SHOE SIZE AS A PREDICTOR FOR TOTAL KNEE ARTHROPLASTY COMPONENT SIZES IN SOUTH AFRICAN PATIENTS

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of

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I Zwelibanzi William Zondo declare that this research report is my own, unaided work. It is being submitted for the Degree of Master of Medicine in the branch of Orthopaedic Surgery at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

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(Signature of candidate)

17 day of MAY 2021 in JOHANNESBURG

Presentations and publications arising from the research project

None so far but the research will be sent for publication

Abstract

Background: For successful total knee replacement surgery to be carried without prior implant size templating; implant companies have to send multiple instrument trays containing different implant sizes for the surgeon to choose from. The effect of sending multiple trays means more autoclaving of trays, increased transportation requirements and ultimately an increase in the carbon footprint. Multiple trays in theatre also cause overcrowding, which can have a negative impact on maintenance of sterility and theatre efficiency. Our study was aimed at exploring an alternative method of templating where a surgeon simply uses a regression equation based on shoe size to predict total knee component sizes. The basis of this study is that the same has been proven in Western and Eastern populations. However, to the best of our knowledge, no such study has been done on an African population. What is unique about our study in a South African population is the diversity of South Africans in terms of race.

Methods: A total of 205 contactable patients who had total knee replacement done at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) between 2016 – 2019 were chosen for the study. Their shoe sizes were collected and a linear regression equation was generated (developed) to see if shoe size could be used as a predictor for total knee component sizes in South African patients. South African races included in the study were black African, Caucasian, mixed race and patients of Indian extraction. All selected patients included had a total knee replacement procedure done using the Smith and Nephew Gen 2 implants.

Results: We found a statistically significant correlation between shoe size and tibial component across all four groups. There was also a statistically significant correlation found in black African and Caucasian patients concerning femoral component size prediction. No statistically significant correlation was found between shoe size and femoral component in the mixed race group and patients of Indian extraction.

Conclusion: Shoe size is a good predictor for total knee component sizes in South African patients.

Keyword: Orthopaedic Templating: is a process where in surgeons using either acetate templates or digital templates estimate the correct size of the prosthesis to be used in surgery.

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Nomenclature and Definition

OA: OSTEOARTHRITIS

CAIG: C ARM INTENSIFIER GUIDE

CAOS: COMPUTER ASSISTED ORTHOPAEDIC SURGERY

CEO: CHIEF EXECUTIVE OFFICER

CMJAH: CHARLOTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

HIV: HUMAN IMMUNODEFICIENCY VIRUS

HREC: HUMAN RESEARCH ETHICS COMMITTEE

PACS: PICTURE ARCHIVING AND COMMUNICATION SYSTEM

THR: TOTAL HIP REPLACEMENT

TJA: TOTAL JOINT ARTHROPLASTY

TJR: TOTAL JOINT REPLACEMENT

TKA: TOTAL KNEE ARTHROPLASTY

TKR: TOTAL KNEE REPLACEMENT

SA: SOUTH AFRICA

UK: UNITED KINGDOM

Definition –

Orthopaedic Templating: is a process wherein surgeons using either acetate templates or digital templates estimate the correct size of the prosthesis to be used in surgery.

CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

1. Introduction

Projections show that the demand for total joint arthroplasty (TJA) done is going to pose a burden to healthcare systems due to the increase in the aging population (1). Kurtz *et al*. (2009) assessed the future demands on the United States health care system for both primary and revision total knee replacements (TKRs) in patients below the age of 65 years, and they found an increasing demand for TKR. The demand for primary TKR among patients below the age of 65 years was projected to exceed 50% by 2030. Furthermore, patients below the age of 65 years were projected to exceed 50% of revision cases by 2030, thus, it is crucial to improve reliability as well as survivorship of joint replacement in order to meet future demands for TKRs (1). In sub-Saharan Africa, most studies done have looked at the outcomes of total joint replacements (TJRs), not projections regarding primary and revision TKR burden. The only country in sub-Saharan Africa reported to have a comprehensive Arthroplasty joint registry is Malawi (2).

Therefore, it is important to establish more cost effective strategies in order to reduce the financial burden on health care systems. It has been shown that TJA procedures yield good results and are less costly than the alternative treatment methods (3). Bedair *et al*. (2014) studied the economic impact on young patients treated conservatively versus TKRs. Their findings were that it was beneficial to the economy of the country to perform TKR in young patients who have advanced OA of the knee with associated activity limiting pain. Restoring these young patients' functions is critical to society since this population can generate future earnings, which will in turn benefit the society and the country at large (3).

Linden *et al*. (2008)'s studied newer technologies such as the computer assisted orthopaedic surgery (CAOS) with the aim to assess the accuracy of modern technology in choosing the correct prosthesis. CAOS has been shown to help improve alignment and position of the components in TKRs. Linden *et al*.'s study revealed that there was more over-sizing of the femoral component in CAOS group when compared to the conventional templating group. The two approaches showed that there was no significant difference for the tibia components (4). Waters *et al*. (2011), in their study which analysed procedure related costs and proposed benefits using patient specific approach in TKR, found that on average conventional, computer navigated and patient specific methods took 90, 129 and 77 minutes, respectively. On average the conventional, computer navigated and patient specific TKR costs $2572.98, $3106.07 and $3106.07, respectively in the United States. On per case basis, patient specific TKR was more costly than the conventional surgical technique but less costly than computer navigation. Patient specific approach provided an average of 28 minutes of operating room time if one takes into account reduction in preparation and operative times when compared to traditional TKR, an additional 67 minutes when patient specific approach was compared to computer navigation. Time saved in patient specific approach is likely to ease health care system burden as this allows more theatre cases to be done and in addition provides accurate pre-selection of prosthesis size (5).

It is important to get this type of the procedure right the first time because failure to do so leads to poor outcomes with increased risk of early revisions of total knee arthroplasty (TKA) and an increased rate of both major and minor complications (5). In TKR, patient satisfaction correlates with a good surgical technique, good implant design and good patient motivation, Waters et al. Most of these techniques that are designed to improve component sizing, positioning and patient satisfaction including patient specific implants and computer assisted systems, are financially costly (5).

Templating in TJA has been shown to give good results but it is technically demanding. In a study by The *et al*. (2005), which compared accuracy of analogue *versus* digital systems in pre-operative planning in total hip and knee arthroplasties, they concluded that analogue plans were more accurate than digital plans (6). There is a need for simpler and quicker ways of predicting TJA component sizes (7). Using patient demographics (e.g. height, weight, gender) and shoe size has been shown to predict component sizes accurately in about 60% of cases and to be within one size in about 90% of the cases (7). Sershon *et al*. (2017) studied the variables such as weight, height, and gender to determine whether there was a linear correlation that could prove useful in predicting component sizes in TKR. Their findings were that there was a very high linear correlation between demographic parameters and tibial/femoral sizes. Femoral and tibial component sizes could be predicted accurately in $71-92\%$ of cases when one uses demographic parameters alone and an improvement of up to 99% was observed when templating was used in conjunction with stated variables. This type of pre-operative planning reduces time taken per case as it reduces the inventory (7). In 2018, Trainor *et al*. investigated a better predictor between shoe size and one's body height. Their findings were that shoe size had a better correlation with femoral and tibial dimensions compared to one's body height. It is generally known that the tibial component size is the same as femoral component size, if not; the femoral component tends to be one size larger. Therefore, if one can predict tibial component, then that information can be used to predict femoral size (8).

Accurate sizing in TKA is vital in ensuring patient satisfaction and implant longevity (9). Dai *et al*. (2014) investigated the effects of increasing the different sizes and shapes in terms of mediolateral and anteroposterior dimensions for TKR. The findings were that those designed for families with wide size variations were able to cater better for different ethnic groups than those with limited variations. Of note, their study was spread across Caucasians, Indians and Korean participants. TKR component-sizes too big or too small were found to have a significant impact on patient satisfaction and longevity of implants, therefore, determining the rate of revision surgeries (9). Fawzy *et al*. (2008) did a study using demographic parameters with the aim to determine femoral size, templating, gender, patient's height, as well as tibial component size. Their finding was that templating: (i) would be accurate in 67% of the cases, (ii) would be acceptable in 33% of the cases and (iii) was found to be never un-acceptable. Height alone was found to be accurate in the 56% of the cases, acceptable among the 38% of the cases and un-acceptable in the 6% of cases. Patient's height when gender is used was found to be accurate in 75% of the cases, acceptable in the 25% of cases and was never found to be un-acceptable. Tibial component size finding was accurate in 56% of the cases, acceptable in the 41% of cases and only un-acceptable in the 3% of cases. In conclusion, their study found that patient's height when gender is used, this combined with templating showed high accuracy in predicting femoral size (10). In 2014, Tu *et al*. developed a better tool to accurately predict femoral component sizes. They used C-arm intensifier guide (CAIG) during surgery to determine the size of femoral component instead of templating. They concluded that CAIG-assisted implantation of a uni-compartmental knee replacement was reliable in selecting correct femoral size (11).

Peek *et al*. (2012) assessed whether the sizes templated preoperatively matched the sizes implanted intra-operatively. The conclusion was that there was a significant correlation between templated sizes and the implanted ones, thus proving that templating is indeed very important (12). Under-sizing of tibial component size may lead to implant subsidence and subsequently early revision due to aseptic loosening. Over-sizing of tibial components leads to chronic pain especially when it is on medial side. Over-sizing or under-sizing of either of the femoral components can cause instability, early component loosening, soft tissue irritation and overstuffing of the patellofemoral joint (13-14).

Among the demographic parameters, shoe size has been shown to correlate well with tibial component size, therefore, one can use shoe size to predict both tibial and femoral component sizes. The femoral size is generally the same size as the tibia component or one size larger. Studies in the literature that have looked at shoe size and component prediction show that shoe size can be used to predict component sizes for TKA in Caucasians and Japanese populations. Furthermore, there are no studies to date that have been done in South Africa (SA) which have investigated the correlation between shoe size and TKA component sizes.

1.1 Problem Statement

Inaccurate templating of knee replacement components is directly correlated with poor outcomes. Traditional methods of templating require resources that are not always readily available in resource poor settings in South Africa. There is a need for a simple, quick, cheap and reliable method of templating in TKR in the South African population.

1.2 Aim and objectives of the study

Aim was:

- To assess if shoe size can be used as an accurate predictor for TKR tibial and femoral component sizes in South African patients who underwent TKA at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH)

Objectives were:

- To determine the correlation between shoe size *versus* (a) tibial and (b) femoral component sizes

- To determine if there could be a quicker alternative method to predict TKA component sizes in comparison to the standard templating done prior to TKA procedure

CHAPTER 2

METHODS

2.1 Study design

The study was a retrospective study with a prospective recall. The retrospective component was retrieving of patients' information to be included in the study and the prospective component was on data collection of the shoe size. The CMJAH does not routinely measure shoe size. To relate shoe size to the implant size, a linear regression equation was developed and the equation is $y = mx + b$

where,

y = predicted femur component

m = rate of change

x = shoe size

b = constant

2.2 Selection criteria

Patient Inclusion criteria were:

- South African patients who underwent primary TKR from 01 January 2016 – 31 December 2019 at Charlotte Maxeke Johannesburg Academic Hospital

- Both male and female patients
- Patients ≥ 18 years old
- Only patients in whom Smith and Nephew Gen 2 implants were used will be included

Patient Exclusion criteria were:

- Patients undergoing revision TKR
- Patients unwilling or unable to give consent
- Patients who were not contactable

2.3 Data collection

Data collection began after ethics clearance was obtained from Human Research Ethics Committee (HREC) (Medical), University of the Witwatersrand (HREC No: **M200620** and see attached in Appendix section). Data were collected from hospital records and patients were contacted telephonically. In those patients where there were doubts, concerning shoe size telephonically and these patients were asked for physical measurements using a UK foot size ruler if they were still residing in Johannesburg. The primary researcher (Dr Zondo) collected the data. Appendix A shows an example of data collection sheet. The UK foot size ruler is a plastic ruler where a patient places his/her foot and a shoe size is physically measured for accurate assessment of the size. This is because South African shoes are commonly measured in UK shoe sizes. A picture Archiving and Communication System (PACS) was used to retrieve x-rays done in order to assess if the implants used were indeed appropriate (i.e. to eliminate any over-sizing or under-sizing of components). All the patients who were involved in the study were found to have appropriately sized implants based on 100% x-rays showing anteroposterior and lateral views of the knees post operatively as assessed by the primary researcher. PACS system comes with measurement software, which was used during the process of data collection.

2.4 Data Analysis

Two statistical tests were used to analyse data namely the Pearson's correlation test and the linear correlation test. A sample size of 205 was selected to participate due to availability and variables such as ''Implant Company" used and ''total number of patients'' who had primary TKR in a three-year period. Limitations of our study were mainly surgical variables *viz*:

- **Patient factors:** degree of joint degeneration could play a role
- **Surgeon factors:** different surgeons from fellows to experienced orthopaedic arthroplasty surgeons were involved in these operations, there may be more frequent under-sizing or over-sizing in those done by junior surgeons.

CHAPTER 3

RESULTS

A total of 329 patients were initially recruited for the study, 124 patients were excluded from the study due to telephone numbers that had either changed or patient had passed away, as well as those patients who had travelled far abroad and could not be traced. Therefore, 205 patients were finally included in the study. Retrieving information on x-rays at CMJAH using PACS system works efficiently, hence, all x-rays for the 205 patients could be retrieved.

STATA version 14.0 statistical package was used for data cleaning and analysis. Descriptive statistics were used to analyse demographic profile of the participants, these were reported as frequency and percentages for categorical variables. The mean and standard deviation (SD) were reported for continuous variables.

For inferential statistics, the Pearson's correlation was applied to measure association between tibial/femur component and shoe size. Furthermore, regression equations were generated to predict the component sizes (tibial and femur).

P-values < 0.05 were considered significant. Final data analysis was done on 205 participants.

3.1 Descriptive statistics for the Participants

Table 3.1 and Figures 3.1 – 3.3 show the descriptive statistics of our selected sample of participants.

Table 3.1: Demographic characteristics of the participants

	Frequency	
	n	**%**
Age (mean = 66.5 years, SD = 8.07)		
40 – 49 years	3	1.5
50 – 59 years	39	19.0
60 – 69 years	89	43.4
70 years and older	74	36.1
Gender		
Female	174	84.9
Male	31	15.1
Race		
Black	147	71.7
Coloured	7	3.4
Indian	13	6.4
White	38	18.5

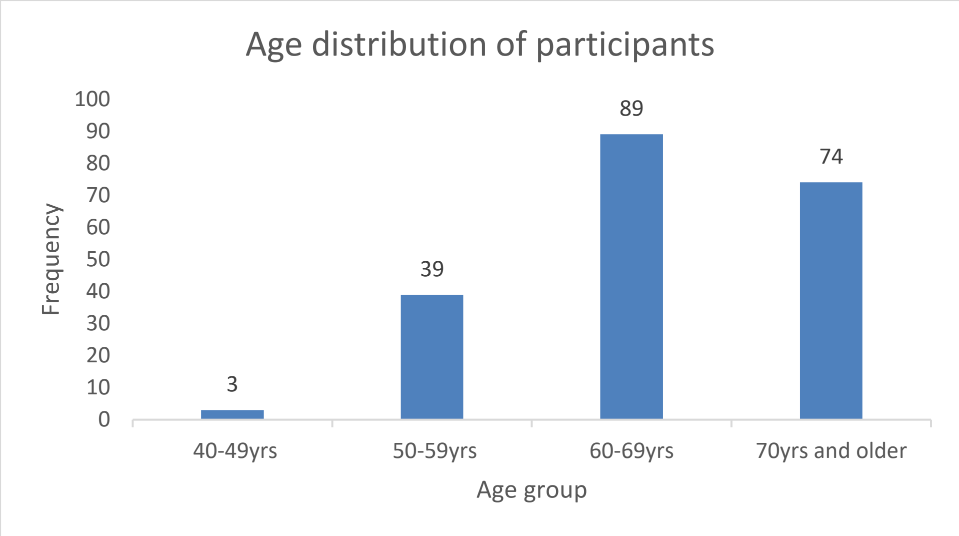

Figure 3.1: Age distribution of the participants

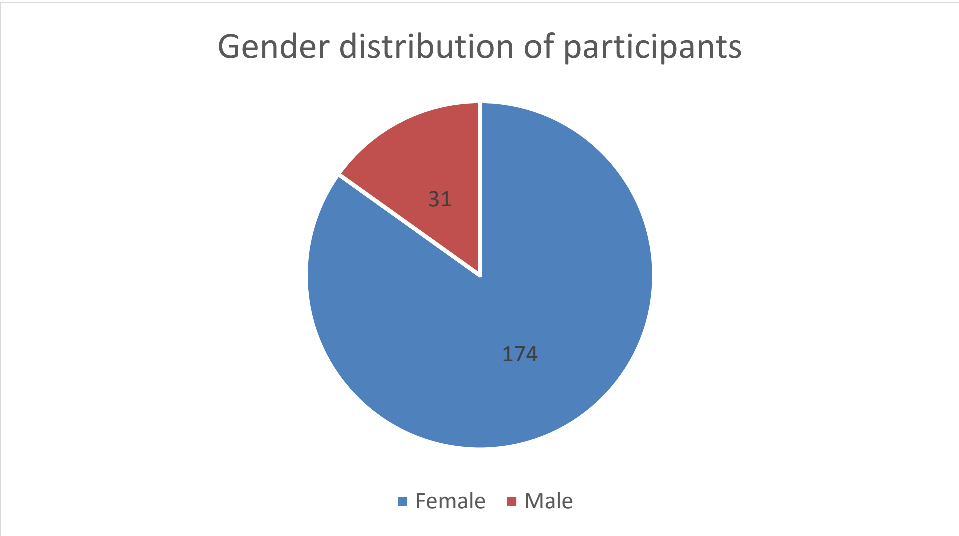

Figure 3.2: Gender distribution of the participants

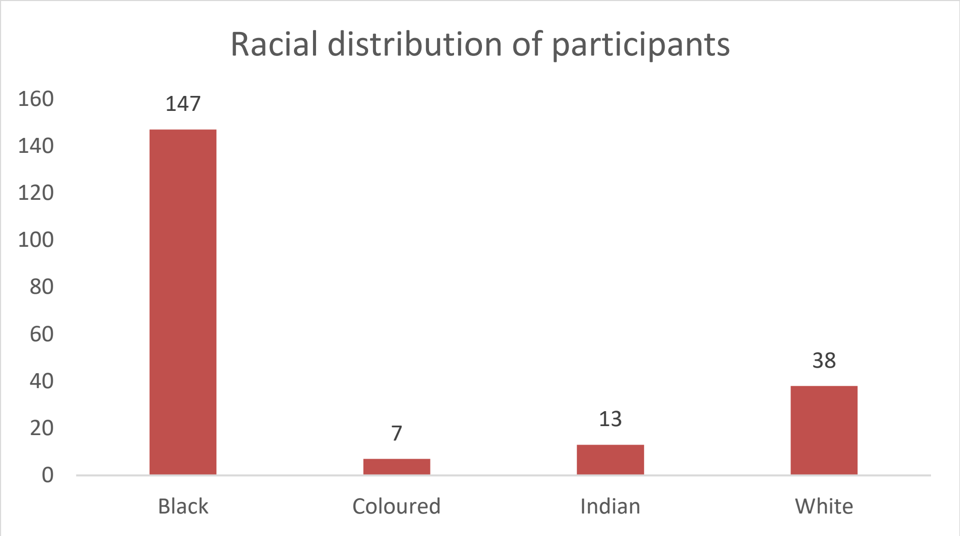

Figure 3.3: Racial distribution of the participants

In summary, Table 3.1 and Figures 3.1 – 3.3 highlight that black female participants aged between 60 and 69 years had the highest number TKR surgeries whereas the least number was recorded in coloured male participants aged between 29 and 49 years. Figure 3.4 below shows the shoe size distribution of our participants. The majority participants used shoe size 7 and the least numbers were recorded in shoe sizes 5.5, 9.5 and 12.

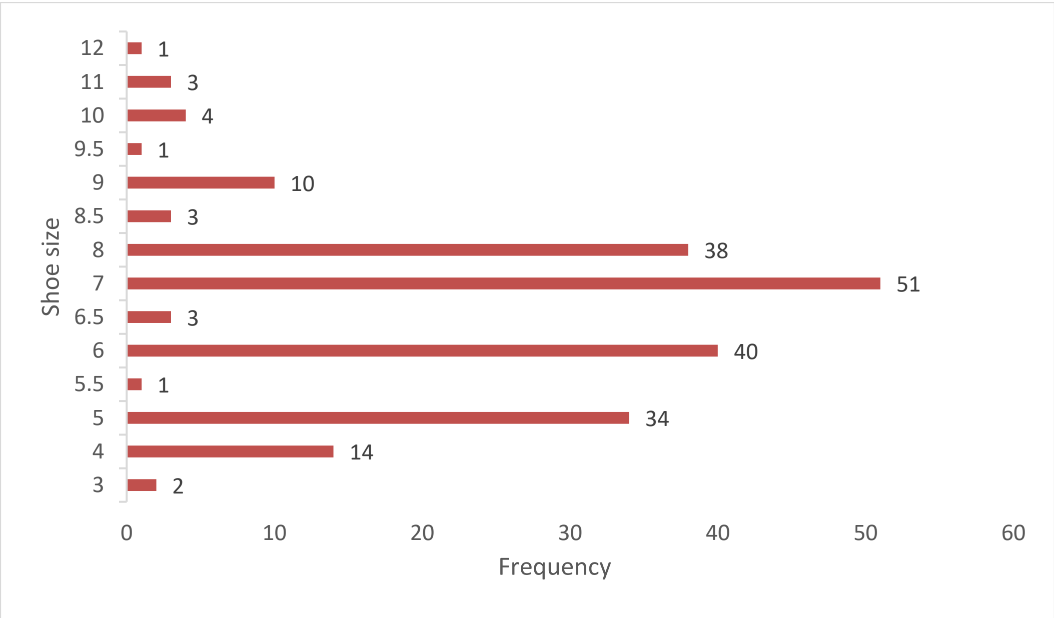

Figure: 3.4: Shoe size distribution of participants

3.2 Inferential statistics - Pearson's correlation and regression analysis

3.2.1 Correlation between shoe size and tibia

Table 3.2: For all the participants (n = 205) (inferential statistics for tibia *versus* shoe size)

	Regression equation using shoe size as a predictor	**R squared**	**Correlation coefficient**	***p*-value of coefficient**
Tibial component	$y = 0.5224x + 0.3287$	0.4247	0.6517	< 0.0001

There was a positive correlation between shoe size and tibial component, correlation coefficient = 0.6517, $p < 0.001$. Shoe size explains 42% of the variation in in tibial component.

Regression equation: $y = mx + b$

where, y = predicted tibial component

m = rate of change

x = shoe size

b = constant

Table 3.3: Disaggregated by gender (Female = 174, Male = 31)

	Regression equation using shoe size as a predictor	**R squared**	**Correlation coefficient**	***p*-value of coefficient**
Tibial component (Female)	$y = 0.4098x + 0.9483$	0.2655	0.5153	< 0.0001
Tibial component (Male)	$y = 0.4579x + 1.399$	0.2629	0.5127	0.032

There was a positive correlation between shoe size and tibial component for both female and male participants, correlation coefficient = 0.5153, $p < 0.0001$ and correlation coefficient = 0.5127, $p = 0.032$, respectively. Shoe size explains 27% of the variation in in tibial component among females and 26% of the variation among males.

Table 3.4: Disaggregated by race (Black = 147, Coloured = 7, Indian =13 and White = 38)

	Regression equation using shoe size as a predictor	**R squared**	**Correlation coefficient**	***p*-value of coefficient**
Tibial component (Black)	$y = 0.4405x + 0.7859$	0.3373	0.5808	< 0.0001
Tibial component (Coloured)	$y = 0.5968x + -0.5484$	0.5811	0.7623	0.046
Tibial component (Indian)	$y = 0.5532x + -0.1653$	0.5252	0.7247	0.005
Tibial component (White)	$y = 0.6310x + 0.0733$	0.5831	0.7636	< 0.0001

There was a positive correlation between shoe size and tibial component across all racial groups. Among blacks, the correlation coefficient = 0.5808, $p < 0.0001$ and shoe size explaining 34% of the variation in in tibial component. For the coloured population, correlation coefficient = 0.7623, $p = 0.046$ with shoe size explaining 58% of the variation in in tibial component. Among the Indians, correlation coefficient = 0.7247, $p = 0.005$ and shoe size explaining 53% of the variation in in tibial component. For the white population, correlation coefficient = 0.7636, $p < 0.0001$ and shoe size explaining 58% of the variation in in tibial component.

3.2.2 Correlation between shoe size and femur

Table 3.5: For all the participants (n = 205) (femur *versus* shoe size).

	Regression equation using shoe size as a predictor	**R squared**	**Correlation coefficient**	***p*-value of coefficient**
Femur component	$y = 0.4012x + 1.8102$	0.3410	0.5839	< 0.0001

There was a positive correlation between shoe size and femur component, correlation coefficient = 0.5839, $p < 0.0001$. Shoe size explains 34% of the variation in tibial component.

Regression equation: $y = mx + b$

where,

y = predicted femur component

m = rate of change

x = shoe size

b = constant

Table 3.6: Disaggregated by gender (Female = 174, Male = 31)

	Regression equation using shoe size as a predictor	**R squared**	**Correlation coefficient**	***p*-value of coefficient**
Femur component (Female)	$y = 0.3454x + 2.119$	0.2198	0.4688	< 0.0001
Femur component (Male)	$y = 0.380x + 2.243$	0.2337	0.4834	0.006

There was a positive correlation between shoe size and femur component for both female and male participants, correlation coefficient = 0.4688, $p < 0.0001$ and correlation coefficient = 0.4834, $p = 0.006$, respectively. Shoe size explains 22% of the variation in femur component among females and 23% of the variation among males.

Table 3.7: Disaggregated by race (Black = 147, Coloured = 7, Indian = 13 and White = 38)

	Regression equation using shoe size as a predictor	**R squared**	**Correlation coefficient**	***p*-value of coefficient**
Femur component (Black)	$y = 0.3508x + 1.9929$	0.2789	0.5281	< 0.0001
Femur component (Coloured)	$y = 0.4516x + 1.7741$	0.4516	0.6720	0.0982
Femur component (Indian)	$y = 0.0426x + 3.6678$	0.0146	0.1207	0.6946
Femur component (White)	$y = 0.4806x + 1.8854$	0.5500	0.7416	< 0.0001

There was a positive correlation between shoe size and femur component among only the black and white populations. Among blacks, the correlation coefficient = 0.5281, $p < 0.0001$ and shoe size explaining 28% of the variation in femur component. For the white population, correlation coefficient = 0.7416, $p < 0.0001$ and shoe size explaining 55% of the variation in femur component.

CHAPTER 4

DISCUSSION

Results of our study show that there is a strong correlation between shoe size and tibial component size. A linear regression equation was generated for tibial component and femoral component sizes. Across all four of South Africa's major race groups, patients of Indian origin, Caucasian, black African; and mixed race patients there was a strong correlation between shoe size and tibial component size, and in addition, this was true across gender. A linear regression equation generated for tibial component was $y = mx + b$, which means if a surgeon wants to calculate the tibial component, say for a patient who wears shoe size 6, the equation would be $y = 0.5224*6 + 0.3287$ (see Table 3.2), this works out to be 3.46, a size 3 tibia. To then calculate femur, $y = mx + b$, $y = 0.4012*6 + 1.8102$ (see Table 3.5) giving $y = 4.2$, a size 4 femur. For those who wear shoe half sizes, for example, shoe size 6.5, the calculated tibial component will be 3.7, which is 0.3 more than the shoe size 6. This will push the surgeon towards size 4 tibia and size 4 femur (femur only changes by 0.2). In other words, shoe half sizes affects tibia sizing more than it affects femur sizing (tibia increases by 1 size while femur remains the same). The surgeon does not have to use regression equation again to calculate the femur size; femur size is either the same as tibia or one size larger. By calculating tibia size, the surgeon automatically gets an indication of the femur size. The linear regression equation will differ slightly depending on the type of implant used as sizes and nomenclature differ between manufacturers. Having such information helps reduce the number of trays in theatre and increases theatre efficiency while ensuring appropriately sized prosthesis are being implanted even where templating resources are sub-optimal.

The study showed that there was no positive correlation between shoe size and femur component in mixed race and patients of Indian origin; this is probably due to a smaller sample size for such races at the centre where this study was conducted (CMJAH). In other studies reported in literature, they also found that shoe size correlates better with tibial component size and that height correlated better with femur component size. We therefore advise the surgeons to use linear regression equation specifically for the tibia. The following observations were noted from linear regression equation, for a female who wears size 6 shoe, her tibia will be size 3, for a male who wears size 6 as well, his tibia will be size 4, for black Africans, patients of Indian origin and mixed race patients, their race specific linear regression equation is fairly similar to the generic equation that applies across all races but for white patients, both tibia and femur component when using race specific equations, our study shows their size is one size bigger than the other races. In other words a calculated tibia size 3 in other race groups, this will be equivalent to a size 4 in Caucasian patients. Closest in size to Caucasian patients were mixed race patients. Surgeons are advised to consider this: correct implant size during total knee replacement surgery is vital to prevent complications such as subsidence and impingement.

4.1 Recommendation

Based on the results from this study the following recommendation is made:

- The linear regression equation generated in our study can be used in combination with a shoe size to predict tibial component size. Once the tibial component size has been predicted, femoral component size will be either the same size as tibia or one size larger.

CHAPTER 5

CONCLUSION

South African population is very diverse; the number of different races seen in one tertiary hospital is not a true representation since certain races were allocated to certain parts of the country because of past apartheid laws. That said, the linear relationship found between shoe size and tibial component sizes across all races is a good alternative to templating considering that templating is time consuming and moreover, requires 100% x-rays, tracing paper and company templates equipment which are not always available in the more resource constrained areas of the country. This study shows that shoe size can be used a quicker alternative method to templating.

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Appendices

Appendix A: Data Collection Sheet

Study ID	**Age**	**gender**	**Tibial component**	**Femur component**	**Shoe size (UK)**

Appendix B: Permission to conduct research study at Charlotte Maxeke Johannesburg Academic Hospital

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. X Dhlamini
Office of the Clinical Director
Email: xolisane.dhlamini@gauteng.gov.za
Tel: (011): 488-3710
05 June 2020

Dear Dr, ZA Zondo

STUDY TITLE: Shoe Size as A Predictor for Total Knee Arthroplasty Component Size in South African Patients.

Permission to conduct the above-mentioned study is provisionally approved. Your study can only commence once Ethics approval is obtained. Please forward a copy of your Ethics Clearance Certificate as soon as the study is approved by the Ethics Committee for the CEO's office to give you the final approval to conduct the study.

Supported / not supported

Dr. PN Africa
Acting Clinical Director
DATE: 05/06/2020

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 05.06.2020

Appendix C: Wits HREC clearance certificate

UNIVERSITY OF THE
WITWATERSRAND
JOHANNESBURG

R14/49 Dr ZW Zondo

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200620

NAME: (Principal Investigator)	Dr ZW Zondo
DEPARTMENT:	School of Clinical Medicine Department of Surgery Division of Orthopaedic Surgery Medical School University
PROJECT TITLE:	Shoe size as a predictor for total knee arthroplasty component sizes in South African patients
DATE CONSIDERED:	2020/06/26
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Drs L Mokete and M Jingo
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/08/21

This clearance certificate is valid for **5 years** from the date of approval. **Extension** may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. I agree to submit a yearly progress report. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **June** and will therefore reports and re-certification will be due early in the month of **June** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

01/11/2020
Date