FACTORS INFLUENCING CHOICE OF IMPLANTS IN PRIMARY TOTAL HIP REPLACEMENT IN KENYA: A MULTICENTER STUDY

A RESEARCH THESIS SUBMITTED AS PARTIAL FULFILLMENT FOR THE DEGREE OF MASTERS OF MEDICINE IN ORTHOPEDIC SURGERY AT THE UNIVERSITY OF NAIROBI.

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STUDENT DECLARATION:

I declare that this study is my original work and has not been presented for the award of any degree at any other institution or university. Where I have used another person's work, I have acknowledged and referenced.

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LIST OF ABBREVIATIONS

UON- University of Nairobi

KNH- Kenyatta National Hospital

THR- Total Hip replacement

PMMA- Polymethylmethacrylate

MMA- Methylmethacrylate

HA- Hydroxyapatite

TCP- Tricalcium Phosphate

KOA- Kenya Orthopedic Association

SPSS- Statistical Package for Social Science

AKUH- Aga Khan University Hospital

ASA- American Society of Anesthesiologists score

NICE- National Institute for Health & Care Excellence

ODEP- Orthopedic Data Evaluation Panel

NHS- National Health Service

MOM- Metal on Metal

MOP- Metal on Polyethylene

COC- Ceramic on Ceramic

COP- Ceramic on polyethylene

POLY- Polyethylene

UHC- Universal health coverage

NHIF –National Hospital Insurance Fund

AVN- Avascular Necrosis

ABSTRACT

Background: Hip replacement surgery has been very successful in the management of debilitating hip conditions that have failed to respond to conservative management. The choice of implants is based on multiple factors, including patient factors such as anatomical and functional demand, surgeon factors, cost, and availability of implants. It is essential to understand the characteristics of implant design fully, the cost, and the availability of implants to understand the reason for the choice of each implant. Understanding these factors would help standardize and optimize implant selection for patients, thus improving clinical outcomes.

Broad Objective: To identify the factors influencing the choice of implants in primary hip replacement in Kenya.

Study design and site: This was a multicenter cross-sectional study carried out at Kenyatta National Hospital, Nakuru Level 5 hospital, Mombasa level 5 Hospital, Aga Khan University Hospital, Nairobi Hospital, MP – Shah Hospital, Mater Hospital, PCEA Kikuyu hospital, and Kijabe Mission Hospital.

Participants and Methods: Through convenient sampling of 345 procedures of primary and secondary osteoarthritis and hip conditions that had failed conservative management and undergoing hip replacement surgery were selected, and surgeons undertaking the procedures interrogated on factors determining the choice of implant. A structured data collection tool was used.

Study results: The mean age of the study participants was 55.5 years, SD 9.84, median 56 years, range 38 – 75 years. Females represented 58% compared to 42% who were males. Indications of hip replacement were osteoarthritis in 187 (54.2%), fracture neck of femur in 76 (22%) patients, and avascular necrosis of the hip in 35 (10%). Others included rheumatoid arthritis 25 (7.3%) and dysplastic hip 22 (6.4%). According to the surgeons, the cost was the most common factor at 47%, followed by quality of bone at 28%, age at 15%, surgeon preference at 8%, and availability at 2%.

Conclusion: The choice of implant is greatly influenced by cost, bone quality, age, and level of activity of the patient. Efforts should be made to reduce the cost of an implant. This would help optimize the selection of implants in patients. Guidelines on hip replacement are needed to help surgeons and patients in clinical decision-making.

CHAPTER ONE

1.0 Introduction

Total hip replacement is the most successful and revolutionary surgery for diseased hip that have failed to respond to non-operative treatment (1). Since its inception and its improvement and modifications by Sir John Charnley in the 1960s, THR remains the most cost effective and successful in terms of improvement of patient's functional status, pain relief and overall improvement of quality of life (2).

The overall most common indications for hip replacement are end stage hip disorders which are either primary or secondary causes of hip osteoarthritis and fracture neck of femur based on the UK National Joint Registry 15th annual report (3).

Locally a retrospective study conducted by Kigera J and Gakuu in 2017, on 655 patients showed that osteoarthritis remains the primary indication for the elderly population while fracture neck of femur and secondary osteoarthritis, mainly osteonecrosis in the young (4). The main principle of Total Hip Replacement (THR) is to restore the native hip biomechanics while reducing the coefficient of friction hence the choice of implants is paramount to a successful surgery. Despite the improvements, THR does not fully restore the native hip biomechanics as the coefficient of friction for the native hip is .002 while for THR is .04 (5).

Based on the need to restore the hip function and the different indications for THR, several factors have to be put into consideration while choosing the implants that will best fit the individual patient. This is to allow the return of patient to his/her activity of daily living and not worsen the patient's mobility and level of independence (6).

A thorough understanding of the characteristic design of the implant to be used puts into perspective reason for its choice in the different indications. The choice of implants is based on several factors including its cost and availability, the surgeon's preference and training and patient factors.

An understanding of these factors that influence choice of implants amongst orthopedic surgeons in this population, will help standardize implant selection and identify population specific gaps in implant design and utilization (7).

Unfortunately, locally THR is affected mostly by cost being a developing country, what implants are available and surgeon factors and less to do with patient factors and indications.

Most available data on choice of implants is the international guidelines including the National Health Service (NHS), National Institute for Health and Care Excellence (NICE) and Orthopedic Data Evaluation Panel (ODEP) which are hard to extrapolate to our local market since our anatomy, activities of daily living and overall functional demand are different compared to the international community where implants are designed.

Currently Malawi is the only African country with an active joint registry assessing all joint replacements that have been carried out in the country. Different local patient factors gathered include, disease burden of HIV and Avascular Necrosis (AVN) due to sickle cell anemia and the social and economic factors as an influence to THR in their population. Presence of local data will help analyze if there is a correlation of what is being used on our patient, its indication and is it ideal for the patient (8). Similar findings have been shown in a systematic review of joint replacement in Sub-Saharan Africa by Davies P et al 2019 (9).

In Kenya we lack an established system like the European ODEP that provides guidelines that state the indication of choice of implants. This study will therefore describe the factors that influence choice of implants to the Kenyan Orthopedic surgeon.

CHAPTER TWO

2.0 Literature Review

2.1 Background

Total hip replacement involves the exchange of the native hip with a prosthesis in end stage hip disorders to correct the biomechanical function of the hip, relieve pain and improve mobility. It involves replacement of both the femoral head and acetabulum with a femoral stem and an acetabular cup (1).

The components of a successful total hip replacement include the prosthesis design and the fixation technique. The prosthetic design which is the femoral and the acetabular component with its bearing surface can be cemented or cementless with the fixation technique being either biologic for cementless, cement fixation or hybrid fixation in which one component is cemented and the other component is cementless (10).

The choice of prosthesis design and fixation technique are influenced by several factors including;

1. Patient factors- age, quality of bone, level of activity, comorbidities.
2. Cost of implants and availability of implant.
3. Surgeon factors- surgeon's technique preference, training.

2.2 Surgical technique and training

The fixation technique and method are dependent on the quality of bone based on the Dorr classification according to Wilkenson et al 2020 (11). The classification uses the ratio of the femoral canal diameter at the level of the lesser trochanter and 10 cm distal to it on AP and lateral radiographs. Type A <0.5, Type B 0.5-0.75 Type C >0.75. Dorr A and some B are fixed cementless while C requires cementation.

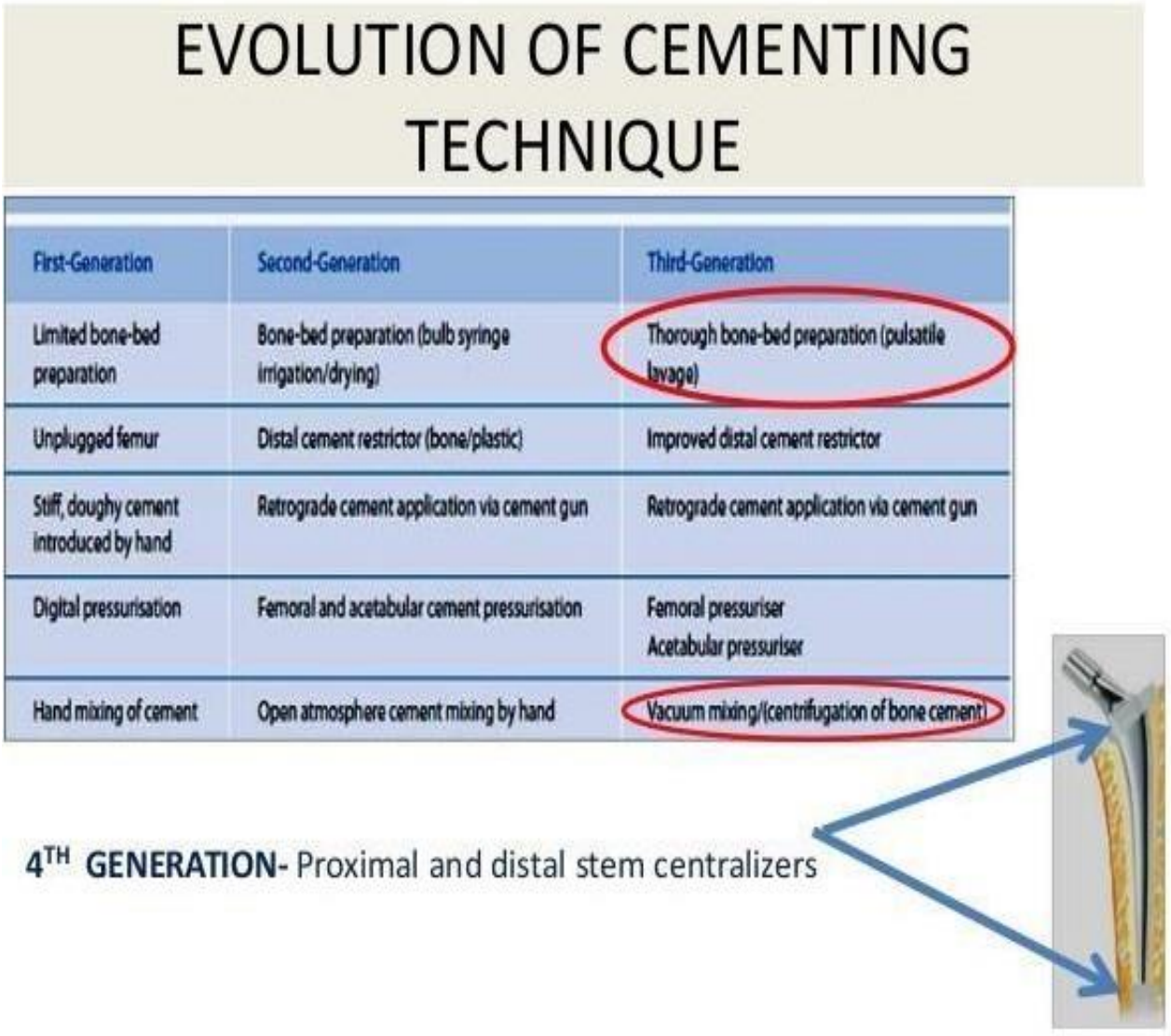
Cement fixation with the use of polymethylmethacrylate (PMMA) was first popularized by Charnley in the 60's by use of cement borrowed from the dentists. The cement used interdigitates and interlocks with bone to act as grout (1). PMMA is an acrylic polymer formed by a liquid MMA and a powdered MMA which when mixed, the liquid monomer polymerizes around the pre polymerized powdered particles to form hardened PMMA (12). The powder has an initiator and a radio-opacifier while the liquid has an accelerator and a stabilizer giving it its set physical and chemical characteristics.

The cementation techniques have been improved over the years to improve implant fixation and survival. The generations of cementation as shown in Table 1.

Table 1: Evolution of Cementing Technique

First Generation	**Second Generation**	**Third Generation**
Limited bone bed preparation	Bone bed preparation (bulb syringe irrigation/drying)	Thorough bone bed preparation (pulsatile lavage)
Unplugged femur	Distal cement restrictor (bone/plastic)	Improved distal cement restrictor
Stiff doughy cement introduced by hand	Retrograde cement application via cement gun	Retrograde cement application via cement gun
Digital pressurization	Femoral and acetabular cement pressurization	Femoral pressurizer Acetabular pressurizer
Hand mixing of cement	Open atmosphere cement mixing by hand	Vacuum mixing (centrifugation of bone cement)

Figure 1: Cementing Technique



Breusch S. J et al, 2000, conducted a comparative study on use of jet lavage during cementation in which the study showed lavage produces better cement penetration than syringe lavage to achieve interdigitation with cancellous bone in cemented THR (13).

Petruskevicius J et al in 2011, conducted a cadaveric study on the benefit of a proximal centralizer in cementing of femoral prosthesis but the sample size was small involving 16 cadavers, 8 with proximal centralizer and 8 without (14). Due to the small sample size bias

could not be ruled out. But results are supported by previous studies conducted byGoldberg et al and Nobel et al in 1999.

The grading system of a good cementation, is based on review of Post-operative radiographs and is divided into A-D, Barrack and Harris classification with A showing a complete canal filling (white out) while D shows gross radiolucency's (10).

Development of cement disease which is a pathological condition occurring at the bony environment surrounding a loosened cemented prosthesis has led to improvement of cementation techniques, cement handling and the cement biomaterial to minimize failure (15).

Biologic fixation was adopted in the 1900 with the advent of the cementless hip, the mechanical lock formed through osteointegration between bone and implant which is achieved by ingrowth or ongrowth. Ingrowth is bone growth in the porous surface of implant, while ongrowth the implant has a roughened surface with microdivots where the bone grows onto. The fixation method can either be press fit where a larger implant than what was reamed is placed or line in line where the implant size is the same as what was reamed (16).

Fixation is optimized by surface coating with bioactive materials like hydroxyapatite and tricalcium phosphate, pore size 50-300um, porosity of up to 50%, gap of <50 between bone and prosthesis with maximum contact and micro motion of <150um. Initial stability is mechanical followed by biologic (17).

2.3 Prosthetic material;

2.3.1 The femoral component

The femoral prosthetic stem can be cemented or cementless. The cemented stem can either be taper slip also known as ‘force closed’ or composite beam also known as ‘shape closed’ with the difference being the shape and the mechanism cement-stem-bone interaction (18). The taper slip is a polished stem which routinely subsides within the cement creating shear forces at the cement-stem interface, protecting the cement-bone interface. As the stem subsides it generates hoop tensile forces and radial compression forces which gradually increase the stability of the implant. The radial compression forces protect the cement bone interface from shear stress and protect the cement against fatigue fractures. Hence the stem should not have a collar to allow subsidence. The implant subsidence does not affect limb length as it is postulated to be 1.3mm in 17 years (19, 20).

The composite beam stems have a collar and cannot subside hence shape closed. Stability of the implant arises from the cement-bone interface. The stem surface is contoured and bonds with the cement applied, integrating to act as a unit hence the shear forces act on the cement bone interface. This stem is less forgiving and must establish cement mantle of adequate thickness and a solid fixation of stem to cement and cement to bone (19, 20).

R.J. Sierra and Kazi HA 2019 in a review of cemented femoral stems of taper vs. composite beam showed statistical and clinical superiority of taper stem 8-year survival with increased incidence of revision for composite beam (19,21).

Australian National Joint Replacement Registry annual report 2013 indicated in a review of patients above the age of 75 years that cementless hips failure is higher than cement fixation primarily due to osteoporosis and a Dorr type B and C femur (4).

The cementless stem, fixation technique is biologic and can be porous or grit blasted with surface coating to allow for faster bone growth hence rapid gap closure. Numerous stems exist with large range of designs in 2011 to minimize the confusion, the Mont group devised a classification system that was based on the bone contact area and fixation site. Despite the design of the stem, the aims are the same, to maximize initial stability and osseous contact to hold the prosthesis steady while the surrounding bone grows onto or into (22).

Initial stability is crucial as the degree of micromotion determines the tissue formed at the bone prosthesis interface as previously mentioned micromotion should be <150um.

Component coating either proximal or extensive in porous stems and extensive in grit blasted increase the surface area for rigid fixation. Extensive coating however may reduce loading of the proximal bone leading to stress shielding proximal coating only seen in porous coated stems, channels weight bearing force through the metaphysis but reduces the area of fixation and stress shielding (22).

Due to preferred metaphyseal fixation and the reduced need for long distal part of stem the short femoral stems where recently developed. This stems where defined by Feyen and Shimmin in 2014 in Bone and Joint Journal as stems with total length less than 2x tip of greater trochanter to base of lesser trochanter distance. The stems were classified by Mont group in 2014 based on loading site and stem fixation principles and by Falez et al 2015 based on primary fixation and osteotomy level (23, 24).

Excellent clinical results are present however the studies are short hence longer studies are needed.

Claudio Castelli el at 2014 reviewed the current and future concepts where they noted that short stems reproduce stress distribution at the level of proximal femur more similar to physiological loading limiting stress shielding from conventional stems on short and midterm studies (25).

Kim Y-H et al, 2014, in a review of long-term results and bone remodeling after THR with a short metaphyseal fitting anatomic cementless stem and significant level IV evidence demonstrated that short metaphyseal stems provide stable fixation without relying on diaphyseal fixation. It was also noted that there was reduced stress shielding and no thigh pain (17).

Kim Y-H in 2008 while studying the result of a proximally coated cementless femoral component in THR noted that cementless anatomical femoral components proximally coated stems with metaphyseal loading but without distal loading encouraged proximal loading and produced satisfactory fixation (26).

National joint registry for England and Wales randomized control trial 2011 study noted that revision rates for cemented stems remain the lowest followed by hybrid and cementless in a 7-year study (27).

Based on Mont classification of femoral stems for complicated and dysplastic hips type 5 and 6 stems that require modular/bimodular and anatomical stems respectively allow for restoration of length, medial offset and version (22).

Biant LC et al in 2008 described the anatomically difficult primary THR. In the medium and long-term results using a cementless modular stem, all patients with a 10 year follow up had excellent clinical and radiological results, low incidence of distal osteolysis and aseptic loosening to justify continued use (28).

Fitch DA et al, 2015 did a comparative study long-term survivorship rate comparison of a cementless modular stem and cementless fixed neck stem for primary THR. The results indicated that the 12-year survivorship for modular stem was 95.8% vs. fixed neck 96.1% hence no adverse effect in survivorship and complication rate in an arthroplasty registry (29).

2.3.2 Acetabular component

Acetabular cups like the femoral component can either be cemented or cementless. Cemented sockets tend to be all polyethylene thick walled cups. They have grooves on the outer surface to increase surface area and stability within the cement mantle and an embedded wire to assess post op x-rays. Modern designs have flanged cups and cement spacer beads to ensure uniform cement mantle and avoid bottoming out resulting in thin discontinuity of mantle. An additional rim flange aids in cement pressurization during cup insertion (30).

Cementless sockets have porous coating metal shell with a liner fastened inside. The coating is over the whole circumference of the shell. Fixation can be press fit or line in line. Mechanical fixation in press fit is achieved with larger acetabular cups usually 1-4mm larger than what was reamed so that viscoelasticity of the acetabulum maximizes the binding forces of the cup (31). Theoretically press fit fixation does not require additional

fixation with screws pegs or spikes as sufficient initial stability is achieved. Mechanical fixation in line is which cup size is the same as the reamed size additional fixation is required and in inexperienced surgeons (30).

Thanner J 1999 study on porous cups with or without HA/TCP coating; HA/TCP coating increased ingrowth and reduced post-operative radiolucency on subsequent x-rays.

The cementless system has different locking mechanisms between the cup and the liner. These have evolved over time from the 1st generation in which the liner was designed to be extruded from the cup, but these easily damaged the locking mechanism with frequent impingement necessitating improvements. Second generation had improved congruity between liner and cup with improved dissociation and thickened liners to endure impingement (31).

Particle debris so called "backside wear" due to motion between shell and liner led to development of 3rd generation cup which liners are designed not to be extruded from cup to prevent collision and cup liner congruity was significantly improved (31).

Cemented acetabular components fail at a higher rate than cementless since cement resists shear poorly, with current trends all acetabular cups should be cementless except in poor bone stock and irradiated bone due to significantly reduced ability to allow bone ingrowth (31).

Thanner J 1999 studied the acetabular component in THR with emphasis on evaluation of the different fixation principles (30). Cement fixation is associated with inferior mechanical properties and higher failure rate compared to cementless porous cups coated with HA/TCP.

In contrast recent studies by clement ND et al 2012 and Van Praet F in a critical literature review articles, on whether to cement or not to cement acetabular sockets (32, 33). Both studies show irrespective of age, cemented acetabular remain the gold standard superior to cementless in terms of long-term survivorship.

Yamada H et al 2009 study on cementless THR past present and future; meta-analysis shows survival rates between cemented and cementless hip, cemented hips have superior survivorship with 95% survival at 10 years compared to 89% for cementless. Primary cause of failure in the cementless hip was osteolysis due to wear (poly and back side wear) and stem periprosthetic fractures due to stress shielding (16).

2.3.3 Bearing surfaces

The bearing surface which is the articular surface is made up of the femoral head and the acetabular liner (1). The femoral head which is the hard surface is either metal usually cobalt chrome or ceramic and the liner can be metal, polyethylene or ceramic. Hence the bearing surface can be hard on soft or hard on hard bearing (34).

The most significant developmental evolution of bearing surface, was Sir John Charnley's low friction arthroplasty concept in 1958 (1) where he used the bearing surface of a small metal head size 22mm on polyethylene liner. A principle that remains unchanged to-date with this bearing surface currently producing the most consistent results in THR.

Long-term survival of the bearing surface in THR is affected by friction, lubrication and wear (5). The aim is to achieve a surface close enough to the native hip, which has a low coefficient of friction capable of significant deformation without failure and no wear without pathology (34). The coefficient of friction of the native hip is 0.002- 0.04 while

THR achieves 0.05-0.15 which is higher hence signifying eventual failure of components with continuous deformation and wear (5, 34).

The ideal bearing surface should have a low coefficient of friction, generate a small volume of wear particles have low tissue reaction to wear and high resistance to 3rd body wear (35). Polyethylene surfaces have the highest wear rate of 75-250um/year leading to osteolysis and aseptic loosening compared to other surfaces which became a major concern in prosthesis survival. This led to improvements done on the poly over the years from the conventional polyethylene to highly cross linked ultrahigh molecular weight polyethylene which has undergone 3 generation of improvement using gamma radiation and thermal treatment. Additional treatment includes anti-oxidative treatment with vitamin E treatment to reduce abrasive and adhesive wear (35).

Hanna SA et al, in 2016 in a comparative study of revision rates between conventional poly and highly cross-linked poly, study shows significantly less osteolysis and revision rate THR with highly cross-linked poly compared to conventional poly (35).

Nebergall AK et al, 2017 in a randomized control trial on vitamin E diffused highly cross-linked polyethylene in THR showed lower wear rate in early and intermediate studies necessitating long term follow up (36).

Hard on soft bearing surfaces include metal on poly liner (MOP) or ceramic on poly (COP) with the soft surface always being the liner. COP is superior MOP due to higher wear particles generated by MOP. This leads to osteolysis with subsequent aseptic loosening and implant failure. The wear of COP is 10-50% lower and is due to lower coefficient of friction, better joint lubrication, ceramic is inert and has a lower susceptibility to 3 body wear (37).

Randomized control trials available in the Australian national joint replacement registry 2015/16 annual report showed reduced revision rates of COP compared to MOP (38).

Hard on hard bearing surfaces include metal on metal MOM or ceramic on ceramic COC. These bearing surfaces have lower wear compared to MOP and COP due to less wear particle generation. MOM had fallen out of favor due to adverse tissue reaction to metal debris but improvements are being done with recent techniques. COC has the highest survivorship compared to all with draw backs being cost and squeaking noise on weight bearing (34).

Zagra L et al 2018 in review of bearing surfaces in primary THR indicated that COC is preferred in young patients due to higher wear resistance and biocompatibility, while COP and MOP are preferred in older patients with good 15 year results (34).

Bedard NA et al in a retrospective study done in 2007-2015 on the trends in THR bearing surfaces, bearing surface choice has significantly changed with MOM bearing decreasing due to adverse effects and the patient's age being an independent predictor of bearing surface (39).

Wyles CC et al, 2015 in a meta-analysis done on the difference in survivorship for both short to mid-term of THR bearing surface showed no evidence in survivorship difference is the popular surfaces in patients aged below 65 years (40).

2.4 Patients factors

2.4.1 Age and level of activity

According to majority of joint registries, the choice of implants is based on the patients' functional level, age, quality of bone and survivorship of implant before revision surgery with a good prosthesis having long term survivorship of 90% for a minimum of 15 years (3).

Unfortunately, local and East African data survey systems and studies are lacking on factors that influence choice of implants however, expert opinions indicate that MOP is the most commonly used for bearing surfaces, cement fixation for the elderly and cementless in the young with few hybrid fixations.

In contrast, with western literature based on the NICE, ODEP and international joint registries, hybrid fixation is the favored choice for all joints in the elderly, with cementless for the young active patients. Bearing surfaces COP is the most commonly used due to low wear rates for patients 40-60 years followed by COC for patients younger than 40 years.

Jamsen E et al, 2014, indicated high early failure after cementless and hybrid hip in octogerian compared to cemented with revision increasing by 2 folds in the 10 year follow up (41).

2.4.2 Comorbidities in choice of implants

Patient comorbidities directly affect implant choice; to cement or not to cement, risk of development of post-operative infection and survivorship of implant both short term and long term (42).

Common comorbidities indicated to affect implant choice include diabetes, chronic kidney failure, heart failure and the neuromuscular disorders including cerebrovascular accidents, Parkinsonism and cerebral palsy.

Lieu D et al 2014, review article on THR in hemodialysis or renal transplant patients indicated despite the indication for THR, both cemented and cementless hip replacement have good short and long-term results (43).

Donaldson AJ et al 2009, while studying bone cement implantation syndrome noted patients with reduced cardiac reserve where at highest risk of cardiac failure and cardiac arrest in cemented total hip replacement (44).

THR in neuromuscular disorder remains challenging as several factors have to be put to consideration including the patient's preoperative mobility level, previous osteotomies or soft tissue procedure done, need for post op bracing and choice of components like a constrained liner or use of dual mobility articulation and the bearing surface used (45).

Newer inventions including the novel bearing surface have been tested with poor outcome and survivorship hence not as common, while the Capital hip in Britain, a modified Charnley by the 3M company failed in the late 20^{th} and 21^{st} century (18,46).

Dual mobility hip designs consists of a small femoral head (22 or 28mm), that is captive and mobile within a polyethylene liner. The large polyethylene liner ball in turn articulates with a metallic acetabular shell (47).

There are two articulating surfaces: a small articulation between the head and polyethylene liner and a large articulation between the polyethylene head and acetabular shell. Majority of the movements occur at the small articulation. These hip designs have lower dislocation

and wear is dictated by the small articulation as well as the polyethylene which is similar to the conventional THR (47).

2.5 Cost

Cost of implants is paramount with the choice and type of implant used (2, 48). According to Pennington et al 2013 in the article Cemented, cementless and hybrid prosthesis for THR a cost effective analysis (49). In this review, cemented hips were the cheapest, followed by hybrid then cementless while hybrid prosthesis provided the best post op quality of life and lifetime quality adjusted life year, this made the hybrid the most cost effective overall. This is in keeping with our local setting where cost of implants and overall cost of surgery are the determining factors to whether a patient gets cemented, cementless vs. hybrid THR.

Industry reports indicate that implants for cemented THR are significantly cheaper ranging from 689.95- 1379.9 USD based on various institutions followed by hybrid which is roughly 1034.93 USD, then finally cementless implants cost 1552.39- 2587.32 USD. In most cases the above cost is inclusive of bearing which is usually metal on ceramic, but if 'special' bearing surfaces are required like ceramic on poly the patient will require to part with an additional 603.7 USD. This is the same for cases where a patient requires modular or anatomical stem. This limits the surgeon's choice making cost the paramount factor affecting choice of implant if the patient can't afford the additional cost.

Patients of lower economic status using the National Health Insurance Fund (NHIF) or universal health coverage (UHC) which only approves up to 2156-3018.5 USD to cover for the full cost of joint replacement, will be at a disadvantage since this capitation from

NHIF means hospitals and surgeons have no choice but are forced to use what fall in the patients affordability range.

2.6 Availability of implants

This factor is primarily applicable for patients in the public hospitals as implant procurement is made based on the overall county requirements, budget for the fiscal year and not necessarily cost based on what the patients covered on NHIF or UHC is valued at. What is available locally vs. internationally example of ceramic liners are unavailable locally and the newer modified metaphyseal stems.

2.7 Problem Statement

THR surgery is increasing globally and Kenya is not left behind with up to 4 hips on the minimum done per week based on different indications in some centers in Nairobi and its environs. The global increase had been postulated by the AAOS in 2018 to be a rise of up to 34% of hips done annually by the end of 2020 (6).

There is limited availability of data on the choice of implants. This has led to lack of uniformity in implant selection amongst orthopaedic surgeons in this region which in turn could contribute to sub-optimal care of patients with hip conditions requiring fixation.

2.8 Study Justification

Having guidelines that state the indication of choice of implants, what is being used, what is available reason for the choice and if it is what is ideal for each patient will help in standardization of care for our patients.

Unfortunately, there is lack of local data available leading to use of international data, surgeon’s experience with the various implant and what is availed by the hospital.

Based on a pilot study done on some of our surgeons, the choice is based on cost, preference, availability and patient's age and or bone quality, but there was no cross board standard answer based on patients of the same age with the same indication for surgery.

Establishment of a systems like the European ODEP, which help critique what implants are being fixed on patients based on different surgeon's experiences will help our scientific community to not only reactivate and push for further development of our own Kenya National joint registry but also possibly join other countries in the African hip registry. This will help review what factors in our local set up lead to choice of the different implants.

In the long run based on patient follow up advancement of the study to a review of what is working best for our patients, the biomaterial used, quality of what is used. Eventually in the long run inform policies of standardization of what implants are available and promote design of implants best suited for our population.

2.9 Research Question

What are the factors that influence the choice of implants in THR in Kenya?

2.10 Research objectives

Broad objective:

To establish the factors that influence choice of implants to the Kenyan Orthopedic surgeon.

Specific objectives:

1. To establish the types of implants used for primary THR and associated cost of the implant.

2. To identify patient socio-demographic and clinical characteristics influencing the choice of implant used.
3. To establish the surgeons' consideration in choosing an implant for a patient for THR.
4. To determine the association between patient characteristics and surgeon's consideration for the type of implant used for THR.

CHAPTER THREE

3.0 Methodology

3.1 Study Design

This was a cross-sectional study carried out over a period of 4 months. The independent variables including, patient factors and surgeons' factors were measured at the same time with the dependent variables, the type of implant and cost of implant.

3.2 Study site

The study was carried out in different centers categorized under;

i. Public hospitals- KNH, Nakuru and Mombasa level 5 Hospitals.

ii. Private hospitals- AKUH, NH, MP-SHAH, Mater Hospital.

iii. Mission hospitals- PCEA, Kijabe Mission Hospital

These hospitals are specialist hospitals and are high volume centers of orthopedic surgery. A significant number of hip replacement surgeries are carried out in these hospitals.

A multicenter approach in this study was necessary to compare different hospital settings in the approach of the process of hip replacement.

3.3 Study population

The study target population included patients undergoing primary THR and Surgeons' performing the surgeries in multiple centers in Kenya, from the specific hospitals in the 3 categories of private, public and mission hospitals.

3.4 Inclusion and Criteria

3.4.1 Inclusion criteria

1. All patients scheduled for primary THR.

2. Surgeons' performing hip replacement surgery.

3.4.2 Exclusion Criteria

1. Patients not fit to undergo the procedure.
2. Patients who decline to participate in the study.

3.5 Study Variables;

3.5.1 Independent:

1. Age
2. Sex
3. Presence of Comorbidities including Diabetes,
4. American Society of Anesthesiologist (ASA) classification
5. Diagnosis
6. Dorr classification
7. Surgeons' experience and level of training

3.5.2 Dependent:

1. Type of implant
2. Cost of implant

3.6 Sample size determination

Sample size will be calculated using the Cochrane formula (1963);

$$n = \frac{(Z_{1-\alpha/2})^2\, p(1-p)}{d^2}$$

Where;

$Z_{1-\alpha/2}$ = critical value for 95% confidence interval that is 1.96

P= expected proportion in a population based on previous studies (total hip replacement increased by 34% in 2020 AAOS 2018)

d= margin of error = 5%

$n = 1.96^2 (0.34 (1 – 0.34)/0.05^2$

Substituting the above formula our sample size (n) = 345 procedures

3.7 Sampling technique

Stratified sampling technique was used to select procedures which meet the inclusion criteria. The study was conducted in 4 months. The stratum of sampling was the nine hospitals where participants were recruited. This technique ensured equal representation of the sample from the different hospital categories.

Approximately 6 hip replacements were carried out in PCEA Kikuyu and Kijabe Mission hospital per week.

To select individual procedures from each hospital, convenient sampling was used.

3.8 Data Collection Process

A data collection sheet in form of a structured data collection tool (Appendix 1) was used to collect data from the study participants in the different hospitals. Primary respondent in this study were the surgeon undertaking the procedure. Patient related information was retrieved from the patient's file.

Both the patient undergoing THR and the surgeon on schedule to perform hip replacement surgery were approached prior to surgery and explained to the study protocol. They were then requested if they would like to participate in the study and if they agreed, informed consent was administered.

Thereafter patient level factors including age, quality of bone, level of activity, comorbidities were captured in the data collection tool from the patient's file. Information on cost of implant was derived from the patients' files as per the billing details.

After conducting the procedure, the surgeon was requested to fill the data collection sheet on the factors that influenced the choice of the implant.

3.9 Data Management

During the data collection process, Principal Investigator (PI) ensured that no patient or surgeon identifying information is captured. This was done by de-identification of patients at all levels of data collection. No personal identifying information was collected. All patients were given codes.

Confidentiality was maintained throughout the study process.

All hard copy forms were then locked in a safe to limit access to only the PI and to only authorized personnel.

3.10 Data Entry

Once data was collected, hard copy data in form of structured interview forms were converted to soft copy using Epi-Info 7.2.2. On data entry, it was counter checked for errors and completeness. The information was kept in a password protected folder and only accessible to the Principal Investigator and Statistician.

3.11 Data Analysis

Statistical Package for Social Sciences (SPSS) Version 26 and Nvivo version 11 was used for data analysis.

For quantitative continuous data, descriptive statistics such as means, modes, and medians were used to describe characteristics of the study participants. Proportions were used for categorical data.

Data was presented in written reports, bar graphs, pie charts and frequency tables.

3.12 Data dissemination

A manuscript will be developed for submission in peer reviewed journal.

Information disseminated in conferences, professional meetings, and interest groups. The study results will be available at the UON orthopedic surgery research library with recommendations shared with the KOA to advocate for the reactivation of a local joint registry since our anatomy, functional demands and overall implant choice patient factors are different compared to the western population.

3.13 Study limitations

This being a cross-sectional study may not establish the causal association however, meticulous study planning and design was ensured that bias is minimized as much as possible and the results are a true representation of the phenomena under study.

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3.14 Ethical considerations

The approval of this study was sought from the Kenyatta National Hospital-University of Nairobi Research and Ethics Committee. The study only commenced once approval was obtained. All patient data was kept confidential at all data abstraction, processing, and analysis stages. Surgeons participating in this study were informed of the study protocol and gave an informed consent once they accepted to participate. Data was anonymized and

key patient identifiers like names, gender, residence, and age among other was de-identified.

Administrative Consent (Appendix 2) to conduct the study was sought from hospital administration / CEO through the Kenyatta National Hospital research office. Data was stored in a password protected database.

CHAPTER FOUR

4.0 RESULTS

This study evaluated prospective qualitative data on surgeons' perspective on what factors influenced the choice of implants on 345 procedures carried out over a 4 month period since December 2021 in 3 categories of hospitals.

The data was evaluated and results highlighted in this section.

4.1 Patient factors;

4.1.1 Patient distribution

Procedure distribution was not equal among the various facilities. This was due to different THR work load and patient availability in the different facilities. The lowest patient representation was seen in the public hospitals, with the surgeons having the lowest THR workload at 21%. Mombasa had the lowest distribution in the category at 3.4%.

The private hospitals had a workload of 24% and the mission hospitals category had the highest patient distribution at 55% with PCEA kikuyu having the highest patient load of 31.5% of the total procedures done (Table 2).

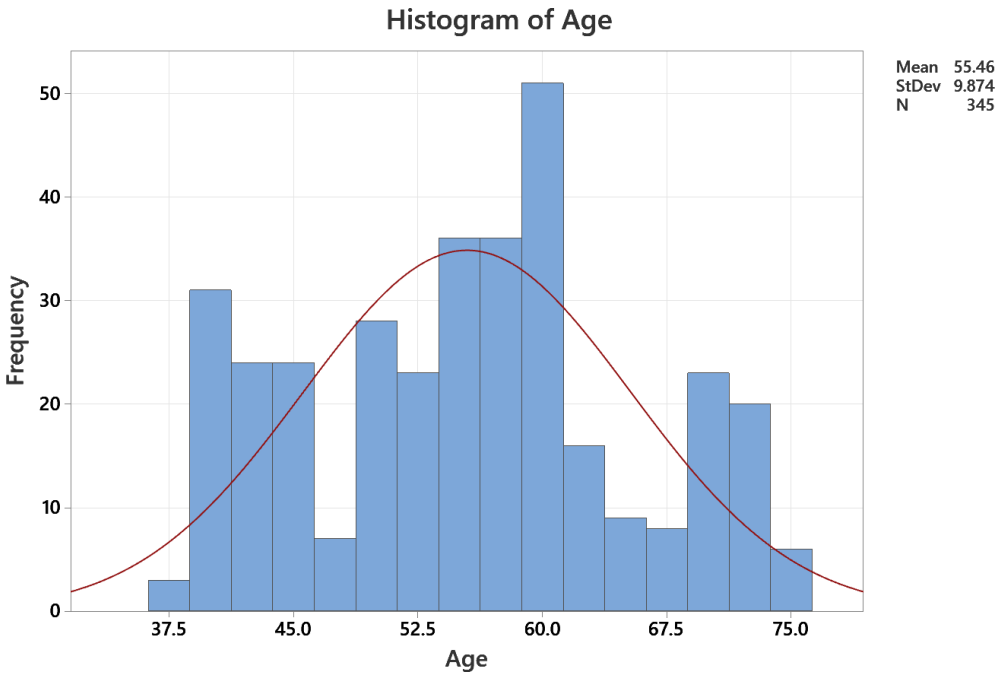
Table 2: Distribution of surgeons in various hospital and caseload over the study period

Hospital	Number of surgeons	Number of procedures done
PCEA Kikuyu	3	109
Kijabe Mission Hospital	2	80
Aga Khan University Hospital	1	16
Mater Hospital	2	20
MP Shah	2	24
Nairobi Hospital	3	24
Nakuru Level V	2	24
Kenyatta National Hospital	2	36
Mombasa CGH	1	12

4.1.2 Age

Age distribution is shown in figure 2.

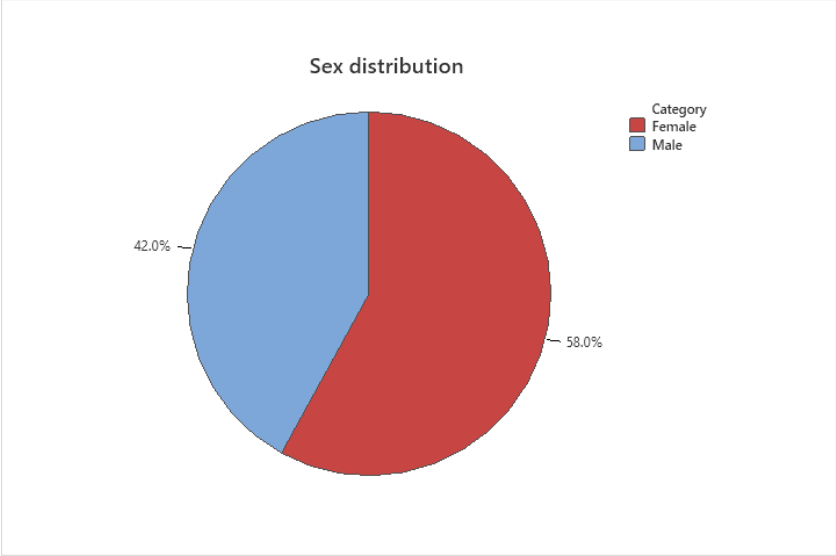
Figure 2: Age distribution



4.1.3 Sex

Majority of patients were females (Figure 3).

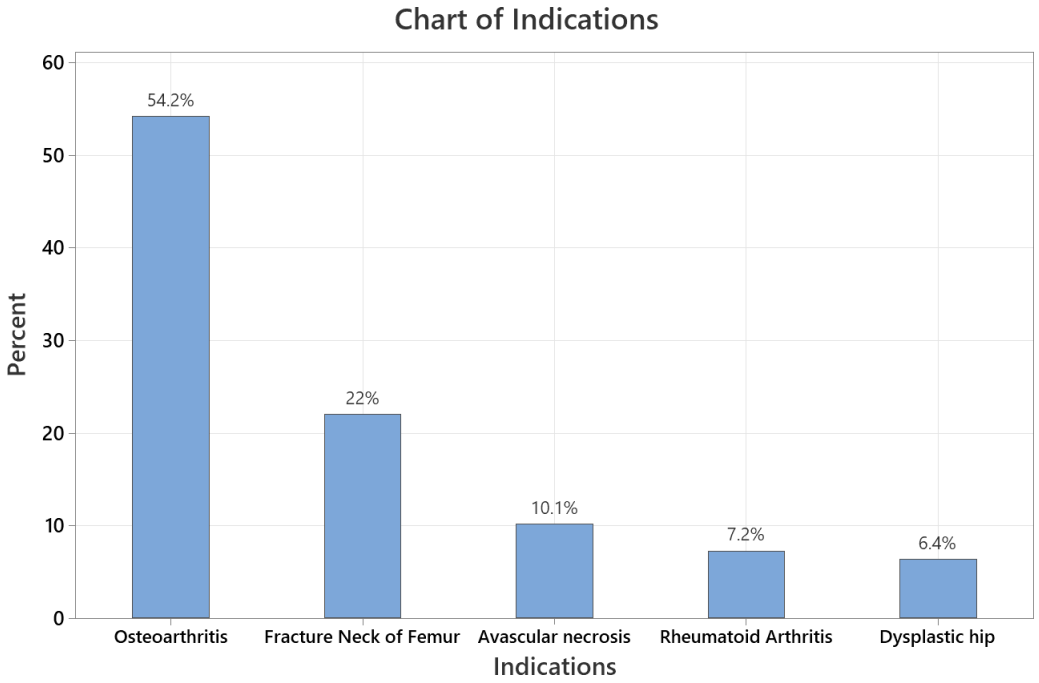
Figure 3: Pie chart showing sex distribution among patients undergoing hip replacement.



4.1.4 Indications for hip replacement.

The most common indication of hip replacement was osteoarthritis of the hip, which was most common in elderly female patients 58-74 years and occurring in 187 out of 345 patients. This was followed by fracture neck of femur in 76 patients, then avascular necrosis of the hip in 35 patients. Other indications included, rheumatoid arthritis 25, dysplastic hip 22 patients (Figure 4).

Figure 4: Indications for hip replacement



4.1.5 Comorbidities

The proportion of patients with comorbidities were 208 out of 345 (60.1%). The commonest comorbidities included hypertension (65.6%), diabetes (21.2%).

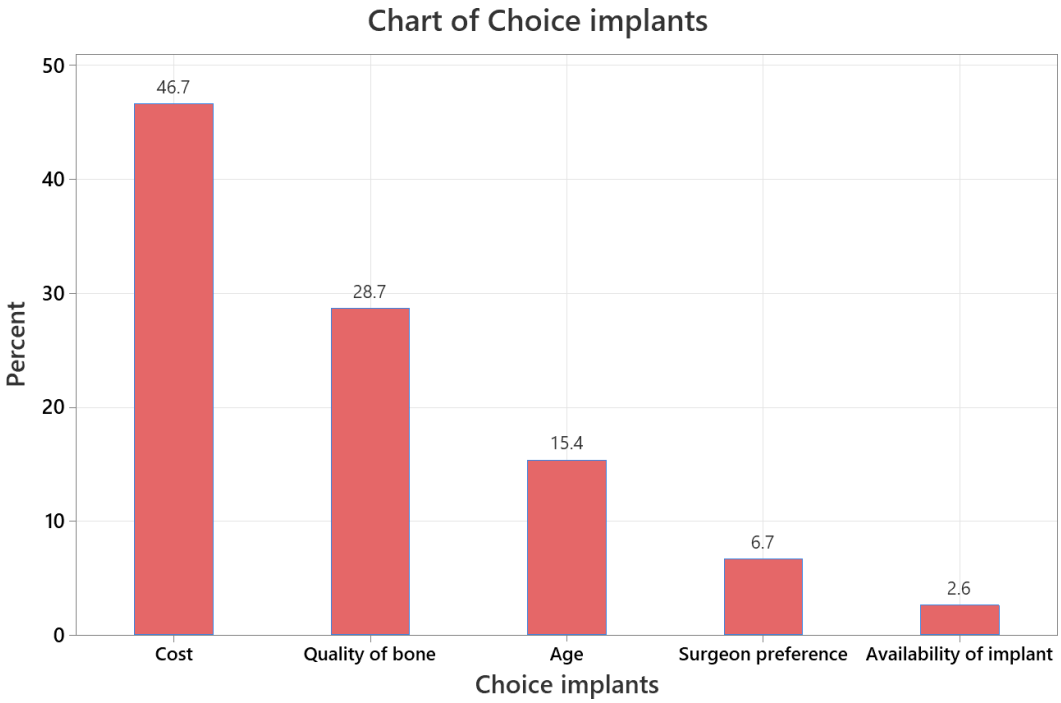
Notable is that no patient with neuromuscular condition was operated on in the same duration and most surgeons reported, they do not do routinely operate on patients with neuromuscular disorders. Alternative procedures are done.

4.2 Choice of implant

According to the surgeons, cost was the most common factor in 161 (47.7%) cases, followed by quality of bone in 99 (28.7%), age at 53 (15.4%), surgeon preference 23 (6.7%), availability at 9 (2.6%) (Figure 5). Comorbidities did not affect the choice of implants and all patients above 55 years required a physician review with and

electrocardiogram and echocardiogram and in some centers a preoperative anesthesiologist/anesthetist review before the procedure was done.

Figure 5: Choice of implants



4.2.1 Quality of bone

For the femoral component the Dorr classification was used, with review of a low centered AP and lateral pelvic radiograph, with Dorr A and 70% Dorr B being given cementless hips while 30% of Dorr B and all Dorr C patients getting cemented hip replacement.

Dorr B was a grey area as several factors apart from bone quality were put to consideration, these included the patients' level of activity, age and cost.

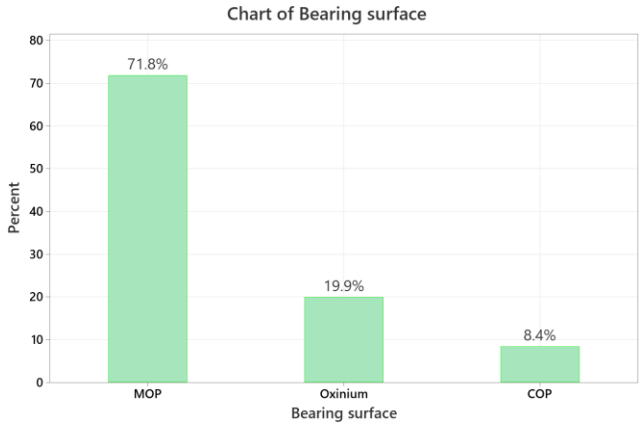
The acetabular component choice was affected similarly by the quality of bone, level of activity and age with 68% being cementless while 32% cemented. Reason for cementation was age with majority of surgeons preferring cementless cups for the younger patients and

in indications of protrusion and dysplasia. All patients above 65 years had cemented hips done.

4.2.2 Bearing surface

MOP was the most common surface used at 249 for all patients despite of age and level of activity followed by oxinium heads on poly at 69 and 29 using COP for patients especially below 40 years due to wear rate (Figure 6).

Figure 6: Bearing surface



4.2.3 Cost of implants

The National Health Insurance Fund (NHIF) or Universal Health Care (UHC) was the predominant mode of payment at 78.3% followed by cash 13.6% and other insurances at 8.1%. The NHIF capitation was limiting as most patients required to top up to get the ideal hips they required.

The average cost of implants for cemented implant was 689.95-1379.9 USD, hybrid implants at 1034.93 USD and cementless implants 1552.39-2587.32 USD. This cost was for the standard implants.

For the individual components prices, table 3.

The patient who needed special components mostly for the bearing surface needed to top up the extra implant cost, as oxinium heads cost an extra 431.2 USD while the ceramic heads required an extra 603.7 USD and for modular stems in dysplastic patients, the top up was up to 1725.6 USD just for the stem.

Table 3; cost of components.

Implant component	Cost in USD
Cemented stem Cup Head	301.8-388USD 258.7-310.4 129.3-224
Cement- antibiotic laced Without antibiotic	112 86
Cementless- stem Cup Liner Screws Head	560-689.9 344.9-413.9 172 51 each 301.8-396.7
Hybrid –cemented stem cementless cup Liner Head Screws	301.8-388 344.9-413.9 172 301.8-396.7 51 each
Cage	603-1034
Bearing surfaces Oxinium Ceramic heads	 431.2 603.7
Modular stems	1725.6

4.2.4 Availability of implants

Implants were easily available through the orthopedic technician/ company representatives or some surgeons had their own sets.

In the private hospitals, the implants were easily accessible according to the surgeons while in public set up, implants were easily accessible in only small percentage of surgeons who either had their sets or had their own arrangement with the hospital. The main limiting factor for the ease of availability, was the long procurement process in the public hospital as explained by the surgeon.

4.2.5 Surgeon preference and experience

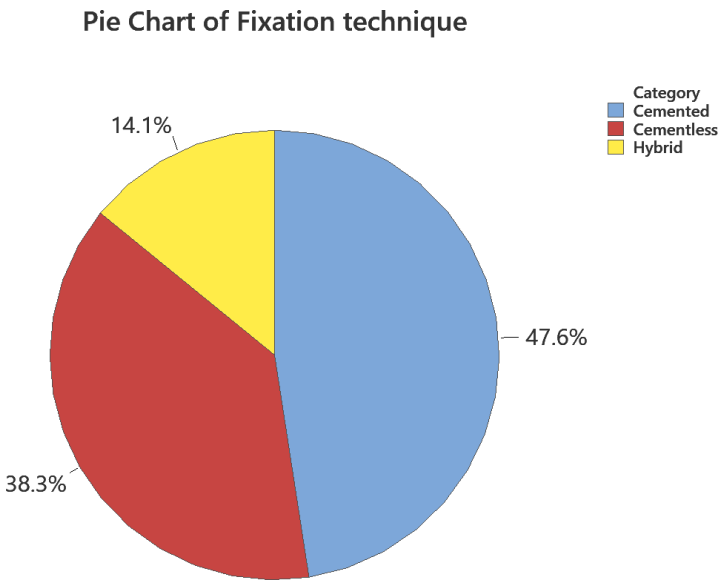
Eighteen surgeons were interrogated in this study. 6 surgeons had experience greater than 16 years. 9 of them had an experience within 6 - 15 years and 3 of the surgeons had

experience of 5 years. Preference despite lack of data, based on the surgeons' experience with the various implants informed their choice to an extent.

4.2.6 Fixation techniques

The cemented hip was done on 165 patients while 133 cementless and hybrid hips at 49 with cementation being a mix of 2nd and 3rd generation cementing techniques (Figure 7).

Figure 7: Fixation techniques



CHAPTER FIVE

5.0 DISCUSSION

Total hip replacement is increasing in Kenya, Africa, and the rest of the world. Primary osteoarthritis was the most common indication for hip replacement, followed by avascular necrosis of the hip due to several factors, including poorly managed fracture neck of femur, sickle cell anemia, steroid use primarily from autoimmune disorders, and alcoholism. Studies across the world have shown a similar pattern of indications of hip replacement (2).

The most important factors considered in the choice of the implant were cost, quality of bone, and surgeon preference.

5.1.1 Implant cost and patient socio-demographic factors

Kenya is a third-world country with a current GDP of 5.06% in 2021, which is postulated to increase by 9.9% in 2022. 36.1% of persons are noted to live below the poverty line due to health problems, economic inequalities, and government corruption.

Cost is and will likely remain the main factor influencing the choice of implants in Kenya. This is echoed in the Malawi joint registry. A study conducted in the country noted the difference in socioeconomic factors in sub-Saharan countries compared to western countries as a significant factor in implant choice (8). This is in contrast with the Western population. A study by P.K Sharkey et al. 1999 in the United States concluded that the most significant factor influencing the choice of implants was the quality of the implants; based on 97% of patients, 84% were willing to pay the additional cost (50). The same was echoed in a recent study by A Fuhrmann et al. 2019. In the Canadian experience, 62% of patients were willing to top up on implant cost for quality implants (51).

Despite the government pushing for all persons to be managed under the NHIF or UHC cover if the capitation remains as it is currently, of 2156- 3018.5 USD, the patients who require specific implants based on the quality of bone, level of activity and indication of hip replacement will likely have to go out of pocket to cater for the additional cost of the implants required for hip replacement.

Similar health systems exist in Sub-Saharan Africa, with 90-95% of health care funded by government tax, as noted in Ghana's national health insurance scheme (NHIS), Malawi's health sector-wide approach, and Uganda's National health policy plan. But as the NHIF, the patients still have and risk financial catastrophe and have to pay an extra surgical fee not covered by the respective health policies. (52)

It is also noted that the health policies primarily cover health services in public government hospitals.

5.1.2 Patient characteristics and surgeons' considerations

The quality of bone measured on a low centered AP and Lateral radiograph and the patient's level of activity is an essential factor as it was what governed the surgeons on when not to cement. However, this was disputed by some surgeons who report no difference in terms of superiority between cemented and cementless hips if the procedure is done correctly. Schmitz MWJL et al. 2013 noted there is no difference in long-term survival and subsequent revision rates. (53).

The majority of surgeons preferred cementless stems for patients with good bone quality and an active lifestyle. Some reasons were given, including preservation of bone stock and ease of implant change during revision surgery. Cementation was left for the patient who

was elderly above 65 years with poor bone stock, irradiated bone due to the properties of cement. (31).

The acetabular component was cementless in the majority of the patients due to surgical preference primarily; this was reported as being due to the higher failure rate of cemented cups noted by the higher revision rates being due to the cup failure from surgical experience. Some surgeons also reported additional stability offered by the additional iliac screws in cementless cups. (30).

The bearing surface was primarily MOP, with most surgeons citing cost as the reason for the choice. But for patients below 40 years, oxinium and ceramic heads were preferred due to low wear rates, and most patients were required to top up the extra cost for these heads. (34, 38)

The age of the patient was the next factor, but it was factored in alongside the patients' level of activity and was less of a factor compared to patients' quality of bone. Patients above 55 years generally required physician clearance before the surgery was cleared. Comorbidities were generally not a contraindication to hip replacement and equally required physician or anesthesiologist/anesthetist clearance. (43).

Neuromuscular disorders were a contraindication to most for hip replacement, and this was based on surgeon experience as they opted for other modes of management such as bipolar. This is due to the complexity of the surgery and implants required, the need for strict post-op follow-up, and complication rates. (45)

Most surgeons in the study had above eight years of practice in arthroplasty in reputable hospitals. The different preferences were mainly due to the individual experience with the various implants despite lack of local data as back up.

5.2 CONCLUSION

Identifying the most appropriate choice of implants during primary total hip replacement is a recognizable priority, given the rise in the number of patients undergoing THR in Kenya and worldwide. The selection of implants is dependent on multiple factors.

Despite the various factors reviewed in this study, age and patient activity level are significant for all surgeons. Still, the implant cost shows an important and determinant value since we are a middle, low-income country, and 1/3 of the nation lives below the poverty line with an income below 1 dollar a day.

Despite a large number of THR's performed annually, there is still little evidence available to allow integration of results and inform decision making.

5.3 RECOMMENDATIONS

Clinical practice and guidance rely on registry evidence; consequently, this review highlights and recommends the need to re-establish our local joint registry with rigorous reporting.

This will enable more surgeon practice interaction to improve all aspects of joint replacement locally.

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LIST OF APPENDICES

Appendix 1: Data Collection Tool

FACTORS INFLUENCING CHOICE OF IMPLANTS IN PRIMARY HIP REPLACEMENT IN KENYA: A MULTICENTER STUDY
STUDY NUMBER……..

1. Age (years)
2. Sex a. male b. female
3. Comorbidities and immune status
    a. Diabetes- yes/no
    b. Chronic kidney disease- yes/no
    c. Heart failure- yes/no
    d. HIV
    e. other
4. Neuromuscular conditions present
    a. None
    b. CVA-yes/no
    c. Cerebral palsy-yes/no
    d. Parkinsonism-yes/no
5. ASA Classification
    I
    II
    III
    IV

V

6. Indications for THR

   Fracture hip

   Osteoarthritis

   AVN

   Developmental Dysplasia

7. Nature of Fracture and classification

   Acetabulum

   Neck of femur

8. Dorr classification

   Type A

   Type B

   Type C

9. Nature of Acetabulum

   Normal

   Dysplastic

   Protrusion

10. Choice of bearing surface

    COM

    COP

    MOP

    COC

11. Mode of fixation

Cemented

Cementless

Hybrid

Reverse hybrid

12. Does the choice of implants change pre vs. post op

Yes / NO

If yes reason for change …….

13. Cementing technique generation

a. 1st generation

b. 2nd generation

c. 3rd generation

d. Combination of 2nd and 3rd

e. 4th generation

14. Reason for implant choice

a. Cost Yes / No

b. Age Yes / NO

c. Quality of bone Yes / No

d. Availability of implants Yes / No

e. Surgeons preference and experience Yes / No

f. Patients physiological age Yes / No

g. Dorr classification Yes / No

h. Nature of acetabulum Yes / No

15. Cost of implants (ksh.) _____

16. Availability of implant (due to cost or procurement)

i. Easily available
ii. Not easily available

Appendix 2: Informed consent English Version

PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY

This Informed Consent form, is for PATIENT UNDERGOING PRIMARY HIP REPLACEMENT SURGERY AND CONSULTANTS PERFORMING THE SURGERY at multiple centers in Kenya. It will be administered directly to both the patient and surgeons. I am requesting you to take part in this research project under the title "**FACTORS INFLUENCING CHOICE OF IMPLANTS IN PRIMARY TOTAL HIP REPLACEMENT IN KENYA: A MULTICENTER STUDY**"

Principal Investigator: Dr. Grace Katuse
Institution: Department of Orthopedic Surgery, School of Medicine, University of Nairobi.

This Informed Consent Form is divided into three parts:

I. The Information Sheet (this gives you in a brief overview about the research).

II. The Consent certificate (for signing if you agree to take part).

III. The researcher's statement/the research assistant.

Attached is a copy of the informed consent.

PART I: The information Sheet

Introduction

My name is Dr. Grace Katuse, a postgraduate student at the University of Nairobi department of Orthopedic and Trauma surgery. I am carrying out research to determine

what factors influence choice of implants in primary total hip replacement at the different facilities in Kenya.

Research purpose

Information will be provided by the principal researcher or assistant and you will be invited to be a participant in this research. After receiving all the information about the study, you are encouraged to ask questions and seek clarification in case of any doubt. This study will elucidate, the different factors that affect choice of implants to the orthopedic surgeon while performing primary total hip replacement based on the different indications, patient age and functional status. The study will also aim to try to justify the implant choice and hopefully push for re-establishment of our local joint registry.

Type of Research Intervention

This research will involve use of questionnaires and medical records/ imaging with the surgeon's and patients' permission [or their representative].

Voluntary participation/ refusal or withdraw from participation

The decision to take part in this study or not will be left to the study participant and you have a choice to refuse or withdraw your participation in this study at any point.

Confidentiality

The information obtained in this study will be treated with confidentiality and only made available to the principal investigator and the study team. Your name and the patient's

name will not be used. Any personal information will have a number on it instead of participants or the patient's name. The identity of those participating in this research will be anonymous.

Study procedure

After agreeing and consenting to take part in the research study, various information will be obtained on the available implant, its cost, patient bio data and a questionnaire will be administered to assess what influenced choice of the various implants.

This choice will be compared with the patient's bio data, functional level

Preoperative choice will be compared with the post-operative and reason for change if any will be reviewed.

All this information will be reviewed by the principal investigator or her representative.

Results dissemination

The information obtained from this research study will be shared with the UON orthopedic department the KOA and orthopedic surgeons through publications and conferences.

Confidential participant or patient information will not be shared.

Study benefits

Contribution made by joining the study are to the advancement of patient care and management.

Study Risks

There is no risk involved in enlisting or failure/ refusal to take part in this study

Cost and compensation

There is no compensation to be given and no extra cost incurred to the participant or patient for taking part in this study.

This research proposal has been subjected to review and approval by the UON/KNH Ethics Committee, this committee's task is to make sure that research participants are protected from harm.

Contact person

Incase of any questions or concerns later, you can contact:

THE PRINCIPAL RESEARCHER:

Dr. Grace K. Katuse
Registrar Department of Orthopedic Surgery,
Faculty of Health Science, University Of Nairobi
Email: dr.katuse@gmail.com
Phone: 0725140820
P.O. BOX 19-90100

Dr. Tom S. Mogire, Consultant Orthopedic and Trauma Surgeon

Lecturer, Department of Orthopedic Surgery, University of Nairobi

Email: tsmogire@gmail.com
Phone: 0722854139

P.O. Box.30197-00100

Dr. John K. Kingori, Consultant Orthopedic and Trauma Surgeon

Lecturer, Department of Orthopedic Surgery, University of Nairobi

Email: John.kingori@gmail.com

Phone: 0725979524

P.O. Box. 30197-00100

The Secretary,
KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website htttp://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERCs

PART IIa: Certificate of Consent by patient

I have read and understood the above information/the above information has been read out to me. I have had the opportunity to ask questions and the questions that I have asked have been answered satisfactorily. I voluntarily agree and consent to participate in this research.

Name of Participant _____

Signature of Participant _____

Date _____

PART IIb: Certificate of Consent by the surgeon

I have read and understood the above information/the above information has been read out to me. I have had the opportunity to ask questions and the questions that I have asked have been answered satisfactorily. I voluntarily agree and consent to participate in this research.

Name of Participant _____

Signature of Participant _____

Date _____

PART III: Statement by the researcher

The information about the research sheet has been read out to the participant, and I have ensured that the participant has understood that the following will be done:

Any decision made either to participate, refusal to participate or withdrawal from the study will not in any way whatsoever compromise the level of care of the patient.

All information on the participant and patient will be handled with utmost confidentiality and anonymity.

The study results may be published to facilitate for further research, improve patient care and clinical guidelines. The participant was given an enough opportunity to ask questions or raise concern about the study, and all the concerns and questions have been answered correctly. I confirm the participant has not been coerced into giving consent, and the approval is voluntarily.

A copy of the Informed Consent has been provided.

Name of principal researcher/person taking consent _____

Signature of principal researcher/person taking consent_____

Date_____

Appendix 3: Informed consent Swahili Version

Fomu Ya Makubaliano Ya Kujiunga Na Utafiti

Fomu ya makubaliano: Kwa mgonjwa

Nimesoma na kuelewa ujumbe niliopewa wa utafiti huu/ nimeelezewa kwa kina. Nimepata fursa ya kutosha na wakati wa kuuliza kwa kina maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti wasaidizi.Nimekubali kushiriki katika utafiti huu kwa hiari yangu

Jina la mshiriki_____

Sahihi la mshiriki _____

Tarehe_____

Fomu ya makubaliano: Kwa daktari mpasuaji.

Nimesoma na kuelewa ujumbe niliopewa wa utafiti huu/ nimeelezewa kwa kina. Nimepata fursa ya kutosha na wakati wa kuuliza kwa kina maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti wasaidizi.Nimekubali kushiriki katika utafiti huu kwa hiari yangu

Jina la mshiriki_____

Sahihi la mshiriki _____

Tarehe_____

Ujumbe kutoka kwa mtafiti

Ujumbe kuhusu utafiti huu nimemsomea mshiriki na kuhakikisha kuwa mshiriki ameelewa na kufahamu yafuatayo:

Uamuzi wowote wa mshiriki kukubali kushiriki, kutoshiriki au kujitoa kwenye utafiti huu hautadhuru mgonjwa kupata matibabu.
Ujumbe kuhusu mshiriki na majibu yake au mgonjwa yatahifadhiwa kwa siri.

Matokeo ya utafiti huu yanaweza kuchapishwa ili kuwezesha utafiti zaidi kwa madaktari wa upasuaji wa mifupa kujua vifaa ambavyo madaktari wenzao wanatumia wakati wa upasuaji wa nyonga na kubadilisha na chuma au plastiki ya aina tofauti.

Ninathibitisha kuwa mshiriki alipewa nafasi ya kutosha ya kuuliza maswali, hoja na yote yakajibiwa vilivyo.

Ninahakikisha kuwa mshiriki alitoa ruhusa kwa hiari yake bila kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti _____

Sahihi ya mtafiti _____

Tarehe_____

Appendix 4: Administrative consent to conduct study in a facility

I Dr. Grace Katuse, a registrar in the Department of Orthopedic and Trauma Surgery, University of Nairobi, would like to seek consent from the Research and Administration department/Office of the_____Hospital to conduct a research study entitled, FACTORS INFLUENCING CHOICE OF IMPLANTS IN PRIMARY TOTAL HIP REPLACEMENT IN KENYA: A MULTICENTER STUDY.

This study entails using patients' files and interrogating surgeons to derive information on factors that make surgeons choose various hip replacement implants for specific patients. No patient identifying information will be collected.

Results of this study was shared with the hospital management among other stakeholders to help improve local policies and guidelines on hip replacement implant selection

…….

Hospital representative

……

Principal Investigator

FACTORS INFLUENCING CHOICE OF IMPLANTS IN PRIMARY TOTAL HIP REPLACEMENT IN KENYA: A MULTICENTER STUDY

ORIGINALITY REPORT

14%	12%	9%	4%
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Dr V.M. MUTISO
24/08/2022