

# **COMPARISON OF NON-MESH (DESARDA) AND MESH (LICHTENSTEIN) METHODS FOR INGUINAL HERNIA REPAIR AT MULAGO HOSPITAL**

**A SHORT-TERM DOUBLE-BLIND RANDOMISED CONTROLLED TRIAL**

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## DECLARATION

I declare that this study is original and has not been published and/or submitted for any other degree award to any university before. The views expressed herein are mine unless otherwise stated, and where such has been the case, acknowledgement or reference has been made.

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The dissertation entitled: “*Comparison of non-mesh (Desarda) and mesh (Lichtenstein) methods for hernia repair at Mulago hospital: a double-blind randomised controlled trial*” has been submitted with our approval as Makerere University supervisors.

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## **DEDICATION**

To my parents, Mr Boaz Musingo and Mrs Mary Musingo who toiled day in and day out to ensure that I got the best education opportunities.

To my dear wife, Shakilah, for the love, unwavering support and encouragement that enabled me to focus on this programme.

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## **LIST OF ABBREVIATIONS**

<b>ANOVA</b>	Analysis of Variance
<b>BMI</b>	Body Mass Index
<b>EOA</b>	External Oblique Aponeurosis
<b>POD</b>	Post-Operative Day
<b>SOPD</b>	Surgical Out-Patient Department
<b>VAS</b>	Visual Analogue Scale

## OPERATIONAL DEFINITIONS

**Desarda's Repair-** it is a technique of inguinal hernia repair that involves reinforcement of the posterior wall of the inguinal canal with a strip of External Oblique Aponeurosis (EOA). It is a pure tissue repair and theoretically believed to be free of tension. It does not require implantation of a foreign material like a mesh.

**Giant inguinal hernia-** This is an inguinal hernia which extends beyond the mid-point of the inner thigh in the standing position.

**Lichtenstein Tension-free technique-** it is a technique of inguinal hernia repair that involves reinforcement of the posterior wall of the inguinal call with a mesh (prosthesis made of polypropylene material). It is free of tension and is considered as the Gold Standard technique for inguinal hernia repair.

**Normal Gait-** The ability to walk comfortably or move freely after surgery (as measured by ability to bend, squat, kneel, stoop, climb a staircase, to drive, to carry luggage weighing 10kg or more).

**Operative Time-** Duration of the repair- will be started at the beginning of a particular repair technique after herniotomy has been performed, and ends when the last stitch of the repair is knotted, before closing the other layers of the wound.

**Primary inguinal hernia-** An inguinal hernia on which no previous operation has been performed.

**Short-term-** A follow-up period of up to 14 days from the day of surgery.

**Wound Sepsis-** Presence of purulent discharge from the wound

## ABSTRACT

**Comparison of non-mesh (Desarda) and mesh (Lichtenstein) methods for inguinal hernia repair at Mulago Hospital: a short-term single-centre double-blind randomised controlled trial.**

**Background:** Despite the high burden of inguinal hernias in Uganda, and the total embrace of the tension-free mesh techniques in the developed countries, hernia repair in Uganda is still based on the traditional modified Bassini method which is attended by postoperative acute and chronic groin pain and high recurrence index. While the on-lay mesh (Lichtenstein) is considered as a gold standard method of hernia repair, its use has remained low in the developing countries because of its prohibitive cost. The Desarda technique is affordable, simple, and easy to do and learn. It does not require complicated dissection or suturing, and it is not associated with tension on the suture line. There was need to evaluate its effectiveness in Uganda by comparing it with Lichtenstein technique. Since short-term outcomes of hernia repair predict the medium and long-term outcomes, they were investigated in this study.

**Study Objectives:** To compare the short-term outcomes of the mesh (Lichtenstein) and non-mesh (Desarda) methods of hernia repair, with regard to acute postoperative pain, day of return to normal gait, operative time and complications.

**Methods:** This was a double-blind randomised controlled study. Participants aged between 18 and 82 with reducible, primary inguinal hernias presenting to the Surgical Out-patient Department (SOPD) of Mulago National Referral Hospital, Uganda were recruited between early April 2009 and July 2009. The participants who met the inclusion criteria were randomly allocated to each of the study arms (Desarda and Lichtenstein). The participants and outcomes assessor were blinded to the treatment method offered. Postoperative acute pain was assessed with the help of a Visual Analogue Scale (VAS) at 1-2hrs, 3 days, 7 days and 14<sup>th</sup> postoperative day. Gait and Postoperative complications were assessed on the 7<sup>th</sup> and 14<sup>th</sup> POD. Data entry and analysis were done with Epidata-Entry 3.1 and STATA 10 packages. Analysis was based on the intention-to-treat design. Mean pain score, day of return to normal gait and operative time were compared using a student's *t*-test. Comparison of complication rates was performed by  $\chi^2$  (chi-square) or Fisher's exact test. Bivariate and multivariate analysis using *t*-test,  $\chi^2$ , analysis of variance (ANOVA) with Bonferroni tests and multiple regression analysis were done to evaluate

the influence of baseline factors on the key outcomes. The power of the study was set at 80%, confidence interval at 95% and a two-sided P value of less than 0.05 was considered statistically significant.

**Results:** There were 101 participants of which 13 (12.9%) were females. Fifty one participants were allocated to the Lichtenstein study arm and 50 were allocated to the Desarda arm. Three participants were lost to follow up (two in the Lichtenstein group and one in the Desarda group). The baseline characteristics were similar in the two study arms. There was no significant difference in the mean pain score between the study arms [3<sup>rd</sup> postoperative day: 3.33±1.75 for Lichtenstein and 2.73±1.64 for Desarda. Effect size (95% CI): 0.59 (-0.088 – 1.272) and the scores on the 7<sup>th</sup> POD were 1.31±1.19 for Lichtenstein and 1.31±1.34 for Desarda, effect size (95% CI): 0.00 (-0.509 – 0.509)]. No difference was observed in regard to mean day of resumption of normal gait [2.44 ±1.62 for Lichtenstein and 2.06±1.13 for Desarda, effect size (95% CI): 0.08 (-0.030 – 0.193)]. A significant difference was recorded in regard to operative time- with the Desarda repair taking a remarkably shorter duration [15.9 ±3.52 minutes for Lichtenstein repair and 10.02 ±2.93 minutes for Desarda's repair, effect size (95% CI): 5.92 (4.62 – 7.20), P=0.0001]. Complication rates were similar in the two study arms.

**Conclusion:** The study showed that the efficacy of the Desarda technique in respect of influencing the early clinical outcomes of hernia repair is similar to that of Lichtenstein method. However the operator in this study showed that the Desarda repair takes a significantly shorter operative time. Thus in the face of resource constraints, Desarda's repair may be considered a more cost effective method.

# CHAPTER ONE

## 1.0 Introduction

### 1.1 Background

The surgical treatment of inguinal hernias has evolved through several stages to reach a modern and successful era. It has been said that the history of groin hernias is the history of surgery itself[1]. The majority of patients in Uganda and in most other African countries present to the hospital after complications like obstruction and pain have developed. These undergo emergency operations often with unacceptably high rates of postoperative complications[1, 2].

Inguinal hernias are still the most commonly seen surgical condition in the outpatient departments of hospitals in Uganda. In Mulago Hospital, emergency hernia operations constitute 68%[2] of the inguinal hernia surgery done. A similar situation is prevalent in Ghana, where only two out of ten patients who require surgery get operated[1]. In Uganda an estimated seven patients are seen in surgical outpatient department (SOPD) on each clinic day, but only two may be operated[3].

Several techniques have been employed in the treatment of inguinal hernias, since Bassini first described his method in 1887. The techniques range from the tissue-repairs such as modified Bassini, Iliotibial tract repair, Shouldice, Nylon-Darn, Halsted-Tanner and McVay, to the tension-free herniorraphies that involve the use of a mesh implant[4]. In Uganda, Bassini repair is still widely used despite its shortcomings[2, 5].

Despite the large armamentarium available for treatment of this common condition, no surgeon has ideal results, and complications such as postoperative pain, nerve injury, infection, and recurrence continue to challenge surgeons[4]. In Uganda, the wide use of Bassini repair presents us with undesirable complications of tension repairs like chronic groin pain and high recurrence rates[2]. The use of a mesh for repair is not widely practised in most African countries because of its prohibitive costs. The Shouldice method which closely compares with the mesh repair is also rarely used in Uganda, probably because of the complexity involved in tissue dissection and repair.

The Desarda's technique of inguinal hernia repair acclaimed by its developer, Prof. Desarda, who has used it since 1990, seeks to get over the challenges faced with the use of the tension tissue-

repair and mesh repair techniques. It is based on the concept of providing a strong, mobile and physiologically dynamic posterior inguinal wall. The technique is simple, easy to learn and do. It does not require complicated dissection or suturing. There is no tension on the suture line. It does not require any foreign material and does not use weakened muscles or transversalis fascia for repair. The results are superior to those previously published in the field of hernia surgery[6-8].

The effectiveness of the Desarda technique has not been sufficiently investigated in Uganda. There are no sufficiently large data from randomised comparative studies to consult. There are reports of its excellent results from the ongoing clinical trials in Poland, Cuba, South Korea, Albania and India[6]. Situma, in a randomised controlled study at Mulago, found no significant difference in short-term outcome between modified Bassini and Desarda's repair in regard to postoperative acute pain and resumption of normal gait[9].

To validate the use of the Desarda's repair in Mulago Hospital and Uganda at large, its comparison to the open mesh (Lichtenstein)- the criterion standard must be established. The purpose of this study is thus to attempt to establish the influence of this new technique on early clinical outcomes of inguinal hernia repair, and if proved to be effective it will be a basis for the promotion of its use in Uganda.

### ***1.2 Problem Statement***

Inguinal hernia is a public health problem in Africa, with an estimated prevalence of 7%.[1] In Uganda it constitutes a percentage greater than 7% of surgical operations done by both surgeons and medical officers[10]. The condition is so common that reports abound of hernia operations being carried out in the backyards by unscrupulous and untrained people in the developing countries- with disastrous outcomes!

It is also reported that the greater majority of hernia operations in the developing world, Uganda inclusive, are done by non-specialists such as medical officers and medical-assistants (Clinical Officers) [11]. This, coupled with the wide use of the tension tissue-repair methods such as modified Bassini, has resulted in high postoperative morbidity. High indices of postoperative chronic pain, wound sepsis and recurrence rates negatively impact on the quality of life of our patients after the hernia tension- repairs.

The majority of people in developing countries are poor and cannot afford the costs involved in the tension-free mesh repairs[12]. The health policy that stipulates, among other issues, the health infrastructure and strategies for health service delivery in Uganda, does not consider the mesh as an essential medical supply item for hernia repair at the district hospital. For the so 30-50%[13] of Ugandans who live on less than a dollar a day, the cost of hernia mesh repair ranging from shs.200,000 (\$102) to shs.500,000 (\$256) per capita[5] would take him/her more than 100days of starving in order to raise just the minimum amount of money required!

The traditional but fairly efficient tissue-repair methods such as the Shouldice technique, its shortcomings notwithstanding, are rarely performed in Uganda because of the extra skill required in their execution. Sadly, the ratio of surgeon to patient being 1: 260,000- 300,000[14] in Uganda means most of the hernia operations are done by non-specialists. The non-specialists invariably use the “obsolete” modified Bassini method. The use of Desarda’s repair, a relatively newer but affordable “tension-free” tissue-repair technique, with a short learning curve, has not been advanced in Uganda. No study has been done to compare it with the Lichtenstein technique, the criterion standard, in Uganda.

### ***1.3 Justification***

The Desarda technique of hernia repair is based on the concept of providing a strong, mobile and physiologically dynamic posterior inguinal wall. It is a simple technique, has a recurrence rate comparable or even better than that of a mesh repair, and does not produce major complications during or after surgery in the hands of non-consultant doctors[6]. It is associated with a short learning curve, can easily be taught to medical officers and can be done under local anaesthesia.

Desarda technique is reported to offer patients an early ambulation postoperatively without the ensuing pain reported with most tension tissue-repair techniques such as the modified Bassini. It is devoid of some of the complications experienced by some patients with implanted prosthetic material. It also offers a ray of hope for the majority of our resource-constrained patients who can not afford the cost of the prosthetic mesh material.

The purpose of this study is therefore to assess its suitability for the treatment of primary inguinal hernias at Mulago hospital by comparing it with the Lichtenstein technique, which is currently considered as the criterion standard method for inguinal hernia repair. It is hoped to become a suitable alternative to the open mesh (Lichtenstein) repair if it is established that it is associated

with comparable or even better short-term clinical outcomes such as acute pain and postoperative wound sepsis which are direct risk factors for the development of chronic groin pain and recurrence after hernia repair.

#### ***1.4 Research Question***

Is there a difference in the short-term outcome of the Desarda's repair compared to the Lichtenstein technique for the treatment of primary inguinal hernias among adult patients at Mulago Hospital?

#### ***1.5 Research Objectives***

##### **1.5.1 General Objective**

To compare the short-term outcome of the Desarda's repair with the Lichtenstein technique for the treatment of primary inguinal hernias among adult patients at Mulago Hospital.

##### **1.5.2 Specific Objectives**

###### **Primary Objectives:**

1. To compare the short-term postoperative mean pain-score among adult patients with primary inguinal hernias who undergo the Desarda's repair and those who undergo the Lichtenstein technique of hernia repair at Mulago Hospital.
2. To compare the time taken to return to normal gait among adult patients with primary inguinal hernias who undergo the Desarda's repair and those who undergo the Lichtenstein technique of hernia repair at Mulago Hospital.

###### **Secondary Objectives:**

1. To compare the proportion of adult patients with primary inguinal hernias who develop short-term post-operative complications following Desarda's repair and Lichtenstein technique of hernia repair at Mulago Hospital.
2. To compare the operative time between the Desarda's repair and Lichtenstein technique of hernia repair at Mulago Hospital.

## ***1.6 Hypothesis***

*Null:* The mean pain score (on the 3<sup>rd</sup> and 7<sup>th</sup> postoperative day), or the mean postoperative day of return to normal gait is the same in adult patients who undergo the Desarda's repair as in those who undergo the Lichtenstein technique of hernia repair at Mulago Hospital

*Alternative:* The mean pain score (on the 3<sup>rd</sup> and 7<sup>th</sup> postoperative day), or the mean postoperative day of return to normal gait is different in adult patients who undergo the Desarda's repair from what it is in those who undergo the Lichtenstein technique of hernia repair at Mulago Hospital.

## CHAPTER TWO

### 2.0 Literature Review

#### 2.1 Background

Between 600,000 and 800,000 hernias are repaired annually in the United States, making hernia repair one of the most common operations performed by general surgeons[4, 15]. It is estimated that 7% of the population will develop an inguinal hernia world-wide[1]. “Hernia” is derived from the Latin word *herniae* for rupture. A hernia is defined as an abnormal protrusion of an organ or tissue through a defect in its surrounding walls[4].

The surgical treatment of inguinal hernias has evolved through several stages to reach a modern and successful era. It has been said that the history of groin hernias is the history of surgery itself.[1] Despite the frequency of this procedure, no surgeon has ideal results, and complications such as postoperative pain, nerve injury, infection, and recurrence continue to challenge surgeons[4].

The true incidence of hernias is unknown. Approximately 75% of all hernias occur in the inguinal region. Two thirds of these are indirect, and the remainder are direct inguinal hernias. Men are 25 times more likely to have a groin hernia than women. An indirect inguinal hernia is the most common hernia, regardless of gender. In men, indirect hernias predominate over direct hernias at a ratio of 2 to 1. Direct hernias are very uncommon in women. Both indirect inguinal and femoral hernias occur more commonly on the right side. This is attributed to a delay in atrophy of the processus vaginalis following the normal slower descent of the right testis to the scrotum during foetal development. The prevalence of hernias increases with age, particularly for inguinal[2, 4].

In Africa, inguinal hernias represent an entirely different problem compared with their European counterpart. Wilhelm et al. calculated the prevalence of inguinal hernias in Ghana as being as high as 7.7% of the adult male population, while in other parts of Africa it is estimated to be as high as 20% [16]. The elective repair rate is significantly lower because many of these hernias are repaired as emergencies. These repairs carry a high complication rate, with a bowel resection rate of 24% and mortality of 6% for strangulated inguinal hernia[17]. Conversely in Western Europe,

the lifetime risk of developing a groin hernia is estimated at 27% for males and 3% of females, and 90% of these hernias are repaired electively[18].

In a prospective descriptive study involving 280 patients at Mulago hospital in 2000, there were 195 (93.7%) inguinal hernias of which 159 (81.5%) were indirect inguinal hernias and 34 (17.4%) were of the direct inguinal variety. Busoga hernias were diagnosed in only 4 (2.05%) of inguinal hernias. There were only 13 (6.2%) femoral hernias[2].

Modified Bassini technique accounts for 68.2% of primary inguinal hernia repaired in Mulago hospital. Nylon darn accounts for 11.3% and Shouldice's repair is seldom carried out[2].

As a result of the introduction of tension-free surgical techniques, more importance has been given to their outcome in terms of patient postoperative pain, length of hospital stay and quality of life[19]. Since recurrence rates have been reduced with mesh repairs, outcome research in groin hernia repair has recently focused on chronic pain. Chronic pain adversely affects daily life for 5–10 per cent of patients[20, 21]. The intensity of acute pain after herniorrhaphy is related to the risk of developing chronic postoperative pain[20]

Pain is the most common discomfort experienced by patients after an ambulatory inguinal herniorrhaphy. It is influenced by age[22], weight, sex, preoperative pain level, operative technique, hernia anatomy, the extent of nerve entrapment or damage of the ilioinguinal, iliohypogastric, and genitofemoral nerves[23], and other postoperative complications [24, 25].

## ***2.2 Lichtenstein Mesh Repair***

Currently, the Lichtenstein technique is considered to be the criterion standard[26], with recurrence rates of less than 1% in the hands of an experienced surgeon.

Numerous open or laparoscopic tension-free surgical techniques using mesh have been developed. These include Lichtenstein repair (flat mesh patch), Plug and Patch, Kugel (mesh device placed behind the defect) and Proline hernia system. These surgical techniques have been shown to be associated with reduced postoperative pain, a shorter recuperation period and a lower complication index[19]. Existing techniques have very low and acceptable recurrence rates, but chronic pain and discomfort remain a problem for many patients. New mesh materials are being developed to increase biocompatibility[27].

In 1958, Usher et al was the first to perform inguinal herniorrhaphy using prosthetic mesh, thereby eliminating the tension associated with tissue approximation. However, mesh repair did not gain widespread acceptance until Lichtenstein et al coined the term “tension-free” repair and advocated this approach in 1986[28].

The Lichtenstein repair uses two types of mesh, either the lightweight or the heavyweight. Koch et al, in a randomised controlled single-centre clinical trial in Sweden, reported that patients with the lightweight mesh had a shorter convalescence than those with the standard heavyweight mesh[27, 29]. Numerous comparative randomised trials have clearly demonstrated the superiority of the tension-free mesh repair over the traditional tissue approximation method. Mesh implantation in front of the transversalis fascia is superior, safer, and easier than open or laparoscopic mesh implantation behind the transversalis fascia[30]. It has a short learning curve. Even in the hands of non-specialised surgeons, recurrence rates for this technique are reported to be less than 2 per cent[11, 31].

The use of an implant, however, exposes the recipient to a lifelong risk of infection. Implants are prone to bacterial colonisation, and opportunistic infections may occur for up to 39 months after implantation[32].

### ***2.3 Desarda’s Repair***

Factors that are said to prevent herniation are not restored in the traditional techniques of inguinal hernia repair and yet 70–98% of patients are cured[8]. The problem of our age is to find an operation that is simple, does not require implantation of a foreign body like a mesh, has a recurrence rate of less than 1–2% and does not produce major complications during or after surgery in the hands of non-consultant staff[6].

In Desarda’s repair the newly formed posterior wall is kept physiologically dynamic by the additional muscle strength provided by external oblique muscle to the weakened muscles of the muscle arch. This new method of inguinal hernia repair is based on physiological principles[8]. The technique involves pure tissue repair of any type of inguinal hernia, based on the concept of constructing a strong and physiologically dynamic posterior wall to the inguinal canal with the help of the external oblique muscle and its aponeurosis[8]. The operation is simple to perform, with a short learning curve, does not require foreign body like a mesh or complicated dissection of the inguinal floor as in McVay or Shouldice. It has shown excellent results with virtually zero recurrence rates[6]. Many operations developed to date deal only with the anatomical aspects of

the repair. Any failure in these operations is because the physiological aspects have not been considered while developing a new operating technique.

Even though the Desarda's repair has been reported to be associated with pleasantly low postoperative morbidities such as pain, wound sepsis and zero recurrence rate, the findings were majorly based on low evidence-level retrospective and single group prospective studies done by Prof. Desarda himself. However, there are reports from Poland, Cuba, Korea, Albania and India of clinical trials being conducted that have shown similar results without recurrence till date[6]

#### ***2.4 Comparison of Desarda and Lichtenstein Repairs, and other comparative studies***

No comparative studies involving Desarda's and mesh repairs have been carried out in Uganda. However reports from other parts of the world indicate the increasing interest in the Desarda' repair method. Clinical trials are being conducted to compare this new method and the mesh repair techniques[6].

In a district hospital in India, Desarda compared his method to the open mesh repair in a retrospective comparative study involving 269 and 225 inguinal hernias in each arm respectively, and found his method to be superior with fewer postoperative complications, statistically significant shorter hospital stay and earlier return to work. However, this was a retrospective study with a likely bias of the author in favour of his method[7]

In Uganda, unpublished studies comparing Lichtenstein repair & modified Bassini repair by Kyamanywa, and Desarda repair & modified Bassini repair by Situma showed no difference in the short-term outcomes between the modified Bassini method and Lichtenstein technique or Desarda's repair respectively[9, 10]. The short-term outcomes were in regard to resumption of normal gait (4.0 days in the mesh group by Kyamanywa, 3.6 days in the Desarda group by Situma, 1.0 days in the Desarda group by Prof. Desarda), and postoperative pain score (2.8 in the mesh group by Kyamanwa, 2.23 in the Desarda group by Situma and 2 in the Desarda group by Prof. Desarda). Complications such as wound sepsis and wound haematomas were the other short-term outcomes they investigated.

Vrijland et al, in a randomised single centre study of 300 patients, found that there was no statistically significant difference in postoperative pain and the quality of life in mesh versus non-mesh repair methods[33].

There are conflicting results regarding the routine use of antibiotics after groin hernia repairs. Gilbert and Felton concluded from a multi-centre study that the routine use of prophylactic antibiotics did not prove to be of significant benefit in reducing infection rates in elective inguinal hernia, whether or not a mesh was used[34]. While Yerdel et al reported a higher infection rate for those without prophylactic antibiotic cover[35].

Desarda used prophylactic antibiotics (intravenous Ampiclox) for all his patients, assuming that they had poor hygiene at home. Kyamanywa, in a randomised controlled study comparing open mesh and modified Bassini methods involving 88 subjects at Mulago hospital, reported 5% of the patients in the open mesh group developed wound sepsis, whereas no sepsis was reported in the modified Bassini group. However, this was reported as not statistically significant in the two groups. Kyamanywa did not use prophylactic antibiotics were not used in this study[10].

## **CHAPTER THREE**

### **3.0 Methodology**

#### ***3.1 Study Design***

The study was a single-centre, double-blind randomised controlled trial.

#### ***3.2 Study Setting***

The study was carried out at Mulago National Referral and Teaching Hospital which has a bed capacity of 1500. The hospital is a main teaching hospital for Makerere University School of Medicine.

Adult patients with inguinal hernias are seen in the general surgical outpatients department (SOPD) after having been assessed and referred by Medical Officers at Mulago Hospital Assessment Centre. Three general surgical out-patient clinics are run on different days in a week. On average of four new inguinal hernia patients are seen per clinic day[3, 5]. The surgical out-patient has a minor theatre where elective hernia operations are done under local anaesthesia as day-care surgeries. The operations are offered at no cost to the patient.

The general out-patients' clinic is run by a Consultant Surgeon who is assisted by Registrars, Senior House Officers, intern doctors, nursing officers and support staff.

The study was conducted for four months, between April and July 2009.

#### ***3.3 Population***

##### **3.3.1 Target population**

All adult patients with groin hernias who sought treatment at Mulago hospital during the study period

##### **3.3.2 Accessible population**

All adult patients with groin hernias who attended the SOPD during the study period

##### **3.3.2 Study population**

All adult patients who presented in the SOPD with a primary, reducible inguinal or inguino-scrotal hernia and consented to participate in the study.

### ***3.4 Selection Criteria***

#### **3.4.1 Inclusion**

Participants:

- Aged 18 and above;
- with a primary, reducible inguinal or inguino-scrotal hernia;
- who consented to participate in the study; and
- who had a telephone contact

#### **3.4.2 Exclusion**

Patients with:

- Giant inguino-scrotal hernias- because they could not be operated under local anaesthesia.
- Obstructive uropathy or chronic obstructive pulmonary disease- because they are contraindications to elective hernia surgery. They are associated with definite poor outcomes such as high recurrence rates.
- Impaired mental state and were unable to consent and to give an accurate assessment of the key outcomes of the operation.

### ***3.5 Sampling Procedure***

Patients with inguinal hernias seen in SOPD were interviewed and clinical assessment made by the Principal Investigator (PI). The purpose of the study and the methods of treatment were carefully explained to the patients individually. They were allowed to ask questions freely to ensure that they had understood.

Screening (see **appendix V**) for suitability for surgery included history taking, physical examination, requesting for and reviewing the laboratory tests. This was aimed at recording the key research variables (see section 3.9 and questionnaire) and major co-morbidities. Those who did not satisfy the inclusion criteria and had other medical problems were offered the routine care given to all patients in SOPD.

Those who met the inclusion criteria and consented to participate in the study were enrolled in the study until the required sample size was attained.

### 3.6 Sample Size Estimation

48 participants in each study arm were anticipated to be enrolled.

This was determined from the formula (t-test) for sample size calculation for an analytical study with continuous and dichotomous variables[36, 37]:

$$N = [ (1/q_1 + 1/q_2) \times (Z_\alpha + Z_\beta)^2 \times S^2 ] \div E^2$$

Where, **N**- total number of subjects required for both arms

**Z<sub>α</sub>**- Standard normal deviate for **α** (0.05) = **1.96**

**Z<sub>β</sub>**- Standard normal deviate for **β** (0.20) = **0.84**

**E**- Effect Size (Minimum expected difference in the mean values of the key outcome variables i.e. Pain score at the 7<sup>th</sup> POD, or Days to resumption of normal gait postoperatively)

**S**- Standard Deviation (Variability of the key outcome variables of each group) - (assumed to be equal for both groups)

**q<sub>1</sub> and q<sub>2</sub>**- proportions of subjects in each study arm = 50% (**0.5**) in each study arm

#### Previous Studies:

	<b>Pain Score( VAS) on 7<sup>th</sup> POD</b>		<b>Time to Resumption of Normal Gait (Days)</b>	
	<i>Kyamanywa</i> [10]	<i>Situma</i> [9]	<i>Kyamanywa</i> [10]	<i>Situma</i> [9]
Mean Values	1.30	1.41	1.80	1.84
<b>Variability (S)</b>	<b>1.36</b>		<b>1.82</b>	
	<i>Kyamanywa</i> [10]	<i>Desarda</i> [6]	<i>Kyamanywa</i> [10]	<i>Desarda</i> [6]
Mean Values	2.8	2.0	4.0	1.0
<b>Effect Size (E)</b>	<b>0.8</b>		<b>3.0</b>	

#### 1. For objective one (Pain score on 7<sup>th</sup> POD)

q<sub>1</sub>=0.5, q<sub>2</sub>=0.5, Z<sub>α</sub>=1.96, Z<sub>β</sub>=0.84,

S=1.36, E=0.8

Thus:

$$N_1 = [(1/0.5 + 1/0.5) \times (1.96 + 0.84)^2 \times (1.36)^2] \div (0.8)^2 = 58.00 \div (0.8)^2$$

**$N_1 = 90.63 \approx 91$  subjects**

## **2. For objective two (Time to resumption of normal gait)**

$q_1 = 0.5, q_2 = 0.5, Z_\alpha = 1.96, Z_\beta = 0.84,$

S=1.82, E=3.0

Thus:

$$N = [(1/0.5 + 1/0.5) \times (1.96 + 0.84)^2 \times (1.82)^2] \div (3.0)^2 = 103.88 \div (3.0)^2$$

**$N_2 = 11.5 \approx 12$  subjects**

## **3. For Objective three (Complications)**

This was determined from the chi-square test for sample size calculation for an analytical study with only dichotomous variables:

$$N = [Z_\alpha \sqrt{\{P(1-P) (1/q_1 + 1/q_2)\}} + Z_\beta \sqrt{\{P_1(1-P_1) (1/q_1) + P_2(1-P_2) (1/q_2)\}}]^2 \div [P_1 - P_2]^2$$

$P_1$  - Proportion of subjects with complications in Lichtenstein arm [13] = 27.9% = 0.279 = **0.28**

$P_2$  - Proportion of subjects with complications in Desarda arm [12] = 12.7% = 0.127 = **0.13**

$q_1$  - Proportion of subjects in Lichtenstein arm = 50% = **0.5**

$q_2$  - Proportion of subjects in Desarda arm = 50% = **0.5**

$P = q_1 P_1 + q_2 P_2 = 0.205$

$$N = [1.96 \times \sqrt{\{0.205(1-0.205)(1/0.5+1/0.5)\}} + \sqrt{\{0.28(1-0.28)+0.13(1-0.13)(1/0.5)\}}] \div [0.28-0.13]^2$$

**$N = 89$  subjects**

**Sample size for the specific objective one was used in the study.**

From previous studies carried out in Mulago hospital, the loss to follow-up was estimated at 4% [2, 9, 10].

Total number (N) required in the study (with loss to follow-up included):

$$N - 4\%N = N_1 \rightarrow N(1 - 0.04) = 91 \rightarrow N = 91/0.96 = 94.79 \approx 95$$

*Therefore, a total of 95 patients will be enrolled, i.e.  $\approx$  48 in each study arm.*

### **3.7 Randomisation**

#### **3.7.1 Sequence generation**

This was a simple (non-restricted) randomisation. A computer-generated randomisation list (based on the closed-sequence method) was made by a statistician. The numbers represented either Lichtenstein (1-**L**) or Desarda (2-**D**) hernia repair techniques.

#### **3.7.2 Allocation Concealment**

The computer-generated randomisation list drawn up by the Statistician was not revealed to the investigators until after the participant recruitment was completed. The assignments (written on small cards with the codes 1-**L** or 2-**D** for Lichtenstein or Desarda methods respectively) were enclosed in sequentially numbered opaque, sealed envelopes. Thus, each envelope bore on the outside only a sequential number. The envelopes were arranged in a sequential order which was followed from the top (serial number 01) of the batch to the bottom (serial number 96) and were stationed in the records office in SOPD. Only the statistician and PI knew what the number/code signified.

#### **3.7.3 Implementation**

Participants were assigned on an individual basis to both Desarda and Lichtenstein treatment arms. The research assistant was responsible for picking the envelopes for the patient due for operation. The serial numbers on the envelopes corresponded to the serial numbers of the participants as they consecutively got enrolled into the study. At the time of operation the research assistant would pick the corresponding envelope. The envelope would then be given to the theatre staff who would open and remove the small card with the code. The surgeon (PI) would be told the code, and thus reveal the arm to which the patient belonged, at the time of placement of the skin incision. The participant would then be operated accordingly. The used envelopes were then securely kept in a cabinet in the records office of SOPD.

#### **3.7.4 Blinding**

Double blinding (participant and assessor for the key outcomes) was employed. However, intraoperative secondary outcome measures were assessed by the surgeon (PI) himself. Participants were given an option to find out the method used on them two weeks after the operation.

## **Evaluation of Blinding**

Success of blinding was evaluated directly by asking participants which treatment they thought they received. They were also asked to indicate the reason for that belief. The interview was done at 1-2 hours and seven days postoperative and the information was recorded in the part V of the questionnaire. The outcomes assessor blinding was also evaluated. The proportion of correct and incorrect guesses was calculated. The proportion of correct guesses therefore reflected the success of blinding at the end of the study.

### ***3.8 Interventions***

#### **3.8.1 Materials and Procedure**

##### **(a) Preparation**

All the operations were done by me (the PI) under the supervision of a Senior Consultant surgeon (the Supervisor).

An informed consent was obtained from the participant. The visual analogue scale for pain assessment was carefully explained to each participant. The participant was then shaved where necessary. He or she was asked to empty the urinary bladder where necessary, before being asked to lie supine on the operating table. Amoxicillin-Clavulanate 1.2g was administered intravenously in the arm at the start of the operation. None of the participants was found to be allergic to Amoxicillin-Clavulanate, otherwise intravenous Ceftriaxone 1g would have been given.

The participant's abdomen and inguinal areas were prepared using Chlorhexidine solution, from the subcostal transverse line to the mid thigh. Lignocaine Hydrochloride 0.5% (plus Adrenaline 1:200,000) was used as a local anaesthetic in a maximum dosage of 3mg/kg body weight. It was constituted from 2% lignocaine hydrochloride and normal saline in the volume ratio of 1:3.

The lignocaine was used as a local infiltration to block the iliohypogastric, ilioinguinal, and genital branch of genitofemoral nerves at three points centered along a line 2cm above and parallel to the inguinal ligament. The first one was applied at a point 2cm medial to the anterior superior iliac spine; second one at the pubic tubercle and the third one at a point between the two. Some infiltration was also applied in areas along the midline to block nerve fibres that cross from the opposite lower inguinal area.

## **(b) Herniotomy**

The groin skin crease (transverse) incision measuring between 7.5cm and 10cm was employed in every participant, starting 2cm above and medial to the pubic tubercle. This exposed the external oblique aponeurosis (EOA), the superficial inguinal ring and the cord. After achieving haemostasis, the EOA was incised in the line of its fibres, starting at the superficial ring to about 2cm laterals to the deep inguinal ring. Care was taken not to damage the ilioinguinal and iliohypogastric nerves just beneath the aponeurosis.

In the male, the spermatic cord was mobilised by placing a finger around the cord at the level of the pubic tubercle. The cremasteric fibres were divided to free the cord from the underlying structures such as the inguinal ligament. The fascial layers of the cord were picked up between two artery forceps, and a dissecting scissor was used to split open these layers over the anteromedial aspect of the cord. The sac was then identified and dissected free from the cord structures with a combination of sharp by scissors and blunt dissection by gauze stripping, and cleared to the level of the deep ring. The freed cord was drawn away from the field using a hernia ring. In the female, the round ligament was left attached to the sac, both being cleared as far as the internal ring. The hernia sac was then opened and the visceral contents examined and manually reduced.

Traction using three haemostats was applied to the opened margins of the sac bringing the deep inguinal ring and the neck of the hernia sac into view. The sac was then twisted, transfixated and ligated with atraumatic Prolene 2/0 suture. In case of a small direct hernia, the sac was invaginated back into the peritoneal cavity. While for the sliding hernia, the cut edges of the peritoneum were repaired by a continuous atraumatic 2/0 Vicryl suture after reducing the viscus back into the abdominal cavity.

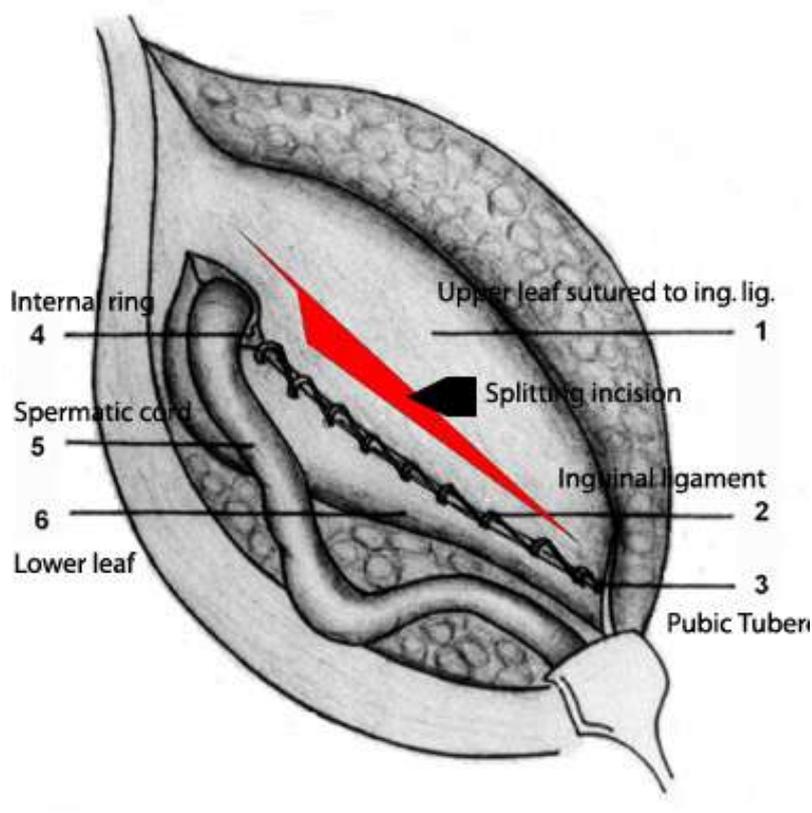
The excess sac was excised about 1cm distal to the ligature, and the cut edges checked for haemostasis before the sac was dropped back behind the aperture in the transversalis fascia. In all large inguino-scrotal hernias the sac was excised and its fundus, adherent onto or continuous with tunica vaginalis, was left in-situ. The repair was then embarked on.

### 3.8.2 Repair Techniques

Timing of the repair was started at the beginning of a particular repair technique after herniotomy had been performed, and ended when the last stitch of the repair was knotted, before closing the other layers of the wound.

#### (a) Desarda's Repair[6]

The medial leaf of the EOA was sutured to the inguinal ligament from the pubic tubercle to the deep inguinal ring using 2/0 Ethilon (Nylon) interrupted sutures. The first 1–2 sutures were taken in the anterior rectus sheath. The last suture is taken so as to narrow the deep ring sufficiently without constricting the spermatic cord (**Fig. 1**)[6].

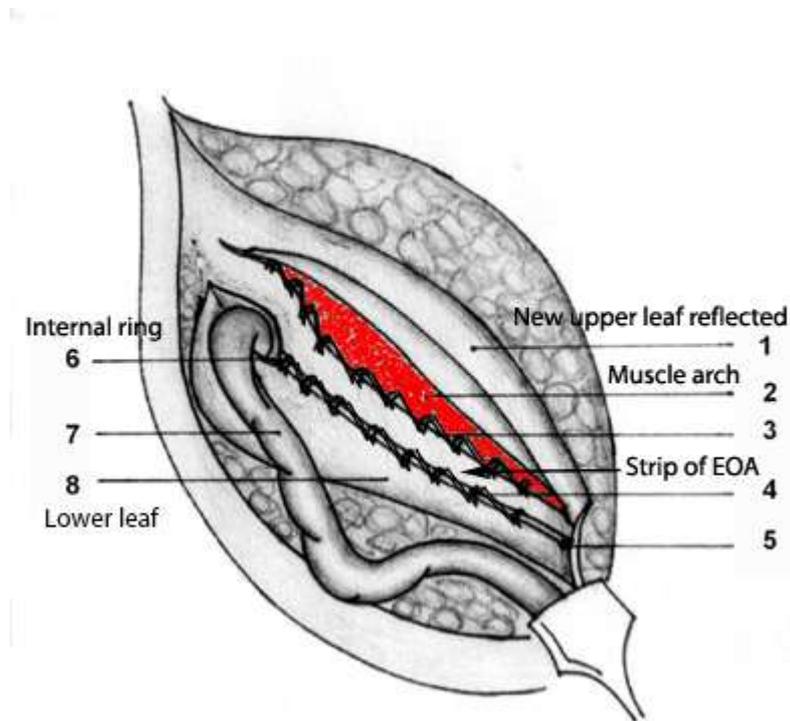


**Figure 1: Illustration of Desarda repair**

*The medial leaf of the external oblique aponeurosis is sutured to the inguinal ligament. 1 Upper (Medial) leaf, 2 interrupted sutures taken to suture the medial leaf to the inguinal ligament, 3 pubic tubercle, 4 deep ring, 5 spermatic cord, 6 Lower (lateral) leaf*

A splitting incision was made in this sutured medial leaf, partially separating a strip of width 1.5–2 cm. This splitting incision was extended medially up to the rectus sheath and laterally 1–2 cm

beyond the deep ring. The medial insertion and lateral continuation of this strip was kept intact. A strip of the EOA was now available, the lower border of which was already sutured to the inguinal ligament. The upper free border of the strip was now sutured to the internal oblique or muscle arch lying close to it with 2/0 Nylon interrupted sutures throughout its length (**Fig. 2**)[6].



**Figure 2: Illustration of Desarda repair**

*Undetached strip of the external oblique aponeurosis forming the posterior wall. 1 Reflected upper (medial) leaf after a strip has been separated, 2 internal oblique muscle seen through the splitting incision made in the upper leaf, 3 interrupted sutures between the upper border of the strip and conjoined muscle and internal oblique muscle, 4 interrupted sutures between the lower border of the strip and the inguinal ligament, 5 pubic tubercle, 6 Internal ring, 7 spermatic cord, 8 Lower (lateral) leaf*

The aponeurotic portion of the internal oblique muscle was used for suturing to this strip wherever and whenever possible without tension; otherwise, it is not a must for the success of the operation. This resulted in the strip of the EOA being placed behind the cord to form a new posterior wall of the inguinal canal. At this stage the patient was asked to cough and the increased tension in the strip is clearly visible. The spermatic cord was placed in the inguinal canal and the lateral leaf of the EOA was sutured to the newly formed medial leaf of the EOA in front of the cord, as usual, again using 2/0 Nylon interrupted sutures. Undermining of the newly

formed medial leaf on both its surfaces facilitates its approximation to the lateral leaf without tension. The first stitch was taken between the lateral corner of the splitting incision and lateral leaf of the EOA. The skin was then closed by interrupted Nylon 3/0 or 4/0 vertical mattress suture, and dressed with two or three layers of haemostatic gauze and elastoplast applied to completely cover the gauze.

### **(b) Lichtenstein's Mesh Repair**

Proline mesh- Monofilament Standard Polypropylene Mesh (PMS3), Size 6 x 11 cm, manufactured by Ethicon was used.

After the sac had been removed, and the cord drawn away, the mesh was fashioned to fit the inguinal canal. A slit 2cm long was made in the lateral aspect of the mesh, and the spermatic cord placed between the two tails of the mesh. The cord was then be tagged in the cephalad direction and the medial end of the mesh was made to overlap the pubic bone by approximately 2cm. The mesh was then sutured to the periosteum of the pubic bone using interrupted Polypropylene (Proline) 3/0 suture. The interrupted sutures were continued laterally, suturing the inferior edge of the mesh to the shelving edge of the inguinal ligament, to a point 2cm lateral to the deep inguinal ring. The superior edge of the mesh was then secured likewise to the internal oblique aponeurosis or muscle approximately 2cm from the aponeurotic edge, while the lower edges of the two tails were sutured to the shelving edge of the inguinal ligament to create a new deep ring made of mesh.

Finally, the cord was allowed to fall back on the strengthened posterior wall of the canal, the aponeurosis of the external oblique repaired with interrupted Proline 3/0 suture and the superficial ring reconstructed to fit snugly around the cord. This was followed by closure of the skin with interrupted nylon 3/0 suture and the wound was then dressed as usual (see Desarda's repair above).

### **3.8.3 Postoperative Care and Follow-up**

After skin closure, 75mg of Diclofenac was injected intramuscularly in the upper lateral gluteal quadrant and the patient discharged on:

- Tabs Diclofenac Sodium 50mg 8hourly for 5days (to be taken after meals). OR Tabs Aceclofenac 100mg 12hly for 5days (for patients with Peptic Ulcer Disease).

- Capsules Ampiclox 500mg 6hourly for 5days.
- Instructions not to open up the wound dressing nor wet it when bathing.
- Instructions to immediately report back to the PI in the event of excessive pain at the incision site, blood, wound discharge, or foul smell arising from the wound.
- Instructions on how to fill the pain VAS at home on the 3<sup>rd</sup> POD were repeated and the patient asked to repeat them for the PI to ensure that they had been understood.
- The patients were allowed drinks as soon as they felt like after the operation (normally 3-4hours after).

The first follow up was done one to two hours after the operation, where pain was assessed using the VAS in part II of the questionnaire. The Patient was then given a copy of the pain VAS to note the level on the third day at home.

The second follow up was done on the 7<sup>th</sup> POD. At this visit part III of the questionnaire was administered and any complications present noted and the assessment of the patient's gait done. The VAS filled at home was also collected at this time. Those who could not read or write would report back verbally. Pain assessment was done based on pain felt in the morning after walking 50-100 metres.

Any complications such as haematomata and scrotal or labial swelling were managed accordingly.

The stitches were then removed and the wound was cleaned with Chlorhexidine solution. The patient was allowed home and was told to report back on the 14<sup>th</sup> POD especially if they had any complications or had not regained normal gait on the 7<sup>th</sup> POD. They were instructed to call the RA or PI, or were called on their mobile phones. Part IV of the questionnaire was then administered.

All patients were instructed not to restrict their normal activities and they could start routine non-strenuous work from 3-4 days after surgery. Patients were told not to drive until 3-4 days after surgery as the foot reaction time does not return to normal until then[6, 38].

### ***3.9 Severe Adverse Events***

Anticipated adverse events included: Lignocaine toxicity, large seromas, severe wound sepsis, large haematomata, spermatic cord injury and acute urinary retention.

For details of prevention and response in case of adverse events, see Appendix V.

### ***3.10 Study Variables***

#### **Predictor Variables:**

- 1) Method of inguinal hernia repair [Mesh (*Lichtenstein*), Non-mesh (*Desarda*)]
- 2) Demographic characteristics: Age, Sex, BMI and Occupation
- 3) Clinical characteristics: Location of hernia, Type of hernia (based on Nyhus classification-*see appendix VI*) and Duration of hernia

#### **Outcome Variables:**

- 1) Pain Score (VAS)
- 2) Time taken to return to normal gait (days)
- 3) Operative time (min)
- 4) Intra-operative complications ( *e.g. vas deferens injury, vessel injury, nerve injury*)
- 5) Post-operative complications (*e.g. wound sepsis, seroma, haematomata, scrotal/testicular swelling, orchitis, others*).

### ***3.11 Data Management***

#### **3.11.1 Data Collection**

Data was collected using a standardised, interviewer-administered questionnaire. The PI together with the RA assessed all the patients. Under the supervision of the consultant surgeon, the PI assisted by a medical officer and a senior nursing officer carried out all the operations. Assessment of the patient for the key outcomes was done by the RA.

The data was edited for completeness, cleaned, coded and entered into a computer using the Epidata-Entry 3.1 and then exported to STATA 10 statistical package for analysis.

### **3.11.2 Data Analysis**

#### **Assessment of Accuracy of Randomisation**

The closed sequence method of random number generation (RNG) was used. The output from the RNG was checked to ensure that the sequence showed no evidence of non-randomicity. This was done by checking the numbers for independence to ensure that there were no particular sequential patterns. The data was not checked for equiprobability, since closed sequence generation inherently provides for equiprobability.

The statistical test used for these checks was the Chi-square Contingency Table test (for independence). Independence was assumed when the two-tailed probability associated with Chi-Square was greater than 0.10 (i.e., there was no evidence of a significant deviation from randomness).

Socio-demographics and other baseline characteristics were assessed for differences in their distribution in each of the intervention arms, using statistical tests of significance (level of significance set at a two-tailed  $P < 0.05$ ).

#### **Baseline demographics and clinical characteristics of the two groups**

The baseline information was presented effectively in tables. For numerical variables, their variability along with average values were reported for each group, and then summarised by mean or standard deviation, or median and ranges if asymmetrical distribution. However categorical variables were reported as numbers and proportions. Bivariate and multivariate analysis was carried out using either parametric or non-parametric tests such as the  $\chi^2$  test,  $t$ -test, Mann Whitney-U test and analysis of variance (ANOVA) whenever appropriate, to evaluate the influence of baseline factors on the key outcome measures.

#### **Objectives one and two: assessment of primary outcome measures**

These were continuous data with a normal distribution and were expressed as mean and compared using a paired  $t$  test.

#### **Objectives three and four: assessment of secondary outcome measures**

Comparisons of dichotomous outcomes was performed by  $\chi^2$  (chi-square) or Fisher's exact test.  $P < 0.05$  (two sided) was considered statistically significant.

Comparison of operative time (a continuous variable) between the two arms was based on a paired  $t$ -test.

The analysis was based on the intention-to-treat design.

### **3.11.3 Stopping Rules**

The results of the study were reviewed (interim analysis) after two months from the start of the trial to enable the study to be stopped early if adverse events were reported (see Appendix V). The level of significance was set at P value of 0.05 and was calculated according to the O'Brien-Fleming stopping boundaries. However overwhelming efficacy of one intervention was not considered a reason for termination of this study.

### **3.11.4 Quality Assurance**

- The PI carried out operations under the supervision of the consultant surgeon. The PI had been trained in the use of both methods of inguinal hernia repair and had successfully carried out both open mesh and Desarda repairs before this study.
- A standardised and pretested questionnaire was used.
- All the sterile materials to be used during the surgery were obtained from Mulago hospital (except the mesh and proline sutures which were procured from Johnson & Johnson, the accredited Ethicon agent in Uganda).
- A statistician helped the PI in data analysis
- The study was registered at <http://register.clinicaltrials.gov> with identifier: NCT00941941

### ***3.12 Dissemination of Results***

1. The results of the study will form the basis of the dissertation to be submitted in partial fulfilment for the award of the degree of Master of Medicine (Surgery) of Makerere University.
2. Copies will be availed to the Department of Surgery, Makerere University; College of Health Sciences Research and Ethics Committee; Sir Albert Cook Medical School Library; Makerere University Graduate School; and Mulago Hospital Management.
3. It is hoped that the study will be published in (an) appropriate surgical journal(s).

### ***3.13 Ethical Considerations***

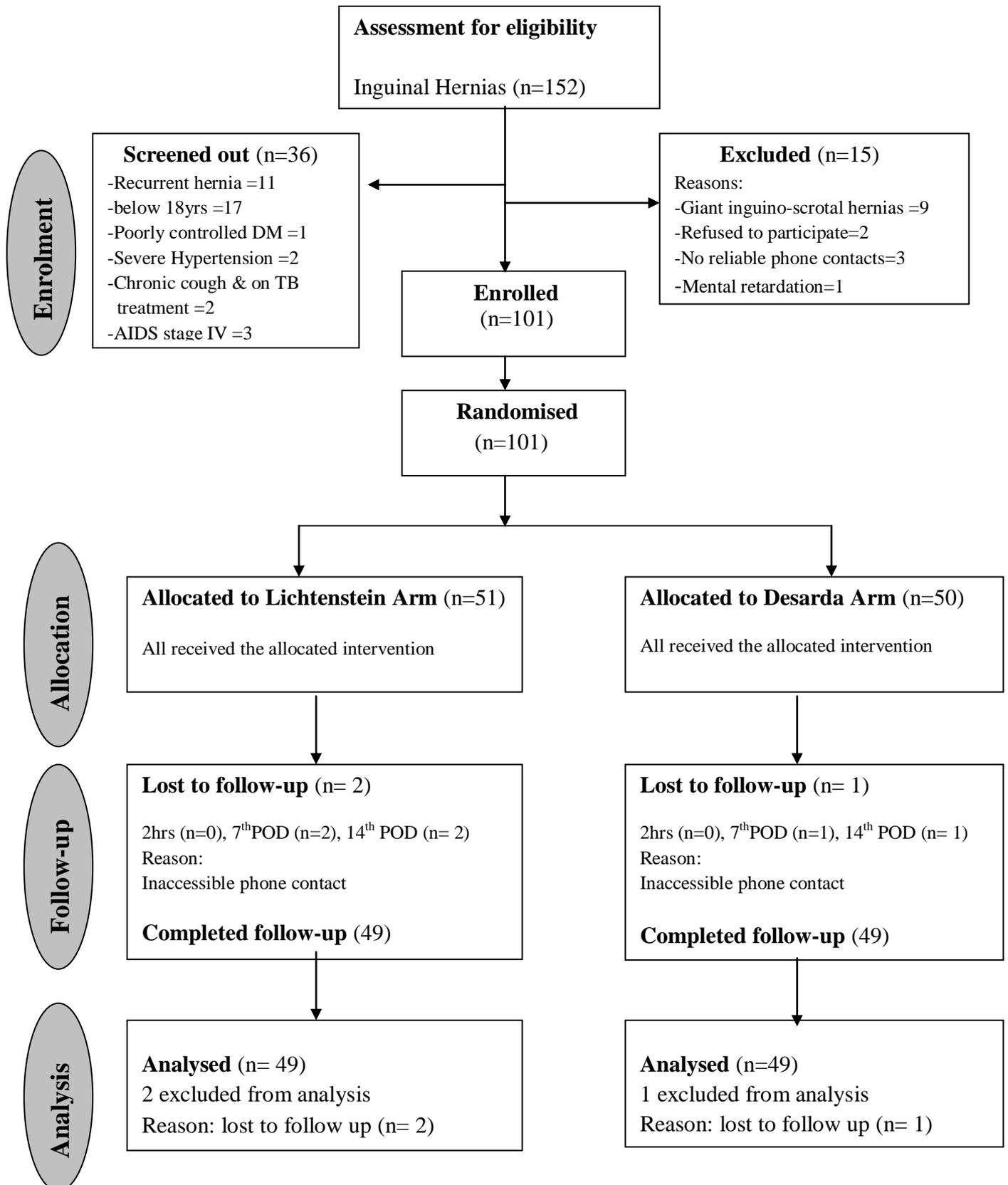
1. Approval to carry out the study was sought from the Department of Surgery, Mulago Hospital, Makerere University College of Health Sciences Research and Ethics Committee, Mulago Hospital Research and Ethics Committee, and Uganda National Council for Science and Technology.

2. The nature and benefits of the study were explained to the participants in a language they understood.
4. Consent was obtained by signature or thumb print on the consent form.
5. Patients' record forms were identified using the study numbers to ensure confidentiality.

# CHAPTER FOUR

## 4.0 Results

Figure 3: Patients Flow Diagram [39]



The enrolment, recruitment and treatment of the study participants were carried out between the month of April 2009 and July 2009. Of the 152 participants who were assessed for eligibility during this period, 36 were screened out, 15 excluded and 101 enrolled into the study. All the enrolled participants were randomised into the two study arms and received the allocated intervention.

While two participants (3.9%) in the mesh (Lichtenstein) arm were lost to follow-up, only one participant (2.0%) in the non-mesh (Desarda) arm did not complete the follow-up. These participants could not be reached on their phones, even at the time of writing this report. However, the difference in the loss to follow-up between the study arms was not statistically significant ( $\text{Chi}^2=0.323$ ,  $P=0.570$ )

#### ***4.1. Accuracy of Randomisation***

The output from the random number generation (RNG) was checked and the sequence showed no evidence of non-randomicity. The two-tailed probability associated with *Chi<sup>2</sup> Contingency Table Test* (for independence) was 0.487 (there was no evidence of a significant deviation from randomness).

The distribution of demographic and clinical characteristics were similar in the two intervention arms as evidenced by the two-tailed Exact Fisher and Pearson  $\text{Chi}^2$  tests of  $P > 0.05$ .

#### ***4.2 Evaluation of Blinding***

**Table 1:** Assessment of blinding of subject and outcomes assessor

<b>Person Blinded</b>	<b>Agreement</b>	<b>Statistical Test</b>	<b>P Value</b>
<b>Subject</b>			
2Hours POD	45.78%	Z = -0.77	0.7908
7 <sup>th</sup> POD	49.45%	Z = -0.10	0.5404
<b>Outcomes Assessor</b>	38.78%	Z = -0.81	0.9879

Eighty six subjects tried to guess the method of treatment offered, but 15 declined because they could not guess at one-two hours after surgery. The percentage agreement was 45.78%. However, out of the 98 participant followed up at the 7<sup>th</sup> POD, 91 tried to guess the method of treatment, with an increased percentage agreement of 49.45%. These percentage agreements were, however, not statistically significant (P= 0.7908, 0.5404 respectively).

Likewise, the percentage agreement of 38.78% by the outcomes assessor was not statistically significant (P=0.9879).

This means the study participants and the outcomes assessor were effectively blinded to the intervention arm to which they were allocated.

### 4.3 Baseline Characteristics of Study Population

#### Descriptive Statistics of Study Population

**Table 2:** Baseline demographic characteristics of the study population

FACTOR	SUMMARY MEASURE	
	N	Percent
<b>Gender:</b>		
Male	88	87.1
Female	13	12.8
<b>Age*:</b>		
<20	15	14.8
20-29	33	32.7
30-39	11	10.9
40-49	16	15.8
50-59	13	12.9
>60	13	12.9
<b>BMI:</b>		
Under-weight (<20)	16	15.8
Normal (20-25)	71	70.3
Overweight (26-30)	12	11.9
Obese (31-35)	1	0.9
Very Obese (>35)	0	0.0
<b>Occupation:</b>		
Manual labourer	42	41.6
Farmer	4	4.0
White-collar	6	5.9
Student	13	12.9
Security Services	8	7.9
Business owner	15	14.8
Others	13	12.9

**\*Age:**

Median	32
Percentile Range (p25-p75)	23-50
Min – Max Range	18-82

Males constituted 87% (88/101) of the subjects in this study, with a ratio of 6.8 males: 1 female.

The age of the study subjects was not normally distributed, with median age at 32 years and percentile range, p25 - p75 (23-50).

The majority, 71/101 (71%) of the subjects had normal BMI. Whereas one subject was obese, none of them was very obese.

Manual labourers, majorly composed of peasants, constituted the vast majority of study subjects (41%). Those coded as “others” included occupations such as human passenger commercial Boda-boda (Motorcycle) riders, commercial truck-drivers, shop attendants, and office attendants.

**Table 3:** Baseline clinical characteristics of the study population

FACTOR	SUMMARY MEASURE	
	N	Percent
<i>Duration of Hernia (Months)*:</i>		
<60	48	47.5
>60	53	52.5
<i>Hernia Location:</i>		
Right Side	63	62.4
Left Side	38	37.6
<i>Hernia Type:</i>		
Indirect	79	78.2
Direct	22	21.8
<i>Nyhus Class:</i>		
I	8	7.9
II	31	30.7
IIIA	22	21.9
IIIB	40	39.6

**\*Duration of Hernia:**

Median	60
Percentile range (p25 – p75)	24 - 108
Min – Max range	1 - 480

More than 52% of the participants presented to Mulago hospital with hernias that had lasted for more than 60 months (5 years), with median duration of 60 months and ranging from one month to 480 months (40 years).

The majority (62%) had inguinal hernias on the right side.

There was 79/101 (78%) indirect hernias, with the majority of them in the Nyhus class IIIB (40%).

## 4.4 Comparison of Baseline Characteristics of Study Groups

### 4.4.1 Demographic Characteristics

**Table 4:** Comparison of demographic characteristics

<b>FACTOR</b>	<b>MESH</b>	<b>NON MESH</b>	<b>P VALUE</b>
	<b>(N=51)</b>	<b>(N=50)</b>	
	<b>n</b>	<b>n</b>	
<b>Gender:</b>			
<b>Male</b>	42	46	0.148 <sup>a</sup>
<b>Female</b>	9	4	0.234 <sup>b</sup>
<b>Age*:</b>			
<b>&lt;20</b>	8	7	
<b>20-29</b>	13	20	
<b>30-39</b>	4	7	0.234 <sup>a</sup>
<b>40-49</b>	8	8	
<b>50-59</b>	8	5	
<b>&gt;60</b>	10	3	
<b>BMI:</b>			
<b>Under-weight (&lt;20)</b>	8	8	
<b>Normal (20-25)</b>	37	34	0.701 <sup>a</sup>
<b>Over-weight (26-30)</b>	5	7	
<b>Obese (31-35)</b>	1	0	
<b>Occupation:</b>			
<b>Manual labourer</b>	22	20	
<b>Farmer</b>	4	0	
<b>White-collar</b>	4	2	0.357 <sup>a</sup>
<b>Student</b>	5	8	
<b>Security services</b>	3	5	
<b>Business owner</b>	6	9	
<b>Others</b>	7	6	

**\*Age:**

Median	40.0	28.5	
Percentile (p25-p75)	23 – 56	23 – 42	P= 0.116 <sup>c</sup>

Computation of P values based on: <sup>a</sup>Pearson Chi<sup>2</sup> test <sup>b</sup>Fisher's Exact test <sup>c</sup>Mann-Whitney U test

The distribution of baseline demographic characteristics was similar in the two intervention arms. There were noticeably more women in the mesh treatment arm than in the non-mesh arm, and more young subjects (median age= 28.5 years) in the non-mesh arm compared to the mesh arm (median age= 40 years). However these differences were not statistically significant (P= 0.2340, 0.1156 respectively).

#### 4.4.2 Clinical Characteristics

**Table 5: Comparison of clinical characteristics**

<b>FACTOR</b>	<b>MESH (N=51)</b>	<b>NON MESH (N=50)</b>	<b>P VALUE</b>
	<b>n</b>	<b>n</b>	
<b>Duration of Hernia (months):</b>			
<b>&lt;60</b>	29	19	
<b>&gt;60</b>	22	31	0.058 <sup>a</sup>
<b>Location of Hernia:</b>			
<b>Right</b>	34	29	
<b>Left</b>	17	21	0.369 <sup>a</sup>
<b>Type of Hernia:</b>			
<b>Indirect</b>	36	43	0.061 <sup>a</sup>
<b>Direct</b>	15	7	
<b>Nyhus Class:</b>			
<b>I</b>	2	6	
<b>II</b>	19	12	0.030 <sup>a</sup>
<b>IIIA</b>	15	7	0.031 <sup>b</sup>
<b>IIIB</b>	15	25	

Computation of P values based on: <sup>a</sup>Pearson Chi<sup>2</sup> test <sup>b</sup>Fisher's Exact test

With the exception of the statistical difference in the distribution of hernias based on the Nyhus classification (P=0.031), the distribution of other baseline clinical characteristics in the two intervention arms was similar (P>0.05).

## 4.5 Summary of Outcomes

**Table 6:** Summary of primary outcomes

<b>FACTOR</b>	<b>MESH (Mean ±SD)</b>	<b>NON-MESH (Mean ±SD)</b>	<b>Difference (95% CI)</b>	<b>P VALUE*</b>
<i>Pain Score (VAS)</i>				
<b>1-2Hours</b>	1.18±1.19	1.40±1.34	-0.22( -0.725 – 0.277)	0.3782
<b>3<sup>rd</sup> day</b>	3.33±1.75	2.73±1.64	0.59 ( -0.088 – 1.272)	0.0874
<b>7<sup>th</sup> day</b>	1.31±1.19	1.31±1.34	0.00 ( -0.509 – 0.509)	1.0000
<b>14<sup>th</sup> day</b>	0.10±0.36	0.02±0.14	0.08 ( -0.030 – 0.193)	0.1507
<i>Days taken to return to normal gait</i>	2.44±1.62	2.06±1.13	0.39 (-0.172 - 0.949)	0.1722

*\*Computation of P values based on Student's t test*

There was generally no significant statistical difference in mean pain scores at the four time points between the two intervention groups ( $P > 0.05$ ). A noticeable, but not statistically significant difference was observed on the 3<sup>rd</sup> POD, with lower mean pain scores among the non-mesh subjects ( $P = 0.0874$ ).

The difference, 0.39 (-0.172 - 0.949), of the mean day of return to normal gait between the groups was not statistically significant ( $P = 0.1722$ ).

## Summary of Secondary outcomes

**Table 7:** Comparison of operative time

FACTOR	MESH (Mean ±SD)	NON MESH (Mean ±SD)	Difference ( 95% CI)	P VALUE*
<b>Operative time(Min)</b>	15.9 ±3.52	10.02 ±2.93	5.92 (4.62 – 7.20)	0.0001

\*Computation of P value based on Student's t test

The mesh repair took longer to accomplish- a difference of 5.92 minutes (95% CI=4.62-7.20) compared to the non-mesh repair (P=0.0001).

**Table 8:** Comparison of complications rates

FACTOR	MESH (N=51)	NON-MESH (N=50)	P VALUE
<b>Complications *:</b>			
<b><u>Intraoperative</u></b>			
None	50	48	0.5460 <sup>a</sup>
Ilioinguinal nerve injury	0	1	
Iliohypogastric nerve injury	1	1	0.6170 <sup>b</sup>
<b>Total</b>	<b>1 (1.96%)</b>	<b>2 (4.00%)</b>	
<b><u>Postoperative(7<sup>th</sup> day)</u></b>			
None	42	44	
Scrotal Oedema	4	4	0.5640 <sup>a</sup>
Scrotal haematoma	2	1	
Seroma	1	0	0.7740 <sup>b</sup>
Wound sepsis	0	0	
<b>Total</b>	<b>7 (13.70%)</b>	<b>5 (10.00%)</b>	
<b><u>Postoperative(14<sup>th</sup> day)</u></b>			
None	42	42	1.0000 <sup>a</sup>
Scrotal oedema	3	4	
Hydrocoele	0	1	0.6130 <sup>b</sup>
Wound sepsis	0	0	
Numbness (pubic)	0	1	
Groin pain (Nerve entrapment?)	4	1	0.1680 <sup>b</sup>
<b>Total</b>	<b>7 (13.70)</b>	<b>7 (14.00)</b>	

\*Computation of complication rates based on Intention-to-treat design

Computation of P values based on: <sup>a</sup>Pearson Chi<sup>2</sup> test, <sup>b</sup>Fisher's Exact test

The proportion of participants experiencing any complications was similar between the mesh and non-mesh groups: 8 (15.7%) of 51 and 9 (18.0%) of 50, respectively.

### **Intraoperative complications**

While two male participants aged 67 and 32, in the non-mesh group, experienced injuries to the ilioinguinal and iliohypogastric nerves respectively, one male participant aged 67 in the mesh group had iliohypogastric injury. However, there was no statistical difference between the two intervention arms ( $P= 0.617$ ). The one ilioinguinal nerve was severed during mobilisation of the spermatic cord from the floor of the inguinal canal. Of the two iliohypogastric nerves, one was inadvertently cut in the process of mobilising the external oblique aponeurosis for the Desarda repair, and the other got torn from excessive retraction during fixation of the mesh superolateral to the deep inguinal ring. An effort was made to identify all these nerves, but the iliohypogastric nerves in two male subjects could not be identified.

### **7<sup>th</sup> POD**

Eight (7.9%) participants developed moderate scrotal oedema in this study, four (7.8%) occurring in mesh group and four (8.0%) in non-mesh group. Three (3.0%) scrotal haematomas were observed, two (3.9%) in the mesh group and one (2.0%) in the non-mesh group. All these complications developed in participants with indirect, especially Nyhus class IIIB hernias. The patients with scrotal oedema and one patient with a small scrotal haematoma were managed conservatively. However, two participants with moderately sized scrotal haematomas improved after needle aspiration.

One male participant, aged 54 in the mesh group, with a Nyhus class IIIB indirect hernia of 40 years duration, developed a small seroma. It developed between the 4<sup>th</sup> and 6<sup>th</sup> POD and had subsided by the 14<sup>th</sup> POD on conservative management.

None of the participants developed surgical site infection (wound sepsis).

There was no statistical difference in the distribution of these complications.

### **14<sup>th</sup> POD**

Four (7.8%) participants in the mesh group and one (2.0%) in the non-mesh group reported pain scores of 1-2 (VAS) on the 14<sup>th</sup> POD. This difference was not statistically significant ( $P=0.168$ ).

The pain was neuropathic in nature- suggestive of nerve entrapment. All these participants had initially experienced complete remission of pain by the 10<sup>th</sup> POD.

The same seven (6.9%) participants who had scrotal oedema on the 7<sup>th</sup> POD were found to have it on the 14<sup>th</sup> POD. However the oedema had steadily reduced by the 14<sup>th</sup> POD.

One participant, aged 25 in the non-mesh group with Nyhus class IIIB hernia, developed a small hydrocoele. He had presented, at the time of surgery, with a small hydrocoele on the contralateral side.

Another male participant, aged 23 with Nyhus class IIIB hernia, in the non-mesh group reported reduced sensation at the operation site.

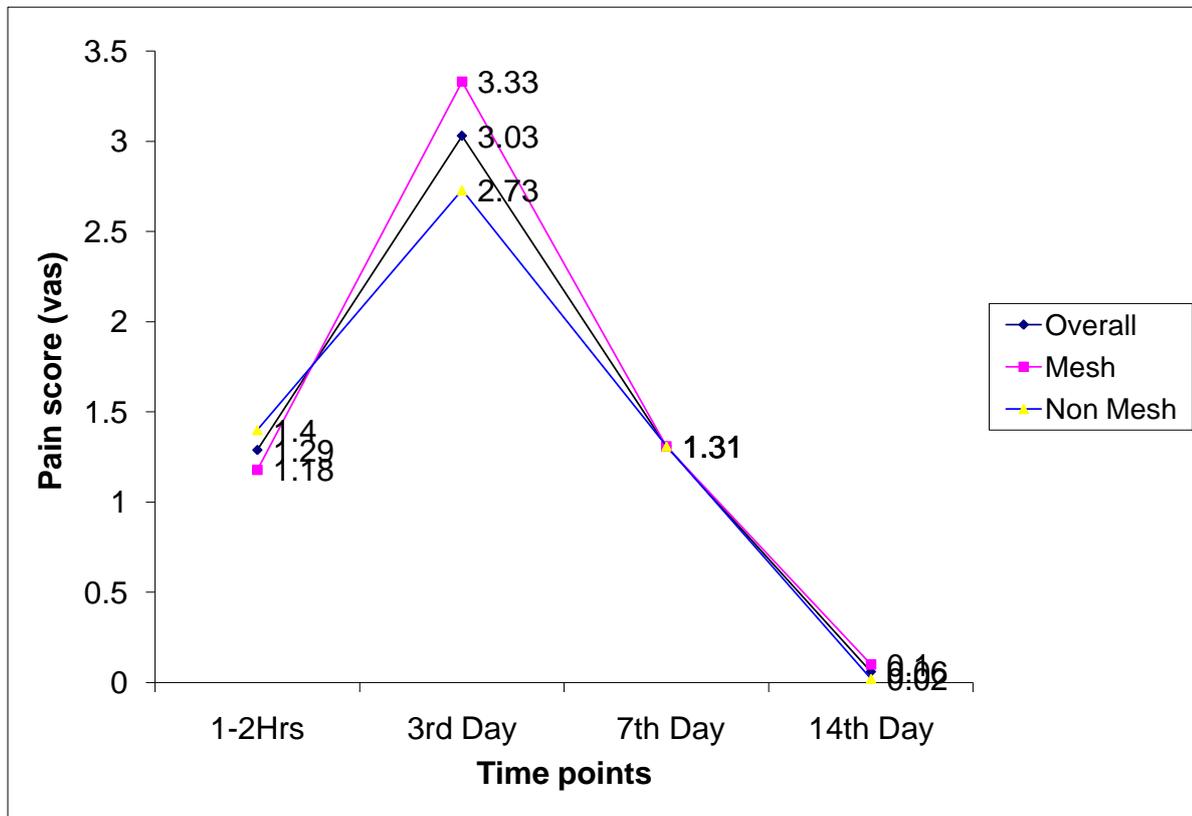
No participant developed wound sepsis on the 14<sup>th</sup> POD.

No single participant developed more than one complication at a time during the study.

## 4.6 Assessment of Primary Outcome Measures

### 4.6.1 Pain Score

Figure 4: Pain score trend



The general trend shows an increase in pain score on the 3<sup>rd</sup> postoperative day, followed by a marked decline in scores on the 7<sup>th</sup> day, and the pain score was nearly zero on the 14<sup>th</sup> day in the non-mesh group.

One-way analysis of pain score and the treatment arm showed a noticeable difference in pain scores on the 3<sup>rd</sup> day. However this was not statistically significant.

The relationship between pain score; postoperative day; and treatment arm was further subjected to analysis by ANOVA. This analysis showed a significant difference in pain scores between the 3<sup>rd</sup> POD and other days (Bonferroni P=0.0001) for both mesh and non-mesh treatment arms. However, the difference between scores at 2hrs and on 7<sup>th</sup> POD was not statistically significant (Bonferroni P=1.0000).

### **Multivariate analysis of Effect of baseline factors on pain score**

**Table 9:** ANOVA- Pain, Postoperative days, Duration of hernia, BMI, Nyhus class, Gender, Age-group and Treatment arm

<b>Factor</b>	<b>F</b>	<b>P Value</b>
<b>Model</b>	18.49	0.0000
<b>Postoperative days</b>	96.09	0.0000
<b>Duration of hernia</b>	0.34	0.5608
<b>BMI</b>	3.23	0.0226
<b>Nyhus class</b>	3.18	0.0242
<b>Gender</b>	0.01	0.9298
<b>Age group</b>	1.46	0.2006
<b>Treatment arm</b>	0.01	0.9348

There was a clear significant association between the postoperative day, BMI and Nyhus class of hernia with pain score.

**Table 10:** ANOVA- Pain, Postoperative days, BMI and Nyhus class

<b>Factor</b>	<b>F</b>	<b>P Value</b>
<b>Model</b>	34.11	0.0000
<b>Postoperative days</b>	96.16	0.0000
<b>BMI</b>	3.43	0.0173
<b>Nyhus class</b>	3.86	0.0097

The association between pain score, postoperative day, BMI and Nyhus class of hernia was found to be a remarkably significant model (P=0.0000), with postoperative day being the most marked (P=0.0000), followed by Nyhus class (P=0.0097) and then BMI (P=0.0173).

**Table 11:** Regression coefficients- Pain, Postoperative days, BMI and Nyhus class

	Pain	Coef.	t	P Value
<b>Postoperative days</b>				
	<b>1</b>	1.237052	7.05	0.000
	<b>3</b>	2.979381	16.86	0.000
	<b>7</b>	1.237113	7.00	0.000
	<b>14</b>	(dropped)		
<b>BMI</b>				
	<b>(Underweight) 1</b>	-1.631672	-2.54	0.011
	<b>(Normal) 2</b>	-1.565825	-2.49	0.013
	<b>(Overweight) 3</b>	-1.157554	-1.79	0.074
	<b>(Obese) 4</b>	(dropped)		
<b>Nyhus class</b>				
	<b>(I) 1</b>	-.6056884	-2.49	0.013
	<b>(II) 2</b>	-.3046576	-1.98	0.048
	<b>(IIIA) 3</b>	.1194813	0.70	0.483
	<b>(IIIB) 4</b>	(dropped)		

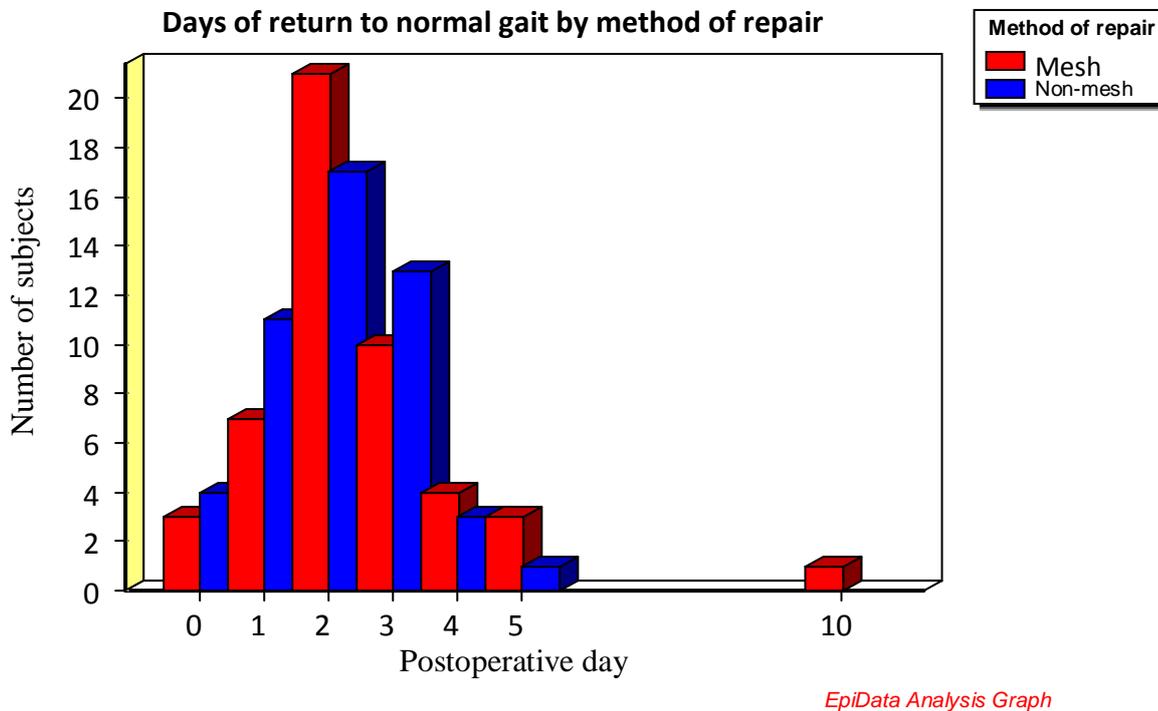
Regression analysis further revealed that the 14<sup>th</sup> POD was associated with remarkably lower pain scores compared to the 1-2 hours, 3<sup>rd</sup> and 7<sup>th</sup> POD (P=0.000).

It was also observed that the obese participants scored higher pain values compared to those who were not obese (P<0.05).

Likewise, participants with Nyhus class IIIB scored higher pain values compared to class I and class II (P<0.05).

### 4.6.2 Return to Normal Gait

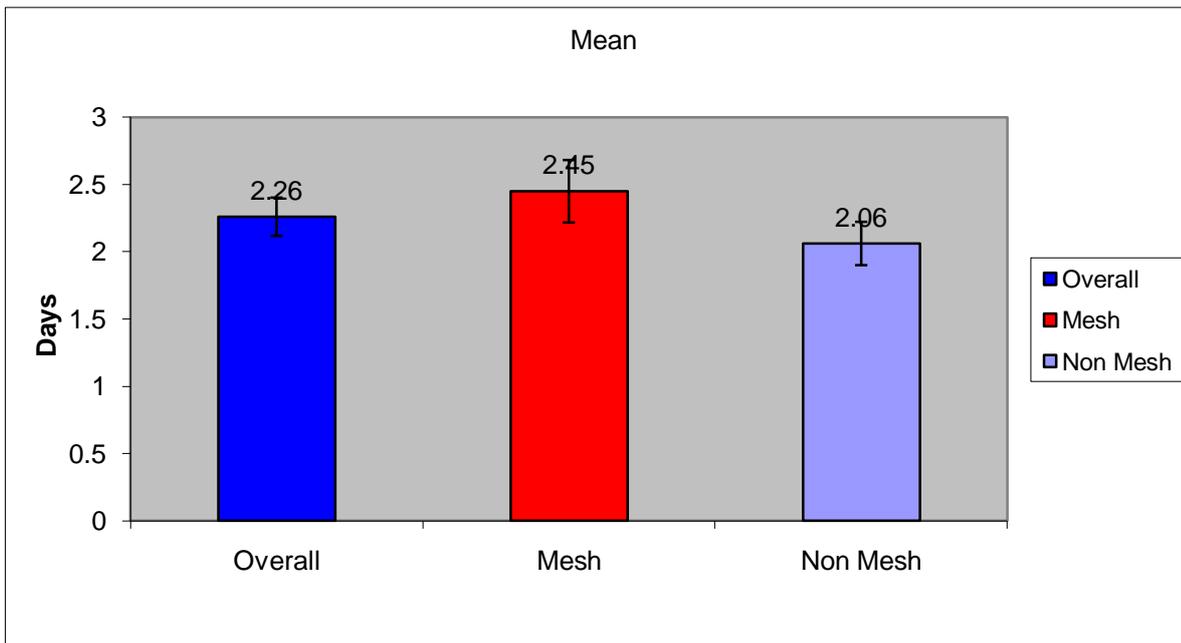
Figure 5: Days of return to normal gait by method of repair



The vast majority of participants in the study population returned to normal gait within 2-3 days. Four participants in the non-mesh group and three in the mesh group resumed normal gait four hours after surgery.

However the lone participant in the mesh group who resumed normal gait on the 10<sup>th</sup> day had also developed moderate scrotal haematoma on the 3<sup>rd</sup> POD and the pain scores were 7, 5 and 1 on the VAS on the 3<sup>rd</sup>, 7<sup>th</sup> and 14<sup>th</sup> POD respectively.

**Figure 6:** Mean day of return to normal gait by method of repair



Overall, the participants in the non-mesh group returned to normal gait earlier than those in the mesh group and the study population

**Multivariate Analysis of effect of baseline factors on return to normal gait**

**Table 12:** ANOVA- Day of return to normal gait, Treatment arm, Age group, BMI, Duration of hernia, Nyhus class.

Factor	F	P value
Model	2.12	0.0211
Treatment arm	1.30	0.2568
Gender	0.51	0.6644
Age group	2.32	0.0508
BMI	0.60	0.6196
Duration of hernia	0.11	0.7357
Nyhus class	2.48	0.0666

The association of the day of return to normal gait with age group and Nyhus class was barely statistically significant (P= 0.0508, 0.0666).

**Table 13:** ANOVA- Day of return to normal gait, Age group, Nyhus class and Treatment arm

Factor	F	P Value
Model	2.92	0.0045
Age group	2.22	0.0592
Nyhus class	2.52	0.0632
Treatment arm	1.68	0.1984

Analysis of variance found the association between day of return to normal gait, age group, Nyhus class of hernia and the method of repair to be a significant model. However both the age group and Nyhus class were not statistically significant (P= 0.0592, 0.0632).

**Table 14:** Regression coefficients- Day of return to normal gait, Age group, Nyhus class and Treatment arm

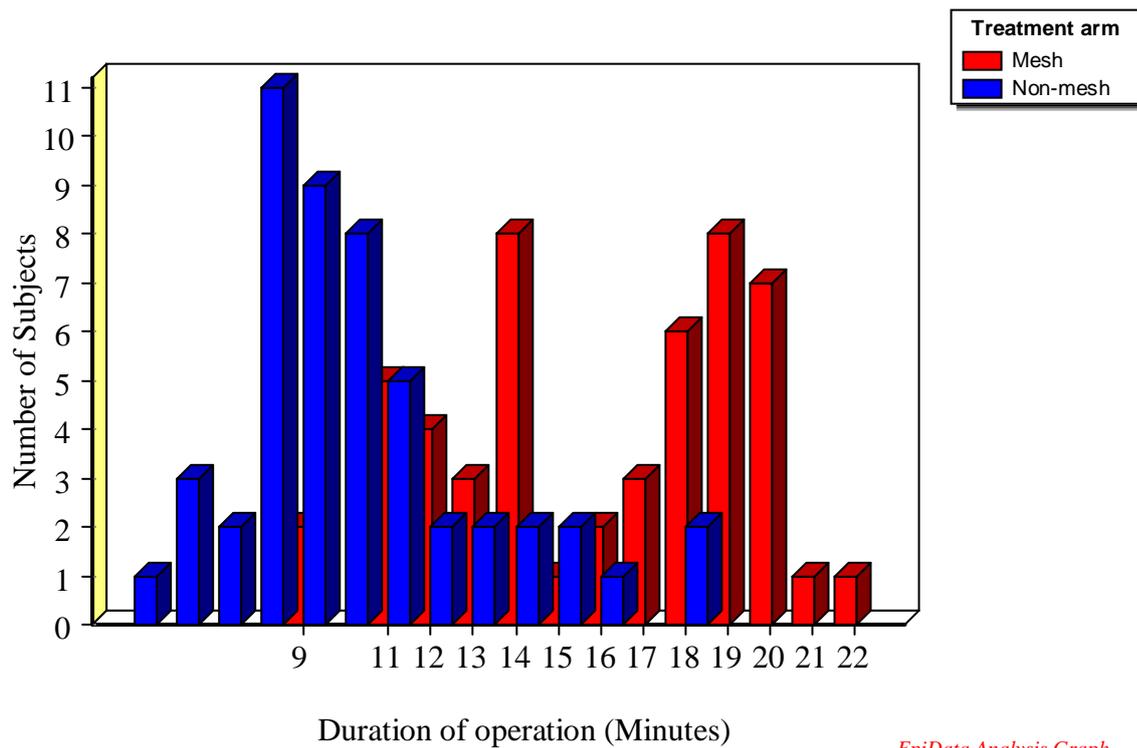
Day of return to normal gait	Coef.	t	P value
<b>Age group</b>			
(<20) 1	-1.141481	-2.07	0.042
(20-29) 2	-1.354611	-2.85	0.005
(30-39) 3	-1.326415	-2.34	0.021
(40-49) 4	-1.085396	-2.14	0.035
(50-59) 5	-1.568784	-2.98	0.004
(>60) 6	(dropped)		
<b>Nyhus class</b>			
(I) 1	-.5264038	-1.03	0.306
(II) 2	-.9260551	-2.73	0.008
(IIIA) 3	-.304458	-0.79	0.433
(IIIB) 4	(dropped)		
<b>Treatment arm</b>			
(Mesh) 1	.3640449	1.30	0.198
(Non-mesh) 2	(dropped)		

Regression analysis further revealed that subjects aged above 60 experienced delayed return to normal gait compared to the other age groups ( $P < 0.05$ ).

#### 4.7 Assessment of Secondary Outcome Measures

##### 4.7.1 Operative Time

**Figure 7:** Duration of operation by method of repair



*EpiData Analysis Graph*

The greater majority of participants in the mesh arm were operated within 13-20 minutes, whereas most of those in the non-mesh arm were operated within 8-11 minutes.

**Table 15:** Bivariate analysis of effect of baseline characteristics on operative time

Factor	Statistical test	P value
<b>Age group (Between age groups 20-29 and &gt;60years)</b>	ANOVA with Bonferroni	0.0399
<b>Gender</b>	Student's t	0.3766
<b>BMI (Between groups)</b>	ANOVA with Bonferroni	0.0820
<b>Type of Hernia</b>	Student's t	0.9905
<b>Nyhus Class (Between groups)</b>	ANOVA with Bonferroni	0.6053
<b>Duration of Hernia</b>	Student's t	0.0801

Hernia repair took a significantly longer duration among participants aged above 60 compared to those aged 20-29 (Boniferroni P=0.0399).

Difference in operative time was also observed with the obese compared to the normal-weight subjects, and hernias that had lasted for less than 60 months compared to those of more than 60 months. However there was no statistically significant difference between these groups (Boniferroni, P= 0.0820 and 0.0801 respectively).

Other baseline characteristics, including gender, did not show an association with operative time.

## 4.7.2 Complications

### 4.7.2.1 Intraoperative Complications

**Table 16:** Intraoperative complications by baseline characteristics

Characteristics	Freq. (N=3)	Percent (3/101=2.9)
<b>Age group:</b>		
[30-39]	1	33.3
[ >60 ]	2	66.7
<b>Gender:</b>		
[Male ]	3	100.0
<b>Duration of Hernia:</b>		
[ >60 ]	3	100.0
<b>Type of Hernia:</b>		
[Indirect]	3	100.0
<b>Body Mass Index:</b>		
[Normal (20-25)]	2	66.7
[Over-weight (26-30)]	1	33.3
<b>Nyhus Class:</b>		
[ I ]	1	33.3
[IIB]	2	66.7

All the three nerve injuries occurred among three male participants with indirect hernias that had lasted for more than 60 months (5 years). Two out of three (66.67%) of these male subjects were aged above 60.

#### 4.7.2.2 Postoperative Complications

**Table 17:** Postoperative complications on 7<sup>th</sup> and 14<sup>th</sup> POD by baseline characteristics

	7 <sup>th</sup> POD	14 <sup>th</sup> POD
<b>Characteristics</b>	<b>Freq (Percent) *</b> <b>14/101 (13.9)</b>	<b>Freq (Percent) *</b> <b>14/101 (13.9)</b>
<b>Age group:</b>		
<20	4 (28.6)	3 (21.4)
20-29	3 (21.4)	3 (21.4)
30-39	0 (0.0)	1 (7.1)
40-49	2 (14.3)	2 (14.3)
50-59	1 (7.1)	2 (14.3)
>60	4 (28.6)	3 (21.4)
<b>Gender:</b>		
Male	14 (100.0)	13 (92.9)
Female	0 (0.0)	1 (7.1)
<b>BMI:</b>		
20-25	12 (85.7)	13 (92.9)
26-30	2 (14.3)	1 (7.1)
<b>Duration of hernia:</b>		
<60	6 (42.9)	7 (50.0)
>60	8 (57.1)	7 (50.0)
<b>Hernia type:</b>		
Indirect	13 (92.9)	11 (78.6)
Direct	1 (7.1)	3 (21.4)
<b>Nyhus class:</b>		
II	4 (28.6)	2 (14.3)
IIIA	1 (7.1)	3 (21.4)
IIIB	9 (64.3)	9 (64.3)

*\*Computation of complication rates based on Intention-to-treat design*

The male participants aged above 60, with indirect or Nyhus class IIIB hernias that had lasted for more than 60 months experienced most of the complications on the 7<sup>th</sup> POD. Similarly, young men aged below 30 experienced more postoperative complications.

Most of the complications on the 14<sup>th</sup> POD occurred among males aged above 60 and below 30 with indirect or Nyhus class IIIB hernias.

#### **Severe Adverse Events** (see appendix VII)

These anticipated complications were not observed in this study.

## CHAPTER FIVE

### 5.0 Discussion

#### Introduction

Inguinal hernia is a common surgical problem in Mulago Hospital. The need to find an efficient, safe but simple and affordable method of hernia repair provided the basis for this study. This study was designed to establish the short-term clinical outcomes of hernia repair using the Desarda's technique, a non-mesh tissue-only repair, which is acclaimed to be able to restore the normal physiology of the inguinal canal as compared to the mesh-based repairs. It is also reported to be free of common postoperative complications normally associated with mesh repairs and other tension tissue repairs such as the Lichtenstein and modified Bassini methods respectively.

In this study there was no statistically significant difference between the Desarda and Lichtenstein methods in regard to acute postoperative pain scores; time to resumption of normal gait (ability to move freely, bend, squat, stoop, walk up a few stairs, or carry light weights of about 10kg); and perioperative complications. However, a significant difference with regard to operative time was observed in this study ( $P=0.0001$ ).

#### 5.1 Demographic and Clinical Characteristics

In this study, the male to female ratio of 6.8:1 compares with previous studies done in Mulago Hospital by Odula (4: 1) [2], Kyamanywa (5.3: 1) [10] and Situma (4.4: 1) [9]. The ages of participants in this study were not normally distributed, with median age at presentation of 32years (p25-p75: 23-50 and min-max: 18-82). This age distribution is similar to a study done at Mulago hospital by Odula (median- 33years) [2]. The body-mass index, occupation and location of hernia in this study were comparable to studies done in Mulago hospital [9, 10]. However, in this study a higher proportion of participants had presented with indirect hernia (78.0%) [Nyhus class IIIB (39.0%)] compared to the proportion of indirect hernia (51.9%) [Nyhus class IIIB (40.7%)] observed in a study done a year earlier at Mulago hospital [9]. Other than seasonal variations, no plausible reason to explain this difference in the prevalence of indirect hernias between the two studies has been found. In Odula's [2] and Kyamanywa's [10] series in 2000 and 2002, indirect hernias constituted 81.5% and 75% of inguinal hernias respectively at Mulago hospital. We found only one (0.99%) pantaloon hernia, similar to Odula's series of two (1.02%) of the 195 inguinal hernias [2]. No Busoga

(Gill Ogilvie) hernia was seen in this study. Similarly no such hernia was reported in the Kyamanywa and Situma series, but Odula reported 2 (1.02%) of the 195 cases of hernia.

The demographic and clinical characteristics have widely been investigated and various studies have reported contradicting findings with regard to their effect on the key outcomes of hernia repair [10, 19, 20, 24, 28]. For example, Lau et al observed that young patients and indirect hernias had significant influence on postoperative pain [24]. However Mayagoitia observed that there was no strong association between complications and the diverse variables of age, sex, anatomic site, time of hernia evolution, type of surgery, antibiotic administration (systemic or local), hernia classification, use of drains and the attending surgeon [19].

The distribution of the demographic and clinical characteristics in the two intervention arms of this study, with the exception of Nyhus class IIIB of hernia, was similar. This implies that the process of randomisation was accurate, and that any influence of these variables on the key outcomes of surgery was similarly distributed in the two study arms.

## **5.2 Assessment of Pain**

Pain was scored on a visual analogue scale of 0 to 10. The pain experienced by the participants in the two study arms was similar at the four time points (1-2hours, 3<sup>rd</sup> day, 7<sup>th</sup> day and 14<sup>th</sup> day). The mean pain score was highest on the 3<sup>rd</sup> POD in both arms. The overall trend showed lower scores among the Desarda group, but this was not statistically significant (P=0.087). The explanation for the higher scores on the 3<sup>rd</sup> POD could be because the postoperative inflammatory process is at its peak. In this study the mean pain scores on the 3<sup>rd</sup> POD were 3.33±1.75 for Lichtenstein and 2.73±1.64 for Desarda [effect size (95% CI): 0.59 (-0.088 – 1.272)] and the scores on the 7<sup>th</sup> POD were 1.31±1.19 for Lichtenstein and 1.31±1.34 for Desarda [effect size (95% CI): 0.00 (-0.509 – 0.509)]. This was comparable to the scores in the studies by Situma [9], Desarda [7], Kyamanywa [10] and Lau et al [24]. Post incisional infiltration of Macaine and a combination of oral Dextropropoxyphene 32.5mg and Voltaren suppositories 50mg were used in the study by Lau et al. The pain scores on the 7<sup>th</sup> POD were however higher in the studies by Situma and Kyamanywa. Desarda scored pain based on the mild-moderate-severe scale, and thus his scores could not accurately be compared to scores in this study.

The similarity in pain scores in the study arms possibly confirms that the Desarda repair, as acclaimed by its inventor and others, is indeed a tension-free tissue repair. That the participants in this study and the one by Situma experienced more pain on the 3<sup>rd</sup> POD, it is recommended that analgesics be adjusted accordingly to control pain at a particular time point after hernia surgery. The relatively low pain scores at 1-2hours after operation was most likely achieved by the prolonged analgesic effect of lignocaine induced by adrenaline 1: 200,000 and by the intramuscular injection of Diclofenac 75mg given to all participants at the end of the operation.

It is interesting to note that whereas four subjects in the mesh group reported neuropathic type of pain (due to nerve injury or entrapment), only one participant developed similar pain in the non-mesh group on the 14th POD. This difference was however not statistically significant. All these participants had experienced complete remission of pain by the 10<sup>th</sup> POD. Long-term follow-up of this group of participants would help to establish if they will develop the dreaded chronic postoperative pain. It is assumed to be chronic postoperative pain if it has persisted for more than three to six months postoperatively [20].

A multivariate analysis with multiple regression analysis established that the postoperative day ( $P=0.0001$ ), obesity ( $BMI >30$ ) ( $P<0.050$ ), and Nyhus class IIIB hernias ( $P<0.050$ ) significantly influenced intensity of pain after hernia repair irrespective of the method used. It is not surprising that the postoperative day influenced pain score in this study, since the period after surgery is a known factor in modifying the course of post-injury inflammatory process. The influence by Nyhus class IIIB hernia on the pain score could be due to the more extensive raw wounds created after dissection and mobilisation of the sac from the cord. This group of participants tended to develop scrotal oedema which may also explain the higher pain scores. Age, as reported by Kyamanywa [10] and Lau et al [24] did not seem to influence pain.

### **5.3 Day of Resumption of normal gait**

The mean day of return to normal gait was  $2.44 \pm 1.62$  for mesh and  $2.06 \pm 1.13$  for non-mesh [effect size (95% CI): 0.08 (-0.030 – 0.193)]. This difference was not significant. Four of the participants in the mesh group and three in the non-mesh group had resumed normal gait four hours after surgery. Other studies have reported slightly higher mean day of resumption of normal gait- Situma (Desarda's repair  $3.62 \pm 1.84$  days, Bassini repair  $3.62 \pm 1.79$  days) [9],

Kyamanywa (Lichtenstein  $4.7 \pm 1.9$  days, Bassini  $4.0 \pm 1.8$  days) [10]. The mean time to return to work, in a retrospective study by Desarda [7], was  $8.48 \pm 2.43$  days with his technique and  $12.462.1 \pm 1$  days in the mesh group. In another study by Desarda [6], 98.25% of the patients were ambulatory with limited movements up to the bathroom within 6–8 hours, whereas 97.6% experienced free movements within 18–24 hours. Although the operative definition of normal gait in this study differed to some extent from that of Desarda [7], these findings seem to confirm that Desarda's repair is comparable, if not superior, to the Lichtenstein mesh repair.

Although from analysis of variance (ANOVA), age group and Nyhus class of hernia seemed to remotely influence the participants' day of return to normal gait, this model ( $P=0.0045$ ) was further subjected to multiple regression analysis. When this was done, the observation was that subjects aged above 60 experienced delayed return to normal gait compared to the other age groups ( $P<0.05$ ). Although these analyses and conclusions, therein, stand a risk of creating spurious associations, other studies have explored and found associations between age and return to normal activities [25]. In this study, the Nyhus class IIIB hernias were associated with delayed return to normal gait compared with Nyhus class II hernias ( $P=0.008$ ). The explanation for the seemingly delayed return to normal gait among these two groups could possibly be due to "senility induced" sedentary life-style among the elderly and the relatively much pain experienced by patients with Nyhus IIIB type of hernia.

#### **5.4 Operative time**

The operative time in this study was taken as the duration of actual repair technique, from the end of herniotomy (ligation of the sac) to the time of placement of the last stitch of repair (before closure of external oblique aponeurosis is embarked on). The duration of  $15.9 \pm 3.52$  minutes for Lichtenstein repair and  $10.02 \pm 2.93$  minutes for Desarda's repair [effect size (95% CI): 5.92 (4.62 – 7.20)] was found to be statistically significant ( $P=0.0001$ ).

The author, a Senior House Officer in general surgery, did all the operations. Thus the difference observed can be ascribed to the challenges inherent in the repair technique itself. However the possibility of the operator's bias towards a particular method of repair could have contributed to this difference. For unbiased assessment of the operative time, a group(s) of surgeons with clearly defined skills in hernia operations based on the two repair techniques should be involved in a study. This approach would improve both the internal and external validity of a study.

In this study, a 6-8 cm long transverse (skin crease) groin incision was employed in all patients. The operator experienced delays in mesh repair as a result of difficult retraction for the placement of sutures superolateral to the internal inguinal ring. No extra retraction was required in the Desarda repair.

Time, being an indispensable resource, should always be considered in the selection of the most cost effective methods of hernia repair.

Situma [9], on average, did a Desarda repair in 13.26 minutes, 2.73 minutes longer than the Modified Bassini repair. Kyamanywa [10], on average, did Lichtenstein repair in minutes 14.50 minutes, 2.20 minutes longer than the Modified Bassini repair. In a comparative study by Desarda [6] operative time was not assessed. Other comparative studies considered duration of operation [5, 12, 25, 27, 28, 34]. However these could not be compared with the findings of this study because the above studies involved other methods of hernia repair and the definition of operative time was not the same as in this study.

An attempt was also made using the bivariate analysis, to evaluate the effect of baseline demographic and clinical factors on the operative time. Participants who were aged above 60 took a relatively longer duration compared to those aged 20-29 ( $P=0.0399$ ). A remotely significant clinical difference was also observed between the obese and other BMI groups ( $P=0.0820$ ), with surgery on the obese taking longer. The difficulties faced in accessing the repair site in the obese patients may explain these differences. The duration of hernia of more than 60 months took longer than those of less than 60 months ( $P=0.0801$ ). The difference in duration based on gender as reported by Kyamanywa [10] was not observed in this study.

## **5.5 Complications**

There was no significant difference between the two study arms with regard to intra-operative and postoperative complications. Desarda [7] observed rates of complications about three times more in the Lichtenstein mesh repair than in his novel technique. The commonest complication in this study was scrotal oedema [eight (7.9%), four (7.8%) in Lichtenstein repair and four (8.00%) in Desarda's repair] and scrotal haematoma [three (3.0%), two (3.9%) in Lichtenstein and one (2.00%) in Desarda]. There were no wound site haematomata.

These complications were successively managed conservatively.

Virtually all these complications arose in males with Nyhus class IIIB hernias, indicating the challenges involved in mobilisation and resection of the sac in in this category of patients. The absence of spermatic cord in females makes it easier to mobilise the hernia sac. The round ligament in the females is often excised with sac. In all large inguino-scrotal hernias the sac was excised and its fundus, adherent onto or continuous with tunica vaginalis, was left in-situ – this safeguards against injury to the cord structures, postoperative haematomas and scrotal oedema that may result from complete excision of the sac.

Wound sepsis was not observed in this study. Intravenous injection of Enhancin (Amoxicillin + Clavulanate) 1.2g was administered to patients at the start of operation in this study. This may, though not exclusively, explain the absence of wound sepsis in this series. Utmost attention was paid to the routine infection control. Kyamanywa [10] recorded a wound sepsis rate of 5% in the Lichtenstein group. None was observed in the Bassini group. Situma [9] reported sepsis rates of 3.8% in the Desarda group and 1.9% in the Bassini group. No prophylactic antibiotics were used in these studies. Odula reported wound sepsis rate of 6.7% in a study involving both emergency and elective hernia repairs at Mulago Hospital [2].

The higher rate of seromas reported in other studies [10, 28] were not observed in this study. Seromas may result from extensive tissue dissection. The studies mentioned above showed that seromas are an inherent problem of mesh-based hernia repairs. The explanation for this is not clear. However it is known that the mesh is rapidly invaded by fibroblasts that fill up the pores in the mesh. This could result in a delayed absorption of the serous fluid accumulating in the wound after the operation, leading to seroma formation [10].

### **Severe Adverse Events**

The absence of severe adverse events in this study demonstrates that both Desarda and Lichtenstein methods can safely be employed in day case surgery under local anaesthesia in surgical out-patient theatre of Mulago hospital, and possibly in theatres in resource-constrained district hospitals.

## ***6.0 Study Limitations***

1. The methods of assessment of normal gait and pain (by use of the Visual Analogue Scale), though widely employed, are subject to participant and observer bias. An effort was made at every stage of the trial to blind the participant and the outcomes assessor. Any possible shortcomings pertaining to the methods of data collection were majorly due to the inherent problems of these methods. The outcomes assessor was specially trained prior to the start of the trial.
2. With regard to the postoperative complications, notably the absence of wound sepsis in this study, its generalisation to the general population is limited only to those patients with similar baseline characteristics and can afford prophylactic antibiotics.
3. Since the follow up of the participants in this study was designed to be done in two weeks, due to the limited time and funds available, some short-term complications that possibly occurred two weeks postoperatively were not documented. Two months would be a suitable period of follow-up if most of the delayed early complications of hernia repair were to be observed.

## ***7.0 Conclusions***

1. This study has shown that the efficacy of the Desarda technique in respect of influencing the short-term outcomes of hernia repair is comparable to those of Lichtenstein method.
2. In the operator's hands, the Desarda repair was shown to take a significantly shorter operative time than the Lichtenstein repair. This in the face of resource constraints should make surgeons consider the Desarda's repair as a more cost effective method.
3. The Desarda and Lichtenstein methods can safely be employed in day case surgery under local anaesthesia in the surgical out-patient theatres of Mulago Hospital and the district hospitals.
4. This study affirmed the fact that in male patients with Nyhus class IIIB hernias, judicious and meticulous approach to the mobilisation and resection of the sac should be observed irrespective of the technique of hernia repair used. Surgery in these patients is attended by more postoperative pain, delayed return to normal gait, increased intra-operative and postoperative complications.

The conclusions above confirm that the null hypothesis of the study was indeed true, and it is therefore accepted.

## ***8.0 Recommendations***

1. A clinical trial comparing the Lichtenstein and Desarda methods for inguinal hernia repair involving a larger study population should be carried out at Mulago Hospital to establish the long-term efficacy of the Desarda method. In addition, there is need for a long-term follow up of the cohort of patients in this study to establish the long-term outcomes such as recurrences and chronic groin pain.
2. Multi-centre trials comparing the Desarda and Lichtenstein methods should be carried out at regional and district hospitals in Uganda to enhance the generalisation of the results because of the anticipated heterogeneity in patient populations and centre practices. This also would help to solicit a wider range of clinical opinions concerning the Desarda method.
3. We are cognisant of the fact that this was a small study. However, in view of available literature- including the study done by Prof Desarda, it is recommended that surgeons, surgical trainees and medical students in training schools in resource-poor communities be encouraged, through continuing medical education, to acquaint themselves with the Desarda method of inguinal hernia repair.

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# APPENDICES

## ***APPENDIX I: CONSENT FORM***

**Title:** Comparison of Desarda (Non-mesh) and Lichtenstein (Mesh) Methods for Inguinal Hernia Repair at Mulago Hospital

I am Dr William Manyilirah of the Department of Surgery, Mulago Hospital. I am conducting a study on hernia treatment

You have been identified as a possible participant in this research because your medical condition requires treatment by surgery

### **Purpose of the Study**

The purpose of this study is to compare results of treatment, by surgery, of two different repair techniques. Both these techniques are safe and practised in different countries of the world. One technique (Desarda repair), however, is new in Uganda and so we want to compare it with the widely recommended and used technique (Mesh repair) to establish how good the outcome is, and see whether we can adopt it for use in Mulago hospital.

### **Nature of the study**

We shall be assessing the pain after the operation and time taken for you to resume walking as you used to before the operation. Another doctor using a questionnaire will do this and you will also take a chart for pain that you will fill on the 3<sup>rd</sup> after the operation. You will be expected to fill the chart in the morning at home before taking your medicine for that day and assessing the pain after moving a few metres or out of your house. The pain and the way you walk will again be assessed on the 7<sup>th</sup> and 14<sup>th</sup> days following the operation.

### **How you will be allocated the method for operation**

The allocation of the method for operation will be done randomly. That is every participant will have an equal chance to be allocated to either of the two methods of operation. You will choose the method to be used on you by picking an envelope from a bunch of sealed envelopes at the records office. This will help us not to bias your thoughts and feelings when you are answering some questions when assessing the outcome of the operation. You will however be free to find

out from me what method was used after the assessment has been done- that is two weeks from the day of operation.

### **The nature of operation**

You will be requested to sign an informed consent for the operation, like we routinely do for all patients who are planned to undergo an operation. A drug to prevent possible wound infection will be administered to you via an injection into the vein on your arm 30minutes before, or at the start of the operation. The surgery will be done under local anaesthesia. This means only the part going to be worked upon is to be anaesthetised. The surgery will involve identifying the hernia and the defect and then repairing the defect. In **Desarda's repair**, the defect is covered by a fibrous sheet of tissue naturally found beneath the skin of the groin region. Where as the repair in **Lichtenstein technique** involves covering the defect with an artificially made material, which is non-absorbable. The covering is held in place by non-absorbable stitches. You will then be allowed home two or more hours after the operation, with medications and instructions on how to care for the wound.

### **Possible complications**

Both these operations are sometimes followed by complications like wound infection, but all effort will be taken to minimise this risk. We do not know which one of the two methods leads to more complications.

### **Benefits to the participant**

Participants in the Lichtenstein study arm will benefit from the mesh repair done at no cost to them. The PI will ensure the operation on you is not affected by the study, but that the surgery is done on time and in the best possible way.

### **Confidentiality**

All efforts will be made to ensure that any information obtained from you during this study is kept confidential.

### **Your rights**

Please note that:

- Participating in this study is voluntary and free of any charge

- You are free to participate or drop out of the study at anytime
- You will not be denied the necessary treatment if you drop out or do not want to be part of the study

In case of any other questions concerning the study, feel free to contact me, **Dr. William Manyilirah**, SHO, Department of Surgery, Mulago Hospital on Telephone No. **0772516430**. If questions concern your rights as a participant, please contact **Dr. Charles Ibingira**, the Chairman, Makerere University Faculty of Medicine Research and Ethics Committee on telephone no **0772 437351**.

I....., after considering the explanations of the study, and after having understood the contents of this consent do hereby give my informed consent to Dr William Manyilirah to include me in the study as a participant.

.....  
 Signature/Thumb print Date

.....  
 Witness: Name and Signature Date

.....  
 Dr. William Manyilirah Date



**Surgery**

Duration of Operation [Repair/Total] (Minutes)...../.....

Perioperative complications: 1=None, 2=Nerve injury, 3=Vas deferens injury, 4=Vessel injury, 5=Others.....[ ]

**PART II**

No Pain						Worst Pain				
<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>

(a) VAS for pain 1-2 hours post operative.....[ ]

(b) VAS on 3<sup>rd</sup> POD (as reported by the patient).....[ ]

**PART III**

FOLLOW-UP at 7<sup>TH</sup> POD

(a) Complications Present: 1=None, 2=Haematoma, 3=Wound Sepsis, 4=Seroma, 5=Scrotal/testicular swelling, 6=Orchitis, 7=Others.....[ ]

No Pain						Worst Pain				
<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>

(b) VAS:.....[ ]

(c) Date of return to normal gait.....

Post-operative day.....[ ]

**PART IV**

FOLLOW-UP at 14<sup>th</sup> POD:

(a) Date of return to normal gait.....

(b) Other possible complaints.....

**PART V**

Evaluation of Blinding at 1-2hrs and 7<sup>th</sup> POD

**At 1-2hrs POD:**

Guessing of the method of treatment offered (by participant):

1. Desarda 2. Lichtenstein (mesh) [ ]

Reason for the above response:.....  
.....  
.....

**At 7<sup>th</sup> POD:**

Guessing of the method of treatment offered (by participant):

1. Desarda 2. Lichtenstein (mesh) [ ]

Reason for the above response:.....  
.....  
.....

Guessing of the method of treatment by the Outcomes Assessor:

1. Desarda 2. Lichtenstein [ ]

**APPENDIX III: PATIENTS' VISUAL ANALOGUE SCALE FOR PAIN ON 3<sup>RD</sup> POD**

**Mulago National Referral Hospital**

**P.O BOX 7051, Kampala, Uganda**

**HERNIA STUDY**

**Visual Analogue Scale**

**For scoring pain on 3<sup>rd</sup> Postoperative day**

Patients Initials:.....

Serial Number:.....

Date of Operation:.....

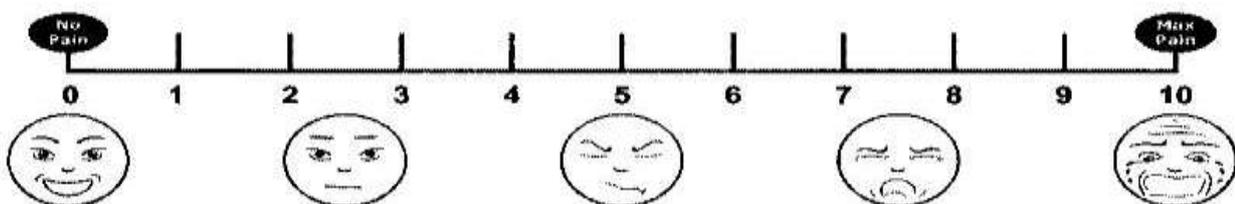
Date of Scoring:.....

**Note: Please identify your current level of pain using the scale below (please circle or tick)**

**No pain**

**Worst Pain**

<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>	<b>10</b>
<i>None</i>	<i>Annoying</i>	<i>Uncomfor- table</i>		<i>Dreadful</i>		<i>Horrible</i>		<i>Agonising</i>		



## **APPENDIX IV: EPIDATA ENTRY CODE SHEET**

Title: Comparison of Non-mesh (Desarda) and Mesh (Lichtenstein) Methods for Inguinal Hernia Repair at Mulago Hospital- Kampala

### **PATIENT IDENTIFICATION**

IDno: Identification number ###

OPno: Outpatients number #####/##

trtarm: Treatment arm # 1= Lichtenstein 2= Desarda

date: Date of operation <dd/mm/yyyy>

### **PATIENT CHARACTERISTICS**

age: (completed years) ##

gender: # 1= Male, 2= Female

maritstatus: Marital status # 1= Married, 2= Single, 3= Divorced, 4= Widowed

occupation: # 1= Manual labourer, 2= Farmer , 3= White-collar , 4= Student, 5= Security services, 6= business owner 7= others

### **CLINICAL ASSESSMENT**

#### **Clinical History**

durahernia: Duration of Hernia (complete months) ###

painepisodes: Number of painful episodes so far suffered ###

#### **Clinical Examination**

bmi: Body Mass Index(Kg/M2) # 1= below 20, 2= 20-25, 3= 26-30, 4= 31-35 5= above 35

hernlocation: Location of Hernia # 1=Right 2=Left

herntype: Type of Hernia # 1= Indirect 2= Direct

hyhusclass: Nyhus Type (confirmed peroperatively) # 1= I, 2= II, 3= IIIA, 4= IIIB

### **SURGERY**

opnduration: Duration of Operation (Minutes) ##

peropcomps: Perioperative complications # 1= none 2= nerve injury, 3= vas deferens injury, 4= vessel injury 5= Others

### **FOLLOW-UP**

vas1: VAS for pain 2 hours postoperative # Scale of 0-10

vas3: VAS on 3rd postoperative day # Scale of 0-10

vas7: VAS on 7th postoperative day # Scale of 0-10

vas14: VAS on 14th postoperative day # scale of 0-10

postopnormgait: Post-operative day of return to normal gait(days) ##

comps7: Complications on 7th postoperative day # 1= none 2= Haematoma, 3= Wound Sepsis, 4= Seroma, 5= Scrotal/testicular swelling, 6= orchitis, 7= others

comps14: Complications on 14th postoperative day # 1=None, 2=Scrotal oedema 3=Wound sepsis 4= Groin pain (nerve entrapment) 5= Hydrocoele 6=Others

follow14: Follow-up on 14th postoperative day # 1= yes 2= no

### **EVALUATION OF BLINDING**

guess1: Guessing the method of treatment by patient (at 1-2hrs Postop) #

1= Desarda 2= Lichtenstein

guess7: Guessing the method of treatment by patient (at 7th POD) #

1= Desarda 2= Lichtenstein

guessra: Guessing the method of treatment by outcomes assessor #

1= Desarda 2= Lichtenstein

## ***APPENDIX V: PATIENT SCREENING PROTOCOL***

### **Part A: Clinical History**

I. Patient identification: name, age, gender, OP.NO, Telephone no.

II. Demographic data: tribe, address, level of education, occupation.

III. Social habits: alcohol consumption, cigarette smoking.

IV. Presenting complaints:

1. Constitutional symptoms (fever, change in appetite, thirst, change in weight, malaise), abdominal (swelling in groin, pain in groin or abdomen, bowel habits), respiratory (cough, chest pain, dyspnoea, wheezing), genitor-urinary (frequency of micturation, urgency, poor urine stream, dribbling), cardiovascular (swelling of face or feet, palpitations, effort intolerance, chest pain), central nervous (headache, confusion, fits, parasthaesias, limb/body paralysis) .

2. Medical history- asthma, hypertension, tuberculosis, epilepsy, mental illness, allergies (to drugs e.g penicillins), Chronic analgesic therapy.

3. Surgical history- Previous hernia surgery, abdominal surgery.

### **Part B: Physical Examination**

I. General examination

- General state, state of nutrition, temperature, pallor, cyanosis, facial/ limb oedema, peripheral lymph nodes, weight, height, BMI.

II. Abdominal examination

1. General- size and shape of abdomen, skin for scars, tenderness, organs (palpable or not) & masses

2. Groin- swelling (when standing & supine, site, size, shape, overlying & surrounding skin, tenderness, cough impulse, reducibility, state of scrotum & its contents).

3. Rectal examination- size of prostate, masses.

III. Respiratory examination

- Respiratory rate, chest excursion, percussion notes, air entry, breath sounds.

IV. Cardiovascular

-Facial/ limb oedema, radial pulse rate, blood pressure, heart sounds.

V. Central nervous examination

- Mental status (mood, orientation, attention, memory).

- Motor & sensation in all limbs.

- Gait.

**Part C: Investigations (if indicated)**

1. General- Blood grouping, haemoglobin, urinalysis, blood electrolytes, BUN & creatinine, liver function tests, blood sugar.
2. Specific- Chest x-ray, ECG, abdominal ultrasound scan.

**Part D: ASA\* Classification**

<b>Class 1</b>	Healthy patient, no medical problems
<b>Class 2</b>	Mild systemic disease
<b>Class 3</b>	Severe systemic disease, but not incapacitating
<b>Class 4</b>	Severe systemic disease that is a constant threat to life
<b>Class 5</b>	Moribund, not expected to live 24 hours irrespective of operation
An <b>e</b> is added to the status number to designate an emergency operation. An organ donor is usually designate as Class 6	

\*ASA- American Society of Anaesthesiologists

***APPENDIX VI: NYHUS CLASIFFICATION OF GROIN HERNIAS***

[40, 41]

- Type I** Indirect hernia (**without dilation of the internal ring**)
- Type II** Indirect hernia (**with dilation of the internal ring**). Intact posterior wall.
- Type III** **Posterior wall defect**
- A** Direct inguinal hernia
  - B** Indirect inguinal hernia (combined hernia)
  - C** *Femoral hernia*
- Type IV** **Recurrent hernia**
- A** *Direct*
  - B** *Indirect*
  - C** *Femoral*
  - D** *Combined*

## ***APPENDIX VII: MANAGEMENT OF ADVERSE EVENTS***

<b>Possible Adverse Event</b>	<b>Prevention</b>	<b>Response in case of adverse event</b>
Lignocaine Toxicity	-Use of low concentration 0.5% lignocaine -Maximum dose of 3mg/kg body weight	-Intravenous fluids ( Crystalloids) to maintain normal blood pressure -Maintenance of airway & breathing with oxygen via face mask or endotracheal tube with ambubag
Severe seromas	-Avoidance of extensive tissue dissection -Use of correct fitting lightweight mesh	-Observation for spontaneous resolution -Percutaneous aspiration
Severe wound sepsis	Observation of standard aseptic techniques	-Regular wound dressing -Appropriate antibiotics after culture & sensitivity -Mesh removal if intractable sepsis
Acute urinary Retention	Adequate analgesia	- Adequate analgesics -Urethral catheterisation (temporary)

## ***APPENDIX VIII: DATA SAFETY MONITORING BOARD (DSMB)***

A DSMB is a group of experts who met monthly to review accumulating data gathered from participants in the trial with the purpose of protecting: (i) the safety of the study subjects; (ii) the scientific integrity of the study; (iii) the validity of study results.

The following members constituted the DSMB:

1. Dr Masiira Mukasa, Senior Consultant Surgeon, Ward 2A, Mulago hospital
2. Dr Sam Kagwa, Consultant Urologist, Head Department of Surgery, College of Health Sciences, Makerere University
3. Dr Josephat Jombwe, Consultant Surgeon, Ward 3C, Mulago Hospital
4. Dr. Peter Kiiza, Consultant Surgeon, Ward 2B, Mulago hospital
5. Dr. Cephas Mijumbi, Cousultant Anaesthesiologist, Mulago hospital
6. Sr. Acuku Endra, Senior Nursing Officer In-charge, Surgical outpatient department, Mulago hospital