Distal Hypospadias Repair: Comparison of Snodgrass versus Modified Mathieu Procedures: A Randomized Clinical Trial

by

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(Amended)

CERTIFICATE OF COMPLETION OF DISSERTATION

I ..CHARLES KABEYA MATUMBA..... hereby certify that this dissertation is the product of my own work and, in submitting it for my M Med/MSc/M Phil/D Phil programme, further attest that it has not been submitted in part or in whole to another University or for general publication.

Signature: ..... **Date:** 20 05 2014
(student)

I/We 1 Prof Lovemore Gwanzura
2 DR. GILBERT MAWERA having supervised and read this dissertation, am/are satisfied that this is the original work of the author whose name it is being presented. I/We confirm that the work has been completed satisfactorily and is ready for presentation to the examiners.
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Supervisor 2 ..Prof L. Gwanzura..... **Date:** 29. May 2014

Chairman: ..... **Date:** 29 May 2014

AS/hc Jan 2012

Background

Hypospadias is defined as the presence of abnormal meatal opening along the ventral aspect of the penile shaft or into the perineum. Of the many operative techniques for distal hypospadias repair, two techniques have particularly attracted the attention: the Snodgrass (TIP) and the Modified Mathieu Procedure (MMP). The effectiveness of the two techniques in terms of success and complication rates remains controversial.

Objectives

The primary objective of the study is to compare the success rates between the two procedures, MMP (Modified Mathieu Procedure) versus TIP (Tubularised incised plate, Snodgrass).
The secondary objectives of the study are:

1. To compare the complication rates between the two procedures.
2. To compare the operative time between the two procedures.

Methods

Eligible boys were randomly assigned with equal probability to undergo one of the techniques of hypospadias repair: the Snodgrass procedure (tubularized incised plate technique, TIP) or the modified Mathieu procedure (parameatal based flap, MMP). We enrolled 118 patients, 59 in each arm, from January 2006 to February 2008. The patients were assessed at the first dressing at day seven and discharged. They were reviewed monthly up to three months post operatively and the complications, namely stenosis (MS), urethral stricture (US), urethrocutaneous fistula (UCF), urethral diverticulum (UD), penile curvature (PC) and wound breaking (WB) were recorded. Success was defined as the absence of the mentioned complications.

Findings

In this study, 83 patients were enrolled. They were aged between 2 years and 13 years, mean age 7.5 years. The success rates were 68.29%, 95% CI (54.20-84.5) for TIP versus 74.35%, 95% CI (57.18-89.91) for MMP. The following complications were recorded: MS (9.75%), US (14.65%), UCF (9.75%) for TIP versus MS (5.12%), US (5.12%), UCF (7.69%), UD (5.12%) for MMP. The complication rates were 34.14%, 95% CI (20.08-50.59) for TIP versus 23.07%, 95% CI (11.13-39.33) for MMP. The mean operative time was 90 ± 24minutes versus 110 ± 25 minutes ($P>0.05$) for TIP and MMP respectively.

Conclusion

The difference of success rates between the two interventions was not statistically significant. The same conclusion was reached in terms of complication rates between the two techniques. The mean operative time was shorter for TIP as compared to the MMP. Both techniques are equally used. The choice being influenced by surgeon's skills.

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Appendix 1

DATA Collection Card

N^{o} :

Name :

D.O.B :

Technique :

Complications at:	1/52	1/12	3/12
1. MS			
2. US			
3. UCF			
4. UD			
5. PC			
6. WB			

Appendix 2

List of Interventions

501 : MMP

502 : MMP

503 : TIP

504 : MMP

505 : TIP

506 : MMP

507 : TIP

508 : TIP

509 : TIP

510 : MMP

511 : TIP

512 : TIP

513 : MMP

514 : MMP

515 : MMP

516 : TIP

517 : TIP

518 : TIP

519 : MMP

520 : MMP

CHAPTER 1 INTRODUCTION

Hypospadias is a debilitating condition in which there is an abnormality of the penis whereby the urethral opening (or meatus) is located ventrally and proximal to its usual opening. (Figure 3). This is referred to as an ectopic site for the urethral meatus. Three penile anomalies define the hypospadias: the meatal opening located on the penile ventrum with or without the presence of a chordee and with or without a hoody prepuce. This condition is relatively common in most societies and affects approximately 1 in every 300 live male births.[1] Hence its repair is a very common paediatric urological procedure. Unfortunately, its surgical management remains controversial[6,9,16] with over 200 reported surgical methods for urethral reconstruction, some being merely modifications of original techniques.[12] However, of the many surgical techniques used for the repair of hypospadias, two techniques have particularly attracted the attention of paediatric urologists and these are the Snodgrass procedure (TIP) and the Modified Mathieu Procedure (MMP). Unfortunately, the difference in effectiveness of the two techniques in terms of success and complication remains controversial[6] although the TIP appears to be more popular among urologists.

In Zimbabwe there are few surgeons who are familiar with paediatric urologic procedures particularly in surgery of the external genitalia such as repair of hypospadias. This lack of expertise is one of the reasons treatment related complications are commonly encountered. Therefore, there is an urgent need to compare the effectiveness of TIP and the MMP in Zimbabwe in order to recommend the best surgical treatment for hypospadias which can then be taught to surgeons and post graduate students interested in this type of plastic surgery.

This will go a long way in improving the quality of life of many children who are affected by hypospadias in Zimbabwe.

Research Question

Which of the two techniques, TIP or MMP is more safer than the other?

Hypothesis

That in a randomized controlled clinical trial, children aged 24 months to 13 years, randomly assigned to undergo surgical repair of hypospadias, the TIP technique is safer than MMP.

Aim

To compare the effectiveness of the two operative techniques, TIP and MMP, in terms of success rates and complication rates.

Objectives

The primary objective of the study is to compare the success rates between the two procedures, MMP (Modified Mathieu Procedure) versus TIP (Tubularised incised plate, Snodgrass).

The secondary objectives of the study are:

1. To compare the complication rates between the two procedures.
2. To compare the operative time between the two procedures.

CHAPTER 2: LITERATURE REVIEW

2.1. Anatomy of the penis

Normally, the external genitalia in males consist of a penis and the scrotum which has the two testes. In the anatomical position that is, standing with both hands on the side of the body, the penis faces downward pointing to the ground (when not erect). Its anterior part is referred to as the dorsal surface while its posterior part is referred to as the ventral surface.

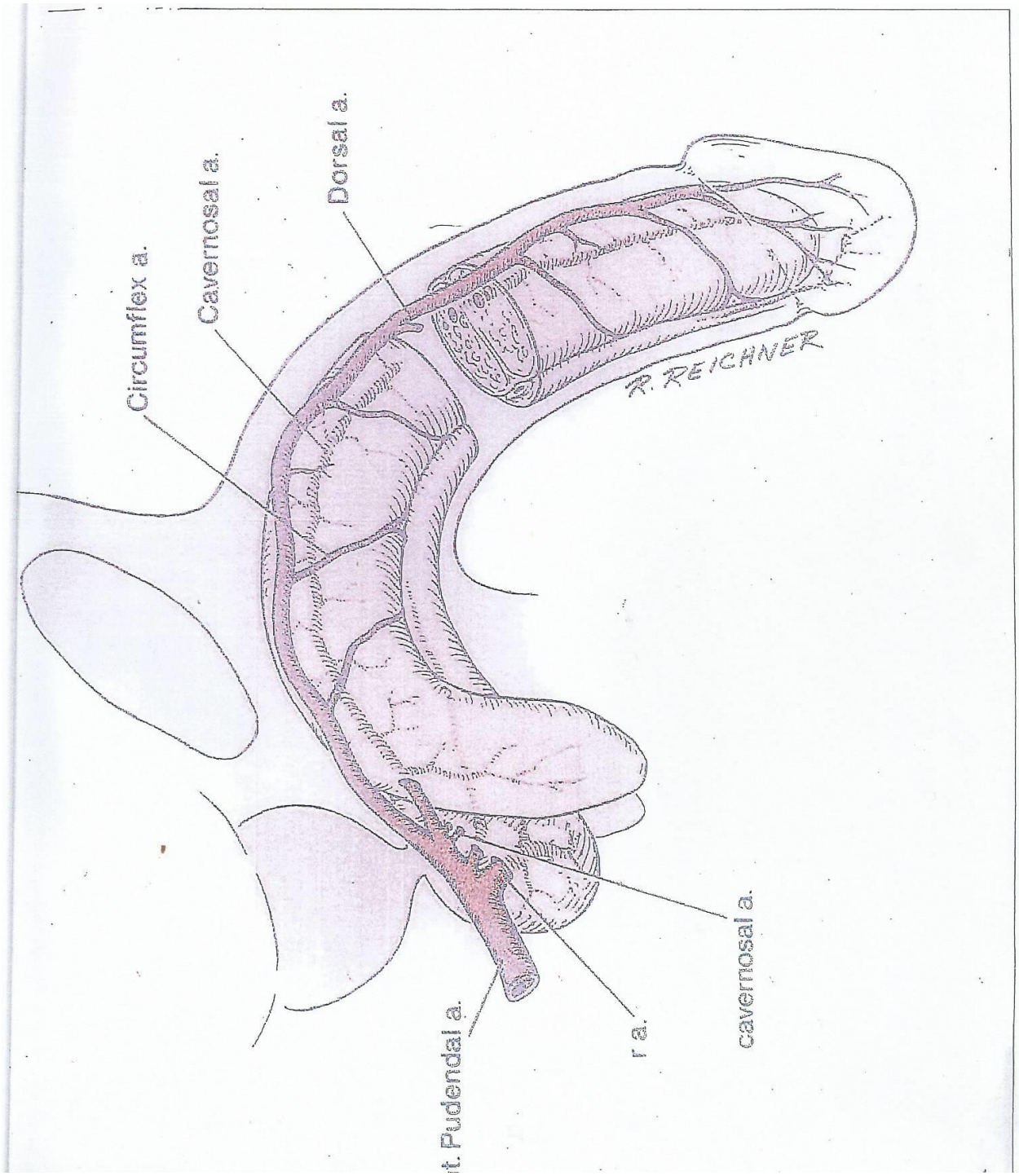
The penis has four parts; a head (the glands penis), a neck (The corona), a body (the penile shaft) and a base (the bulbus) that is attached to the pubic bones of the pelvis that are covered by skin with hair referred to as the pubic hair. The skin of the shaft of the penis covers the glans and is referred to as the prepuce (Fig 1).

The shaft of the penis consists of the three muscles, two on the dorsal side (the corpora cavernosa) and one on the ventral side (the corpus spongiosum). The urethra, which is the passage for urine from the bladder to the outside during micturition, is located ventrally in the corpus spongiosum. It enters the ventral surface of the glans penis where its external opening is referred to as the urethral meatus (Fig 2).

Components of Hypospadias

Anatomically, hypospadias includes the following:-

- A ventrally opened glans penis


Circumflex a.
Cavernosal a.
Dorsal a.
R. REICHNER
t. Pudendal a.
r a.
cavernosal a.

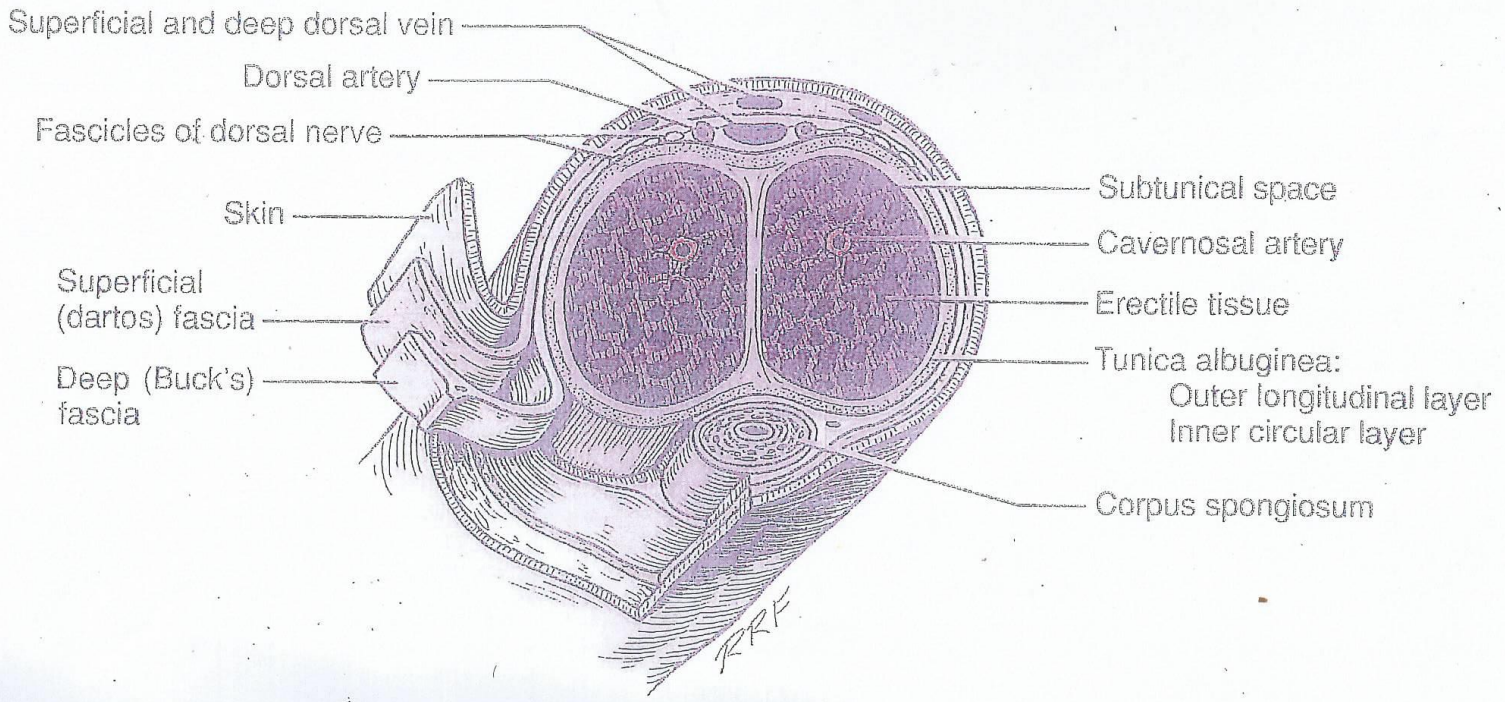


FIGURE 2-4

Figure 2–38. Cross section of the penis, demonstrating the relationship between the corporal bodies, penile fascia, vessels, and nerves. (From Devine CJ Jr, Angermeier KW: Anatomy of the penis and male perineum. AUA Update Series 1994;13:10-23.)

- A missing segment of the urethral tube that is of a variable length which is replaced by a urethral plate extending from the ectopic or abnormal urethral meatus up to the tip of the glands penis (Fig 3).
- A hypoplastic tubular urethra between the two corpora cavernosa that is not surrounded by any corpus spongiosum.

Classically there are three related anomalies found in the hypospadias penis.

- An ectopic opening of the urethral meatus,
- A ventral curvature of the penis (chordee) and
- A hooded foreskin (prepuce) which has a marked excess of skin on the dorsum of the penis and a lack of skin on the ventral surface of the penis

Of note is that the chordee and the hooded foreskin are not constant features of hypospadias.

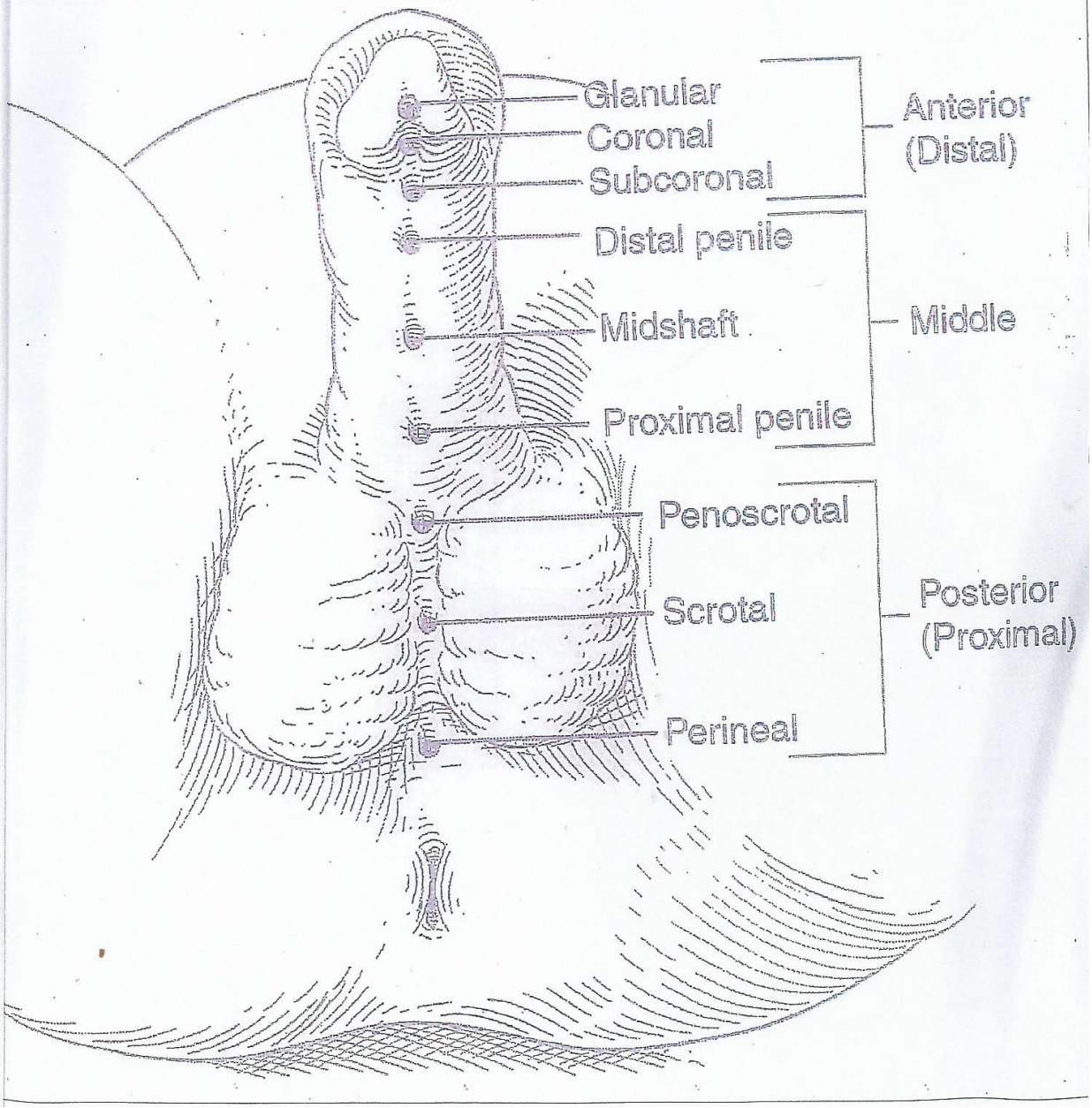
2.2. Classifications of Hypospadias

There are three main types of hypospadias (Fig 3)

Anterior hypospadias

Anterior hypospadias contributes about 50% of cases of hypospadias and it comprises of the following sub-types: glanular, coronal and subcoronal.[1,2]

FIGURE 3 [4]


Glanular
Coronal
Subcoronal
Anterior
(Distal)
Distal penile
Midshaft
Middle
Proximal penile
Penoscrotal
Scrotal
Posterior
(Proximal)
Perineal

Middle Hypospadias

Middle hypospadias contributes about 30% of cases of hypospadias and it comprises of the following sub-types: midshaft and proximal penile.[1,2]

Posterior hypospadias

Posterior hypospadias also called proximal hypospadias contributes about 20% of cases of hypospadias and it comprises of the following sub-types: peno-scrotal, scrotal and perineal. Of note is that there are also extra-penile abnormalities associated with hypospadias. These Include the following:- undescended testes found in 9% of patients with hypospadias and inguinal hernia or hydrocele.[3]

2.3. Incidence of Hypospadias

The incidence of hypospadias is commonly reported as 1 in every 250 to 300 male births.[2,13] However, most authors agree on the incidence of 1 in 300 male births.[2,3,4]

2.4. Aetiology of hypospadias

According to Baver et al (1981), in general, 14% of male siblings are affected by this condition which is more common in whites than in blacks according to Welch (1979). According to Roberts and Lloyd (1973)[3] there is a higher incidence, that is, 8,5 times higher in monozygotic twins than in singleton births. Of note is that a familial link was reported whereby 8% of patients with hypospadias had fathers who also had this condition. Some factors such as abnormal androgen production by the fetal testes, premature loss of androgen stimulation due to early atrophy of leydig cells of the testis are advocated.[2] Unfortunately, the actual cause of hypospadias remains unknown. These are risk factors:

Several causes were advocated in the etiology of hypospadias among them:

genetic factors: familial aggregation, endocranopathy such as Leydig all dysfunction, disturbed androgen activity, gene mutations. Endocrine disruptors, estrogen-like compounds may explain abnormal masculinisation. There is hypothesis that natural or synthetic compounds exciting estrogen-like or antiastrogen effects could result in hypospadias. Also there are syndromes associated with hypospadias[4].

2.5. Surgical treatment of Hypospadias

The surgical treatment of hypospadias includes different phases which can be used in a one-stage or multi-stage operation. These are: - meatoplasty, glanuloplasty, orthoplasty (straightening), urethroplasty, skin-cover and eventually scrotoplasty.

Meatoplasty and Glanuloplasty

Meatoplasty and glanuloplasty are surgical techniques used for the construction of an apical urethral meatus by moving the ectopic urethral meatus to the tip of the glans penis. During glanuloplasty, the wings of the glans penis are approximated and wrapped around the reconstructed urethra.

Orthoplasty

Orthoplasty is a surgical technique used to straighten the shaft of the penis.

Urethroplasty

This is the phase of reconstruction of the missing part of the urethra in the body of the penis.

Skin- cover

When the ventral skin is not enough to cover the reconstructed urethra, the dorsal skin is mobilized to the ventral aspect of the penis using the Byar's technique.

Scrotoplasty

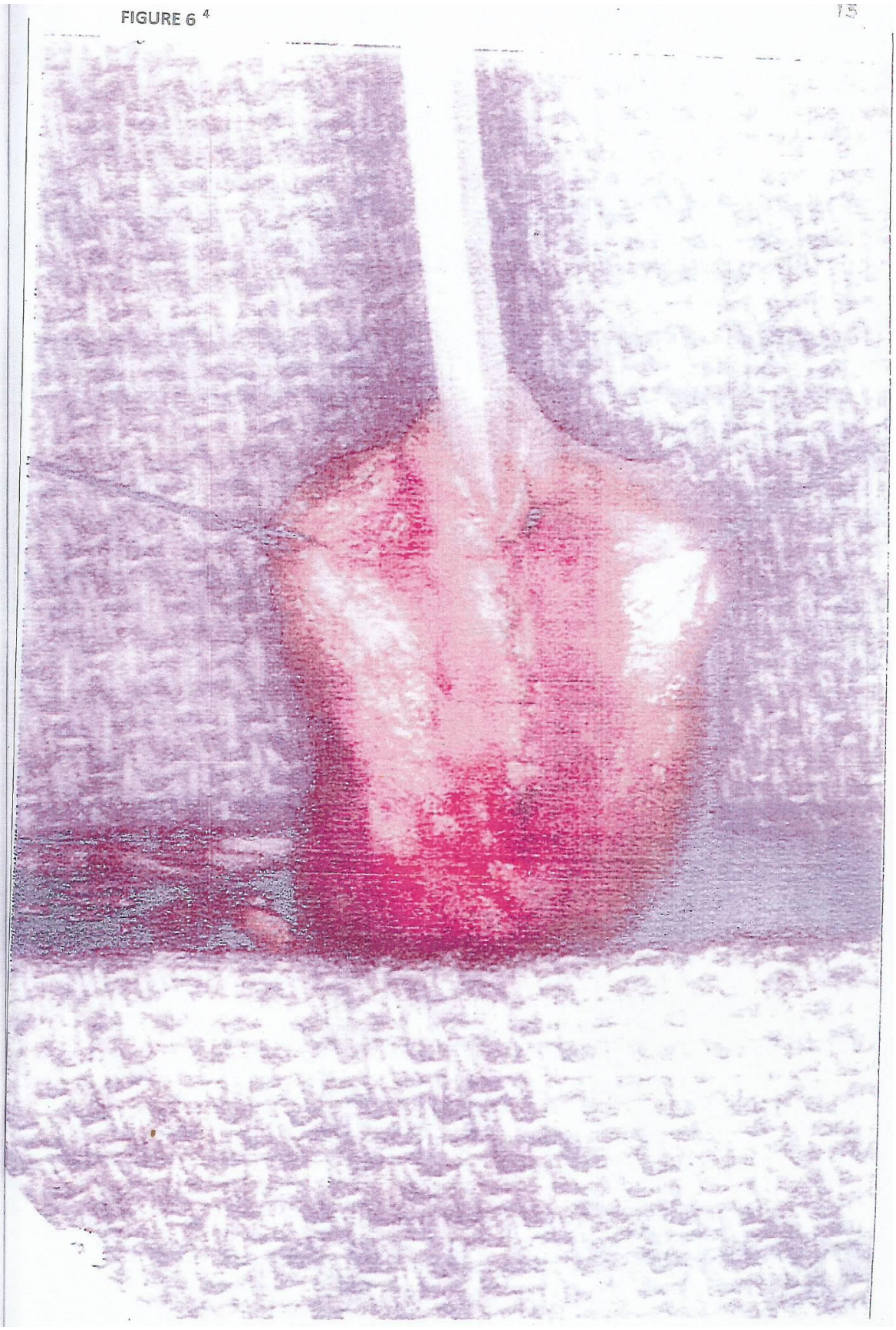
Is the reconstruction of the scrotum for more proximal hypospadias repair. This technique involves the approximation of the separated scrotal halves (hemiscrotum) so that they cover the reconstructed urethra and also to achieve the normal shape of the scrotum.

Snodgrass Procedure

Several well established techniques exist for the repair of all hypospadias defects. The simple urethral-plate Tubularized technique was first described by Thiersch (1869) and Duplay (1880). Warren Snodgrass described a modification of the Thiersch- Duplay technique in 1994, the tubularized incised-plate (TIP) urethroplasty. In this procedure, the urethral plate is outlined at a width of 7 to 9mm and parallel longitudinal incisions demarcating the urethral plate are made from the tip of the glans penis to the urethral meatus (Fig 4). The penile shaft skin is degloved and an orthoplasty is performed with paired dorsal plication if necessary.[4.5] The deep incision of the urethral plate is called a relaxing incision (Fig 5). One should avoid to close the neourethra too distally to prevent meatal stenosis. A longitudinal midline incision of the urethral plate is made to relax the urethral plate which is then rolled around a urethral catheter (Fig 6). A second layer is used to cover the new urethra and it involves the use of a scrotal muscle, the dartos muscle, as a flap (the dartos flap). After this, the wings of the glands penis are then approximated.[4]

FIGURE 4 [4]

FIGURE 6 [4]



Modified Mathieu Procedure

Earlier, in 1932, Mathieu had described the parameatal – based flap technique for hypospadias repair in which the ventral skin had to be thick so that the parameatal flap could have an adequate blood supply for its mobilization and extension. Retik and colleagues later performed para-meatal-based repairs with the addition of dorsal flap coverage of the new urethra: the Modified Mathieu technique[5,6,7] (Fig 7)[14] In this procedure, longitudinal lines outlining the urethral plate are made and carried around the dorsal aspect of the penis. The wings of the glands penis are incised deeply, with partial excision of spongiotic tissue from the glans penis in way to create enough space to fit the new urethra. The penile shaft is degloved before proceeding with the Byar's ventral rotation in which the tissue is folded over the urethral meatus creating the new urethra. A second layer is used as in the Snodgrass procedure to cover the new urethra and it involves the use of the dartos tissue (the dartos flap). The wings of the glans penis are then approximated together to create a conical glans penis configuration as depicted in the diagram (Figure 8).[1,10,14]

2.6 Surgical Morbidity

Oswald[5] compared the parameatal- based flap by Mathieu and the tubularized incised plate urethroplasty by Snodgrass in primary distal hypospadias trying to determine which of the two was the more effective treatment in terms of prevention of fistula formation post-operation, cosmesis of the urethral meatus and duration of the operation. Between July 1997 and August 1998, 60 children underwent distal hypospadias repair in a randomized trial. The authors found that two children who underwent surgery and had the Mathieu procedure used

FIGURE 7 [4]

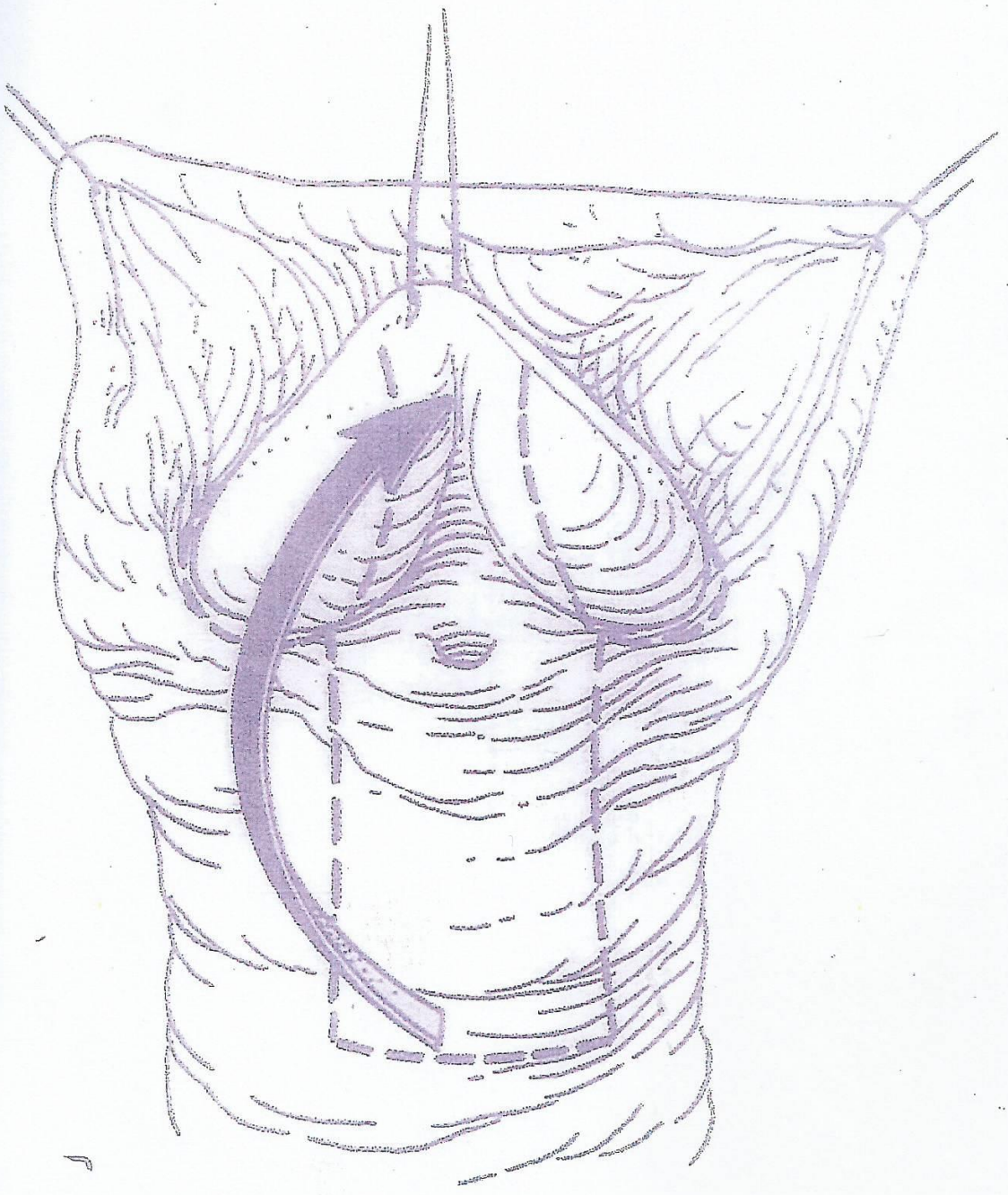
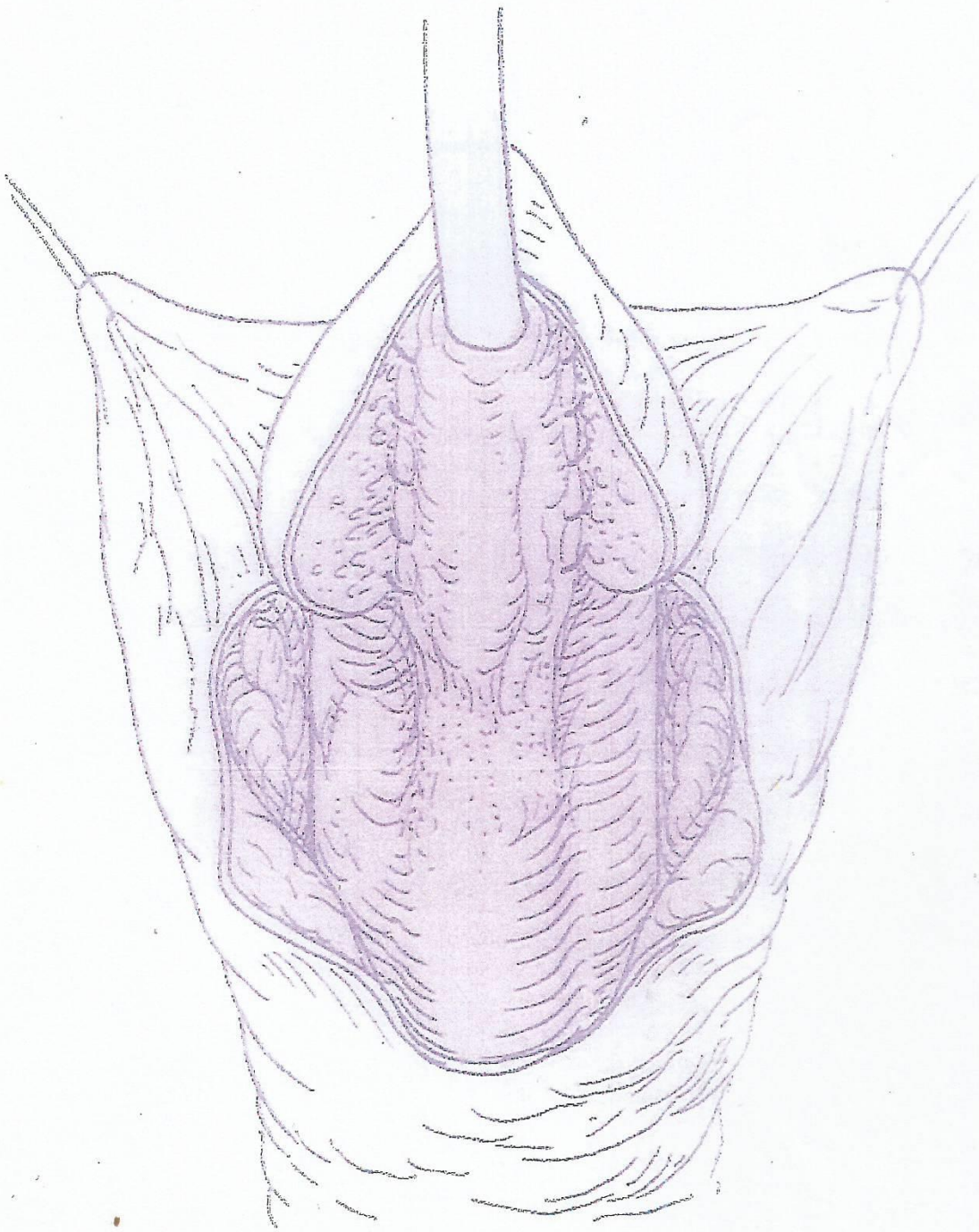


FIGURE 8 [4]



to repair their hypospadias had fistula and one had a urethral meatal stenosis. Only one child in the Snodgrass procedure group had a glanular dehiscence. The mean duration of surgery was significantly lower for the Snodgrass procedure than for the Mathieu repair (75 minutes versus 115 minutes, $p < 0,05$). The authors concluded that the overall complication rate was lower and surgery significant quicker with the Snodgrass urethroplasty procedure than with Modified Mathieu urethroplasty procedure.[4,7,8,9,10]

Hayashi et al used the Modified Mathieu procedure for secondary cases as well as primary for secondary cover. The proximal skin flap was flipped and anastomosed to the distal urethral plate. Additional subcutaneous tissue of the flipped flap was sutured to cover the original suture lines. The procedure was successful in one stage in 13 of the 16 primary repair cases (81%). Twelve of the 13 (92%) were successfully repaired. An overall success rate of 86% was achieved at the first operation for both primary and secondary cases (re-operated). The authors were relatively satisfied with the Modified Mathieu procedure even for secondary repairs. Over a 15 years period 197 MMP were performed by Uygure et al overall 42 patients (21%) had fistula. Their analysis suggests that experience could be considered the most important factor affecting the success rate of hypospadias surgery.[11,12,13]

E Minevich, Barry R. Pecha[10] using Mathieu hypospadias repair in 202 patients found no urethral stricture that the well established procedure provides excellent cosmetic and functional results and it should be the standard for distal hypospadias repair.

Barack and Hamdun operated twenty patients aged one and half to seven years with coronal, subcoronal and midshaft penile hypospadias. They used an incised plate urethroplasty (the Snodgrass Procedure). They had two cases of urethral meatal stenosis (10%) and fistulae occurred in four patients (20%).[10] In a meta-analysis compiling 129 papers for analysis, Wilkinson et al identified an increased incidence of urethral fistula with the Mathieu technique (3,8% vs 5,8%, P= 0,028). An increased incidence of meatal stenosis was identified in the TIP group (3,1% VS 0,7%, P<0.001). They also concluded that there was no clear consensus on the ideal method of repair for distal hypospadias.

Braga P.[6] analysing overall complication rate including fistula, meatal stenosis, recurrent ventral curvature in TIP and Mathieu procedures pointed out some conflicting results among different studies. Some showed that the Snodgrass repair was associated with a lower complication rate et other showing that fistulas were less common after Mathieu procedure as compared to the TIP technique.

Merguerian P.A. evaluating complications (meatal stenosis, and urethrocutaneous fistula) in distal hypospadias repair using the Snodgrass technique, found that multiple layer closure and use of a preputial flap result in a significantly improved complication rate.

2.7 Summary

The Snodgrass as well as the Modified Mathieu procedures are both internationally offered to patients with distal hypospadias among other techniques of repair. The above literature review

revealed that few studies have compared the Snodgrass to Modified Mathieu procedure. This study was designed to compare the success and complication rates of the two procedures among Zimbabweans.

Time to developing complications for each procedure depends on the type of complications being considered, they do not occur all of them at the same time. The wound breaking is usually seen during the first week. Urethral stenosis, urethral stricture as well as urethrocutaneous within fistula will be manifest in approximately six weeks.[17]

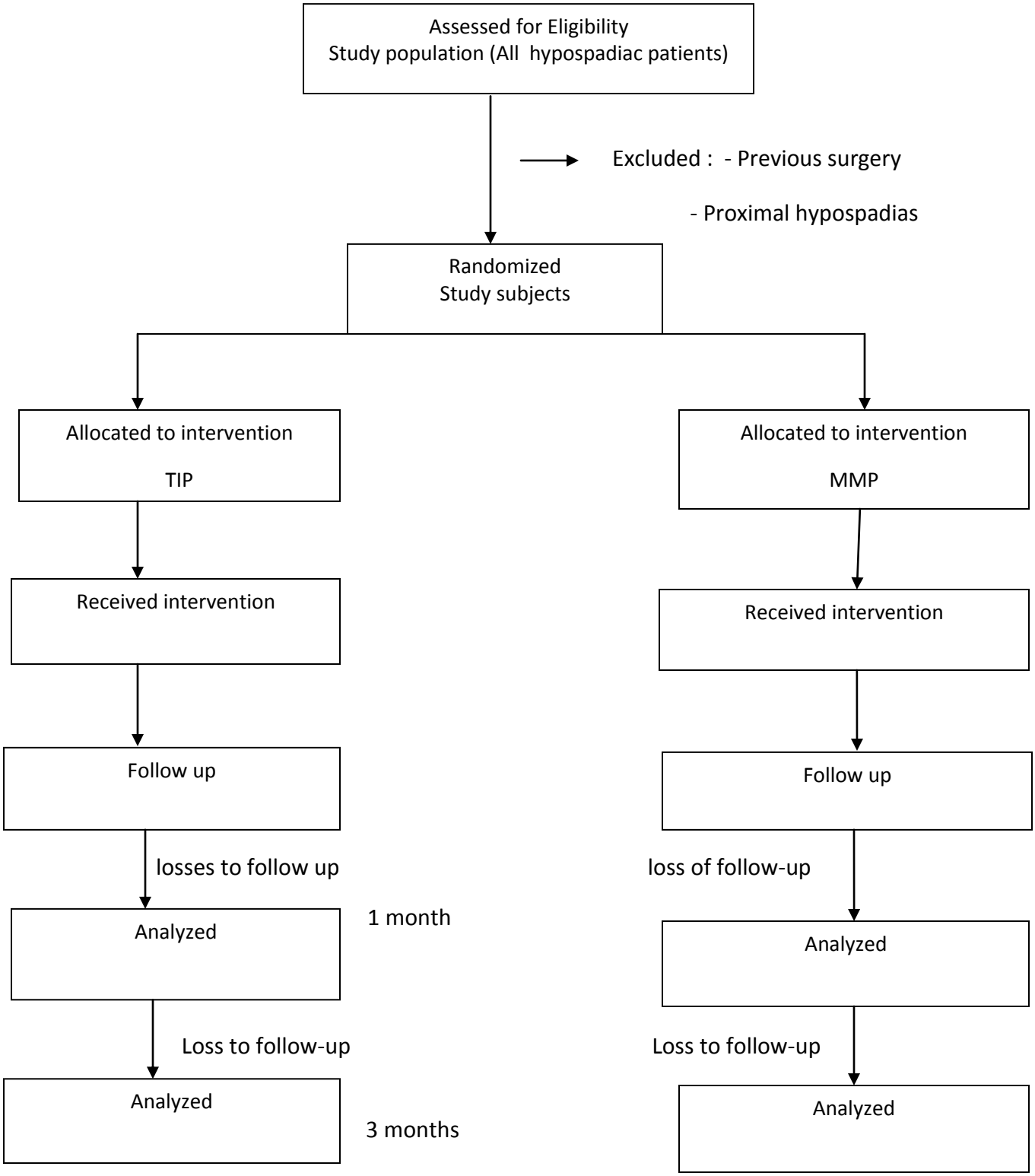
The quality of life after each surgery is obviously associated with the presence or not of post-operative complications. Urethrocutaneous fistula, the most common of them, will need reoperation. Meatal stenosis, urethral stricture might lead to recurrent urinary tract infection even to renal impairment. The meatal stenosis will necessitate a regular meatal dilatation or a meatoplasty and the urethral stricture is likely to undergo a reoperation.

There is no consensus regarding optimal timing of hypospadias repair. The American Academy of Paediatrics recommend surgery be performed between 6 and 12 months[4].

The cost of each procedure in a private hospital in Harare is estimated at around 2000 USD for a 3 day hospital stay. Because of a longer operative time for Modified Mathieu procedure, its cost is relatively higher around (200 USD) than the Snodgrass procedure.

Chapter 3 Methodology

3.1 Study Design: this is a randomized clinical trial.



Methodology

Our study population is constituted of out patients seen in different institutions namely Harare Central Hospital, Parirenyatwa Group of Hospitals, Avenues Clinic, Saint Anne's Hospital during the period starting from January 2006 to February 2008. Patients with primary distal hypospadias were included. Those with proximal hypospadias or who have had previous hypospadias repair (Secondary hypospadias) were excluded. A written consent was obtained from the parents (appendix 3a & 3b. Those included were then randomly allocated to interventions: the tubularized incised plate procedure TIP also called Snodgrass or to the Modified Mathieu procedure (MMP). The patients were reviewed a week after discharge and then monthly up to 3 months. At each visit, the complications were recorded on the data collection card (appendix I).

3.2 Setting

This study was conducted at Harare Central Hospital, Parirenyatwa Group of Hospitals, St Annes Hospital and Avenues Clinic.)

3.3 Sample, Sample Size, Sample Selection

***Sample*:** The sample was of boys with distal hypospadias who had not undergone previous hypospadias repair.

***Sample Size*:** Stata version 10 was the statistical package used to calculate the sample size. Considering the complication rate in distal tubularized incised plate (TIP) repairs for many authors[9,10,16] range between 20-24%, this figure is close to 5% for a Modified Mathieu procedure (MMP). Assuming a proportion of 25% and 5% using the Snodgrass (TIP) and

Modified Mathieu (MMP) procedures respectively, with 95% confidence interval to achieve 80% power, a sample size of 59 patients for each arm was calculated using the Pocock formula:-

$$\frac{P1(100-P_1) + P_2 (100-P_2) f (\alpha,\beta)}{(P_1-P_2)^2} = 59 \text{ Patients for each arm}$$

3.4 Procedure

Children with hypospadiac condition constituted our study population. The patients with other types of hypospadias namely proximal, penoscrotal, scrotal or perineal were excluded. Were also excluded distal hypospadias with previous repair.

Only distal hypospadias without history of previous surgery (primary repair) were accepted. The parents were asked to give an informed consent after explanation by the surgical team. None of them declines the offer. Our study subjects, distal hypospadias with no history of previous repair, were then randomly allocated the treatment namely TIP or MMP. These eligible patients were then randomized in this way: sealed envelopes with the name of the technique were placed in a box, twenty per group (block) and half the number for each technique. An independent person, that is the nurse in the Paediatric ward, was asked to pick up an envelope. A number on a listing starting from 501 to 618 (118 patients) was then assigned to technique (patient). At the same time a data collection card (appendix 1) was established. On this data collection card only appear the patient's name and the number assigned on the list but not the technique itself (MMP or TIP) so that we achieve the masking. This card was kept by the surgeon who then collected all useful information on every patient's

visit. The surgery was done under general anaesthesia and all patients were operated by the same surgeon in four different institutions (Harare Central Hospital, Parirenyatwa Group of Hospitals, Saint Annes Hospital, Avenues Clinic).

3.5 Data Collection

The record cards were kept by the surgeon. On each card appear the patient's name and his number on the list. At each post-operative visit, information (complication) was consigned on the card. The list with number equivalent to the technique that was undertaken and the record cards were only matched at the time of data analysis during which the abbreviations for the surgical procedures ''TIP'' or ''MMP'' were then revealed and added on the record cards, thus matching the patient's name, the number equivalent to the technique that was done. The student's t-test was used to assess the difference in mean age between the population of patients with complications under TIP and MMP. The Chi- square test for independence was used to assess the association between the surgical technique used and the development of a complication. The relative risk (RR) of developing a complication among the patients who received the (TIP) and the MMP was assessed using the RR ratio.

3.6 Ethical Clearance:

The clearance was obtained from the Harare Central Hospital ethical committee, also the joint research ethical committee gave its clearance.

5.7 Budget for the study

The author used his personal funds to finance this study.

Chapter 4 Results

4.1 Baseline characteristics

4.1.1. Demographic characteristics

From January 2006 to February 2008 approximately 2200 patients were seen per year at Harare Central Hospital out- patient clinic, this brought to a figure of 4400 patients seen during the study period. The study population- hypospadiac patients- were 162 patients. Patients with proximal hypospadias or those who were previously operated were excluded. This brought the number of study subjects to 83 patients. The TIP technique was randomly allocated 44 patients and the MMP was allocated 39 patients. Of all patients, 81 (97.6%) were black, 2(2.4%) were white. The mean age for the patients was 7.5 years, ranging from 2 to 13 years. As per the operative time, the mean operative time varied from 90 ± 24 minutes for TIP to 101 ± 25 minutes for MMP.

4.1.2. Location of ectopic meatus in distal hypospadias

Table 1 below summarizes the location of the ectopic or abnormal meatus among the patients that had distal hypospadias. The distribution according to the age group is shown in the table2.

Table 1: Location distribution of ectopic urethral meatus per group.

Baseline characteristics	Type of procedure				P Value
Urethral Meatal Location:	Snodgrass (N=44)		Modified Mathieu (N=39)		
	N	%	N	%	
Glanular	19	(43.18)	14	(35.89)	.786
Coronal	17	(38.63)	17	(43.58)	
Subcoronal	8	(18.18)	8	(20.51)	

Patients were distributed according to their age group as shown in table 2.

Table 2: Distribution per Age group.

Age (Years)	TIP		MMP		P Value
	N	%	N	%	
2 – 4	21	(47.72)	19	(48.71)	P=.159
5 – 7	14	(31.81)	13	(33.33)	
8 – 10	6	(13.66)	7	(17.94)	
11 – 13	3	(6.81)	-	-	
	44	(100)	39	(100)	

4.2 Clinical outcomes

None of the patients allocated to intervention declines the offer. During the first week after discharge, 41 patients from the TIP group and 39 from the MMP group were reviewed. There were 3 losses to follow up from the TIP group and none from the MMP group.

4.2.1 Success Rate at first month

The success rate refers to those patients who were free of complications after surgery. It was 28 out of 41 (68.29%, 95% CI (52.79%-83.79%) for TIP and 30 out of 39 (76.92%, 95% CI (64.9% - 90.87%) for MMP (P=.128).

4.2.2 Complication Rate at first month

A total of 13 out of 41 patients 31.7%, 95% CI (17.71%-46.71%) for TIP and 9 out of 39 patients 23.07 %, 95% CI (9.17%-38.71%) for MMP had complications (P=.128).

Table 3a: Comparison of complications between TIP and MMP at 1st month

Complications	Type of Surgical Technique		P Value
	TIP	MMP	
	N (%)	N (%)	
MS	4 (9.75)	2 (5.12)	.479
US	6 (14.63)	2 (5.12)	.114
UCFs	3 (7.31)	3 (7.69)	.526
UD	-	2 (5.12)	
PC	-	-	-
WB	-	-	-

NB. N: number; %: percentage
MS: meatal stenosis; US: urethral stricture; UCFs: urethro-cutaneous fistulas; UD: urethral diverticulum; PC: penile curvature; WB: wound breaking.

Success rates at 3 months

At the end of the three months period, 28 patients (68.29%) were free of complications from TIP group and they were discharged, whilst 6 patients (14.6%) were lost to follow up. From the MMP group, 29 patients (74.35%) were discharged without complications and 6 patients (15.38%) were lost to follow up.

Complication rates at 3 months

In the TIP group, 14 patients (34.14%) with complications were rescheduled for re-operation and 5 (12.19%) were lost to follow up. In the MMP group, 9 patients (23.07%) with complications were booked for reoperation and 3 (7.69%) were lost to follow up. The complication rates between the two groups were 34.14%, 95% CI (20.08-50.59) for TIP versus 23.07%, 95% CI (11.13-39.33) for MMP.

4.2.3 Complication – comparison

Table 3 b: Comparison of Complications between TIP & MMP at 3rd month

Complications	Type of Surgical Technique		P Value
	TIP	MMP	
	N (%)	N (%)	
MS	4 (9.75)	2 (5.12)	.676
US	6(14.65)	2 (5.12)	.455
UCFs	4(9.75)	3(7.69)	1.000
UD	-	2 (5.12)	
PC	-	-	-
WB	-	-	-
	14/41	9/39	

NB. N: number; %: percentage
MS: meatal stenosis; US: urethral stricture; UCFs: urethro-cutaneous fistulas; UD: urethral diverticulum; PC: penile curvature; WB: wound breaking.

Table 4: Complications in TIP Group in this study as compared to other studies

Complication Rate (TIP)	UCFs	MS	US	DIVERTICULUM
Snodgrass WT[4] (1996)	3%	2%	-	-
Holland et.al[4] (2000)	12%	6%	-	-
Savonelli et.al[4] (2004)	15%	4%	-	-
This study	9.75%	9.75%	14.65%	

NB. N: number; %: percentage
MS: meatal stenosis; US: urethral stricture; UCFs: urethro-cutaneous fistulas; UD: urethral diverticulum; PC: penile curvature; WB: wound breaking.

Table 5: Complications in MMP Group in this study as compared to other studies

	UCFs	MS	US	Diverticulum	WB
Abdul Ghafoor B[11]	16%	4%	-	-	-
Shashzad S M[12]	9.38%	3.12%	3.12%	4%	-
Moradi M[7]	5.55%	0%	-	-	-
This study	7.69%	5.12%	5.12%	5.12%	-

NB. N: number; %: percentage

MS: meatal stenosis; US: urethral stricture; UCFs: urethro-cutaneous fistulas; UD: urethral diverticulum; PC: penile curvature; WB: wound breaking.

CHAPTER 5 DISCUSSION

Hypospadias has a high prevalence worldwide of approximately 1 patient per 300 live births[1,2,3,4]. This is an indication of the need for a safe and proper surgical management to prevent further disabilities and psychological conflicts in the affected children.

The demographic characteristics from this study did not show any statistical significant difference with other study populations even though we had more black children than Caucasians among our patients (P=.159).

The location of the ectopic urethral meatus in distal hypospadias can make a big difference in terms of outcomes. The degree of the operative difficulty being high with the most proximal meatus. The age of the patient also plays a critical role in the outcome of the operation: the smaller the penile size the more difficult is the tissue handling during the urethral reconstruction. More younger patients in one group would have meant more complications in that particular group. The randomization helped us to eliminate this selection bias

The difference between the two groups, in terms of location of the ectopic urethral meatus, was not statistically significant (P=.786) (Tab1), and it shows the same outcome when patients' age is considered (P=.139).

The operative time was shorter in the group of children operated with the Snodgrass procedure. This was also seen in reports by Moradi and Oswald[5,6,7]. Hence the timing in the surgical procedure may predispose to choose this technique as it exposes to lesser anesthetics time and potential ''iatrogenic" complications.

In both techniques, penile curvature (PC) and wound breaking (WB) were not observed. We did not compare the cosmesis between the two techniques. We found no significant difference when comparing the proportions of patients who developed complications following the two surgical techniques (P=.105). The t-test showed that there was no difference between the population of patients presenting with complications under TIP and the population of patients under MMP (P=.483)

Association between surgical technique and complication rate

A Chi-square test for independence showed that there was no significant association between the surgical technique and the development of a complication (P = .117). However, the relative risk (RR) of developing a complication among the patients who received the TIP was 1.48 times higher than those who received the MMP (95% CI (0.90-2.80). This confidence interval included 1, indicating that there was no statistically significant difference in the risk of developing a complication between the two surgical techniques.

Association between surgical technique and type of complication

Using Fisher's exact test, there was no significant relationship between the surgical technique and the type of complication that developed post-operatively (P=.398).

The difference in success rates between the two groups 68.29%, 95% CI (54.20-84.5) for TIP Group versus 74.35%, 95% CI (57.18-89.91) for MMP was not statistically significant.

We found urethrocutaneous fistulas and meatal stenosis (9.75%), whereas (14.65%) in urethral stricture were among the main complications and they are similar to the ones reported by Holland and Savanelli[4] with regard to the TIP group.

In the MMP group, our complications as compared to other studies vary from 5.13% to 7.69% for diverticulum, urethral stricture and urethrocutaneous fistula[9,10,11,12]. This may look a lot at first glance but in comparison to other reports, the difference is not significant. The combined loss to follow up represented 29.98 % from both groups and some reasons were advocated to this quite high figure: long distance to cover from the referral hospital, parents satisfied at first visit could not find another good reason to come back to the hospital, or simply a change of health provider.

The success rates were not different between the two groups and this prompts the question of which is the best technique for the patient in our setting, an issue also raised by many authors in other studies[6,9,12,13,14]. Indeed, the MMP has some technical advantages and among them the fact that the suture lines of the flip-flap are laterally located. This presentation allows the suture lines to be buried deeper in the granular groove created by excision of some spongiotic tissue. The granular suture line does not overlap the suture lines of the flap thus, reducing the risk of fistula formation. This is not the case with the Snodgrass procedure where the tubularization suture line overlaps the glandular suture lines[15,16]. Some authors find that the two suture lines necessary for the flap are increasing the risk in Mathieu procedure[6]. Fortunately, to reduce the risk of fistula in both techniques, a layer of subcutaneous tissue is used to cover the neurourethra. Snodgrass WT has reported that his fistula rate was reduced from 33% to 11% when performing two-layer urethroplasty in proximal hypospadias[6]. Of note is the fact that the distal urethral plate tubularization in the Snodgrass procedure is done in 1980 according to Thiersch-Duplay, a technique that results in a high fistula rate of between 10% and 65%[16].

The major innovation in the Snodgrass technique is the incision of the urethral plate, called relaxing incision, which widens the urethral plate in order to facilitate the tubularization; this technique was also described long before by Ordeszewski (1987)[2,3,4]. This urethral split leaves a raw area on the roof of the urethra that should subsequently epithelialize. In 1998, a modification called the Snodgraft was added to the technique. This innovation simply means that some urologists still believe in the relaxation incision as possible source of stricture of the Snodgrass technique which we also experience in our practice.

Braga[6] analyzing the overall complication rate including fistula, meatal stenosis, recurrent ventral curvature in TIP and Mathieu procedures pointed out some conflicting results among different studies. Some results show that the Snodgrass repair was associated with a lower complication rate and others show that fistulas were less common after Mathieu procedure as compared to the TIP technique.

However, Mouriquand P, Snodgrass WT, evaluated two specific complications namely the meatal stenosis and the urethrocutaneous fistula in distal hypospadias repair using the Snodgrass technique found that multiple layer closure and use of a preputial flap results in a significantly improved complication rate[1,17].

The opinions differ concerning the indication of these two techniques. For some authors the Snodgrass technique is associated with lower complication rate, while other studies demonstrated that fistulas occurred less often after the Mathieu procedure rather than following the Snodgrass technique[5,6,7,9,13]. Snodgrass WT presented a 3% fistula rate for distal hypospadias repair.

Minevitch et al[10] found that the Mathieu repair technique is well established and provides excellent cosmetic and functional results. He went on to conclude that it should be the standard by which distal repair is judged. El-Saket[13] in his early experience reported a very high fistula rates in both techniques, 25% versus 75% in TIP and Mathieu respectively. Shahzad et al. had 0% meatal stenosis in TIP technique and 3.12 % in Mathieu's technique. Their overall complication rate was 6.2% for TIP repair and 21.87% for Mathieu's repair. They concluded that they were satisfied with the TIP technique but applied the Mathieu technique when there was not a healthy urethral plate available. Moradi et al. found no significant difference in fistula formation, 2.63% versus 2.7% and a total complication rates of 2.63% versus 3.6% between the two groups. They had a high success rate than in Snodgrass, 94.45% versus 80.02% ($p > 0.05$). Their conclusion was that these techniques were as effective as each other[7].

Chapter 6 Conclusion, Limitations and Recommendations

Distal hypospadias is a common condition in our environment compared to proximal hypospadias. The diagnosis is easy and should be a reason for early referral. The Snodgrass procedure and the Modified Mathieu procedure have both merits in terms of less complication rates in experienced hands.

At the end of a three month period, this study showed a fistula rate of 9.75% versus 7.69% (P=0.526) and an overall complication rates of 34.14% versus 23.07% for TIP and MMP respectively. The difference was not statistically significant. The complete sample size (N=118) was not achieved, instead only 83 (70.33%) eligible patients were enrolled. We need a larger number of patients to provide more power and also find a way to reduce the percentage of loss to follow up (23% versus 26%). Some authors find that there is no clear consensus on the ideal method of repair for distal hypospadias. In our practice, we continue to use both techniques.

What motivates the author to use either of the techniques depends on the quality of the urethral plate. If the urethral plate is healthy but not wide enough, the choice will go to the Modified Mathieu Procedure, but if it is healthy and large, the Snodgrass will be a better choice. In case where the two techniques are all qualified the choice for one of the techniques will be dictated by the surgeon's skills and experience in either of the techniques

We have come to the conclusion that both techniques are safe but the mean operative time is shorter for the Snodgrass technique. Like Gonzalez R, many surgeons think that the gold standard for distal hypospadias repair has not yet been determined and that the two techniques are as effective as each other.

Hope is that the experience that comes with time will continue to improve the success rate in both techniques. However, the Modified Mathieu procedure has been applied for a very long period of time and has brought more satisfaction in this practice.

Hence at this point, our study cannot yet bring to an end the controversy about the superiority of one technique to another. A bigger sample from a larger recruitment area will be needed before we can reach a safe recommendation.

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Appendix 3a

BSS CONSENT FORM C

TITLE OF RESEARCH PROJECT: Distal hypospadias Repair : Comparison of Snodgrass versus Modified Mathieu

MRCZ# NUMBER

WARD :
STUDY NUMBER :

Explanation of the Research Project

We are asking you to enter a research project with CEU (Clinical epidemiology unit/university of Zimbabwe). The reason for this research is to try to find out the best technique to help the children affected by that condition (distal hypospadias).

Procedure

There are two surgical techniques Tubularized-Incized Plate (TIP) – Modified Mathieu Procedure (MMP).

Risk and Discomforts

There is no danger found in participating in this program if you decline participating on the study the treatment of your child will not be affected.

Benefits

In the future we will be able to choose the best technique without doubt and help better our children who are affected by this common condition in our population.

Confidentiality

The discussion as well as the different results will remain secret; we will be using a number only.

Whom to Contact

In all questions that you might have or want to ask concerning this project, you can talk to DR KABEYA on telephone number (04) 795491/2 or 0772255911. You can also contact the Medical Research Council of Zimbabwe on telephone number (04) 791792 or fax 253979.

If you choose to participate in this program, put your signature below, we shall give you this form to keep it.

Participation in this Research is voluntary. You are to decline to be in this study, or to withdraw from it at any point.

Date: …….. Parent's signature: …….

Date: …….. patient Obtaining Consent: ……..

Note: The interviewer must retain one copy of the signed Consent form on file and must give one copy to the Participant.

BSS Consent form C Appendix 3b

TITLE OF RESEARCH PROJECT: Distal Hypospadias Repair : Comparison of Snodgrass versus Modified Mathieu

MRCZ# NUMBER :
WARD :
STUDY NUMBER :

Explanation of the Research Project
Tiri kukukumbirai kuti mupinde muchirongwa che Research Project ne CEU (Clinical Epidemiology Unit/University of Zimbabwe) nezve Distal Hypospadias Repair (Comparison of Snodgrass versus Modified Mathieu. Chinangwa chechirongwa chino ndechekuedza kutsvaga chirongwa chakanakisisa kukunda chimwe kuti tibatsire vana vaduku vanorwara nechirwere ichi (Distal Hypospadias).

Procedure
Tine zvirongwa zviviri zvekuti tiongorore chirwere zvinoti Tubularized-Incized Plate (TIP) ne Modified Mathieu Procedure (MMP.

Risk and Discomforts
Hapana njodzi inowanikwa mukupinda muchirongwa chino, kana dai mukaramba kupinda muchirongwa mwana wenyu haaregedze kurapwa nanamazvikokota.

Benefits
Nekufamba kwenguva mumazuva anotevera tinenge tichizosarudza chirongwa chinokodzera pasina kutya tobatsira kurapa vana vanechirwere ichi mumanharaunda ose enyika.

Confidentiality
Hurukuro yatichaita uyezve nezvimwe zvatichaongorora zvichange zviri pakati penyu nesu chete pasina mumwe anozviziva. Tichange tichishandisa nhamba chete.

Whom to Contact
Mumibvunzo yese yamuchange muinayo kana yamuchazoda kubvunza maererano nechirongwa chino, munokwanisa kutaura na Dr Kabeya panhamba dzerunhare dzinoti (04) 795491/2 kana 0772255911. Munokwanisazve kutaura neve Medical Research Council of Zimbabwe panhamba dzerunhare dzinoti (04) 791792 kana Fax 253979.

Kana muchinge masarudza kutora nzvimbo muchirongwa chino, nyorai signature yenyu pazasi, tichakusiirai bepa rino kuti murichengete.

Kupinda muchirongwa chino hakumanikidzwe makasununguka kuregedza kutora nzvimbo muchirongwa chino, kana kurega kuenderera mberi chero nguva ipi zvayo.

Zuva ……. Runyorwa rwemubereki …….....

Zuva ……. Murwere ari kubvuma ……

Cherechedzai: Munhu achabvunza mibvunzo achasara nebepa rimwe chete rakaiswa runyoro rwechibvumirano chenyu orichengetedza, uye rimwe racho okupai.