

**EVALUATION OF PERCEPTIONS OF COSMETIC OUTCOMES  
POST HYPOSPADIAS SURGERY IN KENYATTA NATIONAL  
HOSPITAL USING THE PAEDIATRIC PENILE PERCEPTION  
SCORE**

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H58/74215/2014**

**A DISSERTATION SUBMITTED AS PART FULFILMENT FOR  
THE AWARD OF MASTER OF MEDICINE IN PAEDIATRIC  
SURGERY, UNIVERSITY OF NAIROBI**

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## **STUDENT DECLARATION**

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

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## **DEDICATION**

I dedicate my dissertation to my family. To my loving parents, Julius and Josephine Kamwetu. Thank you for your unrelenting words of encouragement, prayers and love. I am eternally grateful. God bless you. My siblings Rose, Faith and James have always supported me and are special.

I dedicate this work to my best friend and loving wife, Lynda Kuto and my wonderful daughters, Mwende and Mumbe. A special thank you for your incessant love, encouragement and support throughout this endeavor. The three of you have been my best cheerleaders.

## **ACKNOWLEDGEMENTS**

First, I would like to express gratitude to my supervisors Dr. Francis Osawa, Dr. Kihiko Kuria and Dr. Swaleh Shahbal of the Department of Surgery at the University of Nairobi. They were always open and ready to provide advice whenever needed throughout my research. I would also like to thank Dr. Tim Jumbi for his invaluable assistance and advice.

Finally, I would like to thank the investigators and co-investigators who were involved in the completion of this dissertation. Without their fervent involvement and input, the dissertation could not have been successfully completed.

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## **LIST OF ABBREVIATIONS**

**HOPE** – Hypospadias Objective Penile Evaluation Score

**HOSE** - Hypospadias Objective Scoring Evaluation

**TIP** - Tubularized Incised Plate

**KNH** – Kenyatta National Hospital

**PPPS** – Paediatric Penile Perception Score

**PPS** - Penile Perception Score

**SPSS** - Statistical Package for Social Sciences

**UoN** – University of Nairobi

## ABSTRACT

**Background:** Hypospadias is a condition whereby the urethral meatus opens onto the penis' ventral surface. The goal of surgical repair of hypospadias is to achieve a functional and cosmetic normal penis. Cosmetic outcome is often overlooked. The Paediatric Penile Perception Score is a validated scoring system for assessing cosmetic outcomes by patients, parents and surgeons.

**Study Objective:** The research evaluated perceptions of cosmetic outcomes by parents and surgeons post hypospadias surgery at the Kenyatta National Hospital using the Paediatric Penile Perception Score.

**Study Setting:** The study was carried out at the Pediatric Surgical Outpatient Clinic at the Kenyatta National Hospital.

**Study Population:** The study targeted 115 male children with hypospadias condition who had undergone urethroplasty procedure between January 2014 and December 2018 (5years) in KNH.

**Study Design:** The study is a descriptive cross-sectional study.

**Methodology:** The study targeted a total of 115 children. 51 parents agreed to participate in the study. The parents/guardians were asked to indicate their contentment according to a 4 point Likert scale of the Paediatric Penile Perception tool and a score calculated by summing up the scores of the items glans, meatus, general appearance, and shaft skin. Standard photographic charts were prepared and shown to 2 surgeons who were requested to grade the pictures using the same criteria and scale as the parents.

**Results:** The patients ranged from 2 years to 18 years with a mean age of 8.2 years. Parents were

found to be more satisfied than the surgeons with a P.P.P score of 10.3(+/-2.6) vs 7.7 (3.6) for surgeon 1 and 7.6 (1.6) for surgeon 2. There was good correlation ( $>0.4$ ) between the various items and general cosmetic appearance. Interrater reliability among the surgeons scores was moderate at 0.53 (0.18 – 0.73),  $p = 0.004$ . Interrater reliability between the parents and the surgeons on the general cosmetic outcome was moderate (0.65,  $p < 0.001$ ).

**Conclusion:** We found the Paediatric Penile Perception Score to be a reliable tool for assessing cosmetic outcome in both parents and surgeons after hypospadias surgery in our population.

# 1 CHAPTER ONE: INTRODUCTION

One classifies Hypospadias using urethral meatus's position. It can be classified as anterior (sub coronal and glanular), mid-penile (midshaft, distal penile, and proximal penile) and posterior (penoscrotal, scrotal, and perineal) translating to 50%, 30%, and 20% respectively.<sup>1</sup>

Hypospadias is a fairly common malformation. Europe has an incidence of 18.6 in 100,000 live births.<sup>2</sup> The American incidence is estimated to be 1 in 250 - 300 male births. It has been found to be common in whites than in blacks, and has been associated with undescended testis and disorders of sexual differentiation.<sup>1</sup>

The goal of surgical repair of hypospadias is to achieve a functional and cosmetic normal looking penis. This can be achieved in a single surgery or in a staged manner. Many procedures for repair of hypospadias have been described. At the moment, the most popular procedure is the Tubularised Incised Plate (T.I.P).<sup>3</sup>

There is not much information available on how the parent's perceive the hypospadias surgery's cosmetic outcome compared with pediatric urologists' views, using objective and validated scoring systems.<sup>4</sup>

Studies comparing surgeon and patient ratings of penile appearance have shown inconsistent findings. This may be due to differences in the method of data collection. Patients will likely judge the cosmetic outcome in relation to what they see in their peers. Surgeons may rate the cosmetic outcome depending on the prevailing surgical standards and the best they can achieve using their preferred technique rather than on true normality. The pediatric Penile Perception Score is a validated scoring system that is used to assess patient and parent self-reported cosmetic outcomes and compare them with surgeon reported outcomes.<sup>5</sup>



Post-operative patient satisfaction is important because of its influence on the patient's psychological status.<sup>6</sup>

Despite a myriad of surgical procedures to repair hypospadias, there are few systems to measure the surgical outcomes. A validated scoring system would give us the ability to compare results between different studies.

## **2 CHAPTER TWO: LITERATURE REVIEW**

Historically, the field has defined the condition's successful repair as a penis which is straight in erection and a meatus close to the glans tip. This permits voiding when standing while making sexual intercourse possible. Experts can use modern surgical techniques to fashion a cosmetic and functional normal penis.<sup>7</sup>

The field has invented many surgical techniques to achieve this, with none being superior to the others. Tubularised Incised Plate technique is the most popular for distal hypospadias and two stage repair is the most commonly used in proximal hypospadias.<sup>8</sup>

### **2.1. Assessment of Cosmetic Appearance**

Cosmetic appearance is commonly evaluated by the urologist/surgeon. This is prone to subjectivity, bias and inaccuracy. It also doesn't factor in the patient's opinion.

Hadidi was amongst the first to propose a scoring system that assessed the cosmetic and functional outcome after hypospadias surgery. The score assesses the glans, location of meatus, the straightness of the penis and presence of complications. It also evaluates the appearance of the penile skin. In terms of function, it assesses the straightness of erection and quality of urine stream. It is relatively easy to use and keep in the patient's file. It also allows for simple retrospective statistical evaluation. Evaluation will however, still depend on the surgeon. It has also not been validated for the pediatric population.<sup>9</sup>

Mureau et al. were among the first to come up with a system to evaluate both patient and surgeon contentment with the cosmetic outcome after hypospadias surgery. They produced a questionnaire to assess genital perception of hypospadias patients. The questionnaire assessed surgeon and patient contentment with size and thickness of the penis, glanular shape and size, meatal position,

penile skin and scrotum. There was no agreement between the surgeon and patient on the penile appearance. The tool was not validated.<sup>10</sup>

Holland et al. proposed the hypospadias objective scoring evaluation (HOSE) system. This system involves the independent assessment of hypospadias patients by parents, pediatric surgeons and nurses. This scoring system in place involves an evaluation of position and shape of meatal, erection's straightness, urinary stream, and the presence and complexity of any urethral fistula. It has been found to have good inter-observer reliability. It, however, does not assess the overall penile appearance and size.<sup>11</sup>

The HOPE system evaluates the appearance of the penis using six items amenable to surgical correction. These are; meatus' position and shape, glans shape, and penile axis and skin. Penile axis includes penile torsion and/or curvature. The HOPE score introduces these factors of objectivity; use of standardized penis photographs, anonymized patients, independent and objective evaluation by a bench of pediatric urologists, appreciation of standards for a normal and healthy appearance of the penis by the panel, evaluation of the level of abnormality and the deployment of reference photographs for the various levels of abnormality. The total HOPE score ranges from 1 to 10.<sup>12</sup>

The Pediatric Penile Perception Score (PPPS) is the latest effort in objective assessment of postoperative outcomes. This is one of the most reliable tools for assessing penile self-perception in boys after the surgery and for evaluation of the surgical outcome by parents and independent urologists/surgeons. The score does include glans appearance, penis size, meatus appearance, penile skin, curvature and general appearance of the penis according to the rating by the patient, surgeon and parents.<sup>5</sup> The PPPS has been validated for the pediatric population. A similar tool called Penile Perception Score (PPS) is valid for the adult population.<sup>13</sup>

Weber et al sampled 147 boys who had undergone hypospadias surgery at their institution. 102 of them met the inclusion and exclusion criteria. 77 (75%) of the families agreed to participate in the study. They were compared with 77 age matched controls who had undergone inguinal hernia repair.<sup>13</sup>

Satisfaction of parents with the cosmetic appearance of the genitalia after hypospadias surgery has been found to be high: they had a mean value which was just greater than 2 (satisfied) for each element of the PPPS. A straight comparison between parents with children suffering from hypospadias and the control group's parents showed that the former were less satisfied. Overall PPPS scores were 9.75(+/-1.95) vs. 9.77(+/-1.97).<sup>13</sup>

Parent satisfaction was better than surgeon satisfaction in all 4 items. (9.75 vs. 6.75 overall PPPS scores). This was unexpected and may be explained by the possibility that patients embarrassed by their appearance may not have participated in the study.<sup>13</sup>

No measurable correlation between the PPPS and the severity of hypospadias, either in the patient self-assessment ( $r = 0.15$ ,  $p = 0.41$ ), urologist evaluation ( $r = 0.16$ ,  $p = 0.23$ ) or parent evaluation ( $r = 0.154$ ,  $p = 0.23$ ), could be found.

The PPPS and the number of operations showed no correlation for patient self-assessment ( $r = 0.04$ ,  $p = 0.73$ ) or parent assessment ( $r = 0.00$ ,  $p = 0.99$ ). However, the team found a correlation with the urologist PPPS ( $r = 0.34$ ,  $p = 0.01$ ).

A randomized controlled study done by Al-Debeiky et al validated the score for comparison between surgeon and parent satisfaction after hypospadias repair. They looked at 60 patients divided into 2 groups. They used the score to compare surgical procedures (T.I.P and Mathieu) for distal hypospadias.<sup>14</sup>

They found that surgeon satisfaction was higher than parent satisfaction in both groups. The urologists' average total of PPPS was 8.43 (1.90) in group A and 8.04 (2.16) in group B with a non-significant difference ( $P>0.05$ ). The parents' average sum of PPS was 7.8 (1.51) in group A and 7.89 (2.21) in group B with a non-significant difference ( $P>0.05$ ).<sup>14</sup>

Mureau et al. published a study on patient contentment after the surgery with a study design similar to the PPPS. They found that patients reported less contentment with the penile appearance than the operating surgeons. They assessed satisfaction with flaccid penile size and thickness, glanular size and shape, position of meatus, presence of scars, scrotum and testes and overall penile appearance.<sup>10</sup>

Snodgrass et al gave parents and surgeons a standardized questionnaire 6 weeks after hypospadias repair using the Tubularised Incised Plate method. They assessed six outcomes: meatus and skin cosmesis, overall penile appearance, size of the penis, voided stream and straightness during erection. Surgeon perceptions of cosmetic outcomes were slightly, but significantly, more positive than the parents'. The scores by the surgeons were higher for distal versus proximal hypospadias outcomes.<sup>15</sup>

Haid et al assessed penile appearance from the parent's point of view by comparing the HOPE and PPPS scores. They prospectively followed 42 boys after hypospadias surgery. Two surgeons independently assessed the HOPE score and the PPPS score, and the parents completed four questions specifically designed by a psychologist. The parents' assessments of the cosmetic results were worse than the surgeons' assessments (81.13% (PPPS) vs. 92.81% (HOPE) of the respectively possible highest score,  $P<0.0001$ ). The data showed no correlation between surgeons' and parents' assessments judging the respective high-score percentages ( $r=0.1358$ , Pearson). All 58 parents (100%) believed the surgery resulted in their son's genitalia's better cosmetic

appearance.<sup>4</sup>

### **Why Pediatric Penile Perception Score (PPPS)**

We have chosen the Paediatric Penile Perception Score for this study because it has been validated for the paediatric population. It is suitable for assessment of cosmetic outcomes by parents, patients and surgeons. It is easy to administer. Unlike the HOPE score, it does not require the presence of reference pictures for comparison.

### **2.2 How important is appearance?**

Postoperative patient satisfaction is important because of its influence on the patient's psychological development. Bracka assessed the physical and psychological sequelae of hypospadias in the long-term in a study of 213 patients over the age of fifteen. He found that 72% of young adults felt that achieving a "normal" look was as central a goal as achieving normal function.<sup>16</sup>

Jones et al found that adolescents who were dissatisfied with their genital appearance had more psychosexual problems than those who were satisfied.<sup>6</sup>

A case-control study conducted in China indicated that the anxiety and depression incidence was measurably higher in adults after hypospadias repair. The data showed a clear correlation between age at operation, the severity of symptoms and penile size.<sup>17</sup>

A systematic review from 2008 that included 13 studies proved that male children living with the illness experience sexual inhibitions and negative genital appraisal.<sup>18</sup>

Table 1: Summary of validated hypospadias assessment tools<sup>7</sup>

<b>Assessment Tool</b>	<b>Item</b>	<b>Remarks</b>
<b>HOSE</b>	Meatal location	Inter-observer reliability tested
	Meatal Shape	Limited items
	Urinary Stream	No general assessment
	Erection/Curvature	No penis size
	Fistula	No adequate preoperative assessment
<b>PPPS</b>	Length of penis	High inter-rater reliability
	Position and shape of meatus	Validated for surgeon and patient
	Glanular shape	Inherent subjective assessment
	Erection/ Curvature	No adequate preoperative assessment
	General appearance	
<b>HOPE</b>	Position of meatus	Reference pictures
	Meatal Shape of	Time consuming
	glans Shape of	No adequate preoperative assessment
	skin Penile torsion	
	Curvature in penile erection	

### **2.3 Problem Statement**

Parent/patient reported outcomes after hypospadias surgery in Kenyatta National Hospital are unknown. The factors affecting these outcomes are also not documented. Knowledge obtained in this study will enable us to come up with protocols on management and follow up of hypospadias patients in our institution.

## **2.4 Study Justification**

Patient-reported outcomes can provide extremely valuable data and information for the assessment of hypospadias patients while aiding effective decision-making, assessment of performance and improvement in quality of care.<sup>19</sup>

The perception of the genitalia of both the patient and their parents is essential for the patient's psychosexual quality of life after hypospadias surgery. Assessment of this will allow us to predict the future quality of life of our patients and to intervene at an earlier stage. Patient reported outcomes after hypospadias surgery in the East African region are not known. Knowledge of patient satisfaction after hypospadias repair will allow us to come up with local protocols for follow up of hypospadias patients. Assessment of our work by uninvolved surgeons will help us evaluate our practices. This will ultimately lead to better patient outcomes in the future.

## **2.5 Study Objectives**

### **2.5.1 Broad Objective**

To evaluate perceptions of cosmetic outcomes after hypospadias surgery in children at Kenyatta National Hospital using the Paediatric Penile Perception Score.

### **2.5.2 Specific Objectives**

- a) To evaluate the parent perception of cosmetic outcome after hypospadias surgery in children at Kenyatta National Hospital using the Paediatric Penile Perception Score.
- b) To evaluate the surgeon perception of cosmetic outcome after hypospadias surgery in children at Kenyatta National Hospital using the Paediatric Penile Perception Score.
- c) To compare parent and surgeon perceptions of cosmetic outcome after hypospadias surgery in children at Kenyatta National Hospital.



## **3 CHAPTER THREE: METHODOLOGY**

### **3.1 Study Setting**

The study was carried out at the Pediatric Surgical Outpatient Clinic at Kenyatta National Hospital (KNH). The clinic has 2 large consultation rooms and 7 examination cubicles. It is manned by 2 nurses and is open from 8 a.m. to 5 p.m. from Monday to Friday. KNH is Kenya's most significant referral facility and the largest in East and Central Africa. Majority of the patients with hypospadias will therefore undergo urethroplasty procedure in KNH making it the most appropriate study setting.

### **3.2 Study Population**

The study target was 115 male children who had undergone hypospadias repair at Kenyatta National Hospital over 5 years, between January 2014 and December 2018. The children's age ranges were 2 years - 18 years.

### **3.3 Inclusion Criteria**

All patients who have undergone hypospadias repair in KNH between Jan 2014 and Dec 2018 and whose parents/guardians give consent and/or patients give ascent.

### **3.4 Exclusion Criteria**

- Patients who had undergone surgery involving the genitals less than 6 months before the study's commencement.
- Patients who had further planned operations for hypospadias.
- Patients with untreated post urethroplasty complications.
- Patients with other signs of disorders of sex development besides hypospadias.

### **3.5 Study Design**

The purpose of this study was to evaluate cosmetic outcomes post hypospadias surgery in Kenyatta National Hospital using the Paediatric Penile Perception Score. Based on this objective, the most appropriate design to achieve it was a descriptive cross-sectional study. This study design allows researchers to collect data at a defined point in time and to assess occurrence of a disease. This design also allows a researcher to examine a relationship between a health condition or a disease and other variables of interest in a defined subset of a population at a given point in time and to generalize the findings to the entire target population.

### **3.6 Study Duration**

The duration of the study was four months from the period of ethical clearance.

### **3.7 Sample Size Calculation**

Data from KNH health information department shows there is an average of 23 cases of hypospadias operated in KNH each year. The target population was therefore 115 children who had undergone hypospadias repair between January 2013 and January 2018 (5 years). We sampled all the patients using the census method.

### **3.8 Data Collection**

A data collection sheet was utilized for data collection. It contained the demographic data of the patient, type of hypospadias as per the patient's clinical record, type of urethroplasty procedure done, any complications following the procedure, number of surgeries done, age at first and last surgery and the parent and surgeon PPP scores. Data was entered by the principal investigator or research assistant at the pediatric surgical outpatient clinic.

Data on type of hypospadias, type of urethroplasty procedure done, any complications following the procedure, number of surgeries done and age at first and last surgery was collected

retrospectively from the patient's record.

The parents/guardians were invited for an interview. Both parents were invited for the interview. They were each interviewed in person concerning penile appearance with regard to meatus' position and configuration; glans appearance and configuration; appearance of the shaft skin, mucosal collar and general penile appearance. The interview took place at the Paediatric Surgery Outpatient Clinic and was carried out by either the principle investigator or the research assistant.

The parents were asked to indicate their contentment with every item using a 4-point Likert scale, which included the ratings of very dissatisfied (0 points), dissatisfied (1), satisfied (2) and very satisfied (3). The PPPS was calculated by summing up the scores of the items glans, meatus, shaft skin and general appearance.

A panel of 2 pediatric surgeons were constituted, both from the KNH Pediatric Surgery department. They were blinded to the identity of the study participants.

The boys with hypospadias were examined and photographs taken by the principle investigator.

Standard color digital photographs were taken with a digital camera (Nikon Coolpix P900).

Photographs were taken:

- Indoors at the Paediatric Surgical Outpatient Clinic.
- In supine position with the groin area exposed.
- With the camera placed on a tripod stand the level of the bed.
- With the camera at a distance of 30cm from the participant.
- Similar lighting conditions for each participant. A portable macro LED ring light was attached onto the digital camera to provide equal lighting of each photo taken with the flash setting.

- Same background was provided by a portable non-woven 1.6x3 meter photography backdrop in white mounted with tape against a wall.
- Minimum camera screen resolution of 640 X 480 pixels.

4 standardized views were taken, namely lateral, oblique, anteroposterior with the penis held against the abdominal wall and anteroposterior with the penis held up straight.

Photographic charts were printed and shown individually to the surgeons. The surgeons were asked to rate the photographs according to the same criteria and with the same scale as the parents.

The type of hypospadias, method of repair, complications, staging of surgery, need for re-operation and age at first and last surgery were recorded from the patient's file.

### **3.9 Data Entry**

Photographs of participants were treated confidentially and were identified via a systematic numbering system that corresponded with the filled data collection forms. Photographs were stored on a laptop and on an external hard-drive that was password protected. Photos were uploaded onto the 'Image J' image processing and analysis software installed on the laptop. Photographic charts were then created and printed.

### **3.10 Data Analysis**

The data collected was cross-checked, cleaned, categorized and entered using the statistical analysis software package, SPSS version 22. The folder containing the data was password-protected and uploaded to a cloud storage drive and backup done daily to prevent missing entries. Measures of central tendency such as mean and standard deviation were used to describe variables with normal distribution while skewed distributions were described in terms of medians and interquartile ranges. Descriptive statistics such as frequencies and percentages were used to

describe categorical variables.

Correlation of single items to general appearance as well as associations between the PPPS and medical characteristics were calculated using Spearman's rank correlation coefficients. Inter-rater reliability between the surgeons and parents was calculated using Multi Rater K statistical analysis. A T test was used to compare surgeon and parent satisfaction scores. All statistical tests were considered significant where the p-value was  $< 0.05$ .

### **3.11 Ethical Considerations**

#### **3.11.1 Informed Consent and Assent**

The parents or legal guardian in the presence of the children in this study were informed by the researcher on the purpose and rationale of the study. Participation was voluntary and the participants were allowed to leave the study at any specified time according to their discretion. A consent form was signed by both the parent or legal guardian and the researcher. An assent form was signed by children aged 6-17 years once the patient agreed to participate in the study.

#### **3.11.2 Confidentiality**

All participants remained anonymous and identification was done by a unique patient identification number. Confidentiality and privacy was observed throughout the duration of the study. The patient data was kept in a password protected data vault and we kept all of our paper records in a locked file cabinet.

#### **3.11.3 Privacy**

The photographs were taken in a private locked room and only the penis was photographed. The photographs were taken by either the principle researcher or the research assistant. Care was taken to avoid showing any identifiable features in the photographs.

#### **3.11.4 Adverse outcome**

Any patients who were found to have very poor cosmetic outcomes were referred to a cosmetic surgeon for reconstructive surgery where possible and counselling services where corrective surgery was not possible.

#### **3.11.5 Research Approval**

Institutional consent was sought from the University of Nairobi, department of surgery and the Ethics and Research committee of KNH.

#### **3.12 Limitation**

- We did not have preoperative pictures to make a comparison.
- We did not score the patients themselves due to age.
- The PPS system has not been validated in Swahili.

#### **3.13 Dissemination of Results and Publication Policy**

The team has disseminated the results to the University of Nairobi research library, KNH/UON Ethics and research committee and will be available for review by participants. Recommendations will be made to relevant policy makers. The findings will also be presented for publication. In this context, the principal investigator will take lead in publication with supervisors and research assistants as co- researchers. The department of surgery in UON and KNH will be affiliated in publications.

## 4 CHAPTER 4: RESULTS

A total of 51 patients were recruited into the study. Their ages ranged from 2 to 18 years with the mean age being 8.2 years and the median age being 7 years. Majority of patients had subcoronal hypospadias (47%). Most patients underwent a single stage procedure with a re-do rate of 19.6%.

Table 2: Demographics

<b>Age (Years)</b>	<b>Frequency (N)</b>	<b>Percentage (%)</b>
<b>&lt;5</b>	<b>10</b>	<b>19.6</b>
<b>5-10</b>	<b>29</b>	<b>56.9</b>
<b>&gt;10</b>	<b>12</b>	<b>23.5</b>

The mean age of the patients was 8.2 (SD=4.8) years, while the median age was 7.0 (IQR=4) years. The minimum age was 2 years while the maximum age was 18 years.

Table 3: Table of Hypospadias

<b>Type of Hypospadias</b>	<b>Frequency (N)</b>	<b>Percentage (%)</b>
<b>Glanular</b>	<b>2</b>	<b>3.9</b>
<b>Coronal</b>	<b>2</b>	<b>3.9</b>
<b>Subcoronal</b>	<b>24</b>	<b>47.1</b>
<b>Anterior penile</b>	<b>4</b>	<b>7.8</b>
<b>Mid-penile</b>	<b>6</b>	<b>11.8</b>
<b>Posterior penile</b>	<b>2</b>	<b>3.9</b>
<b>Penoscrotal</b>	<b>11</b>	<b>21.6</b>

Table 4: Procedure

<b>Procedure</b>	<b>Frequency (N)</b>	<b>Percentage (%)</b>
<b>Single</b>	<b>44</b>	<b>86.3</b>
<b>Staged</b>	<b>7</b>	<b>13.7</b>
<b>Re-do Surgery</b>	<b>10</b>	<b>19.6</b>

#### **4.1 Evaluation of Parental perception of cosmetic outcome**

Table 5: Frequency of the Ratings for Satisfaction by the Parents

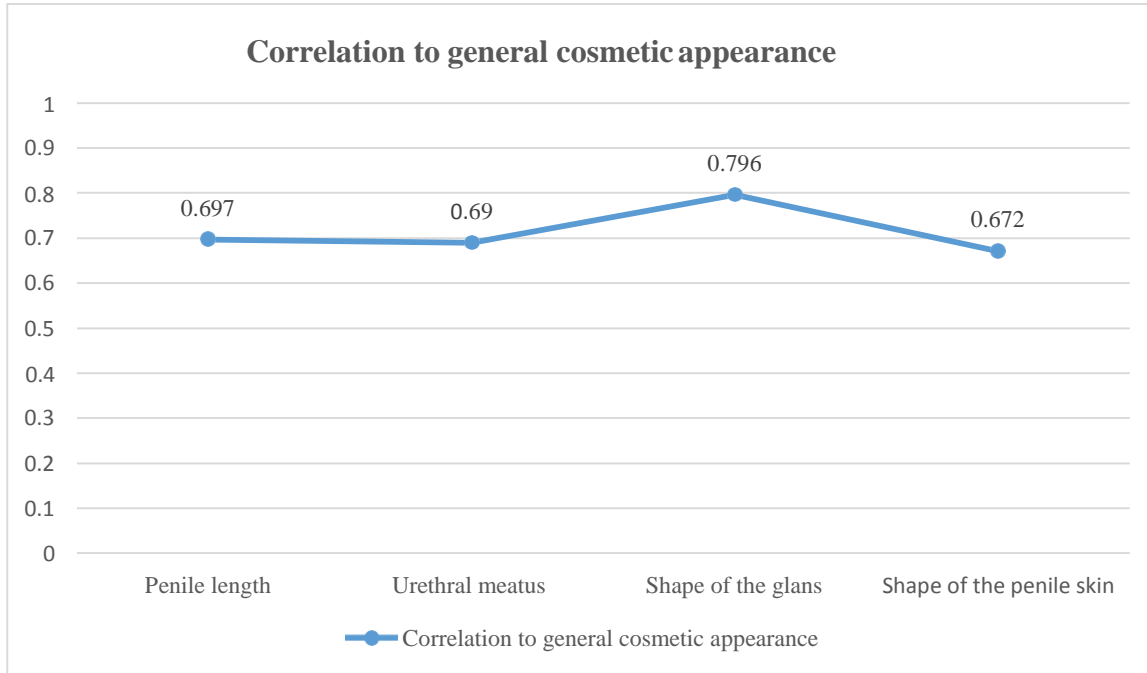
	<b>Very satisfied</b>	<b>Satisfied</b>	<b>Dissatisfied</b>	<b>Very dissatisfied</b>
<b>Penile length</b>	<b>10</b>	<b>35</b>	<b>5</b>	<b>1</b>
<b>Position and shape of urethral meatus</b>	<b>10</b>	<b>20</b>	<b>21</b>	
<b>Shape of the glans</b>	<b>13</b>	<b>35</b>	<b>3</b>	
<b>Shape of the penile skin</b>	<b>13</b>	<b>29</b>	<b>9</b>	
<b>General appearance of penis</b>	<b>12</b>	<b>37</b>	<b>2</b>	

#### **Spearman's Rank Correlation**

Spearman's rank correlation was performed to determine the correlation between the single scored items to general cosmetic appearance, and values less than 0.40 are indicative of a weak correlation, values between 0.40 and 0.69 indicate moderate correlation, values between 0.70 and 0.89 indicate strong correlation, and values equal to and greater than 0.90 indicate very strong correlation.



Figure 1: Spearman’s Rank Correlation



## 4.2 Evaluation of surgeon perception of cosmetic outcome

Table 6: Frequency of the Ratings for Satisfaction by Surgeon 1 and 2

	Very satisfied		Satisfied		Dissatisfied		Very dissatisfied	
	Surgeon 1	Surgeon 2	Surgeon 1	Surgeon 2	Surgeon 1	Surgeon 2	Surgeon 1	Surgeon 2
<b>Meatal position and shape</b>	22	8	8	35	13	8	8	0
<b>Shape of the glans</b>	19	8	23	34	6	9	3	0
<b>Shape of the penile skin</b>	15	1	15	41	11	8	10	1
<b>General cosmetic appearance</b>	19	1	17	40	11	9	4	1

### 4.2.1 Interrater Reliability amongst the Surgeons

Interrater reliability (i.e. agreement or concordance) amongst the surgeons was performed using the Intraclass Correlation Coefficient (ICC), and values less than 0.5 are indicative of poor reliability, values between 0.5 and 0.75 indicate moderate reliability, values between 0.75 and 0.9

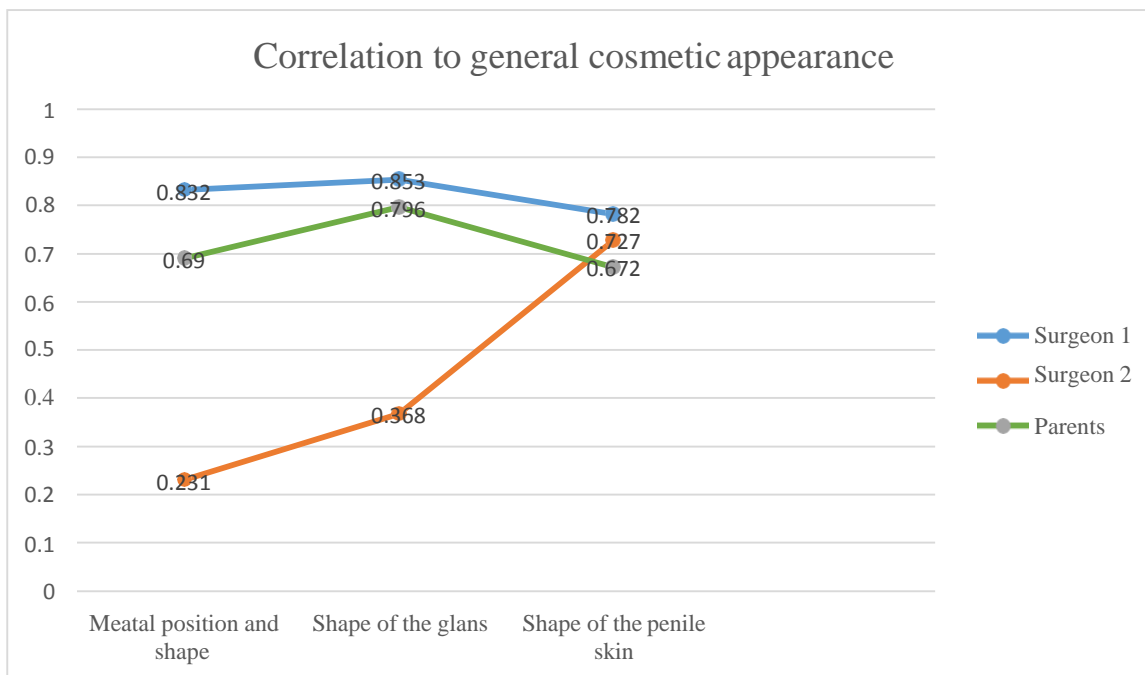
indicate good reliability, and values greater than 0.90 indicate excellent reliability.

Concordance among the surgeons scores was moderate at 0.53 (0.18 – 0.73),  $p = 0.004$ .

### Correlation to general cosmetic appearance

Spearman's rank correlation was performed to determine the correlation between the single scored items to general cosmetic appearance.

Figure 2: Correlation to general cosmetic appearance



Using the Spearman rank correlation coefficient general cosmetic appearance correlated well with single items for surgeon 1, including the meatal position and shape ( $r = 0.832$ ,  $p < 0.001$ ), shape of the glans ( $r = 0.853$ ,  $p < 0.001$ ) and shape of the penile skin ( $r = 0.782$ ,  $p < 0.001$ ). For surgeon 2, there was poor and non-statistical significant correlation between general cosmetic appearance and meatal position and shape ( $r = 0.231$ ,  $p = 0.103$ ), but correlated moderately with shape of the glans ( $r = 0.368$ ,  $p = 0.008$ ), and correlated well with shape of the penile skin ( $r = 0.727$ ,  $p < 0.001$ ).

### 4.3 Comparison of parent and surgeon perceptions of cosmetic outcome

Figure 3: Frequency of satisfaction with general cosmetic appearance among parents and surgeons

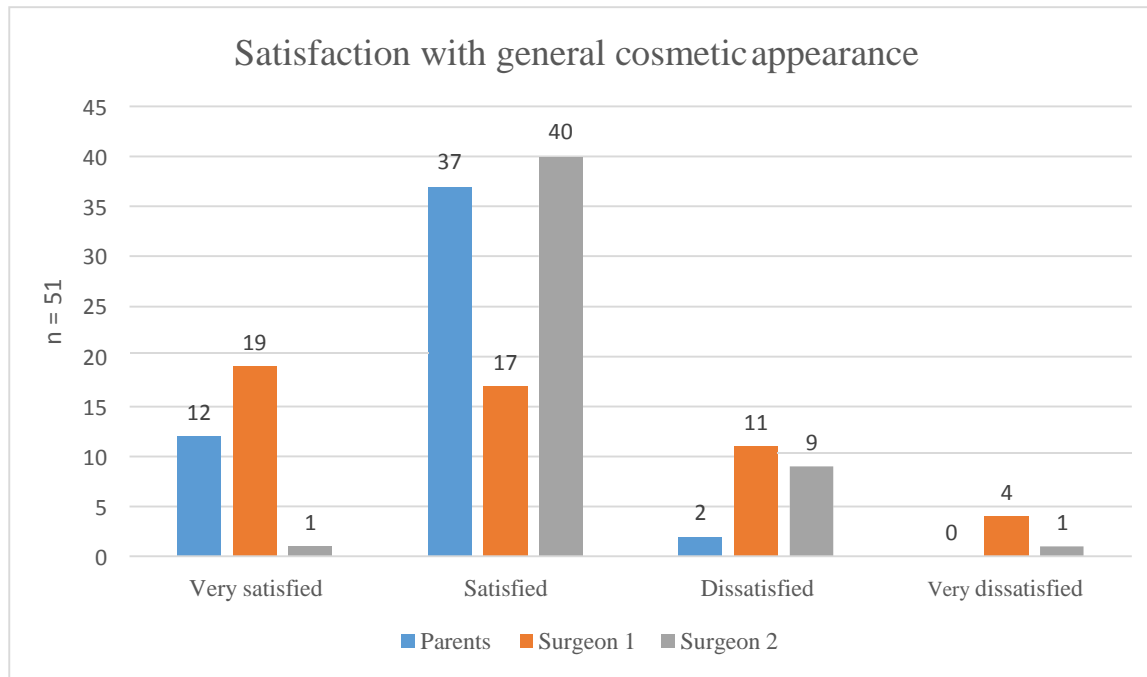


Table 7: Interrater Reliability between the Parents and Surgeons

Interrater reliability (i.e. agreement or concordance) between the parents and the surgeons on the general cosmetic outcome was performed using the Intraclass Correlation Coefficient (ICC).

	ICC (95 % CI)	p-value
<b>Surgeon 1 and parents</b>	<b>0.60 (0.30 – 0.77)</b>	<b>0.001</b>
<b>Surgeon 2 and parents</b>	<b>0.48 (0.09 – 0.70)</b>	<b>0.011</b>
<b>Surgeon 1, 2 and parents</b>	<b>0.65 (0.44 – 0.79)</b>	<b>&lt;0.001</b>

Concordance among the three scores was moderate (0.65,  $p < 0.001$ ).

## **CHAPTER 5: DISCUSSION, CONCLUSION AND RECOMMENDATIONS**

### **5.1 Introduction**

The main objective of this study was to evaluate perceptions of cosmetic outcomes after hypospadias surgery in children at Kenyatta National Hospital. The specific objectives were evaluation of parent perception and surgeon perception using the Paediatric Penile Perception Score and comparison of the two. We found that the parents were generally satisfied with the cosmetic appearance of the penis after surgery (49 out of 51) – mean score of 10.3(+/-2.6). The surgeons were less satisfied than the parents with a mean score of 7.7(+/-3.6) for Surgeon 1 and 7.6(+/=1.6) for Surgeon 2. There was moderate concordance between the surgeons and parent's perceptions. We can conclude that the Paediatric Penile Perception Score can be used to assess cosmetic outcomes in our patients after hypospadias surgery.

### **5.2 Discussion**

The average age of patients in our study was 8.2 years with the minimum age being 2 years and the maximum age being 18 years. Weber et al looked at patients between the ages of 6 and 17 years.<sup>13</sup> Weber et al had 48 patients with distal hypospadias, 26 with penile hypospadias and 3 with penoscrotal hypospadias. Al-debeiky et al looked at 40 patients with distal hypospadias.<sup>14</sup> Haid et al had 42 patients, 26(75.8%) with distal hypospadias, 6 (20.6%) with penile hypospadias and 1(3.4%) with scrotal hypospadias. We had a total of 51 patients, 28 (54.9%)patients with distal hypospadias, 12 (23.5%) patients with penile hypospadias and 11 (21.6%) patients with penoscrotal hypospadias. 34(66.7%) patients underwent a single procedure while 17 (33.5%) patients underwent staged or multiple re-do surgeries. Of the 77 patients in Weber et al's study, 48 (62%) underwent a single procedure, while 29 (38%) underwent 2-stage repair or reoperation for complications.<sup>13</sup> Staged repair in proximal hypospadias has been shown to have better functional

and cosmetic outcomes as compared to single stage surgery.<sup>20</sup>

Our parent satisfaction rate was high (10.3+/-2.6). This agrees well with Weber et al who found that parent satisfaction was high with an overall score of 9.75(=/- 1.95).<sup>13</sup> Al-debeiky et al in a randomized control study looking at 40 patients in 2 groups found the parent scores to be slightly lower at 7.8(1.5) in group A and 7.89(2.21) in group B. They however, only looked at patients with distal hypospadias.<sup>14</sup>

Shape and position of meatus had the lowest score among the parents in our study (1.78). The penile length, shape of glans and shape of penile skin all had scores above 2. This is different from Weber et al who found that all the above parameters had a score above 2.<sup>13</sup> There was good correlation (>0.4) between the items penile length, shape and location of meatus, shape of glans and shape of penile skin to the general appearance of the penis. This was similar to the study by Weber et al.

When we looked at the surgeon perception of cosmetic outcomes, both surgeons in our study were less satisfied than the parents. Surgeon one had a mean score of 7.7 (3.6) and surgeon 2 had a mean score of 7.6 (1.6). This is in keeping with the findings by Weber et al who found that their surgeons were less satisfied than the parents with a mean score of 6.76 (2.04)<sup>13</sup> This differed from Al-debeiky et al who found that surgeon satisfaction was higher than parent satisfaction in both groups. The surgeons' average total of PPPS was 8.43 (1.90) in group A and 8.04 (2.16) in group B with a non- significant difference ( $P>0.05$ )<sup>14</sup>

There was good correlation (>0.4) between the items penile length, shape and location of meatus, shape of glans and shape of penile skin to the general appearance of the penis for Surgeon 1. For surgeon 2, there was poor and non-statistical significant correlation between general cosmetic appearance and meatal position and shape (<0.4) but there was good correlation of the other 3

items to the general appearance of the penis.

There was good concordance between the 2 surgeons and the parents (>0.4). This allows us to compare the two. The parents in our study were more satisfied than the surgeons. This was in keeping with studies done by Weber et al, Al-debeiky et al. This can be postulated to be due to poor outcomes in our patients as suggested by Weber et al.<sup>13</sup> This may also be explained by the fact that both surgeons were part of the department where the surgeries took place. This may introduce some bias according to Bracka et al.<sup>21</sup> This can be cured by including surgeons who are not part of the operating team.

Haid et al in prospective study of 42 boys who underwent surgery for distal hypospadias found that the parents were less satisfied than the surgeons. (81.13% (PPPS) vs. 92.81% (HOPE) of the respectively possible highest score ( $P<0.0001$ ). They postulated that this may be due to foreskin removal in a country (Austria) where only 15% of all men are circumcised. A study by Lorenzo et al on decisional regret after hypospadias surgery found that parental desire to avoid circumcision (OR 7.4, 95% CI 1.1–49.4) was a statistically significant predictor of moderate to strong decisional regret.<sup>22</sup>

Our findings disagree with several authors. Mureau et al. published a study on patient contentment after hypospadias surgery with a study design similar to the PPPS. They found that patients reported less contentment with the penile appearance than the operating surgeons. They assessed satisfaction with flaccid penile size and thickness, glanular size and shape, position of meatus, presence of scars, scrotum and testes and overall penile appearance.<sup>10</sup>

Snodgrass et al gave parents and surgeons a standardized questionnaire 6 weeks after hypospadias repair using the Tubularised Incised Plate method. They assessed six outcomes: meatus and skin cosmesis, overall penile appearance, size of the penis, voided stream and straightness during

erection. Surgeon perceptions of cosmetic outcomes were slightly, but significantly, more positive than the parents'. The scores by the surgeons were higher for distal versus proximal hypospadias outcomes.<sup>15</sup>

### **5.3 Study Limitations**

We were only able to get 51 patients due to travel restrictions instituted by the government to limit the spread of COVID 19.

The sample size is not powered for sub-group analysis, furthermore, the interrater variability analysis is not powered as it only rates 2 surgeons.

The surgeons doing the rating are part of the department where the surgeries took place. This may introduce some bias.

There could have been recall bias in the parents especially for the older patients.

We did not score the patients themselves due to the low average age of our patients.

It was difficult to ask the parents to rate the cosmetic outcome in Swahili.

### **5.4 Conclusion**

The perceptions of cosmetic outcomes among both surgeons and parents were high. Additionally, the results suggest that parents can be reassured pre-operatively and that there is a very high chance of being satisfied with the end result.

We found the Paediatric Penile Perception Score to be a reliable tool for assessing cosmetic outcome in both parents and surgeons after hypospadias surgery in our population.

We recommend that the Paediatric Penile Perception Score should be assessed as part of our patient follow up protocol.

## **5.5 Recommendations**

- Future studies should be multi-centre and strive to get more patients.
- We should try to assess cosmetic outcomes in adolescent and adult patients.
- Preoperative photographs should be part of the patient record to assist in future studies.
- Assessment of parental and patient cosmetic outcome should be part of the patient assessment during the follow up period.
- We should include external surgeons not affiliated to our institution.



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## APPENDICES

### Appendix I: Data Collection Tool

#### EVALUATION COSMETIC OUTCOMES POST HYPOSPADIAS SURGERY IN KENYATTA NATIONAL HOSPITAL USING THE PAEDIATRIC PENILE PERCEPTION SCORE

Serial number.....

##### A. Demographic Data

- a) Current Age            Years \_\_\_\_\_
- b) Sex - Male
- c) Age at diagnosis: Years \_\_\_\_\_ Months \_\_\_\_\_ Weeks \_\_\_\_\_
- d) Age at time of first urethroplasty: Years \_\_\_\_\_ Months \_\_\_\_\_
- e) Age at last surgery: Years \_\_\_\_\_
- f) Number of surgeries: \_\_\_\_\_

##### B. Type of hypospadias

- Glanular
- Coronal
- Subcoronal
- Anterior penile
- Mid- penile

Posterior penile

Penoscrotal

Scrotal

Perineal

**C. Type of Surgery**

Tubularised incised plate repair

Transverse preputial island flap technique

Meatal advancement with glanuloplasty incorporated

Glans approximation procedure

Mathieu procedure

On-lay island flap

Two stage buccal graft repair

Two stage Bracka procedure

**D. Procedure**

Single surgery

Staged

**E. Complications**

- Meatal stenosis
- Urethroplasty breakdown
- Urethral stricture
- Urethral diverticulum

	Very satisfied (3)	Satisfied (2)	Dissatisfied (1)	Very dissatisfied (0)
Penile length				
Position and shape of urethral meatus				
Shape of the glans				
Shape of the penile skin				
General appearance of penis				



	Very satisfied	Satisfied	Dissatisfied	Very dissatisfied
Meatal Position and Shape				
Shape of the glans				
Shape of the penile skin				
General Cosmetic Appearance				



## **Appendix II: Consent Form (English Version)**

### **EVALUATION OF COSMETIC OUTCOMES POST HYPOSPADIAS SURGERY IN KENYATTA NATIONAL HOSPITAL USING THE PAEDIATRIC PENILE PERCEPTION SCORE**

This informed consent form is for parents or guardians with children who have undergone surgery for hypospadias. We are requesting these patients to participate in this research project whose title is **“Evaluation of perception of cosmetic outcomes post hypospadias surgery in Kenyatta National Hospital using the Paediatric Penile Perception Score.”**

Principal Investigator: Dr. Jeremiah Kamwetu

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

Supervisors: Dr. F. Osawa, Dr. Kihiko Kuria and Dr. Swaleh Shahbal

This informed consent has three parts:

1. Information sheet (to share information about the research with you)
2. Certificate of Consent (for 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 1: Information sheet**

### **Introduction**

My name is Dr. Jeremiah Kamwetu, a postgraduate student in Pediatric Surgery at the University Nairobi. I am conducting a study on the perception of cosmetic outcomes post hypospadias surgery in Kenyatta National Hospital using the Paediatric Penile Perception Score.

### **Purpose of the study**

Cosmetic outcome after hypospadias surgery is important as it affects the psychosexual and general quality of life of hypospadias patients. This study aims to measure this outcome as reported by both the parent and the surgeon and some of the factors that may affect it.

### **Study Participation**

I am inviting the child under your care to participate in my study. You will be given an opportunity to ask questions before you decide. Participation in this study is voluntary. If you agree to participate, you will be asked to sign a consent form. No payments will be made due to your participation in the study.

### **Benefits of participation**

Participation in the study will help us to assess our outcomes and come up with a protocol on management and follow up of hypospadias patients.

### **Risk of Participation**

Your child's involvement in this research will be through filling of a data collection form and the taking of pictures. You will not expose yourself to any risk if you consent to participate.

### **Right to decline or withdraw**

You are free to withdraw from the study at any time. The refusal to participate or withdraw from

the study will not in any way compromise the quality of care and treatment given to the patient.

### **Confidentiality**

Any information that is obtained from you in this research will be treated with utmost confidentiality. The patients' name shall not be used.

### **Sharing of results**

Knowledge gained from this study will be shared with other experts through conferences and publications. Confidentiality will be obtained.

### **Cost and Compensation**

There shall be no extra cost incurred by you from participation in the study and there is also no compensation.

### **Contacts of relevant parties**

#### **1. Primary Investigator**

Dr. Jeremiah Kamwetu

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Dr. Swaleh Shahbal

Lecturer in Pediatric Surgery

Department of Surgery

University of Nairobi

P.O Box 19676-00202 KNH, Nairobi

Tel: 0202726300

**Part 2: Consent form**

Statement of consent by parent or guardian.

I ..... freely give consent for my child

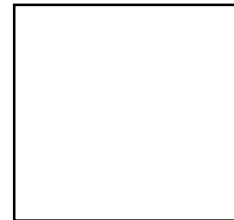
Name ..... to take part in the study “**Evaluation**

**of cosmetic outcomes post hypospadias surgery in Kenyatta National Hospital using the**

**Paediatric Penile Perception Score.”**

I have been informed and have understood that my child’s participation is entirely voluntary. I

understand the information given about the study and I have had the  
opportunity to ask questions and all my concerns have been addressed.



I have the freedom to decline to participate in the study at any time

Signature or left thumb print (Parent/Guardian) .....

Date.....

Statement by witness if parent or guardian is illiterate.

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

Name of witness .....

Signature of witness.....

Date.....

**PART 3: Statement by the researcher**

I have accurately read out the information sheet to the participant and to the best of my ability made sure of the following:

- That the participant consent has been given voluntarily and free of duress.
- Refusal to participate or withdraw from the study will not in any way compromise the quality of care and treatment given to the patient.
- All information will be treated with confidentiality
- The results of this study might be published to enhance the knowledge of the subject of research.
- That I have answered all the questions asked by the participant to the best of my ability and knowledge.
- That a copy of this informed consent form has been provided to the participant.

Name of researcher/ person taking consent.....

Signature of researcher/ person taking consent .....

Date.....

### **Appendix III: Consent Form (Swahili Version)**

#### FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

Fomu hii ya makubaliano ni ya wale watoto ambao wanahudumiwa kwenye kliniki ya upasuaji wa watoto katika hospitali ya Kenyatta na wamealikwa kujiunga na utafiti

EVALUATION OF PERCEPTION OF COSMETIC OUTCOMES POST HYPOSPADIAS SURGERY IN KENYATTA NATIONAL HOSPITAL USING THE PAEDIATRIC PENILE PERCEPTION SCORE.

**Mtafiti mkuu:** Dkt. Jeremiah Kamwetu

**Kituo:** Kitengo cha Upasuaji, Shule ya Afya, Chuo kikuu cha Nairobi.

Fomu hii ya makubaliano ina sehemu tatu:

- Habari itakayo kusaidia kukata kauli
- Fomu ya makubaliano (utakapo weka sahihi)
- Ujumbe kutoka kwa mtafiti

Utapewa nakala ya fomu hii.

SEHEMU YA KWANZA: Ukurasa wa habari

#### **Kitambulizi**

Jina langu ni Dkt. Jeremiah Kamwetu na ninafanya utafiti wa shahada ya juu katika upasuaji wa watoto kwenye chuo kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, “**Evaluation of perception of cosmetic outcomes post hypospadias surgery in Kenyatta National Hospital using the Paediatric Penile Perception Score.**”

#### **Lengo Kuu la Utafiti**

Ujumbe utakaodhihirika kutokana na utafiti huu utawasaidia madaktari kujua wazazi wanavyohisi



juu ya matokea ya upasuaji. Itatusaidia kuwatibu wagonjwa wetu vyema zaidi.

### **Ushiriki wa hiari/ haki ya kukataa**

Ningependa kukualika katika ushiriki wa utafiti huu. Utapata nafasi ya kuuliza maswali kuhusu utafiti huu, aidha kutoka kwangu au kutoka kwa msaidizi wangu. Baada ya kuelewa kabisa undani wa maelezo ya utafiti, ushiriki wako utakuwa wa hiari. Iwapo utaamua kutoshiriki katika utafiti, hautanyimwa matibabu. Isitoshe, ukishaamua kushiriki, ni haki yako kukataa kuendelea na ushiriki huo wakati wowote ule bila madhara yoyote.

### **Taadhimu ya siri**

Ujumbe wote utakaotokana nawe utahifadhiwa kwa siri, na utatumika tu na wahusika wa utafiti kwa malengo ya utafiti pekee. Jina lako halitaorodheshwa popote katika utafiti huu; nambari spesheli itatumika katika utambulizi wako.

### **Utumizi wa matokeo ya utafiti**

Nakala za matokeo ya utafiti huu zitahifadhiwa kwa siri katika maktaba ya Idara ya Upasuaji, Chuo Kikuu cha Nairobi. Kwa minajili ya kuendeleza ujuzi wa Sayansi ya Utabibu, huenda haja ya kuarifu wauguzi wengine kuhusu utafiti huu itokee. Cha muhimu ni kwamba, ruhusa itaombwa kutoka kwa Afisi ya Maadili ya Utafiti inayosimamia utafiti katika hospitali kuu ya Kenyatta na Chuo Kikuu cha Nairobi, kabla ya kutumia matokeo ya utafiti huu katika warsha za Sayansi au kuyachapisha katika majarida ya Sayansi. Nyakati hizo, ujumbe wa kibinafsi hautafichuliwa kamwe.

### **Madhara**

Utafiti huu hauna madhara yoyote kwako.

### **Gharama/ Malipo**

Hakuna gharama ya ziada wala malipo utakayopata kutokana na kushiriki kwako katika utafiti.

## **Anwani za Wahusika**

Ikiwa uko na maswali ungependa kuuliza baadaye, unaweza kuwasiliana na:

### **1. Mtafiti Mkuu**

Dkt. Jeremiah Kamwetu,

Kitengo cha Upasuaji, Shule ya Afya,

Chuo Kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202.

Simu: 0722995701.

### **2. Mtafiti Msaidizi**

Dkt. Faith Bob,

Kitengo cha Upasuaji, Shule ya Afya,

Chuo Kikuu cha Nairobi,

SLP 19676 KNH, Nairobi 00202.

Simu: 0720060319

### **3. Karani**

KNH/ UON-ERC

SLP 20723 KNH, Nairobi 00202

Simu: +254-020-2726300-9 Ext 44355

Barua pepe: [KNHplan@Ken.Healthnet.org](mailto:KNHplan@Ken.Healthnet.org)

### **4. Wahadhiri wahusika**

Dkt. Francis Osawa

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

SLP 19676 KNH, Nairobi 00202.

Simu: 0202726300

Dkt. David Kuria

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

SLP 19676 KNH, Nairobi 00202.

Simu: 0202726300

Dkt. Swaleh Shahbal

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

SLP 19676 KNH, Nairobi 00202.

Simu: 0202726300

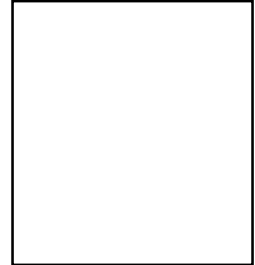
**SEHEMU YA PILI: Fomu ya makubaliano**

Nimeelezwa utafiti huu kwa kina. Nakubali kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumuuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki.....

Sahihi la shahidi/ Alama ya kidole cha mshiriki.....

Tarehe.....



Kwa wasioweza kusoma na kuandika:

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nadhibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi.....

Sahihi la shahidi.....

Tarehe.....

**SEHEMU YA TATU: Ujumbe kutoka kwa mtafiti**

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo;

- Kutoshiriki au kujitoa kwenye utafiti huu hautadhuru kupata kwake kwa matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu yanaweza chapishwa ili kuwezesha kutibu bakteria katika mkojo.

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

Ninahakikisha kuwa mshiriki alitoa ruhusa bila kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti.....

Sahihi ya mtafiti.....

Tarehe.....

**Appendix IV: Assent Form (English)**

This is for children aged 12 to 18 years.

Study Title: EVALUATION OF PERCEPTION OF COSMETIC OUTCOMES POST HYPOSPADIAS SURGERY IN KENYATTA NATIONAL HOSPITAL USING THE PAEDIATRIC PENILE PERCEPTION SCORE.

**Study Site:** Kenyatta National Hospital

My name is Dr. Jeremiah Kamwetu, a postgraduate student in Pediatric Surgery, Department of Surgery, University of Nairobi. I am conducting a study on the above topic. This means that we want to know how satisfied you or your parents are after surgery for hypospadias.

If you agree to be part of this study, I will ask you some questions and take photographs of your penis.

Participation in this study is voluntary and you will not get any monetary benefit from participation in the study.

When we are finished with this study, we will write a report about what was learned. This report will not include your name or that you were in the study.

You don't have to be in this study if you don't want to be. If you decide to stop after we begin, that is okay. Your parents will know about the study too.

If you decide you want to be in the study, please sign your name

Name.....Signature.....

Date.....

Name of Parent or Guardian.....

## **Appendix V: Assent Form (Swahili)**

ASSENT FORM (SWAHILI)

FOMU YA IDHINI YA WATOTO WALIO NA UMRI WA MIAKA KUMI NA MBILI HADI  
KUMI NA NANE.

Jina langu ni Dkt. Jeremiah Kamwetu. Mimi ni daktari ninayesomea upasuaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti kwa anwani ya, **“EVALUATION OF PERCEPTION OF COSMETIC OUTCOMES POST HYPOSPADIAS SURGERY IN KENYATTA NATIONAL HOSPITAL USING THE PAEDIATRIC PENILE PERCEPTION SCORE.”**

Utafiti huu unataka kuangalia matokeo baada ya operesheni ya kurekebisha njia ya mkojo ya watoto walio na ugonjwa wa ‘hypospadias’.

Ukikubali kushiriki katika utafiti huu, utajibu maswali na nitakuchukua picha.

Nitakueleza zaidi kuhusu utaratibu wa kukusanya mkojo ili usichafuke katika hali ile ya kuikusanya.

Kushiriki katika utafiti huu ni kwa hiari yako na hamna masharti yeyote ya lazima. Una haki ya kujiondoa kutoka ushiriki wa utafiti huu wakati wowote upendavyo na uamuzi huo hauwezi dhuru matibabu yako kwa vyovyote vile.

Hakuna hatari wala gharama ya ziada yeyote itakayo kukumba kutokana na kushiriki katika utafiti huu.

Tutakapo maliza utafiti huu, tutaandika ripoti kuhusu tulilojifunza. Hakuna popote pale nitakapotaja jina lako. Hivyo basi hamna atakaye tambua kwa majina walioshiriki.

Mzazi au mlezi wako atajulishwa kuhusu utafiti huu pia.

Nitakupa nakala ya fomu hii ukikubali kushiriki katika utafiti huu.

Kama umekubali kushiriki katika utafiti:

Jina lako.....

Sahihi yako ..... Tarehe .....

Jina la Mzazi au Mlezi.....

Mtafiti aliyekupa maelezo ya utafiti

Jina .....

Sahihi ..... Tarehe.....

**SEHEMU YA PILI:** Fomu ya makubaliano

Nimeelezwa utafiti huu kwa kina. Nakubali kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumuuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la Mshiriki.....

Sahihi la shahidi/ Alama ya kidole cha mshiriki.....

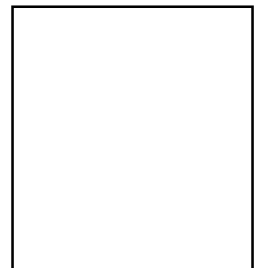
Tarehe.....

Kwa wasioweza kusoma na kuandika:

Nimeshuhudia usomaji na maelezo ya utafiti huu kwa mshiriki. Mshiriki amepewa nafasi ya kuuliza maswali. Nadhibitisha kuwa mshiriki alipeana ruhusa ya kushiriki bila ya kulazimishwa.

Jina la shahidi.....

Sahihi la shahidi..... Tarehe.....





**SEHEMU YA TATU:** Ujumbe kutoka kwa mtafiti

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo;

- Kutoshiriki au kujitoa kwenye utafiti huu hautadhuru kupata kwake kwa matibabu.
- Ujumbe kuhusu majibu yake yatahifadhiwa kwa siri.
- Matokeo ya utafiti huu yanaweza chapishwa ili kusaidia madaktari wengine.

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

Ninahakikisha kuwa mshiriki alitoa ruhusa bila kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti.....

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

**Appendix VI: Participating Surgeon Consent**

Statement of consent by participating surgeon

I.....freely give consent for me to take part in the study “**Evaluation of cosmetic outcomes post hypospadias surgery in Kenyatta National Hospital using the Paediatric Penile Perception Score.**”

I have been informed and have understood that my participation is entirely voluntary. I understand the information given about the study and I have had the opportunity to ask questions and all my concerns have been addressed.

I pledge not to divulge any patient information outside of this study.

I have the freedom to decline to participate in the study at any time

Signature .....

Date.....

## Appendix VII: Ethical Approval



UNIVERSITY OF NAIROBI  
COLLEGE OF HEALTH SCIENCES  
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Telegrams: varsity  
Tel: (254-020) 2726300 Ext 44355

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Website: <http://www.erc.uonbi.ac.ke>  
Facebook: <https://www.facebook.com/uonknh.erc>  
Twitter: [@UONKNH\\_ERC](https://twitter.com/UONKNH_ERC) [https://twitter.com/UONKNH\\_ERC](https://twitter.com/UONKNH_ERC)



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

Ref: KNH-ERC/A/192

Dr. Jeremiah Kaula Kamwetu  
Reg. No. H58/74215/2014  
Dept. of Surgery  
School of Medicine  
College of Health Sciences  
University of Nairobi



26<sup>th</sup> June 2020

Dear Dr. Kamwetu,

RESEARCH PROPOSAL – EVALUATION OF PERCEPTIONS OF COSMETIC OUTCOMES POST HYPOSPADIAS SURGERY IN KENYATTA NATIONAL HOSPITAL USING THE PAEDIATRIC PENILE PERCEPTIONS SCORE (P106/02/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 26<sup>th</sup> June 2020 – 25<sup>th</sup> June 2021.

This approval is subject to compliance with the following requirements:

- Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
- All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
- 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.
- 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.
- Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
- 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.*)
- 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.

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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 Director, CS, KNH  
         The Chairperson, KNH- UoN ERC  
         The Assistant Director, Health Information, KNH  
         The Dean, School of Medicine, UoN  
         The Chair, Dept. of Surgery, UoN  
         Supervisors: Dr. Francis Osawa (Dept. of Surgery, UoN)  
                         Dr. Kihiko Kuria (Dept. of Surgery, UoN)  
                         Dr. Swaleh Shahbal (Dept. of Surgery, UoN)

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## Appendix VIII: Certificate of Plagiarism

Evaluation of Perceptions of Cosmetic Outcomes post hypospadias Surgery in Kenyatta National Hospital Using the Penile Perception Score

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| 1 | Daniel M. Weber, Verena B. Schönbacher, Markus A. Landolt, Rita Gobet. "The Pediatric Penile Perception Score: An Instrument for Patient Self-Assessment and Surgeon Evaluation After Hypospadias Repair", The Journal of Urology, 2008<br>Publication | 5% |
| 2 | Springer, Alexander. "Assessment of Outcome in Hypospadias Surgery – A Review", Frontiers in Pediatrics, 2014.<br>Publication  | 3% |
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