angle: the angle between the femoral and tibial mechanical axes (β). This defines the limb's mechanical axis.
2. Angle betw

een the anatomical axis of the distal femur and the femoral mechanical axis (Ω). This angle defined the valgus correction angle that should ideally be used to perform the distal femoral cut.

3. Bow of the femur. Angle subtended by the lines FpFc and FdFc (α).

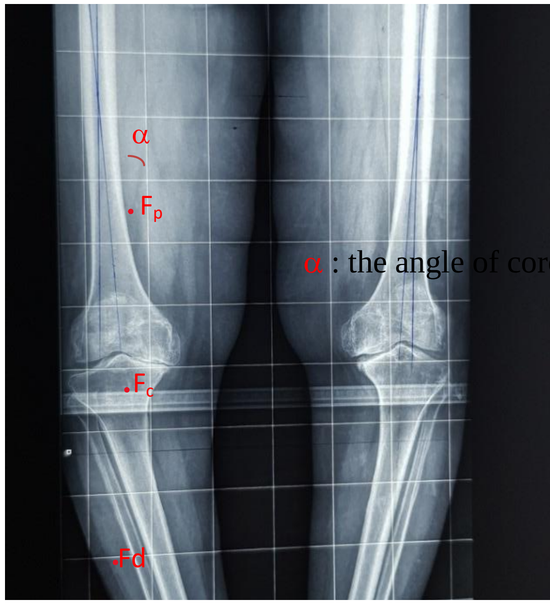


Figure 3 showing the land marks and axes used to measure the bow of the femur

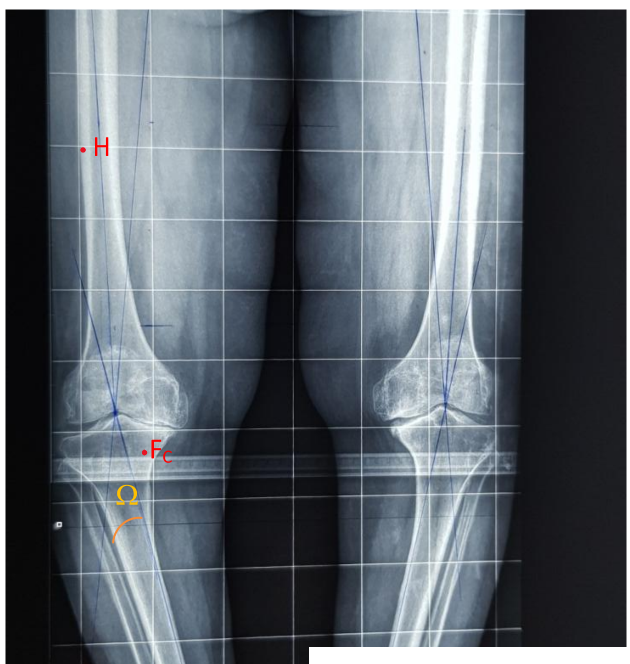


Figure 4: Showing the landmarks and axes u the valgus correction angle.

β :HKAA hip knee ankle angle measures mechanical alignment of the lower limb.

Ω : VCA valgus correction angle to be used to perform the distal femur cut

Data management and statistical analysis

A total of 82 lower limbs that met the inclusion criteria were included in the study and the measurements described above were entered in the Statistical Package for Social Scientists (SPSS) version 21 and analysed.

For purposes of analysis the limbs were analysed in total and in subgroups of valgus and varus alignment. This was done because of the reported higher correlation in literature between preoperative varus alignment of the lower limb and significant lateral bowing of the femur.

Measurements were taken twice on two days apart by the principal investigator to assess for intra-observer variability. p values < 0.05 were considered statistically significant.

Ethical considerations

The use of radiation is a matter of ethical importance. The dose of radiation is calculated using the formula:

$D = g*kV^2*mAs/d^2$

Where:

g : a constant

kV: imaging voltage in kilovolts

mA/s: milliamperes per second

d: distance between the patient and the source of the x ray beams

For a full lower limb radiograph the dose comes to 4.5 milliSieverts . This is below the IAEA dose limits for the extremities of 150 mSv in a year.

This exposure was explained to the patient and consent for the same sought.

Ethical approval was sought and granted by the ethics department of KNH and the hospitals in question.

Patients were guaranteed of confidentiality of their information and informed of their freedom to opt out of the study at any time. Patients who chose not to participate were not prejudiced against. Findings from the radiographs were communicated to the surgeon who performed the surgery for each patient.

Study limitations

The presence of flexion contractures greater than 20^0 precluded the inclusion of these patients in the sample given that this has been shown to result in inaccuracy of measurements on the radiographs. This leaves out a proportion of the population of patients requiring TKR and potentially makes their surgeries more difficult.

Dissemination of findings

A summary of the findings will be presented in the department and copies of the dissertation distributed to the departmental library and the college of health sciences library. Articles summarising findings of the study will be submitted to journals for publication.

RESULTS

Radiographs of 82 lower limbs that met the criteria of end stage osteoarthritis were included in the study from 48 patients with males constituting 23% (11) and females making up 77% (37). The average patient age was 66.79 ± 7 years. Average body mass index was 30.5 ± 5 kg/m^2.

69% (37) of the patients had bilateral osteoarthritis of the knee. The distribution of the 82 lower limbs by limb involvement was equal between left and right lower limbs: 41 left lower limbs and 41 right lower limbs. With respect to the overall lower limb alignment 25.6% (21) were in valgus, 2.4% (2) had neutral alignment and 72% (59) were in varus alignment.

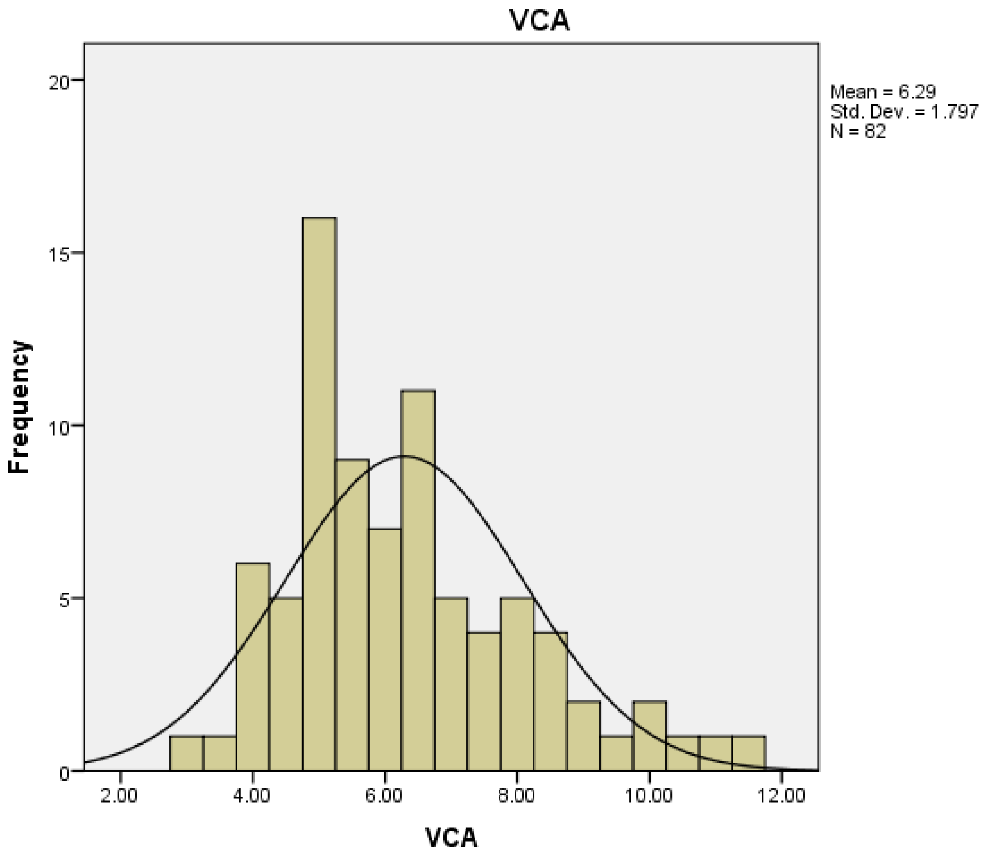
The time up and go test averaged 10.41 ± 2.50 seconds and the stair climbing test for all the patients averaged 21.23 ± 8.44 seconds. Of the 82 limbs studied 52.44% (43) were Kellgren Lawrence grade 3 knees and 47.56% (39) were Kellgren Lawrence grade 4 knees. The measures of central tendency and dispersion of the parameters of interest of all 82 lower limbs are summarised in the table below:

Table 1 showing the measures of central tendency and dispersion of variables of interest for all 82 limbs

		ALIGNMENT(HKAA)	BOW	NSA	VCA
N	Valid	82	82	82	82
	Missing	0	0	0	0
Mean		176.1768	2.4512	126.3659	6.2866
Std. Error of Mean		1.17456	.34690	.69671	.19843
Median		175.0000	2.0000	125.2500	6.0000
Std. Deviation		10.63606	3.14133	6.30894	1.79683
Minimum		160.50	-4.50	110.00	3.00
Maximum		211.00	10.00	145.00	11.50
95% confidence interval (degrees ^{0})		173.88-178.46	1.78-3.13	125.00-127.74	5.90-6.67

The graphical representation of the distribution of the valgus correction angle for all 82 lower limbs is demonstrated in the graph below:

Figure 5 histogram with frequency polygon showing the variation of the valgus correction angles for all the lower limbs regardless of alignment



Comparison of the parameters of interest between limbs in females and males are summarised in the table below:

Table 2 showing the measures of central tendency of the parameters of interest in the limbs studied according to sex of the patient

Variable of interest	Sex	No	Mean^0	Std. Deviation^0	95% confidence interval^0
VCA	Male	17	5.97	1.83	5.11- 6.83
	Female	65	6.37	1.79	5.94-6.80
BOW	Male	17	1.59	3.23	0.06-3.12
	Female	65	2.68	3.10	1.94-3.42
ALIGNMENT	Male	17	176.59	10.93	171.40-181.78
	Female	65	176.07	10.64	173.48-178.66

Table 3 showing the results of t test for significant difference in the parameters of interest in the limbs studied according to sex of the patient

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
VCA	Equal variances assumed	.015	.903	-.813	80	.419
	Equal variances not assumed			-.802	24.623	.430
BOW	Equal variances assumed	.125	.724	-1.277	80	.205
	Equal variances not assumed			-1.247	24.292	.224
ALIGNMENT	Equal variances assumed	.208	.650	.178	80	.859
	Equal variances not assumed			.175	24.545	.862

Comparison of the parameters of interest between left and right lower limbs is summarised in the table below:

Table 4: Showing the measures of central tendency of the parameters of interest for left and right lower limbs

Variable of interest	Side	No	$Mean^0$	Std. $Deviation^0$	Std. Error $Mean^0$
VCA	Left	41	6.38	1.69	5.87-6.89
	Right	41	6.20	1.91	5.61-6.79
BOW	Left	41	2.55	2.78	1.71-3.39
	Right	41	2.35	3.50	1.27-3.43
ALIGNMENT	Left	41	174.00	8.60	171.37-176.63
	Right	41	178.35	12.06	174.67-182.03

There was no significant difference between the left and right lower limbs with respect to the parameters of interest as shown in the table below.

Table 5 showing the results of t test for significant difference in the parameters of interest in the limbs studied according to the side of the limb involved left or right

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
VCA	Equal variances assumed	.557	.458	.459	80	.648
	Equal variances not assumed			.459	78.810	.648
BOW	Equal variances assumed	2.790	.099	.280	80	.780
	Equal variances not assumed			.280	76.143	.781
ALIGNMENT	Equal variances assumed	2.369	.128	-1.882	80	.063
	Equal variances not assumed			-1.882	72.343	.064

The averages for the parameters of interest in limbs with varus alignment is summarised in the table below:

Table 6 showing the measures of central tendency and dispersion of the variables of interest in limbs with varus lower limb alignment.

		ALIGNMENT(HKAA)	BOW	NSA	VCA
N	Valid	59	59	59	59
	Missing	0	0	0	0
Mean		171.0169	2.5424	126.8898	6.5085
Std. Error of Mean		.72717	.44154	.76105	.25427
Median		172.5000	2.0000	125.5000	6.0000
Std. Deviation		5.58552	3.39153	5.84577	1.95310
Minimum		160.50	-4.50	115.00	3.00
Maximum		179.50	10.00	145.00	11.50
95% confidence interval(degrees ^{0})		169.59-172.45	1.68-3.40	125.40-128.39	6.02-7.00

The averages for the same parameters for the limbs in valgus alignment is summarised in the table below:

Table 7 showing the measures of central tendency and dispersion of the variables of interest in limbs with varus lower limb alignment.

		ALIGNMENT	BOW	NSA	VCA
N	Valid	21	21	21	21
	Missing	0	0	0	0
Mean		190.3095	2.4524	125.8095	5.8095
Median		187.0000	2.0000	125.0000	6.0000
Std. Deviation		8.82960	2.38697	6.91462	1.17767
Minimum		181.50	.00	110.00	3.50
Maximum		211.00	7.50	140.00	7.50

Despite the value for the bow and valgus correction angle being lower on average in the patients with valgus lower limb alignment this was not found to be a significant difference as shown in the table below summarising the t test comparing the two groups with respect to the bow and valgus correction angle:

Table 8 showing the value of the t test comparing the bow and valgus correction angle between patients with varus and valgus lower limb alignment

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
BOW	Equal variances assumed	2.871	.094	.112	78	.911
	Equal variances not assumed			.132	50.142	.896
VCA	Equal variances assumed	5.561	.021	1.540	78	.128
	Equal variances not assumed			1.933	58.871	.058

The correlation between the bow and valgus correction angles were assessed for all lower limbs as well as the limbs in varus alignment.

Table 9 showing the correlation between the bow of the femur and the valgus correction angle for all 82 lower limbs

		BOW	VCA
BOW	Pearson Correlation	1	.857**
	Sig. (2-tailed)		.000
	N	82	82
VCA	Pearson Correlation	.857**	1
	Sig. (2-tailed)	.000	
	N	82	82

**. Correlation is significant at the 0.01 level (2-tailed).

Table 10 showing the correlation between the bow of the femur and the valgus correction angle for the 59 varus limbs

		BOW	VCA
BOW	Pearson Correlation	1	.907**
	Sig. (2-tailed)		.000
	N	59	59
VCA	Pearson Correlation	.907**	1
	Sig. (2-tailed)	.000	
	N	59	59

**. Correlation is significant at the 0.01 level (2-tailed).

The correlation between the bow of the femur and the valgus correction angle is demonstrated graphically in the diagrams below:

Figure 6 showing the positive correlation between bow and valgus correction angle for all 82 limbs assessed

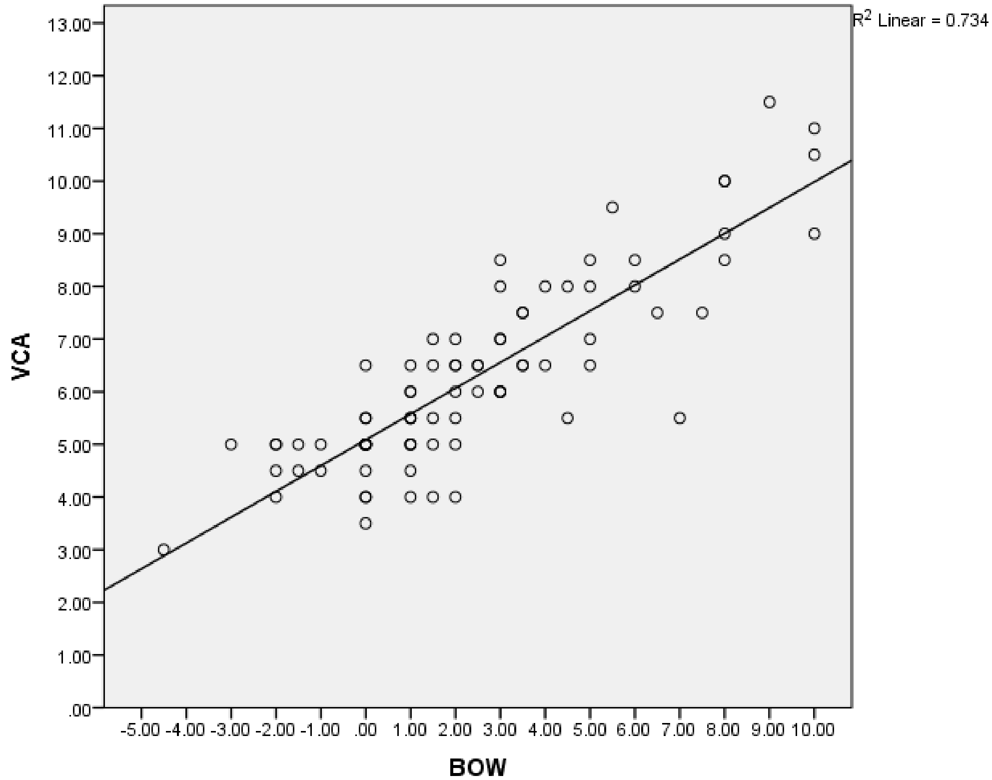
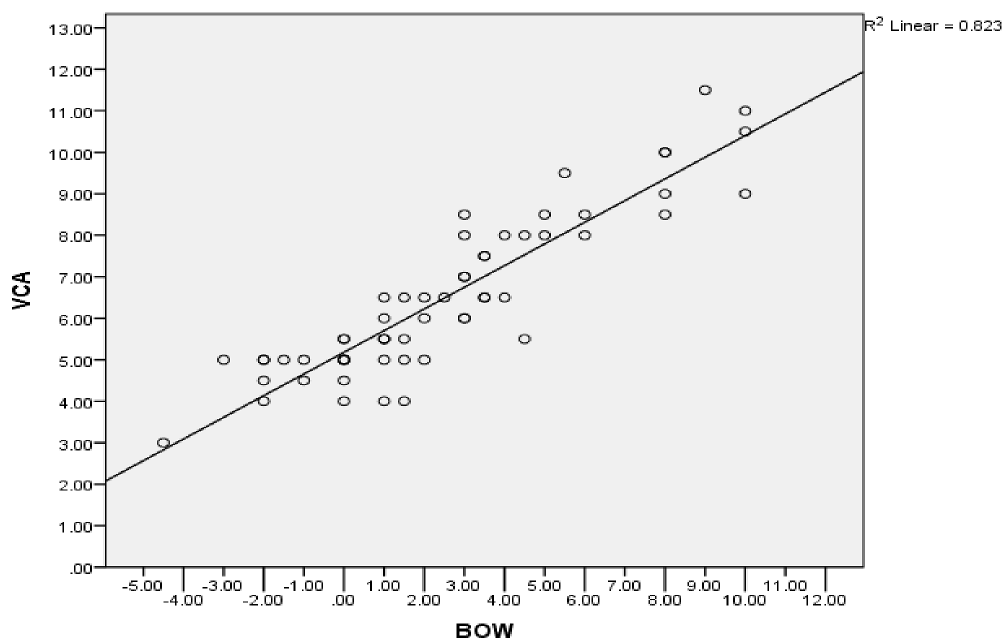


Figure 7 showing positive correlation between bow and valgus correction angle for 59 limbs in varus alignment



The effect of the NSA on the valgus correction angle in the 59 patients with varus lower limb alignment was assessed. The valgus correction angle for the two groups in relation to the NSA is summarised in the table below:

Table 11 showing the valgus correction angle for valgus and varus neck shaft angles in patients with varus lower limb alignment

	Neck shaft angle	N	Mean	Std. Deviation	Std. Error Mean
VCA	Varus	24	6.8333	1.93181	.39433
	Valgus	35	6.2857	1.96396	.33197

An analysis of covariance was performed to determine if the difference in the valgus correction angle between patients with coxa vara and those with coxa valga was significant. This involved several steps:

Step 1: establish no significant difference in the bow of the femur between individuals with coxa vara and those with coxa valga.

Table 12 showing the measures of central tendency and dispersion for patients with varus alignment based on the neck shaft angle

	Neck shaft angle	N	Mean	Std. Deviation	Std. Error Mean
BOW	Varus	24	2.6458	3.58584	.73196
	Valgus	35	2.4714	3.30317	.55834

Table 13 showing no significant difference in bowing of the femur between limbs with coxa vara and those with coxa valga

		Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig.	t	df	Sig. (2-tailed)
BOW	Equal variances assumed	.128	.721	.192	57	.848
	Equal variances not assumed			.189	46.828	.851

The independent t test between the two groups was not significant at p = 0.848.

Step 2: test for correlation between NSA and femoral bowing in the coronal plane. This is demonstrated by the table below.

Table 14 demonstrating lack of correlation between the NSA and bowing of the femur

		BOW	NSA
BOW	Pearson Correlation	1	.125
	Sig. (2-tailed)		.346
	N	59	59
NSA	Pearson Correlation	.125	1
	Sig. (2-tailed)	.346	
	N	59	59

Step 3: Test for homogeneity of regression

Table 15 showing homogeneity of regression between femoral bow and the VCA in patients with varus and valgus neck shaft angles

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	185.350[a]	3	61.783	94.665	.000
Intercept	993.602	1	993.602	1522.406	.000
NSAC	3.007	1	3.007	4.607	.036
BOW	176.633	1	176.633	270.639	.000
NSAC * BOW	.355	1	.355	.544	.464
Error	35.896	55	.653		
Total	2720.500	59			
Corrected Total	221.246	58			

a. R Squared = .838 (Adjusted R Squared = .829)

Step 4: perform the analysis of covariance with the bow as the covariate, the neck shaft angle as the categorical variable with two groups, varus and valgus and the valgus correction angle as the continuous variable. The results of the analysis are summarised in the table below:

Table 16 shows the result of analysis of covariance with lateral bowing as the covariate, neck shaft angle as the categorical variable and valgus correction angle as the continuous dependent variable

Dependent Variable: VCA

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	184.995[a]	2	92.498	142.890	.000
Intercept	998.058	1	998.058	1541.795	.000
BOW	180.725	1	180.725	279.184	.000
NSAC	2.969	1	2.969	4.587	.037
Error	36.251	56	.647		
Total	2720.500	59			
Corrected Total	221.246	58			

a. R Squared = .836 (Adjusted R Squared = .830)

After controlling within group variation attributable to the bow of the femur the valgus correction angle was compared between patients with valgus neck shaft angle with those with varus neck shaft angle. The result was significant at 0.037 indicating that there was a significant difference between patients with valgus neck shaft angles and those with varus neck shaft angles once the variation from the bow of the femur is controlled for. A regression analysis showed that femoral bowing has maximum correlation with the valgus correction angle compared to 2.4% for the neck shaft angle.

Table 17 showing the regression analysis for the valgus correction angle and the bow and neck shaft angle

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
	(Constant)	8.267	2.362		3.500	.001
1	BOW	.528	.032	.916	16.402	.000
	NSA	-.024	.019	-.073	-1.309	.196

a. Dependent Variable: VCA

DISCUSSION

The accuracy of placement femoral component in the coronal plane is one of the determinants of post-operative lower limb alignment in the coronal plane which has been shown to influence survival of the prosthesis. The distal femur cut which is performed during implantation of the femoral component is predicated on the relationship between the mechanical and anatomical axes of the femur. This relationship is influenced by coronal femoral bowing and neck shaft angle which have been shown to vary between populations. This variation potentially affects the accuracy of use of presumptive cuts and may explain the differences in literature on the accuracy of such. The objective of this study was to determine the pattern and variation of the valgus correction angle with respect to femoral bowing and neck shaft angle in the population studied and the effect of these on the accuracy of performing presumptive distal femoral cuts in the same.

The proportion of patients with bilateral osteoarthritis of the knee was higher than that reported by Oyoo et al(43) however it is reported that the incidence of bilateral osteoarthritis is higher in patients with Kellgren Lawrence grade 3 and 4 knees reaching 70%at 12 years of follow up (44). The average valgus correction angle of the 82 lower limbs sampled in the study was $6.29^0 \pm 1.80^0$. The 95% confidence interval for the true population mean for the varus correction angle regardless of lower limb alignment was $5.89^0 – 6.67^0$. Figure five is a histogram with a frequency polygon showing the distribution of the limbs according to the VCA. Calculation of the Pearson statistic for the skew yields a value of 0.16 which according to Hildebrand et al means the distribution can be treated as a normal distribution.

Tables 2 and 3 summarise the parameters of interest according to sex and test for any significant difference in the same between males and females. None of the p values in the two tailed tests for significance were <0.05 indicating no significant difference was found between limbs in males and females with respect to the valgus correction angle, the lower limb alignment and the bow of the femur. Similar to the comparison of the limbs studied on the basis of sex, there was no significant difference in the parameters of interest between left and right lower limbs. This is summarised in tables 4 and 5.

Mullaji et al (1) studied the valgus correction angle in patients with varus lower limb alignment given its high correlation with lateral bowing of the femur in literature. The valgus correction angle in the limbs with varus alignment in the population studied was significantly different from that studied by Mullaji et al. The valgus correction angle in the 59 varus limbs studied averaged $6.51^0 \pm 1.95^0$. The 95% confidence interval for the valgus correction angle in the 59 varus lower limbs was $6.02^0 - 7.00^0$. The 95% confidence interval for the valgus correction angle for the patients with varus lower limbs in the study by Mullaji et al was $7.11^0 - 7.50^0$. The two populations differ significantly $p < 0.05$ with respect to the valgus correction angle with the value being significantly lower in the varus limbs studied in this study as indicated by the lack of overlap in the 95% confidence interval for the two groups. Similarly a comparison of the average valgus correction angle in the population studied with that reported by Kharwadkar & co(14) reveals a significant difference between the two. Kharwadkar et al reported a 95% confidence interval for the valgus correction angle of $5.21^0 - 5.59^0$ which was significantly lower than that for the 82 lower limbs studied as well as the varus lower limbs considered alone $p < 0.05$.

The proportion of patients with valgus correction angles $\geq 9^0$ in the respective studies was 0% in the study by Kharwadkar et al, 9.8% in the sample studied and 18.8% in the study by Mullaji et al. These differences reported by various studies in the valgus correction angle could be explained by differences in the determinants of the relationship between the distal anatomical and mechanical axes of the femur i.e. lateral coronal femoral bowing and the NSA. The spectrum of the valgus correction angle in these studies is summarised in the diagram below:

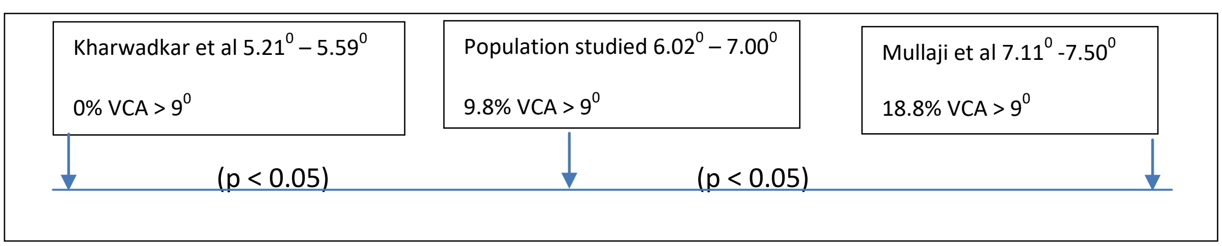


Figure 8 Showing the pattern of variation of the valgus correction angle in our study compared to two other studies

The finding suggest that use of presumptive cuts of 5-6 degrees would result in errors in approximately 9.8% of limbs performed on knee replacements. The findings in the population studied approximated those reported by Kinzel & co and Teter & co who reported error rates of 10% and 8.5% respectively in the absence of use of preoperative imaging to accurately determine the VCA to use to perform the distal femoral cut. They recommended preoperative imaging even in routine knee replacements to determine the valgus correction angle.

With respect to lateral femoral bowing of the femur, this averaged $2.54^0 \pm 3.39^0$ in the 59 varus lower limbs studied. The 95% confidence interval for lateral femoral bowing in these patients was $1.68^0 - 3.40^0$. The 95% confidence interval for the varus limbs studied by Mullaji et al was $3.29^0 - 3.91^0$. The average lateral coronal femoral bowing was lower in the 59 varus lower limbs studied when compared to that of the patients studied by Mullaji et al. The difference however was not significant as indicated by the overlap of the 95% confidence interval for the two populations.

The correlation between the coronal femoral bow and the valgus correction angle showed that lateral bowing of the femur accounted for 82% of the variation in valgus correction angle in limbs with varus lower limb alignment and 73% in all the lower limbs regardless of alignment. Both correlations were significant at $p = 0.01$. Figure 6 and 7 show that this correlation is a positive one i.e. an increase in lateral coronal femoral bowing results in an increase in the VCA. The findings are similar to those of Mullaji & co(1) who reported a strong positive correlation between lateral coronal femoral bowing and the VCA(Pearson's correlation coefficient of 70%).The correlation however is not 100% suggesting that other factors contribute to this variation including the neck shaft angle.

To demonstrate the effect of the NSA on the VCA the value of the same was compared between varus limbs with coxa vara and coxa valga. The comparison involved a number of steps. The first step was to show no significant difference in the bow of the femur between the two groups. This is demonstrated by the lack of significance in the t test between the two groups as summarised in table 10 and 11. The p value for the t statistic is 0.848 which is greater than 0.05 and therefore not significant.

Step two was to demonstrate the lack of correlation between the NSA and the bow of the femur. This is shown in table 12 which shows that the correlation between the two has a p value of 0.346 which again is not significant.

Step three involves performing a test of homogeneity of regression which means that the covariate, in this case the bow of the femur, has the same effect in both groups being compared i.e. patients with coxa vara and those with coxa valga. The value of the statistic for this analysis is shown in table 13 in the row of NSAC*BOW. The statistic has a p value of 0.464 and is therefore not significant.

With all the conditions for the analysis of covariance met a comparison of the two groups could then be performed. The findings are summarised in table 14. In the row for NSAC in the column for the p values the p value is 0.037 which shows that the statistic is significant ($p < 0.05$).

The findings above mean that there was a significant difference in the average VCA between varus limbs with coxa vara and those with coxa valga once the influence of the lateral coronal femoral bowing has been controlled for by analysis of covariance. The valgus correction angle was higher in individuals with coxa vara. This was similar to the findings in a study by Bardakos et al who demonstrated that the valgus correction angle would be lower in patients with coxa valga than in patients with coxa vara(9).

Walensky et al demonstrated that the neck shaft angle was significantly higher in blacks than in Caucasians(11). The average neck shaft angle in limbs studied was 126^0 which was significantly higher than the average neck shaft angle reported by Rickels et al for individuals aged over 50 years(12). Given the demonstration of significantly lower valgus correction angles in patients with coxa valga, the average coxa valga in the population studied may also contribute to the significantly lower average valgus correction angle when compared to that studied by Mullaji et al. The 95% confidence interval for the neck shaft angle in the population studied is 124.63^0 – 127.37^0 which differs significantly from the average neck shaft angle for Caucasian females 95% confidence interval for the neck shaft angle according to Walensky et al 121.20^0 – 121.59^0 ($p< 0.05$). The relative coxa valga in the population studied is also reported by Lakati et al(13).

The average valgus correction angle in the population studied is significantly lower than that reported by Mullaji et al however it was also significantly greater than that reported by Kharwadkar et al. This supports the argument that the valgus correction angle varies as a result of variation in femoral anatomy specifically the neck shaft angle and bowing of the femur in the coronal plane. The populations from which the samples were drawn also varied with respect to the proportion of limbs that would have errors if a presumptive distal femoral cut of 6^0 was used. Of the limbs studied by Mullaji et al 18.8% would potentially have an erroneous cut if a presumptive cut of 6^0 degrees was used. This compared to 9.7% in the limbs studied and 0% in the limbs studied by Kharwadkar et al.

The findings would therefore suggest that the use of individualised valgus correction angles in the population studied could improve the placement of the femoral component as well as the accuracy with which ideal postoperative alignment is achieved. This concurs with the findings of Palanisami et al who performed individualised cuts in one group of patients and presumptive cuts of 5^0 in another, demonstrated significantly greater accuracy in the placement of the femoral component as well as achievement of post-operative neutral lower limb alignment in patients who had individualised cuts(40).

The regression analysis could be used to derive a formula for the calculation of the valgus correction angle of 8.267 + (0.58*bow) – (0.024*neck shaft angle). The analysis of regression also confirms the positive correlation between the valgus correction angle and the bow of the femur and a negative correlation between the NSA and the VCA.

CONCLUSION

The average VCA for the distal femoral cut as predicted by whole lower limb radiographs varies between populations because of variations in the aspects of femoral anatomy that are determinants of the relationship between the anatomical and mechanical axes of the femur. These variations in the valgus correction angle may explain the differences in opinion in literature on the accuracy of using presumptive cuts. These components of femoral anatomy that function as determinants of this relationship are the neck shaft angle and coronal femoral bowing.

The positive correlation between lateral coronal femoral bowing and the valgus correction angle holds true in the population studied as well, however, the severity of lateral coronal femoral bowing was lower compared to some of the populations studied in literature e.g. Mullaji et al(1). The analysis of covariance also showed a significant difference in the VCA between patients with coxa vara and coxa valga. This mirrors the findings of Bardakos & co(9).

The proportion of patients with a valgus correction angle equal to or greater than 9^0 for whom a presumptive distal femoral cut using a valgus correction angle of 6^0 would potentially result in an erroneous cut was also lower than that observed in the study by Mullaji et al however it was larger than that reported by Kharwadkar et al(1,14). It is therefore imperative to study the variation of the valgus correction angle in various populations to determine the accuracy of use of presumptive cuts and potential utility of preoperative whole lower limb radiographs to accurately determine the valgus correction angle.

RECOMMENDATIONS

Based on the study findings the following are the recommendations:

1. The routine use of preoperative whole lower limb radiographs in the study population could potentially reduce the proportion of lower limbs with an error in the valgus correction angle used to perform the distal femoral cut.
2. Given the limited availability of facilities that perform whole lower limb radiographs the use of presumptive cuts is justified. From the study findings a valgus correction angle of between 6^0 and 7^0 should be used in the event of performing a presumptive distal femoral cut. This results in the placement of the femoral component within a prescribed range in 90.2% of lower limbs.
3. The use of preoperative whole lower limb radiographs to determine the valgus correction angle is imperative in patients with history of diaphyseal fractures of the femur or corrective osteotomies of the femur or tibia.
4. The safety of use of presumptive cuts may inherently vary from one population to another due to variation in the aspects of femoral anatomy that influence the valgus correction angle. It is therefore important to determine the pattern of variation of the valgus correction angle in various locales or populations which could influence preoperative practice including the use of preoperative whole lower limb radiographs.

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APPENDIX

DATA COLLECTION FORM

Biodata:

I. Serial Number:
II. Age
III. Sex
IV. Occupation
V. Weight (Kgs)
VI. Height (cms)
VII. Primary disease process
VIII. Time up and go TUG (secs)
IX. Stair climbing task SCT (secs)
X. Telephone number

Radiographic Variables

HKA (^{0}) ______

VCA – β (^{0}) ______

Angle of femoral bowing (^{0}) ________

Neck shaft angle (^{0}) _____________

Kellgren Lawrence grading of severity of osteoarthritis_______

Anatomical tibiofemoral angle on short AP (^{0})_______

PATIENT CONSENT INFORMATION FORM

Study Title: Radiographic Assessment of Coronal alignment of the Lower Limb in Patients with End Stage Osteoarthritis of the Knee

Introduction:

I am a postgraduate student in the department of orthopedic surgery at the University of Nairobi conducting a study for which I need your participation.

The purpose of the study is to use radiographs to establish the pattern of coronal alignment of the lower limb in patients presenting with end stage osteoarthritis. This is important in prognostication and in planning for total knee replacement.

Reason for doing the study

The primary objective of the study will be to examine the valgus correction angle and the incidence and magnitude of factors that influence it on plain whole lower limb radiographs. The valgus correction angle or femoral anatomical mechanical angle describes the relationship between the femoral mechanical and anatomical axes and is used to perform the distal femoral cut during TKR.

Study procedure

The study will enroll patients with end stage osteoarthritis of the knee and take whole lower limb and short AP knee radiographs of the affected limb and use these to determine the stage of the disease process, coronal alignment of the involved limb and the individual's femoral anatomical mechanical angle.

The information obtained will be entered in forms and subsequently stored safely in a computer for research and educational purposes. Your results will not be shared with other participants in the study and your identity and that of the patient will be kept private.

Participation

Your participation is entirely voluntary and refusal to participate will not result in any prejudice towards you and inclusion will not involve any monetary compensation.

Your participation will provide us with information that will improve the future management of patients with end stage osteoarthritis who undergo total knee replacement. At the request of the patient if there are to have TKR their valgus correction angle will be shared with their surgeon for purposes of operative planning.

Risks

The study will involve exposure to radiation but the dose is well below that recommended by the international atomic energy agency.

Confidentiality

Patients will be identified by an assigned number. No names will be recorded and at the conclusion of data collection any information that could be used to identify participants such as telephone numbers will be discarded.

Investigators note:

The purpose of this consent form is to provide you with a detailed knowledge of the study, to enable you to decide whether to participate in this study. Your participation in this research is completely voluntary. If you decide to participate, you may withdraw at any time without consequences or explanation. The results of the study will be treated with strictest confidence.

Patient's note:

My signature below indicates that I have understood the above conditions of participation in this project. I have had the opportunity to have my questions answered satisfactorily.

I VOLUNTARILY AGREE TO BE PART OF THIS STUDY.

Patient (name) ………..……………………………….

Signature/Thumbprint……………….……………………………

Investigator signature …………………………………………….

Date……………………………

For further information, you may contact the following:

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   P.O. Box 20723 (00202)
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Kichwa cha Utafiti: Tathmini ya Radiografia ya Coronal alignment ya Lower Limb katika Wagonjwa na Stage Osteoarthritis ya Knee

Utangulizi:

Mimi ni mwanafunzi wa katika idara ya upasuaji wa mifupa katika Chuo Kikuu cha Nairobi na ninafanya utafiti ambao unahitaji ushiriki wako.

Madhumuni ya utafiti ni kutumia picha zilizopigwa na nishati za X – ray kupima kiasi mguu ulivyojipinda katika wagonjwa wanaougua ugonjwa wa osteoarthritis wa goti. Umuhimu wa utafiti huu ni kutuwezesha kutabiri uwezekano wa ugonjwa huu kidhoofika na wakati wa kupanga upasuaji.

Sababu ya kufanya utafiti huu

Lengo kuu la utafiti litakuwa kuchunguza kipimo ambacho hutumiwa wakati wa kukata mfupa tunapofanya utafiti na kupima kiwango cha tofauti za maumbile ambazo huchangia tofauti kati ya wagonjwa katika kipimo hiki.

Taratibu ya utafiti

Utafiti huu utaandikisha wagonjwa wenye ugonjwa wa osteoarthritis wa goti na utahitaji picha ya mguu wote na picha ya goti zilizopigwa kutumia nishati za X – ray. Picha hizi ziatatumiwa kupima kiasi ambacho ugonjwa umeendelea, kiasi ambacho mguu unaougua umejipinda na kiwango cha kipimo cha mfupa ambao hutumiwa wakati wa kufanya upasuaji.

Taarifa zilizopatikana zitaingizwa kwa fomu na hatimaye kuhifadhiwa salama kwenye kompyuta kwa madhumuni ya utafiti na elimu. Matokeo yako hayatashirikiwa na washiriki wengine katika utafiti na utambulisho wako na wa mgonjwa utawekwa faragha.

Kushiriki

Ushiriki wako ni kwa hiari na kukataa kushiriki hakutathiri matibabu yako ubaguzi wowote na kushiriki kwako hakutaona ukipewa fedha zozote.

Ushiriki wako utatupa habari ambazo zitaboresha matibabu ya baadaye wa wagonjwa wenye ugonjwa wa osteoarthritis ambao watahitaji upasuaji. Kwa ombi la mgonjwa ikiwa katika siku za usoni atahitaji upasuaji matokeo ya utafiti yanayohitajika wakati wa upasuaji yanaweza wasilishwa kwa daktari ambaye atakuwa anamfuatilia.

Hatari

Uchunguzi utahusisha kutumia nishati za radigraphia lakini kiwango ambacho mgonjwa atastahimili kitakuwa cha chini sana na pia kinga ya viongo itatumiwa wakati wa kuchukua picha.

Usiri

Wagonjwa watatambulishwa kutimia nambari. Hakuna majina yatakayonakiliwa wakati wa utafiti na baaada ya kutamatisha utafiti kila namna ya kutambulisha mgonjwa kama nambari ya simu zitatupiliwa mbali.

Wachunguzi wanasema:

Madhumuni ya fomu hii ya idhini ni kukupa ujuzi wa kina wa utafiti, kukuwezesha kuamua kushiriki katika utafiti huu. Ushiriki wako katika utafiti huu ni kwa hiari kabisa. Ikiwa unaamua kushiriki, unaweza kujiondoa wakati wowote bila aathari au maelezo.

Nakili ya mgonjwa:

Saini yangu hapa chini inaonyesha kuwa nimeelewa masharti ya juu ya kushiriki katika mradi huu. Nimekuwa na fursa ya kuwa maswali yangu yamejibiwa kwa kuridhisha.

Nakubali kwa hiari yangu kushiriki katika utafiti huu.

Jina la mulhusika ....

Sahihi / Alama ya kidole ....

Sahihi ya mchunguzi ....

Tarehe ……………………………

Kwa habari zaidi, unaweza kuwasiliana na wafuatao:

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BUDGET

Item	Unit of measure	Number/Duration	Cost per unit (KES)	Total cost (KES)
Radiographs				
Whole lower limb radiographs		48	4000	192,000
Stationery and printing				
Consent form	1 page	48 copies	3	144
Assent form	4 pages	48 copies	3	576
Questionnaire	1 page	48 copies	3	144
Final report binding	50 pages	5 books	3	750
Report binding	Report books	5 books	200	1,000
Other costs				
Research fee	1 submission	2	1500	3,000
Transport of patients to AKUHN	1 trip	24 trips	1000	24,000
Statistician	1	1	40,000	40,000
Research assistant	1	5 months	8,000	40,000
Total				301,614