CRITICAL APPRAISAL OF THE PREDICTION OF RESECTION WEIGHT IN REDUCTION MAMMAPLASTY USING FOUR DIFFERENT MODELS

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Dissertation Submitted in Part Fulfilment of The Requirements for the Award of Master of Medicine Degree in Plastic, Reconstructive and Aesthetic Surgery at The University of Nairobi.

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DECLARATION

I hereby certify that this is my original work and has not been presented for a degree in any other university.

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DEDICATION

To my father, Patrick for his unyielding support in this journey.

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LIST OF ABBREVIATIONS

AKUHN - Aga Khan University Hospital

ANAC - Ascent of the Nipple Areolar Complex

ANOVA – Analysis of variance

ASPS - American Society of Plastic Surgeons

BC - Breast Circumference

BMI - Body Mass Index

BRASS - Breast Reduction Assessed Severity Scale

BSA – Body Surface Area

CC - Chest Circumference

D - The difference between the chest circumference and breast circumference

H- The sum total of medial endpoint to nipple distance plus the nipple to lateral endpoint distance

IMFN - Inframammary fold-to-nipple Distance

KNH – Kenyatta National Hospital

KNH/UoN-ERC - Kenyatta National Hospital/University of Nairobi Ethics & Research Committee

NIFM - Nipple to Inframammary Fold Distance

SF - Short Form 36 quality of life questionnaire

SNN - Sternal Notch to Nipple distance

SPSS – Statistical Package for Social Sciences

UHMC – Upper Hill Medical Centre

UoN – University of Nairobi

ABSTRACT

Preoperative determination of breast weight to be removed aids plastic surgeons in counseling the patient, application for insurance coverage and ensures optimal postoperative breast symmetry. Various mathematical models have been developed to preoperatively predict resection weights. We validate and determine which model is most accurate.

A sample of 24 consecutive women undergoing reduction mammaplasty were involved; anthropometric measurements of each individual breast (48 samples) was collected and used to predict mass of breast excised within a 1 year period. Predicted weight deviations from the actual weight of breast tissue excised were compared between 4 models using repeated measures ANOVA at 95% confidence interval.

Mean age was 32.25±2.14 and 60.8% of the patients undergoing reduction mammaplasty were aged 35 years and below. Three-quarter of the respondents were obese (BMI ≥ 30kg/m2). While two models significantly under-estimated breast mass to be excised; the other two provided accurate predictions with model 1 predicting 78.1% (correlation = 0.884) of actual mass excised and model 2 predicting 77.1% (correlation = 0.879).

The model reported by Yavuz et al can be safely utilized in preoperative prediction of resection weight in reduction mammaplasty.

CHAPTER ONE: INTRODUCTION

BACKGROUND INFORMATION

The breasts play an important role in defining the special functions of the female body and have enormous ethno-cultural significance. Apart from lactatory function that modulates parental behavior, by maintaining close physical proximity of mother to offspring; the breast influences a person's self-conscious perception [(1)]. To the woman it is an important external identification of femininity [(2)]. Poor body image brought about by unilateral or bilateral breast hypertrophy (gigantomastia and macromastia) has been linked to diminished mental performance, low self-esteem, anxiety, depression, sexual dysfunction, dieting and eating disorders. The need for reduction mammaplasty is not only driven by concerns of body image but also by clinical symptoms.

Reduction mammaplasty aims to restore the shape and symmetry of the breast to a naturally appearing breast in harmony to itself and to the patient. The procedure should be performed safely with reliable and predictable results that satisfy the patient. The upward trend in claims for poor cosmetic result in breast care observed in the United States and United Kingdom has created a significant cost burden to the economy [(3, 4)]. Performed well, reduction mammaplasty has high satisfaction rate [(5-7)]. Preoperative determination of whether a breast reduction is cosmetic or functional is especially important for the patient with significant clinical symptoms requiring the procedure as the only alleviating pathway. Functional reduction mammaplasty is covered by insurance companies as determined by various criteria including breast resection weight and persistent clinical symptoms. Thus the need arose to preoperatively predict weight of breast tissue to be removed for reimbursement of insurance claims.

This drove plastic surgeons to develop simple methods to achieve this goal. Patient anthropometry, including breast measurements based on surgical landmarks has been long utilized by plastic surgeons in preoperative planning of reduction mammaplasty [8]. The breakthrough was to use patient clinical parameters easily obtainable during routine surgical planning such as height, weight, chest circumference and breast measurements (nipple to inframammary fold distance, breast circumference, ascent of the nipple areolar complex, sternal notch to nipple distance) to solve this complex problem. While utilizing varied anthropometric measurements that have been positively correlated to predicting breast resection weights; different models have been derived to assist the plastic surgeon in preoperative planning of breast reduction surgery. The aim of this study was to determine which model is most accurate.

STUDY JUSTIFICATION

In reconstruction, the opposite breast often serves as a model of size and symmetry, but in situations where this is not possible, nipple position and breast shape must be judged by the plastic surgeon. This subjective bias means that it is only with experience that a surgeon becomes 'perfect' at reduction mammaplasty. The task of achieving breast symmetry during reduction mammaplasty is challenging even to experienced surgeons [9]. While utilizing known anatomical surgical landmarks, breast anthropometrics have been positively correlated to breast resection weights. The convenient nature of taking anthropometric measurements makes it easily adaptable as it's quite cheap to use a tape measure and quick to perform as an office procedure [10]. Varied models have so far been derived to assist the plastic surgeon in preoperative planning of reduction mammaplasty. A simple and reproducible method of preoperatively predicting resection weight of the breast is essential for the training of plastic surgery residents. Determining the superior predictive model that can be applied by plastic surgeons and plastic surgery residents, not only

increases ease of performing the procedure but may also reduce the learning curve of the residents. As the public awareness increases on the availability of reduction mammaplasty in Kenya; reliable and safe reduction mammaplasty is expected of plastic surgeons. Accurate prediction of tissue resection weight is also important for patients applying for insurance coverage. To the best of our knowledge, there is no study that has tested the four proposed models against each other and determined which is most accurate.

SIGNIFICANCE

Reduction mammaplasty is a relatively routine procedure to the plastic surgeon. Clinical indications like gynecomastia with a pubertal prevalence of up to 70% and middle age to elderly prevalence of up to 65% in the United States accounts for up to 80% of referrals to breast care centers [11-16].

Although several methods have claimed to be accurate in predicting breast tissue resection weight, they have failed to gain universal acceptance as none has been proven to have the highest positive predictive value. Indeed, the specified formula can then be implemented by plastic surgeons increasing ease of preoperative preparation and performing of the breast reduction. This will likely improve their aesthetic outcomes. With a postgraduate residency in plastic surgery ongoing at the University of Nairobi, it is crucial that qualifying surgeons adopt safe, reliable and reproducible techniques in reduction mammaplasty; reducing risk of litigation. Plastic surgeons can also be able to authoritatively fill insurance claim forms preoperatively designating whether the procedure is functional or aesthetic.

STUDY QUESTION

Is there a superior model for preoperative prediction of breast resection weight in reduction mammaplasty?

STUDY OBJECTIVES

BROAD OBJECTIVE

The study determined the most accurate model for preoperative prediction of breast resection weight in reduction mammoplasty

SPECIFIC OBJECTIVES

1. Breast anthropometric measurements in patients undergoing reduction mammaplasty were described.
2. The predicted breast excision weights in patients undergoing reduction mammaplasty under each of the four models were described.
3. The variations of the predicted mass for each model from the actual excised breast mass were described.

HYPOTHESIS

NULL HYPOTHESIS (H_0)

There is no difference in preoperative prediction of breast resection weight among the four commonly utilized models.

ALTERNATIVE HYPOTHESIS (H_1)

There is a difference in prediction of breast resection weight among the four commonly utilized models.

CHAPTER TWO: LITERATURE REVIEW

REDUCTION MAMMAPLASTY

Breast hypertrophy (gigantomastia and macromastia) poses significant physical and psychosocial problems to the patient. The volumetric reduction in the breast bulk by removing excess fatty tissue, glandular tissue and skin is termed as reduction mammaplasty. It may be performed to alleviate clinical symptoms or as a cosmetic procedural choice. Impaired sociocultural relations (conspicuous poor fit clothing, sexual inadequacy/harassment, limited participation in normal activity); significant regional muscle aches (backaches, shoulder aches, neck pain); postural change, breathing difficulties, bra strap grooves and skin conditions (inframammary intertrigo, exacerbated acne and hiddradenitis suppurativa) are some of the clinical indications for reduction mammaplasty [17, 18]. The role of reduction mammaplasty in improvement of quality of life cannot be understated [19-21]. Cosmetic breast reduction, on the other hand, is primarily performed to improve a patient's self-esteem and appearance based on their wishes, social (fashion trend) and ethno-cultural context.

REDUCTION MAMMAPLASTY IN KENYA

Since first described by Dieffenbach in 1848, it was only until the early 1970s that the first reduction mammaplasty was performed in Kenya [22, 23]. The procedure is relatively infrequent in Kenya and is more common in private hospitals: the Aga Khan University Hospital (AKUHN) recorded twenty (20) reduction mammaplasties performed in the year 2015 compared to six (6) performed in the Kenyatta National Hospital (KNH) [24, 25]. A recent roundtable discussion with insurance companies in Kenya revealed either absent medical policy or total exclusion from

coverage of all forms of reduction mammaplasty [26]. This blanket consideration of all reduction mammaplasties as cosmetic procedures leaves significant financial burden onto a patient with clinical symptomatology requiring surgical intervention. Inevitably, these companies shall adopt established medical policies proscribed to by insurance firms practicing in foreign states in Europe and the United States. Irrespective of guidelines from the American Society of Plastic Surgeons (ASPS) stating that resection volume is unrelated to symptom relief; the amount of breast tissue to be excised, either independently or when correlated to the patient's Body Mass Index (BMI) or Body Surface Area (BSA), is considered by most insurance companies as the determining factor as to whether the breast reduction is cosmetic or functional [27-31]. Functional reduction mammaplasty attracts insurance coverage in these countries [32, 33]. Preoperative determination of breast weight to be removed aids plastic surgeons in counseling the patient, application for insurance coverage and determining surgical approach to obtain breast symmetry [34, 35].

PATIENT ANTHROPOMETRICS IN REDUCTION MAMMAPLASTY

The science and art of taking breast anthropometric measurements is simple, reliable, reproducible, cost effective and quick to perform [36, 37]. As the base of the breast lies on the anterior chest wall extending from the second to the sixth ribs vertically, and from the sternal edge to the midaxillary line horizontally; the use of relatively fixed surgical landmarks for deriving female breast morphometric measurements is not only scientifically justifiable but also quite reliable [38]. It is logical to correlate breast mass to the thoracic cage as an "aesthetically perfect" breast shall be in harmony with the patient's body habitus. The nipple to inframammary fold distance, the inframammary crease with its medial and lateral ends are consistent landmarks useful in breast anthropometrics. These direct anthropometric measurements are taken from the patient in a clinical

setting, using linear measures and anthropometric points [39]. With the breast parenchyma being composed of glandular and fatty tissue, the patient's weight influences the weight of the breast as fat is redistributed to the mammary tissue.

The goal of reduction mammaplasty is to achieve a predictable result, retain nipple sensitivity, the possibility of lactation, and obtain an excellent aesthetic outcome; irrespective of the indication of surgery [40]. The more important issue of determining the ideal residual breast volume is overcome by preoperatively predicting the weight of breast tissue to be excised.

PREOPERATIVE PREDICTION OF RESECTION WEIGHT

Various anthropometric measurements of the breast have been positively correlated to the weight of breast tissue excised with models being derived thenceforth [41, 42].

Four models/ formula have so far been reported by different studies as having significant accuracy:

1. Predicted resection weight (grams) = (1.45 × H*NIMF) + (31.5 × D) – 576

Where H is the sum total of medial endpoint to nipple distance plus the nipple to lateral endpoint (limited to the anterior axillary line) distance; NIFM is the nipple to inframammary fold distance; and D is the difference between the chest circumference (CC-taken at the level of inframammary fold) and breast circumference (BC-taken across the fullest point of the breast) [43].

In this prospective study, Yavuz et al adhered to the described protocol and utilized appropriate analytical tools in data analysis. Accuracy was emphasized: a reliability analysis of measurements taken was done and only measurements found to have the strongest correlation were incorporated into the model. Noted limitations were small sample size of thirty nine (39) patients whose

satisfaction rate was not assessed. Sample size determination was also unclear. Despite concluding that their model may be inaccurate in pendulous macromastia; no data was presented to justify this conclusion.

2. Predicted resection weight (grams) = 60(ANAC) + 50(IMFN) – 648

Where ANAC (cm) is the ascent of the nipple areolar complex and IMFN (cm) is the inframammary fold-to-nipple distance [(44)].

This was developed by Hernanz et al in a prospective study that included assessment of patient related outcome measures using the Short Form (SF)-36 quality of life questionnaire and the Breast Reduction Assessed Severity Scale Questionnaire (BRASS Questionnaire). Their key strength was proof that the surgical procedure relieved not only clinical symptoms, but was also cosmetically acceptable thereby ultimately improving the patient's quality of life with documented positive effect sizes. However, there was no data to discount the potential use of other measurements based on negative effect sizes since all their patients were incidentally satisfied. Appropriate analytical tools were utilized and multiple models/scenarios (combinations of different measurements in a potential formula) were tested prior to ascertaining the model with the highest correlation. Their sample size of thirty nine (39) patients was however small and sample size determination was unclear. A comparison was made to other similar studies highlighting key strengths and weaknesses. Confounders identified include higher BMI of their patients (whose predominantly fatty breasts have lower density and thus record less weight for similar volume of tissue excised in a patient with lower BMI) and surgeon bias.

3. Predicted weight = 40.0(SNN) + 24.7(IMFN) + 17.7(BMI) – 1443

Where SNN is the sternal notch to nipple distance; IMFN is the inframammary fold to nipple distance and BMI is the body mass index [45].

Appel et al asserted that the strongest correlation was observed by incorporating SNN, IMFN and BMI. Sample size determination was unclear, although this retrospective study had a large sample size of three hundred and forty eight (348) patients to its strength. Appropriate analytical tools were applied. Patient satisfaction was not considered and reduction mammaplasty techniques performed were not adequately described (no protocol was described). Furthermore, no comparison was made to other similar studies. However, BMI was no longer a confounder as it was incorporated into their model.

4. Breast weight = (35.4 x notch to nipple distance + 60.66 x nipple to inframammary crease distance) - 1239.64

Where SNN is the notch to nipple distance; IMFN is the nipple to inframammary crease distance [46].

Descamps et al derived a model in a retrospective study of a significantly large sample size of two hundred and fourteen (214) patients. Sample size determination was unclear and no justification was given for analyzing data collected over a period of thirteen (13) years. However, they adequately described techniques used, analyzed data appropriately and gave justifiable conclusions. Confounders such as BMI were not adequately addressed despite having patients with predominantly high BMI and no attempt was made to compare their results to other similar studies.

Each of these studies had clear objectives and the models developed have been independently touted as the preferred method of precise estimation of breast reduction weight.

This study put all four models to the test and conclusively determined the most accurate model.

CHAPTER THREE: METHODOLOGY

STUDY DESIGN

This was a cross-sectional analytical observational study that was conducted in one (1) year.

STUDY SITE

The study sites were the surgical departments of the 6 collaborating hospitals: Kenyatta National Hospital (KNH), the Aga Khan University Hospital (AKUHN), the Nairobi Hospital, Nairobi South Hospital, Coptic Hospital and the Upper Hill Medical Center (UHMC).

STUDY POPULATION

Patients undergoing reduction mammaplasty who met the inclusion criteria.

INCLUSION/ EXCLUSION CRITERIA

INCLUSION CRITERIA

Patients undergoing reduction mammaplasty who gave informed consent and informed assent (applicable to children/minors).

EXCLUSION CRITERIA

Patients who declined to participate in the study.

Patients with history of previous breast surgery to same breast undergoing reduction mammoplasty.

SAMPLE SIZE DETERMINATION

Sample size calculation by the Yamane formula [47]:

$$n = \frac{N}{1 + N(e)^2}$$

n = N/ (1+N × 〖0.05〗^2)

Where n is the sample size,

N is the population size i.e. the total number of patients undergoing reduction mammaplasty in both AKUHN (20 patients) and KNH (6 patients)

e is the level of precision, 0.05 for this study

n = 26/ (1+290 × 〖0.05〗^2) = 24.41 ≈ 24 patients

SAMPLING METHOD

Sampling method was consecutive non-randomized sampling until the desired number of 24 patients was achieved.

DATA COLLECTION INSTRUMENT

Data was collected using a data collection tool (Appendix I).

RECRUITMENT AND CONSENTING PROCEDURE

The researcher first explained to the prospective participant what the study was all about before inviting them to ask questions and requesting them to participate in the study. Those who agreed to participate, were taken through pre-consent counselling. English and Swahili versions of the

written explanation of the study were provided to those who were literate and the same read out to those unable to read (Appendix II, III, IV & V). They were clearly informed that refusal to participate or withdrawal from the study would not jeopardize any treatment that they were entitled to. The prospective participants were given a chance to ask questions or seek clarification on any aspect of the study before giving written consent/ assent. Guardians (where applicable) were further required to sign a consent. Recruitment into the study was done once the informed consent/ assent was duly signed.

DATA COLLECTION PROCEDURE

Information obtained included bio data and surgical diagnosis. Anthropometric measurements were taken using a plastic tape measure (metric) and the results taken to nearest whole number in a patient standing in anatomical position with arms at the sides, palms forward and head straight ahead. This was done at the time of markings of the patient's reduction. The measurements (in centimeters-cm) included: nipple to medial endpoint distance (LN), nipple to lateral endpoint (limited to the anterior axillary line) distance (MN), nipple to inframammary fold distance (NIFM/IMFN), chest circumference (CC-taken at the level of inframammary fold), breast circumference (BC-taken across the fullest point of the breast), sternal notch to nipple distance (SNN) and the ascent of the nipple areolar complex (ANAC). Weight and height of the patient was taken using the standard issue hospital weighing scale and height scale. All measurements, clinical features and surgical techniques observed were entered into the data collection tool. Body Mass Index (BMI) was calculated as the weight in kilograms divided by the height in meters squared. The weight of the breast tissue removed at surgery was measured intraoperatively using a non-sterile standard digital weighing scale to avoid sample dehydration. The operating surgeons did

not utilize the models to determine breast resection patterns (skin resection pattern or breast pedicle) and weight; rather they relied on individual experience, judgement and preference.

PATIENT MANAGEMENT

Patients, who were recruited in the study, were subjected to preoperative and intraoperative care as per each hospitals protocols. Post operatively, they were assessed every day during clinical ward rounds and accorded clinical care as per each hospitals protocol. For those who developed complications, appropriate intervention was carried out.

VARIABLES

The dependent variable was the weight (grams) of breast tissue excised during the reduction mammaplasty measured intraoperatively. The operating surgeon was not be informed of any prediction in resection weight. The operating surgeon did not utilize any of the predictive models to intraoperatively determine resection weight. The independent variables were patient anthropometrics (BMI, chest circumference) and breast measurements (NIFM, SNN, ANAC, D, H).

DATA MANAGEMENT, ANALYSIS AND PRESENTATION

All data collection tools were coded and data entered into a computer using SPSS version 21 and analyzed.

Descriptive statistics was analyzed where discrete variables were summarized with frequencies and percentages. Respective measurements were taken for each model and the prediction calculated for each followed by calculation of the difference between the predicted value and weight of breast tissue excised. The operating plastic surgeons were blinded to the predictions.

The differences were compared to determine which model/ formula was more accurate using repeated measures ANOVA with 95% confidence interval.

Results were presented using texts, tables, pie charts and graphs.

ASSUMPTIONS OF THE STUDY

An assumption is made that successful outcome (functional and cosmetic) is achieved in all reduction mammaplasties performed.

ETHICAL CONSIDERATIONS

The study was authorized through ethical clearance certificate number P59/02/2016 of 22nd April, 2016 (Appendix VI) and procedures conformed to the World Medical Association Declaration of Helsinki. The following were the ethical considerations:

Approval

The study commenced soon after approval by the Kenyatta National Hospital/University of Nairobi Ethics and Research Committee (KNH/UoN- ERC) to which this research proposal was submitted in February 2016 (Appendix VI)

Confidentiality

All information collected for this research has been treated with utmost confidentiality and study participants were at all times treated with respect, according to the World Medical Association Declaration of Helsinki. The information obtained has been solely for this study and will be divulged only if it is in the interest of the patients and with his/ her approval. All raw data on hard copy has been destroyed after backing it up in a password protected softcopy database for future reference.

Plagiarism

Extensive literature review has been done, references used have been cited using the Vancouver System as recommended by the university supervisors and the work of other authors appropriately acknowledged. A plagiarism check has also been done (Appendix VII).

All persons who contributed to this study in any way have been duly acknowledged and/ or credited.

Consent

I, the principal investigator recruited participants who met the inclusion criteria. Recruitment of participants who met the inclusion criteria was verbal in the preoperative period where participants were informed of the nature, purpose, potential benefits and harmful effects of the study. Those who agreed to participate in the study, informed consent and informed assent (where applicable) was obtained and subsequently enrolled in the study (Appendix II, III, IV & V).

Feedback

All participants were informed of their individual progress post operatively.

STUDY LIMITATIONS

Limited number of patients, however this was mitigated by increasing data collection points (hospitals) to achieve 24 patients.

CHAPTER FOUR: RESULTS

INTRODUCTION

A sample of 24 women undergoing reduction mammaplasty in 6 hospitals in Nairobi were involved in this study where anthropometric measurements of each individual breasts were collected and used to predict mass of breast excised. 8 participants were drawn from Coptic Hospital, 6 from the Aga Khan University Hospital Nairobi (AKUHN), 4 from the Nairobi South Hospital, 3 from the Nairobi Hospital, 2 from Kenyatta National Hospital (KNH) and 1 was from the Upper Hill Medical Centre (UHMC).

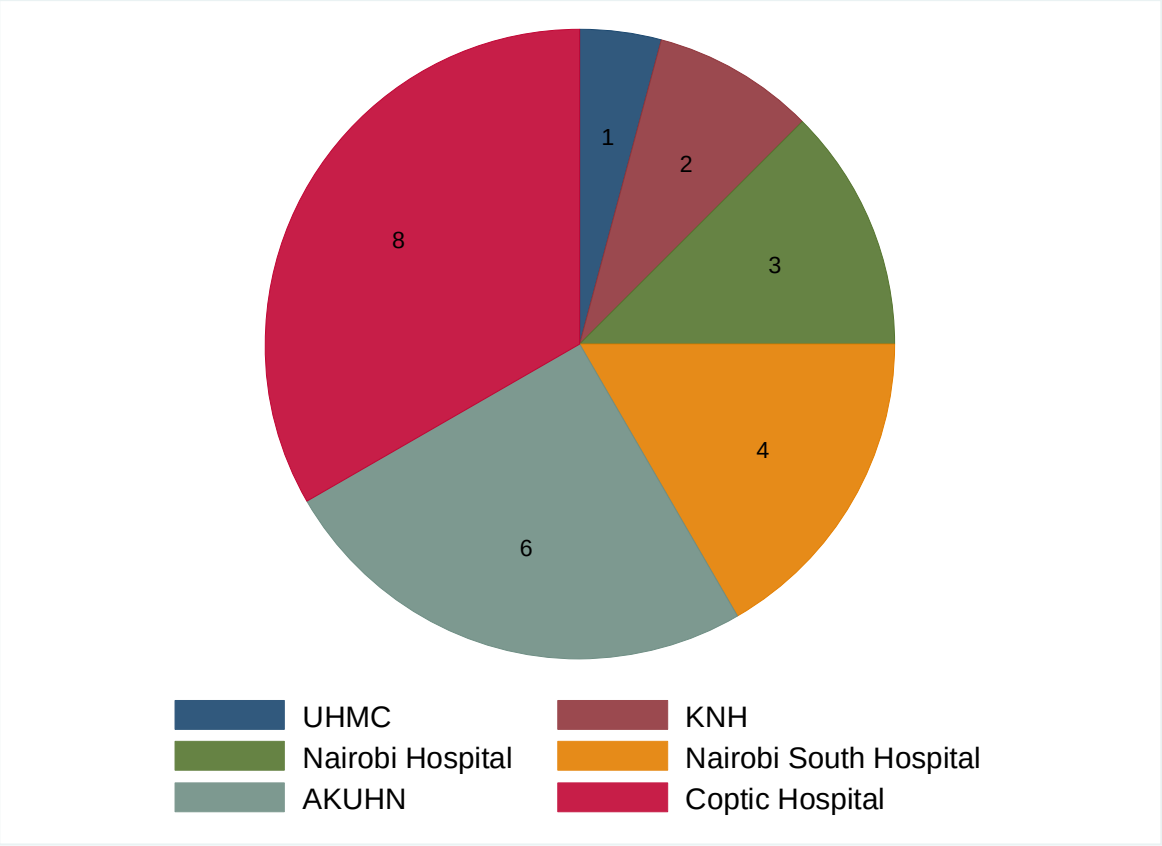


Figure 1: Distribution of Participants by Health Facility

CHARACTERISTICS OF PARTICIPANTS

On average patients were aged 32.25 (Range 32, Mode 30) years and 60.8% of the patients undergoing reduction mammaplasty were aged 35 years and below. Three-quarter of the respondents were obese (BMI ≥ 30kg/m2). Majority (62.5%) of the study participants had been diagnosed with macromastia with 70.8% having superomedial pedicle. Over half (54.2%) of the study participants underwent wise skin resection pattern while 45.8% underwent short vertical scar resection pattern. Half of the participants had Grade 2 breast ptosis.

Table 1: Characteristics of Study Participants

Characteristic		**Frequency**	**Percent (n= 24)**
Age in years	<=25	7	29.2
	26 – 35	7	29.2
	36 – 45	6	25.0
	>45	4	16.7
	Mean Age (Std. error of mean)		**32.25 (2.14)**
Nutritional status	Underweight	1	4.2
	Normal weight	2	8.3
	Overweight	3	12.5
	Obese	18	75.0
	Mean BMI (Std. error of mean)		**33.56 (1.55)**

Diagnosis	Gigantomastia	9	37.5
	Macromastia	15	62.5
Pedicle	Superomedial	17	70.8
	Inferior	5	20.8
	Free nipple graft	2	8.3
Skin resection pattern	Wise pattern	13	54.2
	Short vertical scar	11	45.8
Breast ptosis (n = 48)	Glandular Grade 1	2	4.2
	Glandular Grade 2	24	50.0
	Glandular Grade 3	22	45.8

BREAST MASS EXCISIONS

Majority of the participants had excisions of less than 1500 grams in both left (58.3%) and right (58.4%) breast. On average significantly (Wilcoxon Signed Rank test: Z = -2.374, p-value = 0.018) more weight was excised from the left breast (1235 grams) as compared to right breast (1183 grams).

Figure 2: Actual Excised Breast Mass

As shown in Table 2 below, patients aged above 45 years of age had significantly higher breast mass excised while participants aged between 26 to 35 years had the least breast mass excised. Obese patients and participants diagnosed with gigantomastia also had significantly higher breast mass excised. Participants having superomedial pedicle and those who underwent short vertical resection pattern had significantly lower breast mass excised. Breast mass excised was found to significantly increase with grade of breast ptosis.

Table 2: Characteristics of Study Participants and Breast Mass Excised

Characteristic		**Mean mass excised (g)**	**Kruskal Wallis Test**
Age in years	<=25	1253	$x^2 = 11.923;\ \mathrm{df} = 3;\ \mathrm{p} = .008$
	26 – 35	833	
	36 – 45	925	
	>45	3020	
Nutritional status	Underweight	518	$x^2 = 20.556, \mathrm{df} = 3, \mathrm{p} < .001$
	Normal weight	823	
	Overweight	683	
	Obese	1670	
Diagnosis	Gigantomastia	2233	$x^2 = 33.068;\ \mathrm{df} = 1;\ \mathrm{p} < .001$
	Macromastia	898	
Pedicle	Superomedial	1103	$x^2 = 9.864;\ \mathrm{df} = 2;\ \mathrm{p} = 0.007$
	Inferior	1375	
	Free nipple graft	3208	
Skin resection pattern	Wise pattern	1960	$x^2 = 18.527;\ \mathrm{df} = 1;\ \mathrm{p} < .001$
	Short vertical scar	898	
Breast ptosis	Glandular Grade 1	518	$x^2 = 12.113; \mathrm{df} = 2; \mathrm{p} = .002$
	Glandular Grade 2	960	
	Glandular Grade 3	1600	

VARIATIONS OF PREDICTED MASS TO BE EXCISED FROM ACTUAL EXCISED BREAST MASS

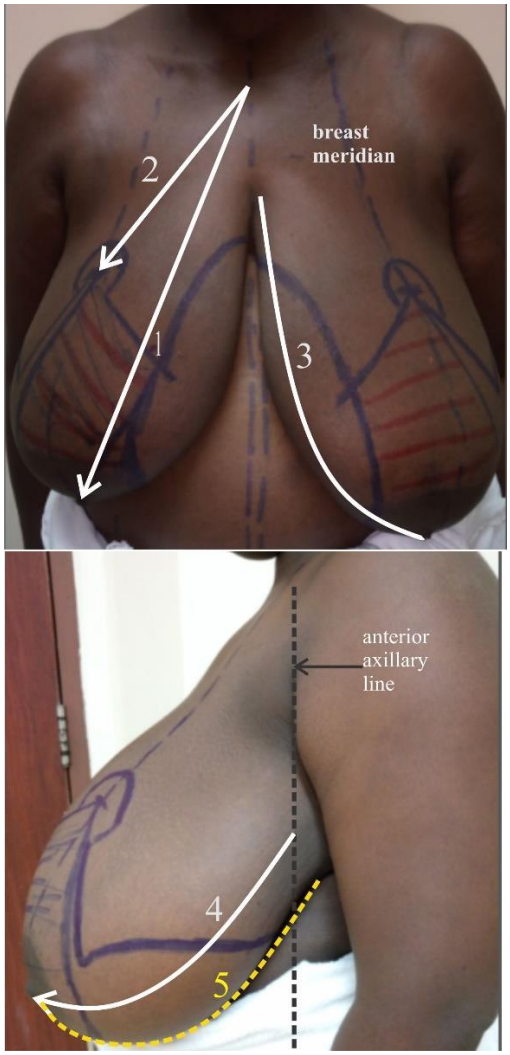
This study sought to assess the accuracy of four models used to predict preoperative breast resection weight in reduction mammaplasty. The four models used to predict preoperative breast resection weight in reduction mammaplasty considered in this study are as shown in Table 3 below.

Table 3: Models used to Predict Preoperative Breast Resection Mass Compared in this Study

Formula/ Model	**Specification**	**Dimensions**
Model 1	(1.45 × H* IMFN) + (31.5 × D) – 576	H = Medial endpoint to nipple distance + Nipple to lateral endpoint distance
		IMFN = Inframammary fold to nipple distance
		D = Breast circumference - Chest circumference
Model 2	60(ANAC) + 50(IMFN) – 648	ANAC = Ascent of the nipple areolar complex
		IMFN = Inframammary fold-to-nipple distance
Model 3	40(SNN) + 24.7(IMFN) + 17.7(BMI) – 1443	SNN = Sternal notch to nipple distance
		IMFN = Inframammary fold to nipple distance

		BMI = Body mass index
Model 4	(35.4 x SNN + 60.66 x IMFN) - 1239.64	SNN = Sternal notch to nipple distance IMFN = Inframammary fold to nipple distance

The breast anthropometric measurements were taken as shown in figure 3 below.



KEY:

1. SNN
2. New SNN
3. Medial endpoint to nipple distance
4. Lateral endpoint to nipple distance
5. NIFM/IMFN

Figure 3: Breast anthropometric measurements

There was significant variation in predicted breast mass to be excised in each of the models. All models had high positive correlation between actual mass excised and predicted breast mass to be excised (See Figure 4). Model 3 and Model 4 significantly under-estimated breast mass to be excised as shown in Figure 5. Although Model 1 and 2 over-estimated breast mass to be excised (by 123 grams and 308 grams respectively), the difference from the actual mass excised was however not significantly different. Model 1 however was more accurate as compared to Model 2 as it predicted 78.1% (correlation = 0.884) of actual mass excised as compared to 77.1% (correlation = 0.879) respectively. This difference in accuracy is not statistically significant.

Table 4: Comparison between Formula/ Model for Predicting Beast Mass to be Excised

Formula/ Model		Mass excised (g)	Mass predicted (g)	Correlation with mass excised	Difference with mass excised (g)	Wilcoxon signed rank test	
						Z	P-value
Formula/ Model 1		1223	1405	0.884	123	-0.995	0.32
Formula/ Model 2		1223	1508	0.879	308	-1.908	0.06
Formula/ Model 3		1223	995	0.924	-372	5.692	0.00
Formula/ Model 4		1223	1002	0.892	-270	5.18	0.00
Friedman test	Friedman	-	175.1	-	159.4	-	-
	P-value	-	0.00	-	0.00	-	-

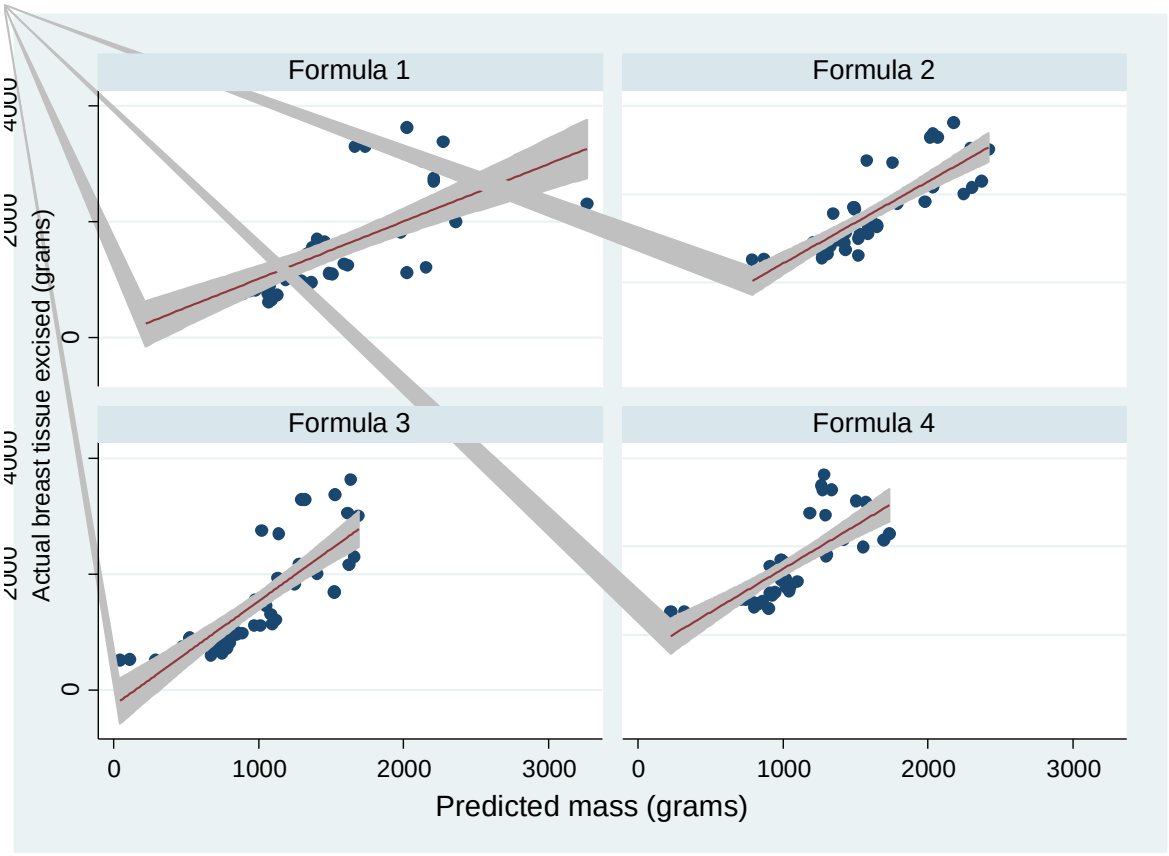


Figure 4: Correlation between Predicted Mass to be Excised and Actual Excised Breast Mass

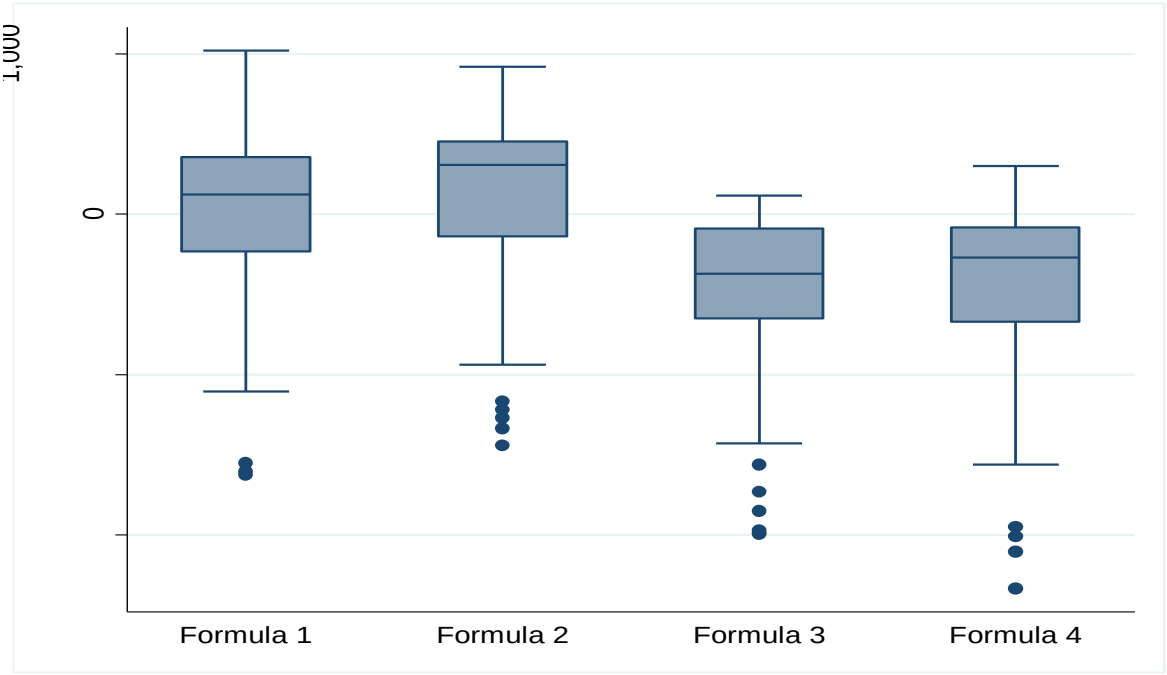


Figure 5: Difference between Mass Excised and Predicted Mass to be Excised

VARIATION IN DEVIATION OF PREDICTED MASS FROM ACTUAL MASS EXCISED ATTRIBUTED TO SURGEON

There was no significant (Kruskal Wallis test: $X^2 = 0.078$, df = 2, p = 0.962) variation in actual breast mass excised by the three surgeons involved in this study (See Table 5). This shows there was no evidence of deviance in breast mass excised attributable to surgeons. In addition, the study found no significant difference in the deviation of predicted mass from actual mass attributable to surgeons in all the four models/ formulas (See Figure 6).

Table 5: Deviation of Predicted Mass from Actual Mass Excised attributed to Surgeon

	Surgeon A	**Surgeon B**	**Surgeon C**	**Kruskal Wallis Test**
Actual Mass Excised	1253	1275	1165	$X^2 = 0.078$, df = 2, p = 0.962
Formula 1 Deviance	13	144	422	$X^2 = 3.828$, df = 2, p = 0.1475
Formula 2 Deviance	313	298	260	$X^2 = 0.216$, df = 2, p = 0.8978
Formula 3 Deviance	-384	-364	-161	$X^2 = 0.638$, df = 2, p = 0.7268
Formula 4 Deviance	-270	-321	-198	$X^2 = 0.595$, df = 2, p = 0.7427

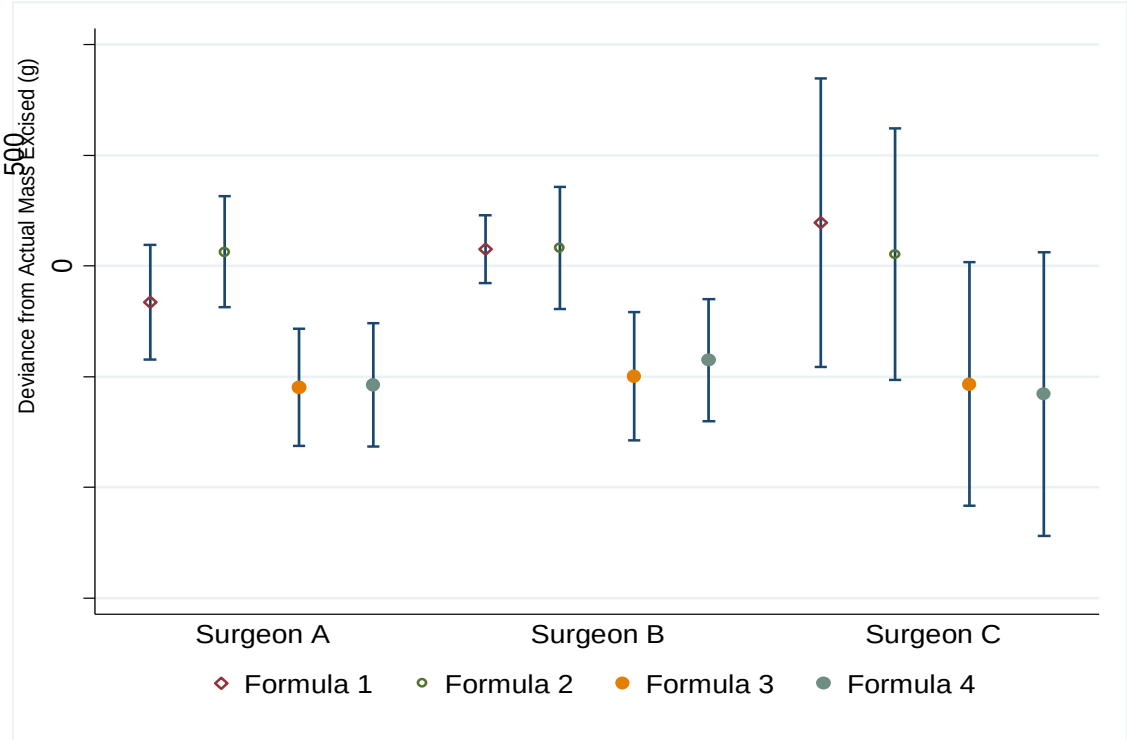


Figure 6: Variation in Deviation of Predicted Mass from Actual Mass Excised attributed to Surgeon

The raw data indicating actual excised breast mass per patient to calculated predictions by the four models is shown in table 6 below.

Table 6: Mass Excised and Predicted Mass

	Left breast					Right breast				
Patient	Mass excised	Formula/ Model 1	Formula/ Model 2	Formula/ Model 3	Formula/ Model 4	Mass excised	Formula/ Model 1	Formula/ Model 2	Formula/ Model 3	Formula/ Model 4
1	1000	1188	1520	839	1046	900	1072	1420	790	924
2	545	580	1270	457	454	520	477	990	288	227
3	3625	2021	2180	1634	1289	3375	2271	2040	1523	1268
4	600	1067	1520	670	899	750	739	1190	476	611
5	1205	2155	1420	1115	1101	1125	2023	1430	1091	1041
6	760	1062	1250	765	864	720	1072	1260	780	838
7	950	1360	1320	846	909	970	1295	1380	886	945
8	2750	2211	1580	1019	1187	2700	2211	1760	1139	1294
9	1265	1586	1650	872	1020	1240	1612	1590	832	985
10	1100	1512	1530	973	1020	1105	1486	1590	1013	1056
11	3290	1665	2020	1294	1278	3290	1737	2070	1319	1339
12	815	981	1330	797	742	805	940	1270	757	707
13	525	242	870	107	320	510	217	790	42	224
14	900	1071	1210	525	672	895	1030	1210	525	672
15	2165	2189	2040	1281	1415	2165	2250	2040	1281	1415
16	850	968	1195	707	651	760	887	1195	707	651
17	3000	2195	2420	1691	1577	3040	2126	2300	1611	1506
18	1650	1459	1495	1070	1010	1550	1370	1350	978	909
19	1920	1833	1800	1129	1273	1780	1868	1790	1114	1298
20	1450	1335	1610	1049	1005	1300	1338	1650	1084	998
21	633	1085	1310	748	806	732	1123	1430	748	806
22	2300	3263	2370	1662	1733	2150	3171	2310	1622	1698
23	1690	1405	1490	1523	988	1700	1405	1490	1523	988
24	2000	2360	2250	1407	1556	1820	1981	1980	1252	1304

CHAPTER FIVE: DISCUSSION

INTRODUCTION

Preoperative prediction of resection weight is helpful in filing of insurance claims and may reduce the learning curve of reduction mammaplasty. This is the first study that tests the four predictive mathematical formulas/ models against each other.

REDUCTION MAMMAPLASTY IN KENYA

Most of the surgeries were performed in private health facilities (22 participants) compared to public health facility (2 participants). The prevalent skin resection pattern was wise pattern (13 participants) which correlated to the degree of breast ptosis and was due to the significant redundant skin encountered. Breast pedicle utilized was surgeon's preference. The massive gigantomastia encountered in two (2) participants' likely necessitated use of free nipple graft. In current practice, any technique (skin resection pattern and breast pedicle) can literally be applied to any breast size (macromastia/ gigantomastia); the choice is often surgeon's preference and experience.

CHARACTERISTICS OF PARTICIPANTS

In this study most of the participants were obese with mean BMI 33.56±1.55. This was similar to two (2) previous studies [36, 38]. It however varied from two (2) other studies whose participants were overweight with mean BMI of 28.9 and 28.1 respectively [34, 35]. BMI was incorporated in model 3. Mean age was 32.25±2.14 which is a similar age group encountered in three (3) previous studies [34, 37, 38].

BREAST RESECTION WEIGHT

Significantly (Wilcoxon Signed Rank test: Z = -2.374, p-value = 0.018) more weight was excised from the left breast (1235 grams) as compared to right breast (1183 grams). This is consistent with results of a previous study [(36)]. Participants who were obese, older than 45years and those with higher grade of breast ptosis underwent significantly more reduction. In obesity fat is distributed to the breast, adding to their weight. These heavier breasts stretch the overlying skin resulting in worsening breast ptosis.

COMPARISON OF THE PREDICTIVE MODELS

Model 1 (Yavuz et al.) was more accurate as compared to Model 2 (Hernanz et al.) as it predicted 78.1% (correlation = 0.884) of actual mass excised as compared to 77.1% (correlation = 0.879) respectively. Although Model 1 (Wilcoxon Signed Rank test: Z = -0.995, p-value = 0.32) and Model 2 (Wilcoxon Signed Rank test: Z = -1.908, p-value = 0.06) over-estimated breast mass to be excised, the difference from the actual mass excised was however not significantly different. Model 3 (Appel et al.) (Wilcoxon Signed Rank test: Z = 5.692, p-value = 0.0) and Model 4 (Descamps et al) (Wilcoxon Signed Rank test: Z = 5.18, p-value = 0.0) significantly under-estimated breast mass to be excised. Model 2 is however noted in Figure 3 to be more stable in its predictions. Preoperative prediction of breast resection weight based on model 1 and 2 is reproducible and either can be used for insurance claims purposes. Reduction mammaplasty is a science and an art. The art of surgery is not tangible and cannot be predicted; because it depends on surgeons preferences based on experience. This weighs heavily in determining amount of breast tissue to be retained.

SURGEON BIAS

There was no significant (Kruskal Wallis test: $X^2 = 0.078$, df = 2, p = 0.962) variation in actual breast mass excised by the three surgeons involved in this study. Furthermore, the study found no significant difference in the deviation of predicted mass from actual mass attributable to surgeons in all the four models. There was no surgeon bias.

CHAPTER SIX: SUMMARY OF FINDINGS, CONCLUSIONS AND RECOMMENDATIONS

SUMMARY

This cross sectional analytical study has identified the most accurate model for prediction of resection weight in reduction mammaplasty. The study objectives were realized and basis for application established.

CONLUSIONS

This study assumed all patients were satisfied by the reduction undertaken. Noteworthy, whilst deriving Model 2; its authors validated the model with the Short Form (SF)-36 quality of life questionnaire and the Breast Reduction Assessed Severity Scale Questionnaire (BRASS Questionnaire) and this likely vouches for its artistic outcomes.

Based on its greater stability and patient satisfaction (surgery as an art) led to the conclusion that the most accurate is model 2. This study may be limited by the sample size. Breast anatomy is quite variable and precise prediction is difficult and unattainable. Thus, the use of models as a guide to actual resection may not be feasible.

RECOMMENDATIONS

The use of predictive model 2 should be standardized in reduction mammaplasty. As a requisite for insurance claims, it will ensure medical coverage or reimbursement to the patient and also legally protects remuneration owed to the plastic surgeon.

The predictive model can be used in plastic surgery residency training with an aim to avert over resection, which is more difficult to revise. The impact of the predictive model on the learning

curve of reduction mammaplasty may be assessed in an analytical study of residents utilizing the model, which further validates its utility.

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APPENDICES

APPENDIX I: DATA COLLECTION TOOL

Date: ……..Hospital no: ……Patient data number: ……

KNH☐Nairobi H.☐ AKUHN ☐ Nairobi South H.☐ Coptic H. ☐ UHMC ☐

Patient consented: yes ☐ no ☐ mobile no: …… Age (years): …….

Weight (kg): …… Height (meters): …..... Calculated BMI (kg/m^2) ……..

Diagnosis: Gigantomastia ☐ Macromastia ☐ Breast Asymmetry ☐

Pedicle: superomedial ☐ inferior ☐ lateral ☐ central ☐ superior ☐

Skin resection pattern: wise pattern ☐ short vertical scar ☐ modified L-plasty ☐

Breast cup requested: A ☐ B ☐ C ☐ undefined ☐

Chest circumference (cm)	……..…….…….
Breast circumference (cm)	…….…….……..

Breast anthropometrics	**right**	**left**
Inframammary fold to nipple distance (cm)	……..……	……..
Sternal notch to nipple distance (cm)	……..……	…….…….
Ascent of nipple areolar complex (cm)	……..……	…….…….
Medial end point to nipple distance (cm)	……..……	…….…….
Lateral end point to nipple distance (cm)	……..…	…….…….

Breast ptosis:	Cutaneous		☐	☐
	Glandular	Grade 1	☐	☐
		Grade 2	☐	☐
		Grade 3	☐	☐
		pseudoptosis	☐	☐

Weight of breast tissue excised (grams) ……..… …….……

Surgeon: A ☐ B ☐ C ☐

Date of procedure: ……..

Data collected by:

Name: ……Designation: ……Date: ……..……

APPENDIX II: CONSENT FORM (ENGLISH)

STUDY TOPIC: CRITICAL APPRAISAL OF THE PREDICTION OF RESECTION WEIGHT IN REDUCTION MAMMAPLASTY USING FOUR DIFFERENT MODELS

This informed consent form is for patients who shall be undergoing reduction mammaplasty. I am inviting you to participate in this research on a voluntary basis.

Principal investigator: Dr. Wamalwa A.O.

Institution: Department of Surgery, School of Medicine, University of Nairobi

Supervisors: Prof. Stanley O. Khainga, Dr. Ferdinand W. Nangole and Dr. Joseph K. Wanjeri

This Informed Consent Form has three parts:

1) Information Sheet (to share information about the research with you).
2) Certificate of Consent (for affirmation/signatures if you agree to take part).
3) Statement by the researcher.

You will be given a copy of the full informed consent form.

PART I: Information Sheet

Introduction

My name is Dr. Alex Okello Wamalwa, a post graduate student in Plastic, Reconstructive and Aesthetic Surgery at the University of Nairobi. I am carrying out a research to determine the most accurate model for pre-operative prediction of resection weight in reduction mammaplasty.

Purpose of the research

Reduction mammaplasty is the volumetric reduction in the breast bulk. Determination of the expected weight of breast tissue to be excised is essential in the pre-operative planning of the plastic surgeon. This also assists in assigning the procedure as either functional or aesthetic as per insurance guidelines. Despite several models being developed, we are not currently certain which is the most accurate. This study therefore aims at identifying which model is most accurate.

I am going to give you information and invite you to be a participant in this research. There may be some words that you do not understand or that you may need clarification. Please ask me to stop as we go through the information and I will explain or clarify.

Name of proposed procedure:

Breast anthropometric measurements

Weighing of breast tissue excised

Description of procedure

The measurements of your breasts shall be taking using a plastic tape measure during markings for the breast reduction surgery you have already consented for. This procedure will involve no anesthesia. This shall be done at the time of markings being done by the operating plastic surgeon. Your weight and height shall also be taken. The weight of breast tissue excised shall be weighed intraoperatively and subsequently disposed off as directed by the operating plastic surgeon. This study shall not change the course, mode or manner of management of your

condition. Analyzed results from the project shall be shared with the patient. Photographs may be taken to illustrate the procedure described.

Voluntary participation/right to refuse or withdraw

You are free to participate or decline participation in this study. Whether you choose to participate or not, will not change your current management and treatment, that is routinely offered in this hospital for your particular condition. You have a right to refuse or withdraw from this study at any point.

Confidentiality

The information obtained will be treated with utmost confidentiality and only be available to the principal investigator and his research team. Your name will not be used. We will not be sharing the identity of anyone participating in this research.

Sharing the results

The knowledge that we get from this study will be shared with the policy makers in the Ministry of Health and doctors through publications, conferences, journals and presentations. Confidential information will not be shared with any third party.

Risks

There are no risks in this study. All parameters are merely observations of your current management; no invasive investigations will be used during the course of this study.

Cost and compensation

There will be no extra cost incurred for participating in this study.

Please read the following:

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any photographs taken and tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that this research has been approved by the Kenyatta National Hospital/University of Nairobi Ethics Review Committee (KNH/UoN-ERC) and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that data about me will be held electronically and may be passed between the Kenyatta National Hospital, the University of Nairobi and any other University/ Hospital/ Research Institute collaborating with KNH/UoN, to facilitate research and my care.

I understand that my involvement in this research will be through clinical evaluation and that you will not expose yourself to any risks if you consent to participate.

I understand that there will be **NO** financial benefits.

I understand that results from this study may be published to enhance scientific knowledge

I understand that refusal to participate or withdrawal from the study will not in any way compromise the quality of care and treatment given to me

Please the tick box below to indicate if you either AGREE □ DISAGREE □

Contacts

This study has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm. The contact information is given below if you wish to contact any of them for whatever reason:

Secretary:

KNH/UoN-ERC,

P.O. Box 20723-00202 KNH, Nairobi

Tel: 020-726300-9

Email: KNHplan@Ken.Healthnet.org , uonknh_erc@uonbi.ac.ke

Principal investigator:

Dr. Alex Okello Wamalwa

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676, Nairobi

Mobile: 0722557547

Email: aleoke@gmail.com

University of Nairobi research supervisors:

Prof. Stanley Ominde Khainga

MBChB, M.MED (Surg.), Cert. Microvascular Surgery (MEDUNSA), FCS PLAS (ECSA)

Consultant Plastic, Reconstructive and Aesthetic Surgeon

Associate Professor of Surgery and Thematic Unit Head of Plastic Surgery,

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19679, Nairobi

Mobile: 0723436408

Email: skhainga@yahoo.com

Dr. Ferdinand Wanjala Nangole

MBChB, M.MED (Surg.), FCS (UCT), Fellow of EBOPRAS (Brussels, Marseille)

Consultant Plastic, Reconstructive, Hand and Hair Transplant Surgeon and Lecturer

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 2212-00202 KNH, Nairobi

Mobile: 0733864249

Email: nangole2212@yahoo.com

Dr. Joseph Kimani Wanjeri

MBChB, M.MED (Surg.), IPTM (Tel Aviv), MPH (UoN)

Consultant Plastic, Reconstructive and Aesthetic Surgeon and Lecturer

Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 58653-00200 City Square, Nairobi

Mobile: 0722708051

Email: kimwanjeri@hotmail.com

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereunder impress my signature / thumbprint as proof of my consent.

Patient/parent/guardian signature: ..... Date: .....

Name (PRINT): .....

Witness' signature: ..... Date: .....

Name (PRINT): .....

Statement of the interpreter (if appropriate)

I confirm that I have interpreted the information to the best of my ability, and in a way in which I believe s/he has understood:

Interpreter's signature ..... Date: .....

Name (PRINT): .....

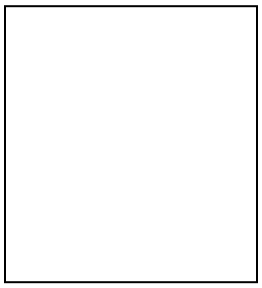
If Illiterate:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness' signature: ..... Date: .....

Name (PRINT): .....

Thumb print of participant:



PART III: Statement by the researcher

I have accurately read out the information sheet to the patient and/or guardian(s), and to the best of my ability made sure that the patient or guardian understands the following:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to enhance the knowledge and understanding of medical professionals regarding the subject of the study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Researcher's signature ..... Date: .....

Name (PRINT): ..... Designation: .....

APPENDIX III: ASSENT FORM (ENGLISH)

STUDY TOPIC: CRITICAL APPRAISAL OF THE PREDICTION OF RESECTION WEIGHT IN REDUCTION MAMMAPLASTY USING FOUR DIFFERENT MODELS

This informed consent form is for patients who shall be undergoing reduction mammaplasty. I am inviting you to participate in this research on a voluntary basis.

Principal investigator: Dr. Wamalwa A.O.

Institution: Department of Surgery, School of Medicine, University of Nairobi

Supervisors: Prof. Stanley O. Khainga, Dr. Ferdinand W. Nangole and Dr. Joseph K. Wanjeri

This Informed Consent Form has four parts:

1. Information Sheet (to share information about the research with you).
2. Certificate of Consent (for affirmation/signatures if you agree to take part).
3. Statement by the researcher.
4. Informed assent

You will be given a copy of the full informed consent/assent form.

PART I: Information Sheet

Introduction

My name is Dr. Alex Okello Wamalwa, a post graduate student in Plastic, Reconstructive and Aesthetic Surgery at the University of Nairobi. I am carrying out a research to determine the most accurate model for pre-operative prediction of resection weight in reduction mammaplasty.

Purpose of the research

Reduction mammaplasty is the volumetric reduction in the breast bulk. Determination of the expected weight of breast tissue to be excised is essential in the pre-operative planning of the plastic surgeon. This also assists in assigning the procedure as either functional or aesthetic as per insurance guidelines. Despite several formulas being developed, we are not currently certain which is the most accurate. This study therefore aims at identifying which model is most accurate.

I am going to give you information and invite you to be a participant in this research. There may be some words that you do not understand or that you may need clarification. Please ask me to stop as we go through the information and I will explain or clarify.

Name of proposed procedure:

Breast anthropometric measurements

Weighing of breast tissue excised

Description of procedure

The measurements of your breasts shall be taking using a plastic tape measure during markings for the breast reduction surgery you have already consented for. This procedure will involve no anesthesia. This shall be done at the time of markings being done by the operating plastic surgeon. Your weight and height shall also be taken. The weight of breast tissue excised shall be weighed intraoperatively and subsequently disposed off as directed by the operating plastic surgeon. This study shall not change the course, mode or manner of management of your

condition. Analyzed results from the project shall be shared with the patient. Photographs may be taken to illustrate the procedure described.

Voluntary participation/right to refuse or withdraw

You are free to participate or decline participation in this study. Whether you choose to participate or not, will not change your current management and treatment, that is routinely offered in this hospital for your particular condition. You have a right to refuse or withdraw from this study at any point.

Confidentiality

The information obtained will be treated with utmost confidentiality and only be available to the principal investigator and his research team. Your name will not be used. We will not be sharing the identity of anyone participating in this research.

Sharing the results

The knowledge that we get from this study will be shared with the policy makers in the Ministry of Health and doctors through publications, conferences, journals and presentations. Confidential information will not be shared with any third party.

Risks

There are no risks in this study. All parameters are merely observations of your current management; no invasive investigations will be used during the course of this study.

Cost and compensation

There will be no extra cost incurred for participating in this study.

Please read the following:

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any photographs taken and tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that this research has been approved by the Kenyatta National Hospital/University of Nairobi Ethics Review Committee (KNH/UoN-ERC) and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that data about me will be held electronically and may be passed between the Kenyatta National Hospital, the University of Nairobi and any other University/ Hospital/ Research Institute collaborating with KNH/UoN, to facilitate research and my care.

I understand that my involvement in this research will be through clinical evaluation and that you will not expose yourself to any risks if you consent to participate.

I understand that there will be **NO** financial benefits.

I understand that results from this study may be published to enhance scientific knowledge

I understand that refusal to participate or withdrawal from the study will not in any way compromise the quality of care and treatment given to me

Please the tick box below to indicate if you either AGREE □ DISAGREE □

Contacts

This study has been reviewed and approved by the KNH/UoN-ERC which is a committee whose work is to make sure research participants are protected from harm. The contact information is given below if you wish to contact any of them for whatever reason:

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P.O. Box 20723-00202 KNH, Nairobi

Tel: 020-726300-9

Email: KNHplan@Ken.Healthnet.org , uonknh_erc@uonbi.ac.ke

Principal investigator:

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Department of Surgery, School of Medicine, University of Nairobi

P.O. Box 19676, Nairobi

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Consultant Plastic, Reconstructive and Aesthetic Surgeon

Associate Professor of Surgery and Thematic Unit Head of Plastic Surgery,

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P.O. Box 58653-00200 City Square, Nairobi

Mobile: 0722708051

Email: kimwanjeri@hotmail.com

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research. I hereunder impress my signature / thumbprint as proof of my consent.

Patient/parent/guardian signature: ..... Date: .....

Name (PRINT): .....

Witness' signature: ..... Date: .....

Name (PRINT): .....

Statement of the interpreter (if appropriate)

I confirm that I have interpreted the information to the best of my ability, and in a way in which I believe s/he has understood:

Interpreter's signature ..... Date: .....

Name (PRINT): .....

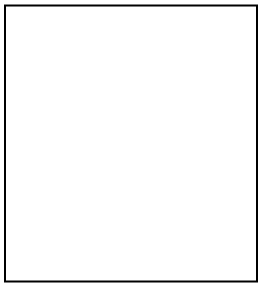
If Illiterate:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness' signature: ..... Date: .....

Name (PRINT): .....

Thumb print of participant:



PART III: Statement by the researcher

I have accurately read out the information sheet to the patient and/or guardian(s), and to the best of my ability made sure that the patient or guardian understands the following:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to enhance the knowledge and understanding of medical professionals regarding the subject of the study.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Researcher's signature ..... Date: .....

Name (PRINT): ..... Designation: .....

PART IV: INFORMED ASSENT

I have read this information (or had the information read to me). I have had my questions answered and know that I can ask questions later if I have them.

I do not wish to take part in the study and I have not signed the assent below.

…….. (initialed by child/minor)

Only if child assents:

Print name of child: ……Signature of child: ……..

Date: …….

I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness (not a parent): …… Signature of witness: ……..

Date: ……

Statement of the researcher

I have introduced myself to the child and have:

□ Clearly stated what the study is about, why it is being done and why we are informing him/her

□ Informed the child that I have spoken to his/her parents and that parental consent is also necessary.

□ Let him/her know that they can speak to anyone they choose about the research before they make up their mind

□ Checked with the child and they understand that participation is voluntary

□ Explained how the procedure is to be performed, follow up procedures and how data will be collected

□ Checked with the child and they understand the procedures involved

□ Checked with the child and they understand the risks and or discomforts involved

□ Checked with the child and they understand any benefits

□ Explained the contents of the recipient consent form

I confirm that the child was given an opportunity to ask questions about the study, and all the questions asked by him/her have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Reasearcher's signature: ..... Date: .....

Name (PRINT): ..... Designation: .....

Parent/Guardian has signed an informed consent: Yes □ No□

APPENDIX IV: IDHINI YA TAARIFA

MADA YA UTAFITI: CRITICAL APPRAISAL OF THE PREDICTION OF RESECTION WEIGHT IN REDUCTION MAMMAPLASTY USING FOUR DIFFERENT MODELS

Fomu hii ya ridhaa ya habari ni kwa wagonjwa ambao wanajiwasilisha hospitali ya Taifa ya Kenyatta na majeraha makuu makubwa ya kuchomeka. Ninakualika kushiriki katika utafiti huu kwa msingi wa hiari.

Mtafiti Mkuu: Dk. Wamalwa A.O.

Taasisi: Idara ya Upasuaji, Kitivo cha utabibu, Chuo Kikuu cha Nairobi

Wasimamizi: Prof. Stanley O. Khainga, Dk. Ferdinand W. Nangole na Dk. Joseph K. Wanjeri

Fomu hii ya Ruhusa ya Ruhusa ina sehemu tatu:

1. Karatasi ya Taarifa (kushiriki habari kuhusu utafiti na wewe).
2. Hati ya Ruhusa (kwa uthibitisho / saini ikiwa unakubali kushiriki).
3. Taarifa ya mtafiti.

Utapewa nakala ya fomu kamili ya idhini.

SEHEMU YA I: Karatasi ya Taarifa

Utangulizi

Jina langu ni Dk. Alex Okello Wamalwa, mwanafunzi aliyehitimu katika plastiki, upyaji na upasuaji wa upasuaji huko Chuo Kikuu cha Nairobi. Ninafanya utafiti ili kuamua ni mfano gani sahihi zaidi wa utabiri wa kabla ya utendaji wa uzito katika kupunguza matiti.

Kusudi la utafiti

Upungufu wa matiti ni kupunguza kwa kiasi kikubwa cha matiti. Uamuzi wa uzito uliotarajiwa wa tishu za matiti kuwa msisimko ni muhimu katika mipango ya kabla ya operesheni ya upasuaji wa plastiki. Hii pia inasaidia kugawa utaratibu kama kazi au ustaarabu kama ilivyo kwa miongozo ya bima. Ijapokuwa mifano kadhaa zimeandaliwa, hatujui sasa ni sahihi zaidi. Kwa hiyo utafiti huu una lengo la kutambua ni mfano gani unao sahihi zaidi.

Nitawapa taarifa na kukualika uwe mshiriki katika utafiti huu. Kunaweza kuwa na maneno ambayo hujui au kwamba unahitaji ufafanuzi. Tafadhali niulize kuacha tunapopitia maelezo na nitasema au kufafanua.

Jina la utaratibu uliopendekezwa:

1. Vipimo vya anthropometric ya matiti
2. Kupima tishu za matiti kusisimua

Maelezo ya utaratibu

Upimaji wa matiti yako utachukua kutumia tepe ya plastiki kupima wakati wa alama za upasuaji wa matiti umekubali tayari. Utaratibu huu hautahusisha anesthesia. Hii itafanyika wakati wa alama zinazofanyika na upasuaji wa plastiki. Uzito wako na urefu wako pia utachukuliwa. Uzito wa tishu za matiti kusisimua utahesabiwa kwa uingilivu na hatimaye kukataliwa kama ilivyoagizwa na upasuaji wa plastiki. Utafiti huu haubadili shaka, hali au namna ya usimamizi wa hali yako. Matokeo yaliyochambuliwa kutoka kwa mradi yatashirikiwa na mgonjwa. Picha zinaweza kuchukuliwa ili kuelezea utaratibu ulioelezwa.

Ushiriki wa hiari / haki ya kukataa au kujiondoa

Wewe ni huru kushiriki au kupungua kushiriki katika utafiti huu. Ikiwa unachagua kushiriki au la, haitabadilisha usimamizi wako na matibabu yako, ambayo hutolewa mara kwa mara katika hospitali hii kwa hali yako. Una haki ya kukataa au kujiondoa kwenye utafiti huu wakati wowote.

Usiri

Taarifa zilizopatikana zitatambuliwa kwa usiri mkubwa na zinaweza kupatikana kwa wachunguzi na timu yao ya utafiti. Jina lako halitatumiwa. Hatuwezi kushirikiana na mtu yeyote anayehusika katika utafiti huu.

Kushiriki matokeo

Maarifa tunayopata kutokana na utafiti huu yatashirikiwa na watunga sera katika Wizara ya Afya na madaktari kupitia machapisho, mikutano, majarida na mawasilisho. Maelezo ya siri hayatashirikiwa na mtu yeyote wa tatu.

Hatari

Hakuna hatari katika utafiti huu. Vigezo vyote ni uchunguzi tu wa usimamizi wako wa sasa; hakuna uchunguzi wowote utatumika wakati wa somo hili.

Gharama na fidia

Hakuweza kuwa na gharama ya ziada inayotokana na kushiriki katika utafiti huu.

Tafadhali soma zifuatazo:

Ninaelewa kuwa huwezi kunipa dhamana ya kwamba mtu fulani atafanya utaratibu. Mtu anayefanya utaratibu, hata hivyo, ana uzoefu mzuri.

Ninaelewa kuwa picha zilizochukuliwa na tishu (ikiwa ni pamoja na damu) zimeondolewa kama sehemu ya utaratibu au tiba zitaonyeshwa na inaweza kutumika kwa ajili ya kufundisha au kudhibiti ubora, na kuhifadhiwa au kupuuzwa kwa namna inayoelekezwa na sahihi, kimaadili, kisheria na kitaaluma viwango.

Ninaelewa kuwa utafiti huu umeidhinishwa na Kenyatta National Hospital/University of Nairobi Ethics Review Committee (KNH/UoN-ERC) na kufanyika kwa mujibu wa viwango vya kimaadili, kisheria na kitaaluma.

Ninaelewa kwamba takwimu kuhusu mimi zitafanyika kwa umeme na inaweza kupitishwa kati ya Hospitali ya Kenyatta ya Taifa, Chuo Kikuu cha Nairobi na Chuo Kikuu chochote / Chuo Kikuu / Taasisi ya Utafiti kinashirikiana na KNH / UoN, ili kuwezesha utafiti na huduma yangu.

Ninaelewa kuwa ushiriki wangu katika utafiti huu utakuwa kupitia tathmini ya kliniki na kwamba huwezi kujificha mwenyewe kwa hatari yoyote ikiwa unakubali kushiriki.

Ninaelewa kuwa hakutakuwa na faida za kifedha.

Ninaelewa kuwa matokeo kutoka kwa utafiti huu yanaweza kuchapishwa ili kuongeza ujuzi wa kisayansi

Ninaelewa kuwa kukataa kushiriki au kuondoa kutoka kwenye utafiti hakutapoteza ubora wa huduma na matibabu niliyopewa

Tafadhali sanduku la alama hapa chini ili uonyeshe ikiwa unakubaliana □ hukubaliani □

Mawasiliano

Utafiti huu umepitiwa na kuidhinishwa na KNH / UoN-ERC ambayo ni kamati ambayo kazi yake ni kuhakikisha washiriki wa utafiti wanalindwa dhidi ya madhara. Maelezo ya mawasiliano yanapewa chini kama unataka kuwasiliana na yeyote kati yao kwa sababu yoyote:

Katibu:

KNH / UoN-ERC,

S.L.P. 20723-00202 KNH, Nairobi

Simu: 020-726300-9

Barua pepe: KNHplan@Ken.Healthnet.org, uonknh_erc@uonbi.ac.ke

Mtafiti Mkuu:

Dk. Alex Okello Wamalwa MBChB

Idara ya Upasuaji, Kitivo cha utabibu, Chuo Kikuu cha Nairobi

S.L.P. 19676, Nairobi

Simu ya mkononi: 0722557547

Barua pepe: aleoke@gmail.com

Wasimamizi wa Chuo Kikuu cha Nairobi:

Prof. Stanley Ominde Khainga

MBChB, M.MED (Surg.), Cert. Upasuaji wa Microvascular (MEDUNSA), FCS PLAS (ECSA)

Mshauri wa plastiki, upasuaji upya na upasuaji wa vipodozi

Profesa wa Upasuaji na Madawa ya Kichwa cha Mkuu wa upasuaji wa plastiki,

Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi

S.L.P 19679, Nairobi

Simu ya mkononi: 0723436408

Barua pepe: skhainga@yahoo.com

Dk. Ferdinand Wanjala Nangole

MBChB, M.MED (Surg.), FCS (UCT), Ndugu wa EBOPRAS (Brussels, Marseille)

Mshauri wa plastiki, upasuaji upya na mkono na kupandikiza nywele na Mhadhiri

Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi

P.O. Sanduku 2212-00202, Nairobi

Simu ya mkononi: 0733864249

Barua pepe: nangole2212@yahoo.com

Dk. Joseph Kimani Wanjeri

MBChB, M.MED (Surg.), IPTM (Tel Aviv), MPH (UoN)

Mshauri wa plastiki, upasuaji upya na upasuaji wa vipodozi na Mhadhiri

Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi

P.O. Sanduku 58653-00200 City Square, Nairobi

Simu ya mkononi: 0722708051

Barua pepe: kimwanjeri@hotmail.com

SEHEMU YA II: Hati ya Ruhusa

Nimeisoma habari hapo juu, au imesomezwa. Nimekuwa na fursa ya kuuliza maswali kuhusu hilo na maswali yoyote niliyoyauliza yamejibiwa kwa kuridhika kwangu. Ninakubali kwa hiari kushiriki kama mshiriki katika utafiti huu. I hapa chini kunifurahisha saini yangu / thumbprint kama uthibitisho wa idhini yangu.

Mgonjwa / mzazi / mlezi / mke wa saini: ..... Tarehe: ....

Jina (PRINT): ....

Shahidi 'saini: .... Tarehe: .....

Jina (PRINT): ....

Taarifa ya mkalimani (ikiwa inafaa)

Ninathibitisha kuwa nimeifafanua habari kwa uwezo wangu wote, na kwa njia ambayo ninaamini s / yeye ameelewa:

Saini ya mkalimani .... Tarehe: .....

Jina (PRINT): ....

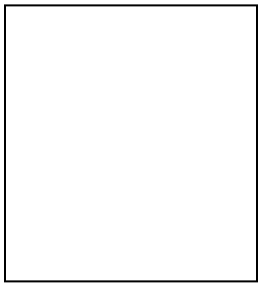
mtu asiyejifunza:

Nimeona usomaji sahihi wa fomu ya kibali kwa mshiriki mwenye uwezo, na mtu huyo amepata fursa ya kuuliza maswali. Ninathibitisha kwamba mtu huyo ametoa ridhaa kwa uhuru.

Shahidi 'saini: .... Tarehe: .....

Jina (PRINT): ....

Chapisha ya mshiriki:



<u>SEHEMU YA III: Taarifa ya mtafiti</u>

Nimesoma kwa usahihi karatasi ya habari kwa mgonjwa na / au mlezi, na kwa uwezo wangu wote ninahakikisha kuwa mgonjwa au mlezi anaelewa yafuatayo:

- Kukataa kushiriki au kujiondoa kutoka kwenye utafiti hakutapoteza huduma ya matibabu kwa namna yoyote.
- Taarifa zote zilizotolewa zitashughulikiwa kwa siri.
- Matokeo ya utafiti huu yanaweza kuchapishwa ili kuongeza ujuzi na uelewa wa wataalamu wa matibabu kuhusu suala la utafiti.

Ninathibitisha kwamba mshiriki huyo alitolewa fursa ya kuuliza maswali kuhusu utafiti huo, na maswali yote aliyoulizwa na mshiriki amejibu kwa usahihi na kwa uwezo wangu mkubwa. Ninathibitisha kwamba mtu huyo hakujazimishwa kutoa idhini, na ridhaa imetolewa kwa uhuru na kwa hiari.

Fomu hii ya Ruhusa imetolewa kwa mshiriki.

Sahihi ya mtafiti ..... Tarehe: ....

Jina (PRINT): .... Uteuzi: .....

APPENDIX V: FOMU YA IDHINI YA WATOTO WALIO NA UMRI WA KATI YA MIAKA KUMI NA MIWILI HADI KUMI NA MINANE

MADA YA UTAFITI: CRITICAL APPRAISAL OF THE PREDICTION OF RESECTION WEIGHT IN REDUCTION MAMMAPLASTY USING FOUR DIFFERENT MODELS

Fomu hii ya ridhaa ya habari ni kwa wagonjwa ambao wanajiwasilisha hospitali ya Taifa ya Kenyatta na majeraha makuu makubwa ya kuchomeka. Ninakualika kushiriki katika utafiti huu kwa msingi wa hiari.

Mtafiti Mkuu: Dk. Wamalwa A.O.

Taasisi: Idara ya Upasuaji, Kitivo cha utabibu, Chuo Kikuu cha Nairobi

Wasimamizi: Prof. Stanley O. Khainga, Dk. Ferdinand W. Nangole na Dk. Joseph K. Wanjeri

Fomu hii ya Ruhusa ya Ruhusa ina sehemu tatu:

1. Karatasi ya Taarifa (kushiriki habari kuhusu utafiti na wewe).
2. Hati ya Ruhusa (kwa uthibitisho / saini ikiwa unakubali kushiriki).
3. Taarifa ya mtafiti.
4. Fomu ya idhini ya watoto walio na umri wa kati ya miaka kumi na miwili hadi kumi na minane

Utapewa nakala ya fomu kamili ya idhini.

SEHEMU YA I: Karatasi ya Taarifa

Utangulizi

Jina langu ni Dk. Alex Okello Wamalwa, mwanafunzi aliyehitimu katika plastiki, upyaji na upasuaji wa upasuaji huko Chuo Kikuu cha Nairobi. Ninafanya utafiti ili kuamua ni mfano gani sahihi zaidi wa utabiri wa kabla ya utendaji wa uzito katika kupunguza matiti.

Kusudi la utafiti

Upungufu wa matiti ni kupunguza kwa kiasi kikubwa cha matiti. Uamuzi wa uzito uliotarajiwa wa tishu za matiti kuwa msisimko ni muhimu katika mipango ya kabla ya operesheni ya upasuaji wa plastiki. Hii pia inasaidia kugawa utaratibu kama kazi au ustaarabu kama ilivyo kwa miongozo ya bima. Ijapokuwa mifano kadhaa zimeandaliwa, hatujui sasa ni sahihi zaidi. Kwa hiyo utafiti huu una lengo la kutambua ni mfano gani unao sahihi zaidi.

Nitawapa taarifa na kukualika uwe mshiriki katika utafiti huu. Kunaweza kuwa na maneno ambayo hujui au kwamba unahitaji ufafanuzi. Tafadhali niulize kuacha tunapopitia maelezo na nitasema au kufafanua.

Jina la utaratibu uliopendekezwa:

3. Vipimo vya anthropometric ya matiti
4. Kupima tishu za matiti kusisimua

Maelezo ya utaratibu

Upimaji wa matiti yako utachukua kutumia tepe ya plastiki kupima wakati wa alama za upasuaji wa matiti umekubali tayari. Utaratibu huu hautahusisha anesthesia. Hii itafanyika wakati wa alama zinazofanyika na upasuaji wa plastiki. Uzito wako na urefu wako pia utachukuliwa. Uzito wa tishu za matiti kusisimua utahesabiwa kwa uingilivu na hatimaye kukataliwa kama ilivyoagizwa na upasuaji wa plastiki. Utafiti huu haubadili shaka, hali au namna ya usimamizi

wa hali yako. Matokeo yaliyochambuliwa kutoka kwa mradi yatashirikiwa na mgonjwa. Picha zinaweza kuchukuliwa ili kuelezea utaratibu ulioelezwa.

Ushiriki wa hiari / haki ya kukataa au kujiondoa

Wewe ni huru kushiriki au kupungua kushiriki katika utafiti huu. Ikiwa unachagua kushiriki au la, haitabadilisha usimamizi wako na matibabu yako, ambayo hutolewa mara kwa mara katika hospitali hii kwa hali yako. Una haki ya kukataa au kujiondoa kwenye utafiti huu wakati wowote.

Usiri

Taarifa zilizopatikana zitatambuliwa kwa usiri mkubwa na zinaweza kupatikana kwa wachunguzi na timu yao ya utafiti. Jina lako halitatumiwa. Hatuwezi kushirikiana na mtu yeyote anayehusika katika utafiti huu.

Kushiriki matokeo

Maarifa tunayopata kutokana na utafiti huu yatashirikiwa na watunga sera katika Wizara ya Afya na madaktari kupitia machapisho, mikutano, majarida na mawasilisho. Maelezo ya siri hayatashirikiwa na mtu yeyote wa tatu.

Hatari

Hakuna hatari katika utafiti huu. Vigezo vyote ni uchunguzi tu wa usimamizi wako wa sasa; hakuna uchunguzi wowote utatumika wakati wa somo hili.

Gharama na fidia

Hakuweza kuwa na gharama ya ziada inayotokana na kushiriki katika utafiti huu.

Tafadhali soma zifuatazo:

Ninaelewa kuwa huwezi kunipa dhamana ya kwamba mtu fulani atafanya utaratibu. Mtu anayefanya utaratibu, hata hivyo, ana uzoefu mzuri.

Ninaelewa kuwa picha zilizochukuliwa na tishu (ikiwa ni pamoja na damu) zimeondolewa kama sehemu ya utaratibu au tiba zitaonyeshwa na inaweza kutumika kwa ajili ya kufundisha au kudhibiti ubora, na kuhifadhiwa au kupuuzwa kwa namna inayoelekezwa na sahihi, kimaadili, kisheria na kitaaluma viwango.

Ninaelewa kuwa utafiti huu umeidhinishwa na Kenyatta National Hospital/University of Nairobi Ethics Review Committee (KNH/UoN-ERC) na kufanyika kwa mujibu wa viwango vya kimaadili, kisheria na kitaaluma.

Ninaelewa kwamba takwimu kuhusu mimi zitafanyika kwa umeme na inaweza kupitishwa kati ya Hospitali ya Kenyatta ya Taifa, Chuo Kikuu cha Nairobi na Chuo Kikuu chochote / Chuo Kikuu / Taasisi ya Utafiti kinashirikiana na KNH / UoN, ili kuwezesha utafiti na huduma yangu.

Ninaelewa kuwa ushiriki wangu katika utafiti huu utakuwa kupitia tathmini ya kliniki na kwamba huwezi kujificha mwenyewe kwa hatari yoyote ikiwa unakubali kushiriki.

Ninaelewa kuwa hakutakuwa na faida za kifedha.

Ninaelewa kuwa matokeo kutoka kwa utafiti huu yanaweza kuchapishwa ili kuongeza ujuzi wa kisayansi

Ninaelewa kuwa kukataa kushiriki au kuondoa kutoka kwenye utafiti hakutapoteza ubora wa huduma na matibabu niliyopewa

Tafadhali sanduku la alama hapa chini ili uonyeshe ikiwa unakubaliana □ hukubaliani □

Mawasiliano

Utafiti huu umepitiwa na kuidhinishwa na KNH / UoN-ERC ambayo ni kamati ambayo kazi yake ni kuhakikisha washiriki wa utafiti wanalindwa dhidi ya madhara. Maelezo ya mawasiliano yanapewa chini kama unataka kuwasiliana na yeyote kati yao kwa sababu yoyote:

Katibu:

KNH / UoN-ERC,

S.L.P. 20723-00202 KNH, Nairobi

Simu: 020-726300-9

Barua pepe: KNHplan@Ken.Healthnet.org, uonknh_erc@uonbi.ac.ke

Mtafiti Mkuu:

Dk. Alex Okello Wamalwa MBChB

Idara ya Upasuaji, Kitivo cha utabibu, Chuo Kikuu cha Nairobi

S.L.P. 19676, Nairobi

Simu ya mkononi: 0722557547

Barua pepe: aleoke@gmail.com

Wasimamizi wa Chuo Kikuu cha Nairobi:

Prof. Stanley Ominde Khainga

MBChB, M.MED (Surg.), Cert. Upasuaji wa Microvascular (MEDUNSA), FCS PLAS (ECSA)

Mshauri wa plastiki, upasuaji upya na upasuaji wa vipodozi

Profesa wa Upasuaji na Madawa ya Kichwa cha Mkuu wa upasuaji wa plastiki,

Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi

S.L.P 19679, Nairobi

Simu ya mkononi: 0723436408

Barua pepe: skhainga@yahoo.com

Dk. Ferdinand Wanjala Nangole

MBChB, M.MED (Surg.), FCS (UCT), Ndugu wa EBOPRAS (Brussels, Marseille)

Mshauri wa plastiki, upasiaji upya na mkono na kupandikiza nywele na Mhadhiri

Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi

P.O. Sanduku 2212-00202, Nairobi

Simu ya mkononi: 0733864249

Barua pepe: nangole2212@yahoo.com

Dk. Joseph Kimani Wanjeri

MBChB, M.MED (Surg.), IPTM (Tel Aviv), MPH (UoN)

Mshauri wa plastiki, upasuaji upya na upasuaji wa vipodozi na Mhadhiri

Idara ya Upasuaji, Shule ya Matibabu, Chuo Kikuu cha Nairobi

P.O. Sanduku 58653-00200 City Square, Nairobi

Simu ya mkononi: 0722708051

Barua pepe: kimwanjeri@hotmail.com

SEHEMU YA II: Hati ya Ruhusa

Nimeisoma habari hapo juu, au imesomezwa. Nimekuwa na fursa ya kuuliza maswali kuhusu hilo na maswali yoyote niliyoyauliza yamejibiwa kwa kuridhika kwangu. Ninakubali kwa hiari kushiriki kama mshiriki katika utafiti huu. I hapa chini kunifurahisha saini yangu / thumbprint kama uthibitisho wa idhini yangu.

Mgonjwa / mzazi / mlezi / mke wa saini: ..... Tarehe: ....

Jina (PRINT): ....

Shahidi 'saini: .... Tarehe: .....

Jina (PRINT): ....

Taarifa ya mkalimani (ikiwa inafaa)

Ninathibitisha kuwa nimeifafanua habari kwa uwezo wangu wote, na kwa njia ambayo ninaamini s / yeye ameelewa:

Saini ya mkalimani .... Tarehe: .....

Jina (PRINT): ....

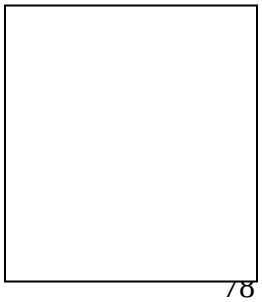
mtu asiyejifunza:

Nimeona usomaji sahihi wa fomu ya kibali kwa mshiriki mwenye uwezo, na mtu huyo amepata fursa ya kuuliza maswali. Ninathibitisha kwamba mtu huyo ametoa ridhaa kwa uhuru.

Shahidi 'saini: .... Tarehe: .....

Jina (PRINT): ....

Chapisha ya mshiriki:



SEHEMU YA III: Taarifa ya mtafiti

Nimesoma kwa usahihi karatasi ya habari kwa mgonjwa na / au mlezi, na kwa uwezo wangu wote ninahakikisha kuwa mgonjwa au mlezi anaelewa yafuatayo:

- Kukataa kushiriki au kujiondoa kutoka kwenye utafiti hakutapoteza huduma ya matibabu kwa namna yoyote.
- Taarifa zote zilizotolewa zitashughulikiwa kwa siri.
- Matokeo ya utafiti huu yanaweza kuchapishwa ili kuongeza ujuzi na uelewa wa wataalamu wa matibabu kuhusu suala la utafiti.

Ninathibitisha kwamba mshiriki huyo alitolewa fursa ya kuuliza maswali kuhusu utafiti huo, na maswali yote aliyoulizwa na mshiriki amejibu kwa usahihi na kwa uwezo wangu mkubwa. Ninathibitisha kwamba mtu huyo hakujazimishwa kutoa idhini, na ridhaa imetolewa kwa uhuru na kwa hiari.

Fomu hii ya Ruhusa imetolewa kwa mshiriki.

Sahihi ya mtafiti ..... Tarehe: ....

Jina (PRINT): .... Uteuzi: .....

SEHEMU YA IV: FOMU YA IDHINI YA WATOTO WALIO NA UMRI WA KATI YA MIAKA KUMI NA MIWILI HADI KUMI NA MINANE

Nimesoma habari hii (au nilikuwa na maelezo ya kusoma kwangu). Nimekuwa na maswali yangu akajibu na kujua kwamba ninaweza kuuliza maswali baadaye kama ninavyo.

Sitaki kushiriki katika utafiti na sijaini saini hapa chini.

.... (iliyowekwa na mtoto)

Tu ikiwa mtoto anaidhinisha:

Jina la uchapishaji wa mtoto: ..... Saini ya mtoto: ....

Tarehe: …….

Nimeona usomaji sahihi wa fomu ya kukubali kwa mtoto, na mtu huyo amepata fursa ya kuuliza maswali. Ninathibitisha kwamba mtu huyo ametoa ridhaa kwa uhuru.

Jina la uchapishaji (si mzazi): ..... Saini ya shahidi: .....

Tarehe: ……

Taarifa ya mtafiti

Nimejulisha kwa mtoto na kuwa na:

 Nimemueleza wazi ni nini utafiti huo unahusu, kwa nini unafanywa na kwa nini tunamjulisha

 Nimemfahamisha mtoto ya kuwa nimewaambia wazazi wake na kwamba kibali cha wazazi pia ni muhimu.

 Ajue kwamba anaweza kuzungumza na mtu yeyote anayechagua kuhusu utafiti kabla ya kufanya akili zao

 Kufuatiliwa na mtoto na anaelewa kuwa ushiriki ni wa hiari

 Kufafanua jinsi utaratibu utafanyika, taratibu za kufuatilia na jinsi data zitakusanywa

 Kufuatiliwa na mtoto na wanaelewa taratibu zinazohusika

 Kufuatiliwa na mtoto na wao kuelewa hatari na au wasiwasi kushiriki

 Kufuatiliwa na mtoto na wao kuelewa faida yoyote

 Nimeeleza yaliyomo fomu hii

Ninathibitisha kwamba mtoto alipewa fursa ya kuuliza maswali kuhusu utafiti huo, na maswali yote aliyoulizwa naye yamejibu kwa usahihi na kwa uwezo wangu mkubwa. Ninathibitisha kwamba mtu huyo hakulazimishwa kutoa idhini, na ridhaa imetolewa kwa uhuru na kwa hiari.

Sahihi ya Mtafiti: ..... Tarehe: ....

Jina (PRINT): .... Uteuzi: .....

Mzazi / Mlezi / mke amesajili kibali cha wazi: Ndio Hapana

APPENDIX VI: KNH-UON ERC LETTER OF APPROVAL

UNIVERSITY OF NAIROBI
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

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

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 22 APR 2016 KNH-UoN-ERC P.O. Box 20723-00202 NRB.

Ref: KNH-ERC/A/140

22nd April, 2016

Dr. Alex Okello Wamalwa
Reg. H58/74583/2014
Dept.of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Wamalwa

REVISED RESEARCH PROPOSAL: CRITICAL APPRAISAL OF THE PREDICTION OF RESECTION WEIGHT IN REDUCTION MAMMAPLASTY USING FOUR DIFFERENT MODELS (P59/02/2016)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and **approved** your above proposal. The approval period is from 22nd April 2016 – 21st April 2017.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF M.L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Deputy Director, CS, KNH
The Assistant Director, Health Information, KNH
The Chair, KNH- UoN ERC
The Dean, School of Medicine
The Chair, Dept.of Surgery, UON
Supervisors: Prof. Stanley O. Khainga, Dr.Ferdinand W. Nangole, Dr. Joseph K.Wanjeri

APPENDIX VII: TIMELINE OF THE STUDY

- ✓ October 2015- December 2015: Proposal development
- ✓ January 2016 – March 2016: Ethical approval
- ✓ April 2016- March 2017: Data collection
- ✓ April 2017 – June 2017: Data analysis
- ✓ July 2017 – September 2017: Report writing

ACTIVITY	**Oct -**	**Jan -**	**Apr -**	**July –**	**Oct –**	**Jan –**	**Apr –**	**July –**
Proposal development	■							
Ethical Approval		■						
Data Collection			■	■	■	■		
Data Analysis							■	
Dissertation writing								■

APPENDIX VIII: BUDGET

Budget item	**Unit cost (Ksh.)**	**Quantity**	**Total (Ksh.)**
Plastic tape measures (metric)	300	5	1200
Digital weighing scales	3000	5	12000
Pens-No./Box of 20	500	1	500
Photocopying papers – A4 ream/500 sheets	500	4	2000
Paper punch-medium size (No.)	500	1	500
Stapler-medium size (No.)	500	1	500
Staple pins-medium size (No./Box)	500	2	1000
Box file (No.)	250	1	250
Printing and Binding	20000	-	20000
Statistician	30,000	1	30000
Research fee for KNH/UoN-ERC	5000	-	5000
Research Assistants	15,000	5	75000
subtotal			**147950**
Contingencies (20% of subtotal)			29590
TOTAL			**177540**