MORPHOMETRIC DIMENSIONS OF DISTAL FEMUR AND PROXIMAL TIBIA INFERENCE TO KNEE JOINT PROSTHESIS DESIGN IN TANZANIA SUBPOPULATION.

Michael Deodatus Kilimba (BScN)

A dissertation to be submitted in partial fulfillment of the requirement for the Master of Science in Anatomy of the Muhimbili University of Health and Allied Sciences.

October, 2024

Muhimbili University of Health and Allied Science

Department of Anatomy

MORPHOMETRIC DIMENSIONS OF DISTAL FEMUR AND PROXIMAL TIBIA INFERENCE TO KNEE JOINT PROSTHESIS DESIGN IN TANZANIA.

By

MICHAEL DEODATUS KILIMBA

A dissertation to be submitted in partial fulfillment of the requirement for the Master of Science in Anatomy of the Muhimbili University of Health and Allied Sciences.

October, 2024

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for examination by the Muhimbili University of Health and Allied Sciences, a dissertation entitled **morphometric dimensions of distal femur and proximal tibia inference to knee joint prosthesis design, Tanzania** in partial fulfilment of the requirement for the degree of master of science in anatomy of the Muhimbili University of Health and Allied Sciences.

……..

Prof. Dennis A. Russa

(Supervisor)

…….

Date

……..

Dr. Emmanuel Suluba

(Co - Supervisor)

…….

Date

DECLARATION AND COPYRIGHT

I, Michael Deodatus Kilimba, declare that this dissertation is my own original work and that it has not been presented and will not be presented to any other university for a similar or any other degree award.

Signature ……. Date …….

This dissertation is copyright material protected under the Berne convention, the copyright Act of 1999 and other international and national enactments, in that behalf, on intellectual property. It may not be produced by any means, in full or in part, except for short extract in fair dealings, for research or private study, critical scholarly review or discourse with acknowledgement, without the permission of director of postgraduate studies, on behalf of author and the Muhimbili university of health and allied sciences.

ACKNOWLEDGEMENTS

I would like to express my deepest gratitude to the almighty God for enabling me to complete my studies and to my sponsor, my mother (Mrs. Deodatus Kilimba), for the unwavering support.

I am profoundly thankful to my supervisors, Prof. Dennis Russa and Dr. Emmanuel Suluba, whose guidance, patience and unwavering support have been helpful throughout this research journey.

I would like to acknowledge my colleagues and the staff members at MUHAS anatomy department for their support and encouragement throughout this academic endeavor.

I also appreciate good support from MOI staff members for great cooperation during data collection and to Mr. Justin Nchimbi for his technical support during radiology sessions.

DEDICATION

I dedicate this dissertation to my lovely wife, Dr. Rose Venance Tarimo, to my beloved daughter Hopever Michael and to my parents Mr. and Mrs. Deodatus Kilimba.

TABLE OF CONTENTS

CERTIFICATION i

DECLARATION AND COPYRIGHT ii

ACKNOWLEDGEMENTS iii

DEDICATION iv

LIST OF ABBREVIATIONS x

DEFINITION OF KEY TERMS xi

ABSTRACT xii

CHAPTER ONE 1

1.0 INTRODUCTION 1

1.1 Background 1

1.2 Problem Statement 2

1.3 Research Questions 3

1.3.1 Main research question 3

1.3.2 Specific research questions 3

1.4 RESEARCH OBJECTIVES 3

1.4.1 Broad Objectives 3

1.4.2 Specific objectives 3

1.5 Rationale of the Study 4

CHAPTER TWO 5

2.0 LITERATURE REVIEW 5

2.1 Osteology of the Knee Joint 5

2.2 Diseases of the Knee Joint 5

2.3 Knee Prosthesis Design 5
2.4 Morphometric Measurements of the Knee Joint. 6
2.5 Gender Differences in Knee Morphometry 7
2.6 Differences of Knee Anthropometry between Population Groups. 8
2.7 Morphometric Measurements of the Knee Joint in the Tanzanian Population 9
CHAPTER THREE 10
3.0 MATERIALS AND METHODS 11
3.1 Type of the Study 11
3.2 Study Population 11
3.3 Study Setting and Study Area 11
3.4 INCLUSION AND EXCLUSION CRITERIA 11
3.4.1 Inclusion Criteria 11
3.4.2 Exclusion Criteria 12
3.6 Sampling Technique 12
3.7 Study Variables 12
3.7.1 Independent Variable 12
3.7.2 Dependent Variable 12
3.8 Data Collection 12
3.8.1 Femoral morphometrics: 13
3.8.2 Measurements of proximal tibia condylar measurements 14
3.9 Data Analysis 14
3.9.10 Aspect Ratio (AR) 14
3.10 Pilot Study 14
3.11 Quality Control 15

3.12 Ethical Consideration. 15
3.13 Dissemination Plan 15
3.14 Limitations and Mitigations 15
3.14.1 Limitation 15
3.14.2 Mitigation 15
CHAPTER FOUR 16
4.0 RESULTS 16
4.1 Cadaveric Morphometrics. 16
4.1.2 Morphometrics of the Distal Femur 17
4.1.3 Comparing left and right femur 18
4.1. 4 Morphometrics of Proximal Tibia 19
4.1. 5 Comparison of the left and right tibia 20
4.2 Magnetic Resonance Imaging Morphometrics (Mri-Knees). 21
4.2.1 Comparison of the Male and Female Morphometrics. 22
CHAPTER FIVE 23
5.0 DISCUSSSION 23
5.1 The Femoral Component: 23
5.1.1 Comparing the right and left sides of distal femur: 23
5.1.2 Comparing gender differences of the distal femur: 24
5.2 Tibial Component: 24
5.2.1Comparison of gender morphometric dimensions of tibia 25
CHAPTER SIX 26
6.0 CONCLUSIONS AND RECOMMENDATION 26
6.1 Conclusions 26

6.2 Recommendations 26

REFFERENCES 27

Appendix 31

Appendix I: Proforma Data Form- Femur 31

Appendix II: Proforma Data Form- Tibia. 32

Appendix III: Ethical clearance letter 33

LIST OF FIGURES

Figure 1: A and B: Shows different bone collections that were used during data collection....16
Figure 2: Shows different measurements that were done on distal femur as seen from different view. 17
Figure 3: shows different bones (femur) arranged according to their laterality. 18
Figure 4: a,b and c: Shows different measurements done on proximal tibia....19
Figure 5: a, b and c shows different images acquired from MRI during different measurements. 21

LIST OF TABLES

Table 1: Summary of dry bones used in the study 16
Table 2: below summarizes the measurements of the femur: 17
Table 3: Shows comparison between the left and right femur:-....18
Table 4: The summary of measurements of tibia(s). 19
Table 5: Summary of Comparison between Left and Right Tibia Dimensions 20
Table 6: Summary of MRI study participants 21
Table 7: Summary of comparison of male and female proximal tibia morphometrics as observed under MRI; -....22

LIST OF ABBREVIATIONS

TKA	Total knee arthroplasty
MRI	Magnetic resonance imaging
TDHS	Tanzania demographic health survey
MUHAS	Muhimbili university of health and allied sciences
MOI	Muhimbili orthopedic institute
SPSS	Statistical package for social sciences
ML	Mediolateral dimensions
APMC	Anteroposterior diameter of the medial condyle
APLC	Anteroposterior diameter of lateral condyle

DEFINITION OF KEY TERMS

Distal femur: Is defined as the region from the metaphyseal-diaphyseal junction to the articular surface of the knee, involving approximately the distal 15 cm of the femur.

Magnetic resonance imaging: Refers to a noninvasive medical imaging test that produces detailed images of almost every internal structure in the human body, including the organs, bones, muscles and blood vessels.

Proximal tibia: Is the upper part of the shinbone that connects to the knee joint.

Knee joint: Is a hinge type synovial joint, which mainly allows for flexion and extension (and a small degree of medial and lateral rotation)

Prosthesis: An artificial body part, such as a limb.

Morphometry: Refers to the study of shape variation of organs and organisms and its covariation with other variables

ABSTRACT

Introduction: The knee joint is a hinge type of synovial joint, which mainly allows for flexion and extension and a small degree of medial and lateral rotation. It is formed by articulations between the patella, femur and tibia. The knee joint is fundamentally prone to chronic disease conditions of whom knee replacement have proven to be an effective definitive management. Total knee replacement involves precisely replacing the articulating surfaces of the joint with prosthetic designs. In our settings, however, scanty data is available on knee morphometric dimensions which are essential in selecting patients specific knee joint prostheses. The currently available knee joint prosthetic models are based on western morphometries. In this study therefore we hypothesize that, the knee joint morphometries in our population is different from those from the western population.

Purpose of the study: This study aimed to obtain preliminary morphometric measurements that are Tanzanian population specific.

Broad objective: To determine the morphometric dimensions of the distal femur and proximal tibia of the Tanzanian subpopulation.

Rationale of the study: to establish preliminary morphometric dimensions that will be useful in designing Tanzanian population specific prostheses

Materials and Methods: The femur and tibia, were carefully selected and the intended morphometrics were measured. Furthermore, a skilled radiologist took and examined magnetic resonance images of a normal adult Tanzanian knee. The data were entered into Excel workbook sheets (Microsoft Office Excel; Microsoft Corporation, US; version 2020). Statistical Package for Social Sciences (version 23.0; SPSS Inc., Chicago, IL) was then used to clean and analyze the data. Measures of dispersion were among the statistical analyses performed. To ascertain whether there is a statistically significant difference in the morphological measurements between the sexes, a student's t test for equality of means was conducted**.**

Results: The mean aspect ratio of the femur was 1.13 while Tibia was found to have mean aspect ratio of 1.38. Further there was a statistical difference between male and female morphometrics in the proximal tibia, being more significant in male p=0.003.

Conclusion: The anatomical data collected in this study provides a preliminary data about the morphometry of dry adult distal femur and proximal tibiae, which will provide the basis for designing the optimal knee prosthesis in knee arthroplasty for Tanzanian population into consideration as a small sized prosthesis may show mediolateral under sizing and larger sized prosthesis may show mediolateral overhang which will lead to poor otucomes.

Budget: This study utilized a budget of 2,085,000/=Tanzanian shillings

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

The knee joint is the biggest synovial joint in the body, the knee regulates posture and the center of body mass throughout daily activity. The knee joint is formed by two joint components, an articulation between the distal femur and the proximal tibia and the other being the patellofemoral joint (1).The knee joint is virtually predisposed to different disease conditions, such as osteoarthritis (2). Some of these conditions will require restoring or replacing the function of the knee joint by using prosthetic designs such as implants (3). In most cases, knee replacement is a precision surgery that requires accurate bone cutting, balancing of the soft tissues, and proper coverage of the resected bony surface by prosthetic designs for a successful outcome (4).

The success or failure of knee arthroplasty depends a lot on the choice and type of knee prosthesis used in the procedure (1). Evidence from studies suggests that there is a racial difference in morphometric measurements of the body parts, including the knee joint (5). Furthermore, It is well understood that in order to improve the design and efficiency of knee prostheses in any population so as to duplicate patients knee anatomy almost closely to normal, there is a need for population-specific prostheses (2). The currently available knee prostheses are western population-standardized, and the Tanzanian subpopulations are observed to have different body build and stature compared with their Western counterparts. This leads to the problem of an implant mismatch with the resected bony surface in Tanzanian patients (6). It is known that the tibial component is more prone to complications in total knee arthroplasty as compared to the femoral components. In this situation, it becomes important to properly size the tibial prostheses to cut the surface of the proximal tibia to achieve the best stability and longevity for the implant (7)(8). Furthermore, the correct sizing of the components in both the anteroposterior and mediolateral dimensions is crucial for the success of knee arthroplasty (9).

Therefore, in the current study, different morphometric measurements of the distal femur and proximal tibia were taken from preserved dry bones at the MUHAS dissection laboratory, and further comparison with magnetic resonance imaging (MRI) from the Muhimbili Orthopedic Institute (MOI) were done. These anthropometric measurements will provide preliminary data for designing knee prostheses that are specific to the Tanzanian population.

1.2 Problem Statement

The demand for total knee arthroplasty has raised following increased life expectancy(10). In most cases elderly age group is mostly prone to different knee condition of whom knee arthroplasty have been proven to be safe and economical(1).Good clinical outcomes and long-term prosthesis survivability depend on appropriate coverage of the bone surface in knee prosthesis design (11,12), whereas mismatches between prostheses and the bony surface continues to be across the world (13).

Furthermore, any mismatch between the prosthesis and the bone surface, such as an overhang or under-sizing, can lead to a number of serious problems. Overhang on the tibia prosthesis could cause chronic pain (9). Under-sizing in this scenario could result in prosthesis sinking on the distal femur and possibly require revision (12,14). To our knowledge, no one publication has morphometric information on the proximal tibia and distal femur in the Tanzanian population.

Thus, the purpose of this study was to determine adult Tanzanian knee morphometric dimensions using cadaveric and radiographic methods that will help in designing population specific knee prostheses.

1.3 Research Questions

1.3.1 Main research question

What are the morphometric profiles of the distal femur and the proximal tibia among normal adult Tanzanian knees?

1.3.2 Specific research questions

- What are the morphometric dimensions of the distal femur and proximal tibia among normal adult Tanzanian knees?
- Is there a sex difference between the morphometric dimensions of the distal femur and proximal tibia among normal adult Tanzanian knees?
- What is the mean aspect ratio of the distal femur and proximal tibia among normal adult Tanzanian knees?

1.4 RESEARCH OBJECTIVES

1.4.1 Broad Objectives

To determine the morphometric dimensions of the distal femur and proximal tibia among Tanzanian subpopulation.

1.4.2 Specific objectives

- To determine the morphometric dimensions of the distal femur and proximal tibia in the Tanzanian subpopulation using categorized dry bones and MRI of the knee.
- To assess the morphometric differences of the distal femur and proximal tibia between sexes.
- To determine the mean aspect ratio of the distal femur and proximal tibia in normal adult Tanzanian knees.

1.5 Rationale of the Study

The demand for knee prostheses has raised drastically following improvement of technology and new interventions in health care system and also with increased life expectancy scales up the number of elderly of whom chronic knee conditions are commonly affecting them. In most cases total knee replacement is the definitive management which has been proven to be safe and economical. Therefore, this study will help to establish preliminary morphometric dimensions that will be useful in designing Tanzanian population specific prostheses.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1 Osteology of the Knee Joint

The knee joint is the biggest synovial joint in the body, the knee regulates posture and the center of body mass throughout daily activity. This calls for both the capacity to tolerate strong forces and a wide variety of motions in three dimensions (1,15,16). Furthermore, it is the most complicated joint in the human body, It is composed of a complicated configuration of fluid, muscle, soft tissue, and bone. It consists of three separate and partially separated compartments: two condyloid joints (tibio-femoral joints) form a complex hinge joint; a third joint (patello-femoral joint) connects the patella to the femur. The other two condyloid joints are formed between each femur condyle and the corresponding meniscus and tibia condyle. This articulation allows for mobility in six degrees of freedom and renders the knee joint inherently unstable and especially susceptible to damage (13).

2.2 Diseases of the Knee Joint

Numerous inflammatory and degenerative conditions affect the knee joint; osteoarthritis is the most prevalent. A chronic degenerative condition of the joints, osteoarthritis is typified by the peri-articular bone remodeling and loss of articular cartilage. The most common cause of locomotor impairment in the elderly is osteoarthritis of the knee. Individuals who are unable to manage their pain and experience increasing difficulty with daily activities may be candidates for surgery. In these situations, total knee replacement has been shown to be a safe and economical means of treating the condition, reducing pain, and enhancing quality of life (8,17).

2.3 Knee Prosthesis Design

At present, most total knee replacement (TKR) prostheses on the market are designed according to the sizes of Caucasian patients (1,12). The first prosthesis was introduced in 1972, and The first prosthesis to replace the knee's three compartments was this one. In a modern complete

knee arthroplasty, the damaged articular surfaces of the knee are removed, and then the knee is resurfaced with prosthetic components made of polyethylene or metal (18). When surgery is done correctly, the patient experiences great pain relief, improved function, and an overall improvement in quality of life (2,8,19)

A knee replacement surgery's outcome could be affected by prosthesis selection-related factors. Over time, advancements in prosthesis design have led to increased success rates. There are a huge variety of manufacturers and designs of knee prostheses, and currently there is no consensus on prosthesis choice, leading to wide variance among individual surgeons (16,20).

An inadequate fit between the implant and the bony surface after total knee replacement causes a number of issues. Components that are too tiny will result in a diminished bone-implant interface, which will raise contact stresses, raise the risk of fracture, and hasten the loosening process (21). The Swedish Knee Arthroplasty Register (2006) indicated this condition as the leading reason for total knee arthroplasty revisions between 1995 and 2004 (17). However, too big components may stick to the surrounding ligaments and capsular tissues, producing pain and reducing the joint's range of motion (6,9).

2.4 Morphometric Measurements of the Knee Joint.

The scientific study of the dimensions and proportions of the human body is known as anthropometry (1,22). A three-dimensional model of the knee joint's morphometry has been created using a variety of anthropometric measures. The femur and tibia's anteroposterior and mediolateral dimensions are the standard measurements. The patellar measurements measured are mediolateral and superoinferior breadth (4). A crucial metric for correlation and comparison with different knee arthroplasty systems is the femur's aspect ratio, which is the ratio of the mediolateral dimension to the anteroposterior dimension (3).

A study by Hitt et al. examined the morphometric parameters of 295 patients undergoing primary arthroplasty of the whole knee. The mean femoral aspect ratios for men and women, which are 0.81 and 0.84, respectively, clearly show gender differences. After comparing the

measurements of the proximal tibial and distal femoral with those of the present knee arthroplasty systems, it was found that the prostheses were not suitably proportioned(6) .

Dong et al. used three-dimensional measures of the 172 knees' proximal tibia and distal femur to assess the anthropometric measurements with five total knee prostheses in China. They discovered that the tibial Medio-lateral dimension was undersized in the smaller prosthesis and had an overhang in the larger prostheses. Both the femur and the tibia showed a decrease in aspect ratio with an increase in anteroposterior diameter, in contrast to the constant aspect ratio of a typical total knee prosthesis (23). These results show that detailed anthropometric measures of the knee joint are necessary to develop better prostheses and perhaps improve outcomes from total knee arthroplasty procedures. So far, studies have measured anthropometrically on arthritic knees intraoperatively after resection, or through the use of magnetic resonance imaging or computed tomography. However, figuring out the exact measurements and proportions of the human knee requires analyzing normal joints and bones. Only radiographic and dry bone measures will be able to accomplish this.

2.5 Gender Differences in Knee Morphometry

It is necessary to investigate the anatomical variations between male and female knees to determine whether a sex-specific implant design is necessary. Based on three differences in the anatomy between the female and male knees, numerous studies have argued that a whole knee design tailored specifically for females is necessary. These include a reduced medial-lateral to antero-posterior femoral condylar aspect ratio, an increased q angle, and less pronounced anterior medial and lateral femoral condyles (2,18,20).

The complementary angle that forms between the patellar tendon and the quadriceps muscles' resulting line of force is known as the q angle. Numerous studies have revealed that women have a larger q angle than men (2).

To our knowledge there is no easily retrievable scientific literature available about the gender differences in knee anthropometric measurements in the Tanzanian population.

2.6 Differences of Knee Anthropometry between Population Groups.

Studies on anthropometry have revealed that racial variations in knee anthropometry are not taken into account in the designs of knee prostheses currently in use. Due to the fact that the majority of commercially available prostheses are made using anthropometric data from Caucasian knees, African people may experience component mismatches (7,8,24).

In order to compare the knee anthropometric measurements of healthy Chinese and Caucasian patients, Yue et al. used three-dimensional models of the knees created by CT and MRI scans. According to the study, Chinese men had a wider proximal tibia than their Western counterparts, whereas Chinese females had a substantially narrower distal femur than Caucasian females. The findings supported the idea that the knees of Chinese and Caucasian people differ significantly in size and shape.

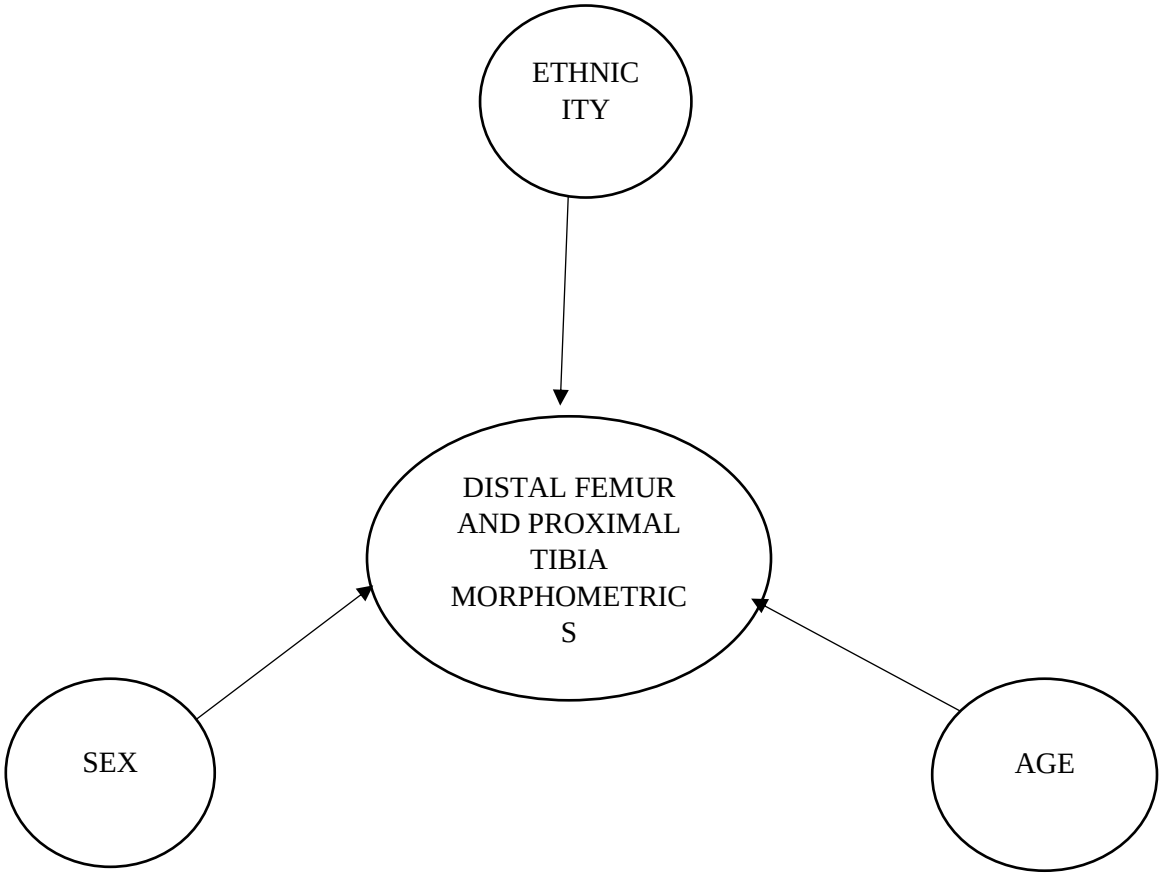
Kwak et al. measured the morphometric properties of the resected femurs of seventy patients who had total knee replacements and contrasted them with five of the most popular femoral implants on the market. It was discovered that three implants tended to overhang because their medial-lateral breadth was greater than the width of the distal condyle that had been removed. According to the study's findings, femoral implants which had previously been demonstrated to be appropriate for use in Caucasian patients were unsuitable for use in Chinese patients. As a result, manufacturers were required to develop femoral implants that were more appropriate for Chinese patients (12).

The size and shape of the knee varies significantly between races, according to these and related studies conducted in Japan, Korea, and Taiwan. This could have an effect on the implants used in total knee arthroplasty. In Tanzania, loosening of the implants has also been identified as a contributing factor to revision arthroplasty, particularly total hip arthroplasty(14) .

2.7 Morphometric Measurements of the Knee Joint in the Tanzanian Population

In Tanzania, no known study has been done to assess the knee joint morphometrics. Hence, there is scanty data available on the morphometric measurements of the knee joint. In this case it is difficult to obtain best fit knee prostheses. Furthermore, even imaging studies, which may provide accurate measurements needed for designing prostheses (1), have never been done so far.

2.8 Conceptual framework



The above conceptual framework depicts how sex, age and ethnicity many influence variations in morphometrics of distal femur and proximal tibia**.**

Source: researcher own construction.

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Type of the Study

This study employed a descriptive cross-sectional study design. A cross-sectional study design is suitable for ascertaining the relationship between two variables at the same time.

3.2 Study Population

This study involved data collected from dry bones (femur and tibia) from the MUHAS dissection room and magnetic resonance images of the knees from Muhimbili Orthopedic Institute.

3.3 Study Setting and Study Area

MUHAS and MOI are the two distinct contexts in which the study was carried out. Tanzania's oldest and biggest health sciences institution, MUHAS, provides a variety of courses pertaining to health. Every academic year, following standard dissections, the department of human anatomy maintains a dissection room where various specimens, including bones, are prepared and kept. MOI is a university hospital with national specialization that provides training, research services, and care in orthopedics, neurosurgery, and traumatology. The institute can accommodate 150 beds and sees 166 patients a day on average. It is situated in Tanzania's Upanga, Ilala district, in Dar es Salaam. With 5,383,728 residents, Dar es Salaam is a large city, according to the results of the 2022 census. The knee MRIs was acquired from MOI, and the dry bones was selected from the MUHAS dissection Laboratory.

3.4 INCLUSION AND EXCLUSION CRITERIA

3.4.1 Inclusion Criteria

Dry bones without any pathological condition from cadaveric specimens (femur and tibia)

Knee MRI images of subjects above 18 years

3.4.2 Exclusion Criteria

Dry bones without any pathological condition but cannot be used in the study because of macerated condyles and non-pathological deformities.

3.5 Sampling size and sampling technique.

3.5.1 Sample size

Sample size included all the available specimens in the dissection laboratory.

3.5.2 Sampling technique.

Simple random sampling technique was employed in which after collecting all the available dry bones that can be used, the researcher created a table of random numbers where lottery method was employed in selection of final specimens to be used in the study.

3.6 Study Variables

3.6.1 Independent Variable

Sex, age and ethnicity

3.6.2 Dependent Variable

Distal femur morphometrics

Proximal tibia morphometrics

3.7 Data Collection

With a resolution of 0.01 a sliding digital caliper was used to measure the dry bones. There was enough "trial and error" time before the systematic recording of measurements is done. Standardized measurements were made of the knee's dimensions, with an accuracy of 1/100th of a millimeter. To minimize any potential intra-observer bias, every measurement was performed by the primary investigator, vocalized, and recorded on a smartphone.

Further for each individual patient enrolled, the 1.5 Tesla Knee MRI (Magnetom Avanto-Siemens, Image J program ver. 1.44, JAVA, California, CA, USA) was collected and the slice spacing was 3 mm. The NW, medial condylar width, and lateral condylar width of each patient was measured at an intermediate imaging, among the obtained ones, the popliteal grooves was observed under the T1 coronal view of MRI.

A repeat measurement was conducted the same way on a different day. Once all of the measurements have been completed, the readings were recorded into the data form. The following was measured, among other:

3.7.1 Femoral morphometrics:

i. Medio-lateral length (ML): The greatest distance along the trans-epicondylar axis between the two femoral condyles shall be the definition of this dimension.
ii. Antero-posterior length (AP): The biggest measurement along its length will be used to define the antero-posterior length of the lateral (APLC) and medial (APMC) condyles, which will be measured independently.
iii. Width of condyles (W): This dimension was defined as the maximum thickness of the medial (WMC) and lateral (WLC) condyles at the trans-epicondylar plane.
iv. Height of condyles (H): This dimension was described as the greatest separation between the superior aspect of the articular surface of the medial (HMC) and lateral (HLC) condyles and the tangent drawn to each condyle (parallel to the transepicondylar axis).
v. Depth of intercondylar notch (DIC): The antero-posterior depth of the femoral intercondylar notch at the transepicondylar plane **wa**s used to describe this dimension.
vi. Width of the intercondylar notch (WIC): This dimension was defined as the maximum width of the femoral intercondylar notch.

3.7.2 Measurements of proximal tibia condylar measurements

The maximal anteroposterior length of the lateral (APLC) and medial (APMC) tibial condyles will be measured independently.

i. Anteroposterior length (AP) The anteroposterior distance in the intercondylar region across from the tibial tuberosity will be used to establish the midline anteroposterior length (MAP).
ii. The maximal length in the mediolateral dimension is known as the mediolateral length (ML).

3.8 Data Analysis

The data was entered into Excel workbook sheets (Microsoft Office Excel; Microsoft Corporation, US; version 2020). SPSS (version 23.0; SPSS Inc., Chicago, IL) was used to clean by correcting the errors in the data set, categorical and numerical variables and then finally analyze the data. Measures of dispersion and measures of central tendency were among the statistical analyses that was performed. To ascertain whether there is a statistically significant difference in the morphological measurements between the sexes, a student's t test for equality of means was be conducted.

3.9Aspect Ratio (AR)

We used different femur and tibia dimensions to record the aspect ratio, which was computed as the medio-lateral dimension divided by the anteroposterior dimension.

For the femur, AR = ML/APMC.

For the tibia, AR = ML/APMC.

3.10 Pilot Study

Pretesting of the survey form for data collection and tool optimization for data collection was carried out. In the optimization procedure, magnetic resonance imaging and dry bones was used.

The information gathered during the pilot study served as a roadmap for the subsequent stages of the investigation however the principal researcher did not include these findings in the final data set. The data from pilot study were discarded so as to prevent any chance for data contamination.

3.11 Quality Control

The methodology for obtaining data from magnetic resonance imaging and dry bone samples were be taught to the research assistant. Research assistants with experience in radiographic images and dry bone00s were used.

3.12 Ethical Consideration.

The ethical clearance was sought from the Muhimbili University of Health and Allied Sciences (MUHAS) institutional review board, and permission to conduct the study was obtained from the MUHAS and MOI authorities as attached in appendix III.

3.13 Dissemination Plan

The results of this investigation was combined into a dissertation, which was presented to the postgraduate studies directorate at Muhimbili University of Health and Allied Sciences (MUHAS) in partial fulfillment of the requirements for the Master of Science in Anatomy Degree. The library and MUHAS repositories will have copies available. The manuscript is going to be ready for submission to a peer-reviewed publication.

3.14 Limitations and Mitigations

3.14.1 Limitation

The available dry bones demographics are unknown.

3.14.2 Mitigation

This was mitigated by supporting the obtained data with MRI-knee morphometric dimensions.

CHAPTER FOUR

4.0 RESULTS

4.1 Cadaveric Morphometrics.

A total of 212 unpaired dry bones were used in the study. Of the 212 dry bones 100 were tibia and 112 were femur. Of the 112 femur(s) 70 were right sided whereas 42 were left sided and of the 100 tibia bones 60 were right sided and 40 were from left side.

Table 1: Summary of dry bones used in the study

Dry bone	**Frequencies**
Femur	Left =42
	Right= 70
Tibia	Left =40
	Right =60
Total(N)	N=212



Figure 1A and B: 1A shows bones collection that were used during the study and Figure 1B shows different bones that were excluded during data collection due to various reasons such as macerated condyles, periosteal reactions and other deformities.

4.1.2 Morphometrics of the Distal Femur

Morphometric measurements were done for 112 unpaired femur(s),70 were from right sided whereas 42 were left sided.

The mean aspect ratio was found to be 1.13

Table 2: below summarizes the measurements of the femur:

Morphometric measurements	Mean	Median	Standard deviation	Range
APMC	63.17	72.88	16.00	36.25
APLC	46.95	41.84	10.34	24.69
ML	71.47	71.82	6.85	16.92
Aspect ratio (ML/APMC)	1.13	0.98	0.43	0.47



Figure 2A,B and C: Figure 2A shows measurement of mediolateral dimension of medial condyle, 2B shows measurement of anteroposterior of the medial condyle and figure 2C shows measurement of anteroposterior dimensions of the lateral condyle of the femur.

4.1.3 Comparing left and right femur

On comparison of the right and left femurs in dry bones it was found that the mean APMC and Aspect ratio were significantly different between right and left femurs. The mean APMC of the right side was 71 .24 and that of the left side was 70.14, the difference of the APMC was 1.1 mm (left more than right, p value 0.03). The mean Aspect ratio of the right side was 1.18 and that of the left side was 1.07, (right more than left, p value 0.02). There was no statistical difference between means of Length, APLC or ML

Table 3: Shows comparison between the left and right femur:-

Morphometric measurements	Left femur mean	Right femur mean	P value
APMC	71.24	70.14	0.03
APLC	56.33	41.32	0.2
ML	75.93	68.75	0.07
Aspect ratio(ML/APMC)	1.07	1.18	0.02



Figure 3A and B: Figure 3A and B shows different bones (femur) arranged according to their laterality as seen from different view.

4.1. 4 Morphometrics of Proximal Tibia

Morphometric measurements were done on 100 unpaired tibia(s), 60 were from right and 40 were from left side. The mean aspect ratio was found to be 1.38.

Table 4: The summary of measurements of tibia(s).

Morphometrics	Mean	Median	Standard deviation	Range	
				Minimum	Maximum
APMC	50.54	51.65	2.76	47.08	53.97
APLC	49.67	51.65	2.75	46.60	52.52
MAP	50.08	51.42	3.70	45.96	54.87
ML	69.76	68.43	9.34	80.56	56.78
Aspect ratio(ML/APMC)	1.38	1.32	3.38	1.71	1.05

APMC- Anteroposterior length of medial condyle; APLC-Anteroposterior length of lateral condyle; MAP- Midline anteroposterior length; ML- Mediolateral length.

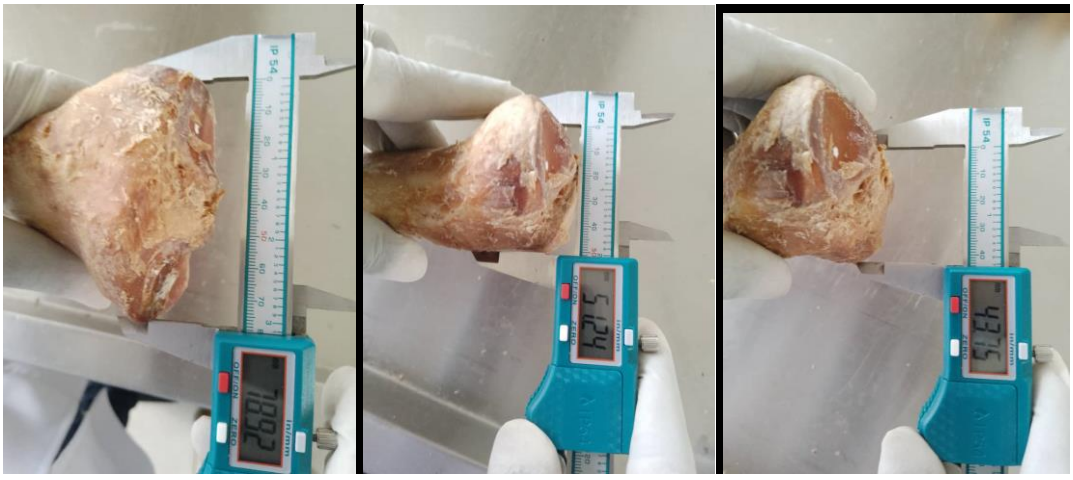


Figure 4 A,B and C: Figure 4A shows measurement of the mediolateral dimensions of the proximal tibia, figure 4B shows anteroposterior dimension of the medial condyle and 4C shows measurement of the anteroposterior dimension of the lateral condyle.

4.1. 5 Comparison of the left and right tibia

On comparison of the right and left tibias in dry bones it was found that there was no significantly difference between the means of any dimension as shown in Table 5:-

Table 5: Summary of Comparison between Left and Right Tibia Dimensions

Morphometrics	Right tibia mean	Left tibia mean	P-value
APMC	50.32	50.85	0.33
APLC	49.17	50.43	0.46
MAP	49.93	50.33	0.44
ML	74.93	62.00	0.25
Aspect ratio (ML/APMC)	1.49	1.22	0.76

APMC- Anteroposterior length of medial condyle; APLC-Anteroposterior length of lateral condyle; MAP- Midline anteroposterior length; ML- Medio-lateral length.

4.2 Magnetic Resonance Imaging Morphometrics (MRI-Knees).

A total of 20 MRI-knees Tesla T2-weighted images were examined by using DICOM radiant software and the following results were obtained. Among the studied MRI images female participants contributed about 55%. Further majority of the study participants who were involved in the study were 61 years of age and above (50%).

Table 6: Summary of MRI study participants

Variables	Frequency (n)	Percentages (%)	Mean	P-value
Sex				
Male	9	45	3.2	0.03
Female	11	55		
Age groups				
19-45 years	3	15		
46-60 years	7	35	1.45	
61 and above	10	50		0.07

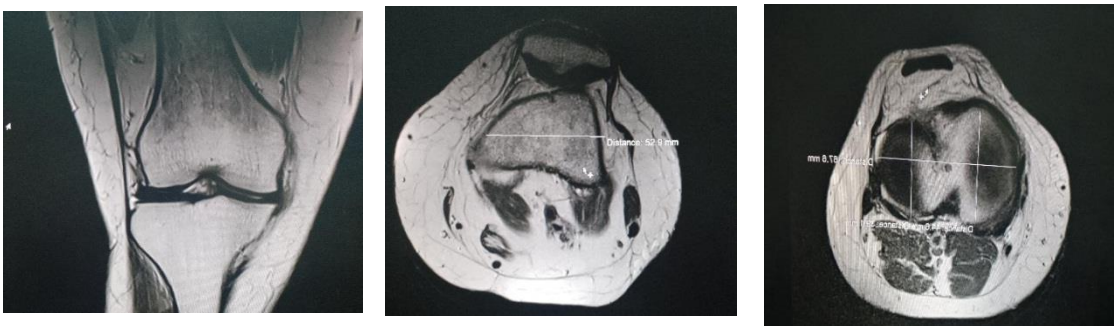


Figure 5: a, b and c shows different images acquired from different views on MRI during different measurements.

4.2.1 Comparison of the Male and Female Morphometrics.

There was a statistical significant difference between the proximal tibia in male and female (APMC-P=0.003, APLC-P=0.03, ML-P=0.03) being more significant in male than female.

Table 7: Summary of comparison of male and female proximal tibia morphometrics as observed under MRI; -

Measurement	Male	Female	P-Value
APMC	49.01	45.01	0.003
APLC	43.70	41.10	0.03
MAP	50.08	48.52	0.06
ML	69.76	66.10	0.03

APMC- Anteroposterior length of medial condyle; APLC-Anteroposterior length of lateral condyle; MAP- Midline anteroposterior length; ML- Medio-lateral length

CHAPTER FIVE

5.0 DISCUSSSION

This research was aimed to study the morphometry of normal adult knees in the Tanzanian population in order to assess the need for Tanzanian population specific prosthesis designs by measuring the various dimensions of the distal femur and proximal tibia in categorized cadaveric dry bones and MRI-knees measurements.

Morphometric measurements in general have been used in research for; identifying and characterizing structural differences among different populations, ethnic groups and between gender. In knee arthroplasty related studies, morphometric measurements of the knee joint have been done to describe racial and gender differences and also to understand prosthesis designs.

5.1 The Femoral Component:

In the sizing of the femoral component, the anteroposterior diameter of medial condyle (APMC) is important in maintaining flexion - extension spacing and optimal tension in the quadriceps mechanism (25). Whereas the mediolateral diameter (ML) determines adequate coverage of the resected bone surface, allowing even stress distribution, tension-free wound closure, and smooth tracking of the patellar component in the trochlear groove during flexion (26).Accurate sizing of the femoral component is essential in the anteroposterior dimension and the permissible error in component selection should not exceed 3 to 4 mm (26). Oversizing in the anteroposterior dimension alters the balance in flexion-extension spacing, resulting in postoperative flexion tightness because of increased tension in the quadriceps mechanism (14,25,27).

5.1.1 Comparing the right and left sides of distal femur:

In this study, in the comparison of right and left femurs in dry bones it was found that amongst most parameters there was no difference between the dimensions of the two sides except that of APMC which showed a statistically significant difference between the mean of right 71.24 and left side 70.14, but this difference of 1.22 mm may not be clinically significant. This difference was not observed in the measurements of the MRI. Other studies within each racial group also showed no statistical difference between right and left sides for distal end of femur (28). This

therefore proves the assumption in common practice that, there are no significant differences on anatomical and functional comparison of parameters from one side to the other (although symmetry is unknown) (19).

5.1.2 Comparing gender differences of the distal femur:

There has been ongoing controversial school of thoughts, with conflicting suggestions regarding whether distinct knee prosthesis components with different sizes and shapes are necessary to accommodate morphologic differences of the distal femur between men and women. Given that women are the recipients of approximately two third of all total knee arthroplasty surgeries performed, if in fact there are gender differences in the shape and dimensions of the distal femur, then a design that accommodates these differences might be appropriate.

On comparing between male and female dimensions of the distal femur in this study was based on data obtained from MRIs, was found that the means of all dimensions including APMC (males: 61.28 ± 11.6 mm; females: 57.34 ± 5.36 mm, p value 0.16), APLC (males: 62 ± 9.08 mm; females: 57.9 ± 3.74 mm, p value 0.03); ML (males: 77.74 ± 8.62 mm; females: 73.39 ± 4.16 mm, p value 0.02), were more in males than in females and correspondingly the Aspect Ratio (males: 1.27 ± 0.06 mm; females: 1.28 ± 0.03 mm, p value 0.77) females more than males. The analysis does not reveal a statistically significant difference [with p value > 0.05(except in case of APLC and ML)] between the two genders. This could be due to the small sample of MRI images studied. These are similar to the findings of Vaidya et al. in Indian population showing that the mean AP in men was 61.09 mm and in women was 55.58 mm studied on eighty six knees measured using CT scans (25).

5.2 Tibial Component:

In knee arthroplasty, the geometry of the tibial component should match the normal anatomy as closely as possible. This would provide for the best stability and load transfer (29) . For the design of a tibial component with maximal coverage, it is essential to have anthropometric data of the proximal tibia at the condylar level. In the present the dimensions studied in the proximal tibia were: Anteroposterior length of medial condyle (APMC); Anteroposterior length of lateral

condyle (APLC); Anteroposterior length at the midline (MAP); Maximum mediolateral length (ML).

In this study, of 100 proximal tibias the mean MAP was 50.08 ± 4.8 mm; ML was 69.76 ± 4.9 mm this was almost similar to a study done by abdelnasser et al., who studied 100 tibias in the north african population showed that mean MAP was 48.3 ± 5.4 mm and ML was 74.3 ± 6.6 mm. In view of the similarity in the dimensions between the present study and the other two studies which used radiological means for measurement (MRI and CT respectively) it can be suggested that, unlike the femoral component, the tibial component size can be effectively predicted using radiological means preoperatively. There is however, paucity of further anthropometric data on proximal tibia in Tanzanian population and from other racial groups.

Further study showed that there was no statistically significant difference between any of the dimensions while comparing the two sides in both dry bones and cadaveric measurements. Therefore, as seen in the femoral dimensions, it would be safe to assume no difference on anatomical and functional comparison of parameters from one side to the other. Comparing gender differences of proximal tibia.

5.2.1Comparison of gender morphometric dimensions of tibia

In this study there was statistically significant difference in APMC: APMC males was 49.01 mm, females were 45.01 mm (difference of 4.0 mm; males more than females, p value 0.07) and APLC: APLC males was 43.70 mm, females were 41.10 mm (difference of 2.6 mm; males more than females). Furthermore, there was significant difference between genders in the MAP or the ML dimension. This is similar to the study by Samuel frank et., al.(1), where MAP males was 53.8 ± 6.6 mm and in females was 46.6 ± 3.6 mm (p value 0.00), also ML in males was 83.0 ± 6.2 mm and in females was 71.7 ± 4.0 mm were also different.

CHAPTER SIX

6.0 CONCLUSIONS AND RECOMMENDATION

6.1 Conclusions

The present study found that the morphometric features of the distal femur in normal Tanzanian adult knees shows great gender differences, with females showing significantly smaller dimensions than males. Also, the inter-individual variety of the distal femur and proximal tibia morphometrics should be taken into account when choosing the proper femoral and tibial component size during operation. These data may also be useful for designing racial-specific TKA prostheses in Tanzania.

6.2 Recommendations

Overall, the results obtained from this study supports the need for Tanzanian population specific knee prosthesis. Therefore, the findings from this study could possibly be used in designing such prosthesis. However, to our knowledge this is the first study to be conducted regarding morphometric dimensions of the distal femur and proximal tibia and the sample cannot be fully used to generalize the findings. Hence, it is recommended that further studies are need for a large sample so as to have a good population representation toward designing Tanzanian population specific knee prosthesis.

REFFERENCES

1. Branch A. Morphometric analysis of the adult knee and its correlation with current knee arthroplasty systems. 2013; Available from: http://repository-tnmgrmu.ac.in/id/eprint/11700

2. Loures FB, De Araújo Góes RF, De Sousa EB, Cavanellas N, Barretto JM, Tamaoki MJS, et al. Intraoperative morphometric study of distal femur in Brazilian patients undergoing total knee arthroplasty. PLoS One. 2020;15(5):1–12.

3. Ke S, Ran T, Ma T, Qin Y, Zhang B, Wang M. A Morphometric Study of the Distal Femoral Resected Surface In Osteoarthritis Knees of the Patients in Southwest China and a Comparison with Femoral Components in Six Total Knee Arthroplasty Systems. Orthop Surg. 2023;15(4):953–60.

4. Bonnin MP, Schmidt A, Basiglini L, Bossard N, Dantony E. Mediolateral oversizing influences pain, function, and flexion after TKA. Knee Surgery, Sport Traumatol Arthrosc. 2013;21(10):2314–24.

5. Eboh DEO, Igbinedion EN. Morphometry of the distal femur in a South-South Nigerian population. Malaysian J Med Heal Sci. 2020;16(4):197–201.

6. Hitt K, Shurman JR, Greene K, Mccarthy J, Moskal J, Hoeman T, et al. Anthropometric Measurements of the Human Knee : Correlation to the Sizing of Current Knee Arthroplasty Systems. 2009;PubMed Central.

7. Gandhi S, Kumar Singla R, Mehta V, Kumar Suri R. Morphometric analysis of upper end of tibia. J Clin Diagnostic Res. 2014;8(8):10–3.

8. Akhtar MJ, Reeti R, Kumar B, Sinha RR, Kumar A. Morphometric study of upper end of tibia and its implications in total knee replacement. Indian J Clin Anat Physiol. 2021;8(3):213–8.

9. Bonnin MP, Bossard N, Dantony E, Victor J. Morphometric analysis of the distal femur in total knee arthroplasty and native knees. 2016;98(1):49–57.

10. TDHS. Demographic and Health Survey and Malaria Indicator Survey. Pap Knowl Towar a Media Hist Doc. 2022;1–23.

11. Zhang Z, Zhang Q, Chen Z, Jin Z. Morphological Measurements of the Normal Distal Femur and Proximal Tibia between Han Chinese and Mongolian Chinese in a Healthy Chinese Population Morphological Measurements of the Normal Distal Femur and Proximal Tibia between Han Chinese and Mongolian C. 2019;(June).

12. Kwak DS, Surendran S, Pengatteeri YH, Park SE, Choi KN, Gopinathan P, et al. Morphometry of the proximal tibia to design the tibial component of total knee arthroplasty for the Korean population. Knee. 2007;14(4):295–300.

13. Davies PSE, Graham SM, Maqungo S, Harrison WJ. Total joint replacement in sub-Saharan Africa: a systematic review. Trop Doct. 2019;49(2):120–8.

14. Saguda Nilla A, Sunzu R, Mtui EB, Jorgen Rutegard N, Haonga BT. Rate and Causes of Total Hip Arthroplasty Revision at a Reference Hospital in Tanzania 2008-2018. Asian J Orthop Res [Internet]. 2022;7(2):28–34. Available from: https://www.sdiarticle5.com/review-history/81809

15. Abulhasan JF, Grey MJ. Anatomy and physiology of knee stability. J Funct Morphol Kinesiol. 2017;2(4).

16. Gayathri UP, Bamne A. A study on morphometric dimensions of tibial condyles in Indian population. Indian J Clin Anat Physiol. 2020;7(3):280–4.

17. Robertsson O. From the Department of Orthopedics The Swedish Knee Arthroplasty Register Validity and O utcome Otto Robertsson Thesis. 2015;(December).

18. Patil S, McCauley JC, Pulido P, Colwell CW. How Do Knee Implants Perform Past the Second Decade? Nineteen- to 25-year Followup of the Press-fit Condylar Design TKA. Clin Orthop Relat Res. 2015;473(1):135–40.

19. Tay KS, Lo NN, Yeo SJ, Chia SL, Tay DKJ, Chin PL. Revision total knee arthroplasty: Causes and outcomes. Ann Acad Med Singapore. 2013;42(4):178–83.

20. Shojaolsadati P, Yüzbasioglu N, Nalbant A, Ormeci T, Albay S, Ortug A, et al. The magnetic resonance imaging evaluation of morphometry of the distal femur and proximal tibia on adult anatolian population. J Anat Soc India. 2020;69(1):9–14.

21. Berend ME, Ritter MA, Meding JB, Faris PM, Keating EM, Redelman R, et al. Tibial component failure mechanisms in total knee arthroplasty. Clin Orthop Relat Res. 2004;428(428):26–34.

22. Chui CS, Leung KS, Qin J, Shi D, Augat P, Wong RMY, et al. Population-Based and Personalized Design of Total Knee Replacement Prosthesis for Additive Manufacturing Based on Chinese Anthropometric Data. Engineering [Internet]. 2021;7(3):386–94. Available from: https://doi.org/10.1016/j.eng.2020.02.017

23. Dong X hui, Huang X hui, Chen M, Chang YH, Ling M, Yang B. Three-dimensional morphometric differences of resected distal femurs and proximal tibias in osteoarthritic and normal knees. BMC Musculoskelet Disord [Internet]. 2021;22(1):1–6. Available from: https://doi.org/10.1186/s12891-021-04889-z

24. Phombut C, Rooppakhun S, Sindhupakorn B. Morphometric analysis and three-dimensional computed tomography reconstruction of thai distal femur. Appl Sci. 2021;11(3):1–14.

25. RANAWAT CS. The patellofemoral joint in total condylar knee arthroplasty: pros and cons based on five-to ten-year follow-up observations. Clin Orthop Relat Res. 1986;205:93–9.

26. Mihalko WM, Ali M, Phillips MJ, Bayers-Thering M, Krackow KA. Passive knee kinematics before and after total knee arthroplasty: are we correcting pathologic motion? J Arthroplasty. 2008;23(1):57–60.

27. Mahoney OM, Kinsey T. Overhang of the femoral component in total knee arthroplasty: risk factors and clinical consequences. JBJS. 2010;92(5):1115–21.

28. Fitzpatrick CK, FitzPatrick DP, Auger DD. Size and shape of the resection surface geometry of the osteoarthritic knee in relation to total knee replacement design. Proc Inst Mech Eng Part H J Eng Med. 2008;222(6):923–32.

29. Uehara K, Kadoya Y, Kobayashi A, Ohashi H, Yamano Y. Anthropometry of the proximal tibia to design a total knee prosthesis for the Japanese population. J Arthroplasty. 2002;17(8):1028–32.

Appendix

Appendix I: Proforma Data Form- Femur

1. Study ID number:

2. Side:

Measurement	(mm)	(mm)
AP length at medial condyle		
AP length at lateral condyle		
ML length at epicondyles		
Width of medial condyles		
Width of lateral condyles		
Height of medial condyles		
Height of lateral condyles		
Depth of intercondylar notch		
Width of intercondylar notch		

Appendix II: Proforma Data Form- Tibia.

1. Study ID number:

2. Side:

Measurements of the tibia	**(mm)**	**(mm)**
AP length at medial condyle		
AP length at lateral condyle		
Midline AP		
Maximum ML length		

Appendix III: Ethical clearance letter

UNITED REPUBLIC OF TANZANIA

MINISTRY OF EDUCATION, SCIENCE AND TECHNOLOGY

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

OFFICE OF THE DIRECTOR – RESEARCH, PUBLICATIONS AND INNOVATIONS

Ref. No.DA.282/298/01.C/2242 Date: 17/05/2024

MUHAS-REC-05-2024-2242
MICHAEL DEODATUS KILIMBA
COLLEGE OF MEDICINE
MUHAS

RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED: MORPHOMETRICS OF THE DISTAL FEMUR AND PROXIMAL TIBIA: CADAVERIC AND RADIOLOGICAL STUDY INFERENCE TO KNEE JOINT PROSTHESIS DESIGNING IN TANZANIA.

Reference is made to the above heading,

I am pleased to inform you that the Chairperson has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 17/05/2024
EXPIRATION DATE OF APPROVAL: 17/05/2025

STUDY DESCRIPTION:
Purpose:
The purpose of this cross sectional is study to obtain preliminary morphometric measurements of the distal femur and proximal tibia that are Tanzanian population specific.

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided: https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2015367.pdf and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain Data Transfer Agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain Material Transfer Agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country.
8. Apply for and obtain permission to publish the results from National Institute for Medical Research. The application should be before submitting to a publisher and not concurrently through the email publications@nimr.or.tz.
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website https://drp.muhas.ac.tz/.

Dr. Nahya Salim Masoud,
Chairperson, MUHAS Research and Ethics Committee