REPRODUCTIVE OUTCOMES AMONG INFERTILE FEMALE PATIENTS WHO HAVE UNDERGONE MYOMECTOMY AT JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL (JOOTRH), KISUMU, KENYA

BY

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SCHOOL OF MEDICINE

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DECLARATION

I declare that this thesis is my original work, carried out under the guidance of my supervisors, and has not been submitted to any other university for the award of a degree.

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DEDICATION

This work is dedicated to my parents, Benta and Christopher Onyango, whose prayers and encouragement have carried me throughout my education; to my children, Carl and Elsie, who were patient through the long hours this training demanded; and to my husband, Paul Ogolla, who supported me through every stage of this process.

I also dedicate this work to the women living with fibroid-associated infertility. I hope these findings, drawn from the experiences of women treated at JOOTRH, help improve the care and reproductive outcomes of those who come after them.

ABSTRACT

Uterine fibroids are a common cause of infertility in sub-Saharan Africa, where assisted reproductive technology is largely unavailable and myomectomy is often the main fertility-directed treatment. Local evidence on reproductive outcomes after myomectomy in Kenya is limited. This study assessed reproductive outcomes and associated factors within two years of myomectomy among women with infertility at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH). It described reproductive outcomes within two years of surgery, identified patient-related factors associated with conception, assessed the association between fibroid characteristics, selected intraoperative factors and conception, and estimated the time to confirmed pregnancy. A single-arm retrospective cohort design was used. Records of women who underwent myomectomy between January 2019 and January 2024 were reviewed, and follow-up interviews were conducted to ascertain outcomes. Of 250 records screened, 184 women were eligible and 168 (91.3%) completed follow-up. Data were analysed with IBM SPSS version 26.0 using descriptive statistics, chi-square tests, logistic regression, Kaplan–Meier analysis and Cox regression. Within two years, 54/168 (32.1%) women conceived; the cumulative probability of conception at 24 months was 35.0%. Of the 54 pregnancies, 34 (63.0%) ended in live birth and 15 (27.8%) in miscarriage. The median time to conception among women who conceived was 14.0 months (IQR 9.25–17.75). Previous uterine surgery was associated with lower odds of conception (AOR 0.47, 95% CI 0.23–0.94) and slower conception (aHR 0.50, 95% CI 0.27–0.93). Larger fibroid diameter was associated with lower odds of conception (AOR 0.85 per cm, 95% CI 0.72–0.997), although this estimate was imprecise. The largest proportion of participants, 75/168 (44.6%), were aged 35 years or older, and 129/168 (76.8%) had secondary infertility. About one-third of women conceive within two years of myomectomy, and previous uterine surgery is associated with lower and slower conception. These findings support realistic counselling, complete pre-operative fertility evaluation and structured follow-up for women undergoing myomectomy.

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LIST OF ABBREVIATIONS

aHR	Adjusted Hazard Ratio
ANC	Antenatal Care
AOR	Adjusted Odds Ratio
ART	Assisted Reproductive Technology
BMI	Body Mass Index
BTL	Bilateral Tubal Ligation
CI	Confidence Interval
ECM	Extracellular Matrix
FIGO	International Federation of Gynecology and Obstetrics
HMGA2	High-Mobility Group AT-Hook 2 (gene)
HR	Hazard Ratio
HSG	Hysterosalpingography
IBM SPSS	International Business Machines Statistical Package for Social Sciences
ICSI	Intracytoplasmic Sperm Injection
IQR	Interquartile Range
ISEREC	Institutional Scientific and Ethics Review Committee
IUI	Intrauterine Insemination
IVF	In Vitro Fertilisation
JOOTRH	Jaramogi Oginga Odinga Teaching and Referral Hospital
KM	Kaplan–Meier
KNBS	Kenya National Bureau of Statistics

LNMP	Last Normal Menstrual Period
MED12	Mediator Complex Subunit 12 (gene)
NACOSTI	National Commission for Science, Technology and Innovation
OR	Odds Ratio
PCOS	Polycystic Ovary Syndrome
SD	Standard Deviation
SGS	School of Graduate Studies
WHO	World Health Organization

OPERATIONAL DEFINITION OF TERMS

Assisted reproductive technology (ART): Fertility treatment involving the in vitro handling of gametes or embryos, mainly in vitro fertilisation and intracytoplasmic sperm injection.

Body mass index (BMI): Weight in kilograms divided by the square of height in metres, calculated from the pre-operative record and categorised using World Health Organization cut-offs: underweight < 18.5; normal 18.5–24.9; overweight 25.0–29.9; obese ≥ 30.0 kg/m².

Conception: A pregnancy confirmed by a urine pregnancy test and/or ultrasound within 24 months of the index myomectomy, ascertained from LNMP during the the structured follow-up interview. Measured as a binary variable (conceived or did not conceive).

Endometrial cavity distortion: Distortion of the uterine cavity by fibroids, as documented on pre-operative imaging or in the operation notes (yes or no).

Endometrial cavity entry: Breach of the endometrial cavity during myomectomy, as documented in the operation notes (yes or no).

Fibroid characteristics: The number of fibroids removed, the diameter of the largest fibroid (cm), the predominant fibroid location (submucosal, intramural, subserosal or mixed) and the uterine size (weeks), as recorded in the operation notes and pre-operative imaging.

Infertility: A documented inability to achieve a clinical pregnancy after 12 months or more of regular, unprotected sexual intercourse, as recorded in the medical file before myomectomy. Classified as primary (no prior pregnancy) or secondary (inability to conceive after a previous pregnancy).

Intraoperative factors: Characteristics of the operation recorded in the operation notes: endometrial cavity entry, estimated blood loss (mL) and perioperative blood transfusion.

Live birth: The delivery of a baby showing signs of life, typically after 28 weeks of gestation, as reported at the follow-up interview and verified against antenatal or birth records where available.

Myomectomy: Surgical removal of uterine fibroids with conservation of the uterus. In this study, all myomectomies were performed by laparotomy, as laparoscopic myomectomy was not performed for women with infertility at JOOTRH during the study period.

Patient-related factors: Characteristics of the woman recorded before surgery: age at surgery, body mass index, parity, type and duration of infertility, menstrual regularity, previous pregnancy loss and previous uterine surgery.

Post-operative complications: Any complication documented in the medical record during the post-operative period following the index myomectomy (yes or no).

Pregnancy outcome: The final status of a pregnancy conceived within two years of myomectomy, categorised as live birth, miscarriage, ongoing pregnancy or ectopic pregnancy, as reported at the follow-up interview.

Previous uterine surgery: A documented history of any uterine procedure before the index myomectomy, namely previous myomectomy, caesarean section or other uterine surgery, as recorded in the medical file (yes or no).

Reproductive outcome: Primarily, conception within two years of myomectomy, measured as a binary variable; pregnancy outcomes among women who conceived were reported descriptively.

Time to confirmed pregnancy: The interval in months from the date of myomectomy to the date on which pregnancy was first confirmed, or, where the confirmation date was unavailable, to the date estimated from the last normal menstrual period recorded in the antenatal booklet. Women who did not conceive were censored at their last follow-up.

Uterine fibroids: Benign tumours arising from the smooth muscle of the myometrium, diagnosed on pre-operative imaging and confirmed at surgery.

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CHAPTER ONE

INTRODUCTION

1.1 Background of the Study

Infertility is a major health challenge affecting millions of individuals worldwide. According to the World Health Organization, approximately one in six people, around 17.5% of the adult population, experience infertility during their reproductive lifetime, making it a major contributor to reproductive morbidity globally (World Health Organization, 2023). The burden of infertility is particularly high in low- and middle-income countries, where access to fertility evaluation and assisted reproductive technologies remains limited. Infertility is not only a health issue; it carries profound psychological, social and economic consequences, especially in societies where childbearing is highly valued (Abebe et al., 2020).

Fibroids are the commonest benign uterine neoplasms affecting women of reproductive age. Although many remain asymptomatic, they are a common cause of gynaecological morbidity and infertility (Bulun et al., 2025). Fibroids are monoclonal tumours arising from the smooth muscle cells of the myometrium and are composed of varying proportions of smooth muscle and fibrous connective tissue (Bulun et al., 2025). They are classified according to their location in the uterus as submucosal, intramural or subserosal (Munro et al., 2011). Epidemiological evidence indicates that the estimated cumulative incidence of fibroids by the age of 50 years exceeds 80% in Black women and is approximately 70% in White women, showing a large racial disparity in disease occurrence (Sefah et al., 2023).

Several risk factors have been associated with the development of uterine fibroids, including increasing age, African ancestry, obesity, nulliparity, early menarche and a positive family history (Sefah et al., 2023). Women of African descent are disproportionately affected; they tend to develop fibroids at younger ages and to present with larger, more numerous and more

symptomatic fibroids than women of other races (Sefah et al., 2023). As a result, uterine fibroids constitute a significant reproductive health burden in sub-Saharan Africa, where they are among the leading indications for gynaecological surgery (Morhason-Bello & Adebamowo, 2022).

Most fibroids remain asymptomatic; others are associated with abnormal uterine bleeding, pelvic pain, pressure symptoms, recurrent pregnancy loss and infertility. Fibroids may impair fertility through several mechanisms, including distortion of the uterine cavity, interference with implantation, altered uterine contractility, inflammation and disruption of endometrial receptivity (Don et al., 2023; Donnez et al., 2024). The effect on fertility depends mainly on the size, number and location of the fibroids. Fibroids that distort the uterine cavity, especially submucosal fibroids, are known to reduce implantation and pregnancy rates; large intramural fibroids may also compromise fertility, whereas subserosal fibroids generally have little effect on the ability to conceive (Donnez et al., 2024).

In sub-Saharan Africa, where infertility remains a major reproductive health concern and access to assisted reproductive technologies is often limited by cost and availability, myomectomy continues to play a central role in the management of women with fibroids who wish to conceive. Myomectomy involves the surgical removal of fibroids while conserving the uterus and may be performed hysteroscopically, laparoscopically or through an abdominal approach, depending on the characteristics of the fibroids and the available surgical expertise (Donnez et al., 2024). Evidence suggests that myomectomy is followed by improved reproductive outcomes in selected women, particularly those with cavity-distorting submucosal fibroids and symptomatic intramural fibroids associated with infertility (Donnez et al., 2024).

Despite myomectomy being frequently performed, reproductive outcomes after the procedure remain variable. A retrospective study conducted in Addis Ababa, Ethiopia, reported a pregnancy rate of 56.7% following myomectomy and examined patient- and fibroid-related

factors associated with conception (Jeldu et al., 2021). Studies from other settings have similarly shown that reproductive outcomes following myomectomy may be influenced by patient-related factors such as age and duration of infertility, fibroid-related characteristics including size, number and location, and intraoperative factors such as uterine cavity entry (Donnez et al., 2024; Jeldu et al., 2021).

In Kenya, uterine fibroids are commonly encountered in gynaecological practice, and myomectomy remains one of the most frequently performed uterus-conserving procedures in tertiary hospitals (Morhason-Bello & Adebamowo, 2022). However, published evidence on reproductive outcomes following myomectomy among women with infertility remains limited, data from western Kenya are scarce, and the factors associated with conception following surgery have not been adequately characterised. This study therefore assessed reproductive outcomes within two years of myomectomy, and the factors associated with them, among women with infertility at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH).

1.2 Statement of the Problem

At JOOTRH, myomectomy is the principal surgical intervention offered to women with uterine fibroids who wish to conceive, and in a setting where assisted reproductive technology is largely unavailable or unaffordable, it is often the only fertility-directed treatment these women receive. Yet the reproductive outcomes that follow the procedure at the facility, namely how many women conceive, how soon they conceive, and how their pregnancies end, have not been systematically documented. The patient, fibroid and intraoperative characteristics associated with conception after surgery in this population are likewise unknown.

In the absence of local evidence, decisions on patient selection, the timing of surgery and the counselling of women before and after myomectomy at JOOTRH rely on data drawn largely from high-income settings and from laparoscopic or hysteroscopic series, where patient

profiles, fibroid burden, surgical approach and access to adjunctive fertility treatment differ substantially (Donnez et al., 2024; Orlando et al., 2021). This mismatch risks unrealistic expectations, delayed recourse to alternative fertility care and surgery whose expected benefit for the individual woman is uncertain. There is therefore a need for locally derived evidence on reproductive outcomes, and their associated factors, within a defined period after myomectomy among women with infertility at JOOTRH.

1.3 Justification of the Study

The study is justified by the need to inform treatment decisions for women with fibroid-associated infertility at JOOTRH. Although myomectomy is routinely performed for this indication in Kenya (Mumo et al., 2024), the evidence used to guide it comes almost entirely from high-income countries and from laparoscopic or hysteroscopic series, and may not transfer to the local context because of differences in fibroid burden, genetic background, surgical approach and access to care (Donnez et al., 2024; Orlando et al., 2021; Sefah et al., 2023).

Low- and middle-income settings such as Kenya also face distinct health-system challenges that shape outcomes. Assisted reproductive technologies such as in vitro fertilisation are largely unavailable and unaffordable while the burden of infertility is high (Abebe et al., 2020; World Health Organization, 2023), and specialised fertility investigations such as hysterosalpingography and semen analysis are inconsistently performed (Muteshi & Chesire, 2025). Because uterine fibroids are the sole cause of infertility in only 2–3% of cases (Don et al., 2023), coexisting tubal, ovulatory and male-factor causes may substantially influence conception irrespective of surgery, yet local data on which women are most likely to conceive after myomectomy are lacking.

Locally derived estimates of the likelihood and timing of conception after myomectomy, and of the characteristics associated with conception, will allow clinicians at JOOTRH to select patients for surgery more appropriately, to give women realistic expectations before and after the operation, and to decide when alternative or additional fertility care should be considered. The study therefore addresses a practical gap in the evidence used to make treatment decisions in this and similar resource-limited settings (Morhason-Bello & Adebamowo, 2022).

1.4 Significance of the Study

Uterine fibroids are a common cause of infertility among women of reproductive age, and the burden is particularly high in sub-Saharan Africa, where women of African ancestry tend to develop fibroids earlier and to present with larger, more numerous and more symptomatic tumours (Morhason-Bello & Adebamowo, 2022; Sefah et al., 2023). In Kenya, fibroids are among the most frequently encountered gynaecological conditions in tertiary practice, including at JOOTRH (Mumo et al., 2024), and myomectomy remains the principal uterus-conserving option for women who wish to conceive (Donnez et al., 2024; Metwally et al., 2020).

The study contributes to the field in three ways. First, it provides the first institutional estimates from western Kenya of conception within two years of myomectomy among women with infertility, of live birth among those who conceive, and of the time to confirmed pregnancy. These figures serve as local benchmarks for pre-operative counselling and treatment decisions. Second, it identifies the patient, fibroid and intraoperative characteristics associated with conception in this population, supporting better patient selection in keeping with recommendations that myomectomy for fertility be guided by careful case selection(Carranza-Mamane et al., 2015; Penzias et al., 2021). Third, it documents the completeness of the pre-operative fertility work-up, including tubal patency and male-partner assessment, and thereby

identifies a specific, modifiable gap in the care of women undergoing myomectomy for infertility.

For women with fibroid-associated infertility, for whom childbearing carries considerable social and psychological weight, the findings translate into individualised information about their likelihood and expected timing of conception (World Health Organization, 2023). For the hospital and the wider health system, the evidence can inform protocols for pre-operative fertility evaluation and structured post-operative follow-up. Finally, by providing data from a western Kenyan tertiary setting where such information is currently lacking, the study strengthens the regional evidence base and lays the groundwork for future prospective, multicentre research and for locally relevant clinical guidelines.

1.5 Objectives

1.5.1 Broad Objective

To assess the reproductive outcomes and associated factors within two years of myomectomy among women with infertility at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH).

1.5.2 Specific Objectives

1. To describe the reproductive outcomes within two years following myomectomy among women with infertility at JOOTRH.
2. To identify the patient-related factors associated with conception within two years following myomectomy among women with infertility at JOOTRH.
3. To assess the association between fibroid characteristics, selected intraoperative factors and conception within two years following myomectomy among women with infertility at JOOTRH.

4. To estimate the time to confirmed pregnancy within two years following myomectomy among women with infertility at JOOTRH.

1.6 Research Questions

1. What are the reproductive outcomes within two years following myomectomy among women with infertility at JOOTRH?
2. Which patient-related factors are associated with conception within two years following myomectomy among women with infertility at JOOTRH?
3. What is the association between fibroid characteristics, selected intraoperative factors and conception within two years following myomectomy among women with infertility at JOOTRH?
4. What is the time to confirmed pregnancy within two years following myomectomy among women with infertility at JOOTRH?

1.7 Conceptual Framework

The study was guided by a conceptual framework that sets out how patient-related factors and fibroid and intraoperative factors are expected to relate to reproductive outcomes following myomectomy among women with infertility (Figure 1.1).

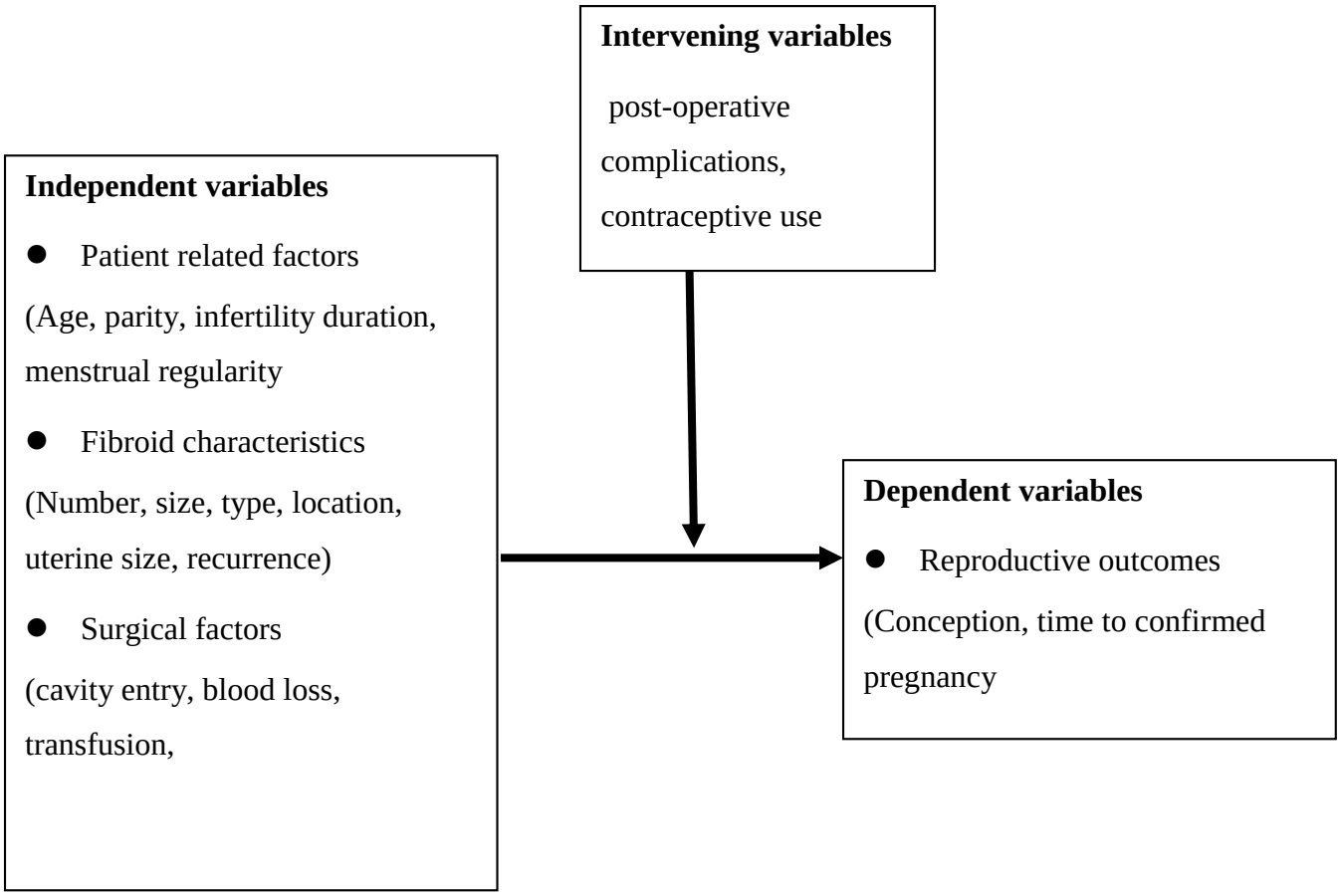


Figure 1.1: Conceptual Framework

The independent variables comprise three domains. Patient-related factors include age, body mass index, parity, type and duration of infertility, menstrual regularity and previous uterine surgery. Fibroid factors include the number of fibroids removed, the diameter of the largest fibroid, fibroid location, uterine size, endometrial cavity distortion and endometrial cavity entry during surgery. These characteristics are present at, or determined during, the operation and are the exposures examined under Objectives 2 and 3.

The dependent variables are conception within two years of myomectomy, the time to confirmed pregnancy and, among women who conceive, the pregnancy outcome. The framework proposes that the independent variables influence both the likelihood and the timing of conception.

Post-operative complications and post-operative contraceptive use are shown as intervening variables. Both occur after surgery; post-operative complications may lie on the pathway between fibroid and intraoperative characteristics and conception (for example, through adhesion formation), while contraceptive use reduces the time during which conception is possible. Their role in the analysis is described in Section 3.12.

Male-factor and tubal-factor infertility are recognised determinants of a couple's fertility. Evaluation of the male partner and of tubal patency was, however, outside the scope of this study, which focused on the woman, her fibroids and her surgery, and these factors were inconsistently documented in the records. They are therefore not included as study variables in the framework; their potential influence on the findings is acknowledged in the study limitations (Section 6.3).

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Uterine fibroids (leiomyomas) are the most frequently diagnosed benign tumours in women of reproductive age. Arising from the smooth muscle cells of the uterine wall, they vary widely in size, number and anatomical location. Although the estimated cumulative incidence reaches 70–80% by the age of 50 years, only about a quarter of affected women become symptomatic, and fewer still experience fertility-related complications (Sefah et al., 2023). For those who are affected, fibroids can produce a broad spectrum of reproductive and gynaecological problems, including subfertility, miscarriage, abnormal uterine bleeding and adverse obstetric outcomes (Donnez et al., 2024).

The relationship between fibroids and infertility is not uniform; it is governed largely by fibroid type, size and location, which explains much of the inconsistency across the literature (Turkgeldi et al., 2024). Submucosal fibroids are the most consistently implicated in reduced fertility, primarily because they distort the endometrial cavity and impair implantation, and their removal is the scenario in which benefit is least disputed (Turkgeldi et al., 2024). Large or multiple intramural fibroids may also compromise fertility by disrupting uterine contractility and endometrial receptivity, but the evidence here is conflicting and the benefit of removing them remains contested (Metwally et al., 2020). Subserosal fibroids are usually regarded as having minimal effect on fertility unless they are very large or exert pressure on adjacent reproductive structures (Turkgeldi et al., 2024).

Myomectomy remains the standard uterus-conserving treatment, and it assumes particular importance in low-resource settings where access to assisted reproductive technology (ART) is limited (Donnez et al., 2024; Morhason-Bello & Adebamowo, 2022). Removal of cavity-

distorting submucosal or large intramural fibroids is associated with improved fertility, yet the range of benefit is highly variable and is shaped by patient age, ovarian reserve, fibroid burden, surgical technique and intraoperative findings (Donnez et al., 2024; Lebovitz et al., 2019). Reproductive outcomes may be further modified by post-operative consequences such as pelvic adhesions, fibroid recurrence and the risk of uterine rupture in future pregnancies (Carranza-Mamane et al., 2015).

These considerations have led to efforts to identify which women achieve favourable reproductive outcomes after myomectomy, since understanding how demographic, fibroid-related and surgical factors interact is key to good surgical decision-making and realistic pre-operative preparation (Donnez et al., 2024). This chapter therefore examines the existing evidence on reproductive outcomes following myomectomy and their determinants, paying particular attention to data from sub-Saharan Africa and other resource-constrained settings, where such surgery is frequently performed in the absence of ART (Morhason-Bello & Adebamowo, 2022).

2.2 Burden of Uterine Fibroids on Women with Infertility

Internationally, the reported prevalence of uterine fibroids varies widely, from 20% to 70%, but this variation is driven less by true population differences than by differences in study design, diagnostic method and whether asymptomatic women are screened, since imaging-based studies detect far more disease than symptom-based ones (Morhason-Bello & Adebamowo, 2022). When women are followed to the age of 50 years, the estimated cumulative incidence rises to 70–80%, confirming that the apparent variability reflects detection rather than a low underlying burden (Sefah et al., 2023). A consistent international finding is the disproportionate burden borne by women of African descent, who are roughly two to three times more likely to develop fibroids than White women, tend to present at a

younger age, and more often have larger, more numerous and more symptomatic tumours (Sefah et al., 2023).

Among women with infertility specifically, fibroids are identified in approximately 5–10%, but they are considered the sole cause of infertility in only 2–3% of cases (Don et al., 2023). Infertility in women with fibroids is therefore frequently multifactorial, a point developed further in Section 2.8.

Within Africa, fibroids constitute a substantial clinical burden and are a leading cause of gynaecological morbidity and major surgery across the continent (Morhason-Bello & Adebamowo, 2022). However, the true prevalence in many African settings is likely to be underestimated, because limited access to imaging, normalisation of symptoms such as menorrhagia and pelvic discomfort, and sociocultural barriers to care-seeking all suppress diagnosis and formal reporting (Morhason-Bello & Adebamowo, 2022). As a result, hospital-based African studies, which capture predominantly symptomatic women presenting for care, tend to report lower prevalence figures than the imaging-based cumulative-incidence estimates from high-income settings, even though the underlying burden among women of African descent is high.

The context in which fibroid-associated infertility is managed also differs markedly between settings. In high-income countries, ART is widely accessible, and myomectomy is frequently combined with, followed by or replaced by in vitro fertilisation, so that the reproductive outcome of a woman with fibroids reflects both surgery and assisted conception. In sub-Saharan Africa, including Kenya, ART is costly, largely confined to private urban centres and beyond the reach of most women, while the burden of infertility is high (Abebe et al., 2020; World Health Organization, 2023). Myomectomy is therefore often the only fertility-directed intervention offered, it is usually performed for larger and more numerous fibroids, and subsequent conception depends largely on natural fertility (Morhason-Bello & Adebamowo,

2022). Outcomes reported from high-income settings cannot therefore be assumed to apply to women managed in this region.

At the regional level, fibroids are among the most frequently encountered gynaecological conditions in Kenyan tertiary facilities. A retrospective review at JOOTRH in Kisumu found that uterine fibroids accounted for 4% of gynaecological ward cases, with the highest prevalence among women aged 35–39 years and among nulliparous women, that is, predominantly women of reproductive age (Mumo et al., 2024). This shows that fibroids cluster among women in their peak reproductive years, underlines their relevance to fertility in the study setting and provides the immediate context for the present study.

2.3 Pathophysiology of Uterine Fibroids

Uterine fibroids are monoclonal tumours that arise from the smooth muscle of the myometrium, and their growth reflects a combination of hormonal, genetic and molecular mechanisms. Oestrogen and progesterone are key drivers that promote smooth muscle growth and the deposition of extracellular matrix (ECM), which gives fibroids their characteristic firm, fibrous texture. Fibroid tissue usually expresses a higher density of oestrogen and progesterone receptors than normal myometrium, which accounts for its marked hormonal sensitivity (Sefah et al., 2023).

Genetic alterations are equally important in fibroid pathogenesis. The best-characterised finding is somatic mutation of the MED12 gene, present in approximately 70–77% of fibroids, which disrupts transcriptional control and cell-cycle regulation and enhances signalling pathways that favour cell survival and ECM production. A second, largely mutually exclusive, pathway involves rearrangements of the HMGA2 gene, reflected in recurrent cytogenetic changes such as trisomy 12 and translocations between chromosomes 12 and 14, which further contribute to fibroid initiation and progression (Bulun et al., 2025).

The reproductive impact of fibroids depends largely on their anatomical characteristics: size, number and location. Submucosal fibroids, which protrude into the endometrial cavity, show the strongest association with impaired fertility, obstructing implantation, provoking endometrial inflammation and disrupting normal uterine contractility (Donnez et al., 2024). Large intramural fibroids, usually those greater than 4 cm or those distorting the cavity contour, may also hinder conception by altering endometrial receptivity, disturbing uterine peristalsis or compressing the interstitial portion of the fallopian tubes (Turkgeldi et al., 2024).

Beyond these anatomical effects, fibroids induce local biochemical and vascular changes that render the uterine environment less favourable to conception. These include increased expression of pro-inflammatory cytokines, altered angiogenic signalling and abnormal ECM composition, together with impaired endometrial blood flow and disturbed sperm and embryo transport, all of which can compromise implantation and early placentation (Don et al., 2023; Donnez et al., 2024). Myomectomy may reverse several of these effects, most clearly when the fibroids substantially distort the endometrial cavity. Reproductive outcomes after surgery nevertheless remain variable, depending on the number and location of fibroids removed, the degree of anatomical restoration achieved and any post-operative complications (Donnez et al., 2024; Metwally et al., 2020).

2.4 Reproductive Outcomes After Myomectomy

Reproductive outcomes after myomectomy are most often described in terms of the clinical pregnancy rate, the live birth rate and the miscarriage rate among women who wish to conceive. In the most comprehensive systematic review comparing fertility-preserving treatments, myomectomy was associated with the highest rate of successful pregnancy (75.6%), exceeding that of uterus-preserving alternatives such as uterine artery embolisation, which carried the lowest live birth rate and the highest miscarriage rate (Khaw et al., 2020). A separate systematic

review of women attempting conception after myomectomy reported a comparable pregnancy rate of 77.9% and a live birth rate of 54.4%, showing that although most women in these series conceived, a substantial proportion of pregnancies did not proceed to live birth (Margueritte et al., 2021).

Reported outcomes vary widely between studies, with pregnancy rates ranging from roughly 50% to nearly 80%. This reflects differences in study populations, fibroid burden and location, surgical approach, duration of follow-up, and the definitions used for pregnancy and live birth, rather than a true inconsistency in the effect of surgery (Donnez et al., 2024; Khaw et al., 2020) . Current evidence indicates that myomectomy does not reduce fertility and tends to be followed by improved reproductive outcomes, most clearly when submucosal fibroids that distort the uterine cavity are removed, while the benefit of removing intramural fibroids remains less certain (Metwally et al., 2020).

The time to pregnancy is directly relevant to a two-year outcome window, since most pregnancies after myomectomy occur within this period. The mean interval between surgery and conception has been estimated at approximately 17.6 months, which means that follow-up of two years captures the majority of women who will conceive and provides a clinically meaningful period over which to describe outcomes (Margueritte et al., 2021).

Evidence from sub-Saharan Africa, though more limited, is broadly consistent with these international findings. A retrospective study from Addis Ababa reported a post-myomectomy pregnancy rate of 56.7%, situating regional outcomes within the range reported globally despite differences in fibroid burden and access to care (Jeldu et al., 2021). Such data remain scarce across the region, and few studies describe reproductive outcomes specifically among women who underwent surgery for fibroid-associated infertility, as opposed to mixed indications (Morhason-Bello & Adebamowo, 2022). This gap is particularly pronounced in Kenya, and in western Kenya specifically, where reproductive outcomes following myomectomy at tertiary

facilities such as JOOTRH remain largely undocumented. Describing these outcomes within a defined two-year period is therefore essential to establishing a local evidence base for counselling and surgical decision-making.

2.5 Patient-Related Factors Associated with Reproductive Outcomes

Among the determinants of fertility after myomectomy, patient-related characteristics are consistently reported as the most influential, and of these, maternal age is the strongest and most reproducible predictor. Older age is associated with a markedly lower probability of conception, reflecting the parallel decline in ovarian reserve and oocyte quality that occurs independently of the fibroids themselves (Donnez et al., 2024). This pattern is evident across settings: in a study of intramural myomectomy, successful conception was concentrated among younger women (Lebovitz et al., 2019), and in a sub-Saharan African cohort, women older than 35 years were substantially less likely to conceive after surgery than women in their early twenties (Jeldu et al., 2021).

Because the age effect operates largely through ovarian reserve, markers of reserve are increasingly examined as predictors of post-surgical fertility, with lower anti-Müllerian hormone concentrations associated with a reduced likelihood of pregnancy in women undergoing uterus-conserving surgery (Won et al., 2021). This emphasises that a woman's baseline fertility potential, rather than the fibroid burden alone, contributes to the outcome of surgery.

Nutritional status and ovulatory function are further patient-related determinants of fertility. A high body mass index adversely affects ovulation, menstrual regularity, natural fertility and the success of fertility treatment, and is associated with an increased risk of early pregnancy loss, so that women with obesity may conceive less easily after myomectomy even after successful removal of their fibroids (Penzias et al., 2021). Menstrual regularity is a clinically accessible

marker of ovulatory function: regular, predictable cycles suggest reliable ovulation, whereas oligomenorrhoea or irregular cycles may imply an ovulatory disorder that limits conception regardless of the surgical outcome (Penzias et al., 2021). These factors are especially important in sub-Saharan African settings, where obesity is both a recognised risk factor for fibroids and an increasingly prevalent coexisting condition among women of childbearing age.

The duration and type of infertility are also important considerations. A longer duration of infertility before surgery and primary rather than secondary infertility are associated with poorer reproductive outcomes, and the indication for surgery matters, with women operated on for unexplained infertility showing distinct conception patterns compared with other groups (Jeldu et al., 2021). Closely related is the presence of coexisting causes of infertility: because fibroids are the sole cause of infertility in only a small minority of women, unrecognised or untreated tubal, ovulatory or male factors substantially limit the fertility benefit that can follow myomectomy (Don et al., 2023; Donnez et al., 2024). A history of previous uterine surgery is a further consideration, because prior operations on the uterus are a recognised cause of pelvic and intrauterine adhesions that may impair tubal function and implantation (Bortoletto et al., 2022).

Taken together, these findings indicate that the women most likely to conceive after myomectomy are younger, have adequate ovarian reserve, a healthy body mass index, regular ovulatory cycles, a shorter duration of infertility and no significant coexisting infertility factors. However, most of the supporting evidence originates from high-income settings, and data from sub-Saharan Africa remain limited to a small number of studies (Jeldu et al., 2021; Morhason-Bello & Adebamowo, 2022). This scarcity of region-specific evidence on patient-level predictors reinforces the need to characterise these factors among women undergoing myomectomy at JOOTRH, where patient profiles, duration of infertility and access to fertility

evaluation may differ appreciably from those in the settings where existing predictors were derived.

2.6 Fibroid Characteristics and Intraoperative Factors

Of the fibroid characteristics that influence reproductive outcome, anatomical location is the most decisive. Submucosal fibroids, which distort the endometrial cavity, carry the highest risk of impaired fertility and pregnancy loss, and their removal produces the most consistent improvement in conception rates (Turkgeldi et al., 2024). Intramural fibroids occupy an intermediate and more contested position: large or cavity-distorting intramural fibroids appear to reduce fertility, whereas small, non-cavity-distorting ones may not, and the reproductive benefit of removing them is correspondingly uncertain (Metwally et al., 2020). Subserosal fibroids, by contrast, exert little effect on fertility and are least likely to change outcomes when excised (Turkgeldi et al., 2024).

Fibroid size and number are also relevant, though their effects are less clearly delineated than that of location. Larger intramural fibroids, particularly those exceeding 4 cm or distorting the cavity contour, are more likely to compromise reproductive function (Donnez et al., 2024). A greater number of fibroids has been associated with a lower probability of conception after surgery, as demonstrated in a sub-Saharan African cohort in which the number of fibroids independently predicted the post-myomectomy pregnancy rate (Jeldu et al., 2021). Several mechanisms plausibly explain this association: removal of multiple fibroids requires more, and often deeper, myometrial incisions; it increases the extent of serosal and endometrial disruption and therefore the risk of pelvic and intrauterine adhesions; and it may leave a uterine wall of poorer structural and functional integrity (Bortoletto et al., 2022; Margueritte et al., 2021). Multiple fibroids are also more likely to recur. The number of fibroids removed was therefore

retained as a study variable, given the large and numerous fibroids typical of women in the study setting.

Beyond the fibroids themselves, the conduct of the operation can shape subsequent fertility, principally through its effect on the integrity of the endometrial cavity. Intraoperative entry into the uterine cavity is a recognised event during myomectomy and is of particular concern because it may predispose to intrauterine adhesions, which can in turn impair implantation and future conception. In a large cohort, post-operative intrauterine adhesions occurred in a relatively low proportion of women (9.3%) and did not vary with the number or size of fibroids removed; however, resection of submucosal fibroids was independently associated with an increased risk of adhesion formation, again implicating cavity-involving disease as the key determinant (Bortoletto et al., 2022).

Other intraoperative variables may serve as markers of surgical complexity and thus of reproductive prognosis. Prolonged operative time and greater intraoperative blood loss have been associated with lower rates of subsequent pregnancy in women undergoing uterus-conserving surgery, plausibly reflecting more extensive dissection and tissue trauma (Won et al., 2021). Furthermore, the depth of myometrial dissection and the use of energy during surgery influence the quality of uterine healing and, ultimately, the safety of any subsequent pregnancy, although the evidence linking these factors directly to conception rates remains limited (Margueritte et al., 2021).

Taken together, the literature indicates that cavity-distorting fibroids and intraoperative disruption of the endometrium are the fibroid- and surgery-related factors most consistently linked to reproductive outcomes, while the independent contributions of fibroid size, number and specific intraoperative details remain incompletely defined. Much of this evidence derives from high-income settings and from laparoscopic or hysteroscopic series, whereas intraoperative parameters are seldom documented in the open (abdominal) myomectomies that

predominate in sub-Saharan Africa (Bortoletto et al., 2022; Margueritte et al., 2021). This gap underscores the value of examining how fibroid characteristics and selected intraoperative factors relate to reproductive outcomes among women undergoing myomectomy at JOOTRH.

2.7 Time to Pregnancy After Myomectomy

The interval between myomectomy and confirmed pregnancy is an important reproductive outcome in its own right, because it determines how much of a woman's remaining reproductive lifespan is consumed before conception is achieved. Current evidence indicates that conception after myomectomy is not immediate: in a large systematic review, the mean interval from surgery to pregnancy was approximately 17.6 months, with a median of 13.3 months, meaning that most women who conceive do so more than a year after their operation (Margueritte et al., 2021). This timing has direct implications for study design, since a two-year window captures the majority of women who will conceive while remaining clinically practical (Khaw et al., 2020; Margueritte et al., 2021).

There is still no consensus on how long women should wait before attempting to conceive after myomectomy, and no professional guideline specifies a minimum interval. In clinical practice, advice varies widely, with roughly one-third of women counselled to wait three to six months and a further third to wait six to twelve months, on the rationale that uterine healing is radiologically evident by three to six months (Margueritte et al., 2021). The available evidence is, however, insufficient to support any specific minimum interval, and the risk of uterine rupture in a subsequent pregnancy appears low and unrelated to the length of the interval between surgery and conception (Margueritte et al., 2021). Prolonged post-operative delay is of particular concern for women who are older or have diminished ovarian reserve, in whom conception is least likely to occur promptly (Donnez et al., 2024).

Several factors are likely to lengthen the time to conception after myomectomy, and these largely mirror the determinants of conception itself. Advanced age and coexisting causes of infertility prolong the interval to pregnancy, as unresolved tubal, ovulatory or male factors continue to affect fertility after the fibroids are removed (Don et al., 2023; Donnez et al., 2024). Intraoperative entry into the endometrial cavity and the resulting risk of intrauterine adhesions may further delay conception through impaired implantation, while a heavier fibroid burden is associated with both lower and later conception (Bortoletto et al., 2022; Jeldu et al., 2021). The time to pregnancy therefore reflects the combined influence of patient, fibroid and surgical factors rather than the effect of surgery alone.

Evidence on the time to conception derives almost entirely from high-income settings and predominantly from laparoscopic or robot-assisted series, with very little data from sub-Saharan Africa, where open (abdominal) myomectomy predominates and post-operative follow-up systems are often weak (Margueritte et al., 2021; Morhason-Bello & Adebamowo, 2022). Consequently, the interval to confirmed pregnancy after myomectomy among African women with infertility remains poorly characterised, and studies such as the present one at JOOTRH are needed to estimate this interval in a resource-limited context and to inform realistic pre-operative counselling (Jeldu et al., 2021).

2.8 Consideration of Other Causes of Infertility

Because uterine fibroids are identified in only 5–10% of women with infertility and are considered the sole cause in just 2–3% of cases, infertility in women with fibroids is frequently multifactorial rather than attributable to the fibroids alone (Don et al., 2023). This has an important clinical corollary: before infertility is ascribed to fibroids, and before myomectomy is offered as a fertility-directed procedure, a systematic evaluation of both partners is valuable, since unrecognised coexisting factors will persist after surgery and limit any benefit (Donnez

et al., 2024). A complete assessment examines ovulatory function, tubal patency, the uterine cavity and ovarian reserve in the female partner, together with semen analysis as the first-line investigation in the male partner (Muteshi & Chesire, 2025).

The pattern of infertility causes in sub-Saharan Africa makes this consideration particularly pressing. A continental meta-analysis found that female-related factors accounted for approximately 54% of infertility, male-related factors for around 22% and both partners for a further 21%, with only about 10% remaining unexplained (Abebe et al., 2020). In women, pelvic inflammatory disease, tubal factors and previous pregnancy loss were the leading contributors, each with a pooled prevalence close to 39%, while among men, oligospermia, asthenozoospermia and varicocele predominated (Abebe et al., 2020). The high burden of tubal-factor infertility in the region is driven mostly by untreated sexually transmitted infections, especially gonorrhoea and chlamydia, which ascend the reproductive tract and cause tubal damage (Abebe et al., 2020). This regional profile means that a substantial proportion of women presenting for myomectomy may have a coexisting tubal or male factor capable of preventing conception irrespective of the surgery.

A thorough evaluation is therefore important. Failure to identify and address coexisting causes limits the fertility benefit that can follow myomectomy, so that a woman with cavity-distorting fibroids but untreated bilateral tubal occlusion is unlikely to conceive naturally even after successful surgery (Don et al., 2023; Donnez et al., 2024). In addition, the presence of such factors confounds the interpretation of post-myomectomy outcomes, because failure to conceive cannot always be attributed to the fibroids or the surgery when other causes remain unresolved.

These considerations informed the design of the present study. The study population comprised women with both uterine fibroids and infertility who underwent myomectomy, reflecting the population encountered in routine clinical practice rather than a highly selected group. Women

who had undergone bilateral tubal ligation were excluded, since a deliberate and permanent non-fibroid cause of infertility would preclude any meaningful assessment of conception following myomectomy. Other coexisting factors were not used as exclusion criteria, in part because reliable retrospective data on hormonal profiles and tubal patency are frequently incomplete or absent from hospital records; this limitation is acknowledged in the interpretation of the findings.

2.9 Gaps in Literature

The evidence reviewed in this chapter establishes that myomectomy is the principal uterus-conserving treatment for women with fibroid-associated infertility and that it is generally followed by favourable reproductive outcomes (Donnez et al., 2024; Khaw et al., 2020). Yet several gaps limit the direct application of this evidence to women managed at JOOTRH, and it is these gaps that the present study was designed to address.

First, reproductive outcomes after myomectomy remain highly variable, with reported pregnancy rates ranging from roughly 50% to nearly 80% across studies, and much of this evidence derives from high-income settings and from laparoscopic or hysteroscopic series (Khaw et al., 2020; Margueritte et al., 2021). Data from sub-Saharan Africa are comparatively scarce, and the few available studies rarely focus specifically on women operated on for infertility as opposed to mixed surgical indications (Jeldu et al., 2021; Morhason-Bello & Adebamowo, 2022). Reproductive outcomes following myomectomy among women with infertility in western Kenya, in particular, remain largely undocumented; this is the gap addressed by the first objective.

Second, although patient-related factors such as age, ovarian reserve, duration of infertility and coexisting infertility factors are consistently reported as determinants of conception after myomectomy, the supporting evidence originates predominantly from settings whose patient profiles differ appreciably from those in western Kenya, where women often present later and with more advanced disease (Donnez et al., 2024; Lebovitz et al., 2019). The extent to which

these patient-level factors operate in this local population has not been characterised, which the second objective seeks to establish.

Third, while fibroid characteristics, especially cavity-distorting location, and intraoperative factors such as endometrial cavity entry are recognised influences on fertility, the independent contributions of fibroid size and number, and of specific intraoperative details, remain incompletely defined (Bortoletto et al., 2022; Morhason-Bello & Adebamowo, 2022; Turkgeldi et al., 2024). Moreover, these intraoperative parameters are seldom documented in the open (abdominal) myomectomies that predominate in the region, leaving their relationship to reproductive outcomes locally unexamined; addressing this is the aim of the third objective.

Fourth, the interval between surgery and conception is an important but poorly characterised outcome, with almost all existing estimates drawn from high-income, minimally invasive series and virtually none from sub-Saharan Africa, where post-operative follow-up systems are often weak (Margueritte et al., 2021; Morhason-Bello & Adebamowo, 2022). The time to confirmed pregnancy after myomectomy among African women with infertility is therefore unknown, and estimating it is the focus of the fourth objective.

Underlying all four gaps is a broader interpretive challenge. Because fibroids are rarely the sole cause of infertility, and coexisting tubal, ovulatory and male factors are especially prevalent in sub-Saharan Africa, reproductive outcomes after myomectomy cannot be understood in isolation from a woman's wider fertility profile (Abebe et al., 2020; Don et al., 2023). A pragmatic study that reflects the population actually treated at a tertiary referral hospital, rather than a highly selected cohort, is therefore needed to generate locally applicable evidence. This study responds to these gaps by retrospectively examining reproductive outcomes, and the patient, fibroid and intraoperative factors associated with them, among women with infertility who underwent myomectomy at JOOTRH.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Study Design

This study adopted a single-arm retrospective cohort design. The study was conceptualised in March 2025 and reviewed the medical records of women with infertility who underwent myomectomy at JOOTRH between January 2019 and January 2024, supplemented by structured follow-up interviews to ascertain reproductive outcomes. Three time frames are distinguished in this thesis. The procedure window is the five-year period from January 2019 to January 2024 during which the myomectomies included in the study were performed. The outcome window is the 24 months following each woman's surgery, within which conception was assessed. The data-collection period comprised record review followed by follow-up interviews in March and April 2026, by which time every participant had passed at least two years since her surgery.

3.2 Study Area

The study was carried out in Kisumu County, in the western region of Kenya. The county lies on the north-eastern shores of Lake Victoria, within the Lake Victoria basin, and forms part of the former Nyanza Province. Administratively, Kisumu County is divided into seven sub-counties: Kisumu Central, Kisumu East, Kisumu West, Seme, Nyando, Muhoroni and Nyakach. The county had a population of 1,155,574 at the 2019 Kenya Population and Housing Census (Kenya National Bureau of Statistics, 2019), and its residents, together with those of the neighbouring counties of western Kenya, depend largely on public health facilities for specialised medical care.

The population of the area is predominantly Luo, with substantial representation of other Kenyan communities in Kisumu city. Childbearing carries high social value in the region;

infertility is associated with considerable stigma, marital strain and social pressure, particularly for women, and women with infertility often seek care late after trying traditional and informal remedies. Specialised fertility services, including assisted reproductive technology, are not available in the public health sector in the region and are accessible only through private providers at a cost beyond the reach of most families. Surgical treatment of fibroids at a public referral facility is therefore the main fertility-directed treatment available to most women in the area.

3.3 Study Site

The study site was Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), the largest public health facility in Kisumu County and the wider Nyanza and western Kenya region. JOOTRH is a Level 6 teaching and referral hospital that serves as the principal referral centre for county, sub-county and private facilities across more than ten counties in western Kenya. It offers comprehensive specialised services, including obstetrics and gynaecology, is a major centre for gynaecological surgery in the region, and functions as a teaching and research facility affiliated with the Maseno University School of Medicine.

Uterine fibroids constitute a substantial share of the gynaecological workload at the hospital. A retrospective review of admissions to the JOOTRH gynaecological ward reported that uterine fibroids accounted for 4% of gynaecological ward cases, with the highest prevalence among women aged 35–39 years (31%) and among nulliparous women (27%). In that review, myomectomy was the second most common treatment overall (27% of cases) after total abdominal hysterectomy (42%), and it was the principal uterus-preserving procedure offered to women wishing to retain fertility (Mumo et al., 2024).

During the procedure window, all myomectomies performed on women with infertility at JOOTRH were done by laparotomy; laparoscopic myomectomy was performed at the facility

only for indications other than infertility. A total of 250 myomectomies were performed on women with infertility over this period. The hospital maintains structured clinical, theatre and medical records, which enabled retrospective retrieval of surgical and reproductive data and made it a suitable site for this retrospective cohort study.

3.4 Study Population and Target Population

The target population comprised women of reproductive age with infertility who undergo myomectomy for uterine fibroids. These women represent the population managed with uterus-conserving surgery for fibroid-associated infertility within the regional setting.

The study population consisted of women who underwent myomectomy at JOOTRH for the management of uterine fibroids, with a documented history of infertility before surgery, between January 2019 and January 2024. Participants were identified through review of theatre registers, the gynaecological surgical registry and inpatient files.

3.5 Eligibility Criteria

Participants were considered eligible for inclusion in the study on the basis of the following inclusion and exclusion criteria.

3.5.1 Inclusion Criteria

1. Women of reproductive age (18–45 years) at the time of surgery.
2. A documented history of infertility preceding the myomectomy.
3. Underwent myomectomy at JOOTRH between January 2019 and January 2024.

3.5.2 Exclusion Criteria

1. Women who had undergone bilateral tubal ligation (BTL), since a deliberate and permanent non-fibroid cause of infertility would preclude any meaningful assessment of conception following myomectomy.
2. Women with incomplete medical records for the key study variables.

3.6 Sample Size Determination

Yamane's formula was used to establish the minimum number of participants required to estimate the primary outcome, the proportion of women achieving pregnancy following myomectomy, with 95% confidence and a 5% margin of error. The minimum required sample size was therefore 172 participants. The identification of eligible women and their retention through follow-up are described in Section 3.7 and summarised in Figure 4.1.

Yamane's formula :(Yamane 1967)

$$n = N / 1 + N (e^2)$$

n = desired sample size

N= total population (250)

e = margin of error

$n= 250 / 1+250(0.05)^2 = 250/1.625$

=154 participants

To account for potential nonresponse or missing data, a 10% adjustment was be applied

Adjusted sample size:

Adjusted n = n / (1 − non-response rate)

Adjusted n = 154 / (1 − 0.10)

Adjusted n = 154 / 0.9

Adjusted n = 171.1

Adjusted n ≈ 172 participants

3.7 Sampling Technique

Eligible participants were identified using a list-based approach from the gynaecological surgical registry and the gynaecology ward admission and discharge records at JOOTRH. Together, these records provided a comprehensive list of women who underwent myomectomy between January 2019 and January 2024. Participant files were screened for eligibility on the basis of documented infertility preceding the index myomectomy, a confirmed diagnosis of uterine fibroids and the availability of adequate information through medical records and follow-up interviews.

Although systematic random sampling was considered at the protocol stage, the eligible population was finite and, after eligibility screening and follow-up, the number of women with complete outcome data was smaller than the calculated sample size. All eligible women who met the study criteria and completed follow-up were therefore included in the final analysis. Women who could not be traced or who lacked complete outcome data were necessarily excluded, and the potential for loss-to-follow-up bias arising from this is addressed in the limitations of the study.

3.8 Study Recruitment Strategy

Patient records were identified from the Gynaecological Surgical Registry at JOOTRH, which records names, inpatient numbers, the date of surgery and the indication for surgery for women

who underwent myomectomy between January 2019 and January 2024. Using this information, individual patient files were retrieved from the hospital medical records department for review.

Each file was reviewed to determine eligibility against the inclusion and exclusion criteria. For eligible participants, initial telephone contact was made using the contact information documented in the medical records. During this first call, the purpose of the study was explained and permission was sought to contact the participant for a follow-up interview. Participants were asked to identify a convenient date and time for the interview and were encouraged to prepare relevant medical documents, such as antenatal clinic booklets, delivery records, discharge summaries or follow-up clinic notes, that could improve the accuracy of recall.

A second telephone call was then conducted at the agreed time using a structured interview guide to obtain reproductive outcome information following myomectomy. Participants were encouraged to be in a quiet and comfortable environment during the interview and to allow adequate time for the discussion. Where clarification of missing or inconsistent information was required, additional follow-up calls were made. Eight participants who preferred face-to-face interaction were interviewed in person at the hospital.

Two research assistants, both qualified clinical officers trained by the principal investigator, participated in file review, follow-up interviews and data entry under the supervision of the principal investigator. All collected data were de-identified and stored securely, and access to study data was restricted to the principal investigator and authorised research assistants.

3.9 Pilot Study

Before the start of the main data collection, an internal pilot study was conducted with twelve participants. The pilot assessed the feasibility and practicality of the study procedures, the clarity and completeness of the data abstraction tool and the follow-up interview guide, the

adequacy of the participant contact procedures and the flow of the telephone interviews, and identified potential challenges in the retrieval or interpretation of patient records.

An internal rather than an external pilot was chosen because the source population was finite and fully listed: it comprised all women who underwent myomectomy for infertility at JOOTRH during the procedure window, and no comparable pool of women was available elsewhere for piloting.

The pilot size of twelve participants follows the methodological recommendation that twelve participants are sufficient for a pilot study whose purpose is to assess feasibility and to estimate variability. The tools were found to be clear, complete and usable, and no modifications were made to either the data abstraction tool or the follow-up interview guide. As the tools remained unchanged, the twelve pilot participants were retained and included in the final analysis.

3.10 Data Collection Procedures

Data collection was conducted in two phases using standardised tools to ensure systematic and reliable collection of information. The first phase involved abstraction of clinical data from patient medical records, and the second involved structured follow-up interviews to obtain information on reproductive outcomes.

In the first phase, a structured data abstraction tool (Appendix 3) was used to retrieve demographic, reproductive, clinical and surgical information from the medical records of women who underwent myomectomy at JOOTRH between January 2019 and January 2024. Information collected included age at surgery, height, weight, parity, type and duration of infertility, previous pregnancy loss, previous uterine surgery, fibroid characteristics (number, size and location), uterine size, intraoperative findings including uterine cavity entry, estimated blood loss and transfusion, post-operative complications, and fertility-related investigations

such as hysterosalpingography and male-partner assessment where available. The completeness of fibroid removal was taken from the operation notes.

In the second phase, structured follow-up interviews were conducted in March and April 2026 using a standardised interview guide, to add to and verify the information obtained from medical records. Contact details recorded in the patients' medical files were used to make an initial telephone call, during which the study was introduced, verbal consent was sought and a convenient date and time for the interview were agreed. Participants were asked to prepare any available medical documents, such as antenatal clinic booklets, discharge summaries or birth records, that could improve the accuracy of the information provided.

Follow-up interviews were conducted at the agreed time, either by telephone or, for participants who preferred, in person at the hospital. Information collected during the interview included whether a pregnancy had been confirmed after surgery, the date of confirmation or the last normal menstrual period as recorded in the antenatal booklet, post-operative contraceptive use, frequency of intercourse, pregnancy outcome, gestational age at delivery and mode of delivery. Where information was missing or inconsistent, participants were contacted again for clarification. Data collection and interviews were carried out by the principal investigator and two trained research assistants, who were trained on the study objectives, ethical considerations, confidentiality and the correct use of both tools to ensure standardised data collection and minimal inter-observer variability.

3.11 Data Quality Assurance

Several measures were implemented to enhance the validity and reliability of the data. Internal validity was strengthened through strict application of the inclusion and exclusion criteria, ensuring that only women with documented infertility preceding myomectomy for uterine fibroids were included. Standardised definitions of the key outcomes, namely confirmed

pregnancy, live birth, miscarriage and time to confirmed pregnancy, were applied consistently to all participants.

Reliability of data collection was enhanced through the use of standardised instruments, comprising a structured data abstraction tool and a follow-up interview guide, which were tested in the internal pilot described in Section 3.9. Data collectors were trained by the principal investigator in the standardised application of the tools. Additional quality-control measures included routine checks for complete data collection forms, double-entry verification during data entry, and follow-up clarification calls where information obtained from records or interviews was incomplete or inconsistent.

The use of records created before the study was conceived was inherent to the retrospective cohort design. The exposures examined, namely patient, fibroid and intraoperative characteristics, were documented during routine clinical care between January 2019 and January 2024, at least 14 months before the study was conceptualised in March 2025, when neither clinicians nor patients were aware that a study would follow. Their documentation could not, therefore, have been influenced by the research question or by knowledge of the outcome. The potential sources of bias and the measures taken to minimise them were as follows:

- Selection bias: all myomectomies performed during the procedure window were identified from theatre registers and the gynaecological surgical registry, all eligible women were approached, and exclusions at each stage (48 incomplete records, 18 not meeting the inclusion criteria and 16 not reachable) are reported transparently in Table 4.1 and Figure 4.1.
- Information bias: a pilot-tested, standardised abstraction tool and standard outcome definitions were used, with double data entry and clarification calls; variables with

substantial missing data (tubal patency and male-partner assessment) were not imputed or forced into the regression models.

- Recall bias: participants were asked in advance to have antenatal booklets, discharge summaries and birth records available during the interview, and reported information was cross-checked against hospital records where these were available.
- Confounding: potential confounders were addressed through multivariable logistic regression and Cox proportional-hazards regression, as described in Section 3.12.

Residual bias that could not be eliminated is acknowledged in the study limitations (Section 6.3).

3.12 Data Analysis

Data were entered, cleaned and analysed using IBM SPSS Statistics version 26.0. Descriptive statistics were used to summarise the sociodemographic, reproductive, fibroid-related, intraoperative and outcome variables. Continuous variables were assessed for normality using the Shapiro–Wilk test and summarised as means with standard deviations or medians with interquartile ranges, as appropriate, while categorical variables were summarised as frequencies and percentages. Body mass index was categorised using the World Health Organization cut-offs adopted by the Kenya Ministry of Health: underweight (< 18.5 kg/m²), normal (18.5–24.9 kg/m²), overweight (25.0–29.9 kg/m²) and obese (≥ 30.0 kg/m²).

The primary outcome was conception within two years (24 months) of myomectomy, analysed as a binary variable (conceived or did not conceive). Pregnancy outcomes among women who conceived were analysed descriptively.

Bivariate associations between categorical independent variables and conception were assessed using Pearson's chi-square test, or Fisher's exact test where expected cell counts were small. Continuous variables, which were not normally distributed, were compared between women

who conceived and those who did not using the Mann–Whitney U test. Crude (univariable) logistic regression was then performed for each candidate variable to obtain crude odds ratios (ORs) with 95% confidence intervals (CIs); continuous variables (number of fibroids removed, largest fibroid diameter and uterine size) were modelled per unit increase. Because the chi-square test is a test of independence on the contingency table whereas the p-value for a crude OR comes from the Wald test of the logistic regression coefficient, the p-values reported for the same variable by the two procedures need not be identical. Similarly, the Mann–Whitney U test compares the rank distributions of a continuous variable between the two outcome groups, whereas crude logistic regression tests a linear change in the log-odds of conception per unit increase; with skewed data, the two procedures can yield different p-values for the same variable.

Variables were selected for the multivariable models through an explicit, two-part procedure. A variable was entered if (a) it was associated with conception at $p < 0.05$ in the crude analysis, or (b) it was an established determinant of fertility after myomectomy in the literature reviewed in Chapter Two. Variables in category (b) were identified from the conceptual framework and agreed with the supervisors. The variables entered into each model, their role and the basis for their inclusion are summarised in Table 3.1.

Table 3.1: Variables Entered into the Multivariable Models, Their Role and the Basis for Inclusion

Model	Variable	Role	Basis for inclusion
Objective 2: multivariable logistic regression (Table 4.8)	Previous uterine surgery	Exposure of interest	Crude association (p = .023)
	Age group	Potential confounder	Established determinant (Donnez et al., 2024; Jeldu et al., 2021)
	Body mass index category	Potential confounder	Established determinant (Penzias et al., 2021)
	Type of infertility	Potential confounder	Established determinant (Jeldu et al., 2021)
	Duration of infertility	Potential confounder	Established determinant (Jeldu et al., 2021; Orlando et al., 2021)
Objective 3: multivariable logistic regression (Table 4.12)	Largest fibroid diameter	Exposure of interest	Established determinant (Donnez et al., 2024; Metwally et al., 2020)
	Number of fibroids removed	Exposure / confounder	Established determinant (Jeldu et al., 2021)
	Fibroid location	Exposure / confounder	Established determinant (Turkgeldi et al., 2024)
	Endometrial cavity entry	Exposure of interest	Established determinant (Bortoletto et al., 2022)
	Post-operative complications	Intervening variable	Conceptual framework; potential mediator (Section 3.12)
Objective 4: Cox proportional-hazards regression (Table 4.15)	Previous uterine surgery	Exposure of interest	Crude association; principal patient-related factor
	Age group	Potential confounder	Established determinant (Donnez et al., 2024)
	Largest fibroid diameter	Exposure of interest	Principal fibroid-related factor
	Fibroid location	Potential confounder	Established determinant (Turkgeldi et al., 2024)
	Endometrial cavity entry	Potential confounder	Established determinant (Bortoletto et al., 2022)

Note. **Parameters (degrees of freedom): Objective 2 model, 7 (7.7 events per parameter); Objective 3 model, 7 (7.7 events per parameter); Cox model, 8 (6.75 events per parameter); 54 conception events.**

Two separate multivariable logistic regression models were fitted, corresponding to Objectives 2 and 3, and results are presented as adjusted odds ratios (AORs) with 95% CIs and p-values. Parity was not entered into the patient-related model because it overlaps substantially with type of infertility (primary versus secondary), and including both would have added parameters without adding distinct information. Tubal patency and male-partner assessment were not modelled because they were not assessed in 77.4% and 50.6% of women respectively; they are reported descriptively, and their omission is acknowledged as a limitation.

Because the number of conception events (n = 54) limits the number of parameters that can be estimated reliably, model complexity was judged by the number of parameters (degrees of freedom) rather than the number of variables. The patient-related model contained seven parameters and the fibroid and intraoperative model seven parameters, giving 7.7 events per parameter for each; the Cox model contained eight parameters, giving 6.75 events per parameter. Although below the conventional guideline of ten events per variable these ratios lie within the range of five to nine events per variable at which simulation studies have shown estimation in logistic and Cox regression to be acceptable. The estimates are nevertheless interpreted with caution, with emphasis on effect sizes and confidence intervals.

Post-operative complications were included in the fibroid and intraoperative model as an intervening variable, consistent with the conceptual framework. Because complications occur after surgery and may lie on the pathway between fibroid characteristics and conception, adjustment for them may attenuate or alter the estimates for upstream fibroid variables the estimates from this model are therefore compared with those from the Cox model, which did not include post-operative complications.

Time to confirmed pregnancy was analysed using the Kaplan–Meier method, with time measured in months from the date of myomectomy to the date of confirmed pregnancy. Women who had not conceived were censored at their last follow-up. In this analysis, "survival" denotes

the probability of remaining non-pregnant, and the cumulative probability of conception is its complement. A life table summarising the number of women at risk, conceptions and the cumulative probability of conception at fixed intervals was constructed alongside the Kaplan–Meier curve; because time to conception was recorded in completed months, producing many tied event times, the life table provides a tabular summary of the same data shown graphically in the curve. Cox proportional-hazards regression was then performed to identify factors associated with time to conception, with results presented as adjusted hazard ratios (aHRs) with 95% CIs. The proportional-hazards assumption was assessed using Schoenfeld residuals.

Statistical significance was set at $p < 0.05$. In line with current guidance on the interpretation of p-values, results are interpreted primarily through their effect sizes and confidence intervals, and a non-significant result is regarded as an association not demonstrated in this sample rather than as evidence of no effect.

3.13 Ethical Considerations

Ethical approval for this study was obtained from the Institutional Scientific and Ethics Review Committee of JOOTRH (approval number ISEREC/JOOTRH/200/25). A research licence was subsequently obtained from the National Commission for Science, Technology and Innovation (NACOSTI licence number NACOSTI/P/26/4186815) before the commencement of data collection, and an approval letter was obtained from the hospital Chief Executive Officer to access patient files (Appendices 4–7).

Because the study involved the retrospective review of patient medical records followed by telephone follow-up, the ethics committee and the office of the hospital Chief Executive Officer granted approval to access existing medical records for the purposes of identifying eligible participants and retrieving their documented contact details, and to contact these participants

for follow-up. Procedures were observed throughout to protect participants' rights, dignity, privacy and confidentiality.

Participants were contacted using the telephone numbers documented in their medical records. During the initial telephone call, the purpose of the study was explained in a language the participant understood, and verbal consent was sought both to use their medical information and to contact them for a follow-up interview (Appendices 1 and 2). Participants who agreed were scheduled for the interview at a convenient date and time. Verbal confirmation of willingness to proceed was obtained again immediately before the structured follow-up interview began. Participants who preferred face-to-face interaction were interviewed in person at the hospital.

Participation was voluntary. Participants were informed that they were free to decline participation or to withdraw at any stage without any effect on the medical care they received. No financial incentives were provided, and no invasive procedures were performed. The study posed minimal risk, principally the possibility of emotional discomfort when recalling reproductive or surgical experiences. To minimise this, interviews were conducted respectfully and privately, and participants were able to pause or end the interview at any point.

To protect confidentiality, participant identifiers were removed during data entry and each participant was assigned a unique study code. Data were stored securely, were accessible only to the principal investigator and the research team, and were used solely for the purposes of this study. Although there was no direct clinical benefit to participants, the findings may contribute to improved fertility care and post-operative follow-up for women undergoing myomectomy in similar healthcare facilities.

3.14 Data Dissemination

This study was conducted in partial fulfilment of the requirements for the award of the degree of Master of Medicine in Obstetrics and Gynaecology at Maseno University. The findings will be shared with the Department of Obstetrics and Gynaecology and the management of JOOTRH, presented at scientific forums and submitted for publication in a peer-reviewed journal.

CHAPTER FOUR

RESULTS

4.1 Introduction and Participant Flow

This chapter presents the results of the study according to the specific objectives. Data were extracted from patient files, theatre records, laboratory and imaging reports and follow-up interview records, and were analysed using IBM SPSS Statistics version 26.0.

Of the 250 records screened, 48 were excluded because of incomplete records and 18 because they did not meet the inclusion criteria, leaving 184 eligible women. Of these, 16 could not be reached for follow-up because their documented telephone contacts were invalid, unreachable or could not be verified against the medical record. Follow-up was therefore completed for 168 of the 184 eligible women, a follow-up response rate of 91.3%, and these 168 women formed the final analytic sample. The analytic sample represented 97.7% of the calculated minimum sample size of 172. The participant flow is summarised in Table 4.1 and Figure 4.1.

Table 4.1: Participant Screening and Enrolment of Women with Infertility Who Underwent Myomectomy at JOOTRH, January 2019–January 2024

Study stage	n
Total patient records screened	250
Excluded: incomplete records	48
Excluded: did not meet inclusion criteria	18
Total eligible participants identified	184
Excluded: not reachable for follow-up	16
Included in final analysis	168

Note. Follow-up response rate = 168/184 (91.3%). The 16 women not reachable were those whose documented telephone contact was invalid, unreachable or could not be verified against the medical record.

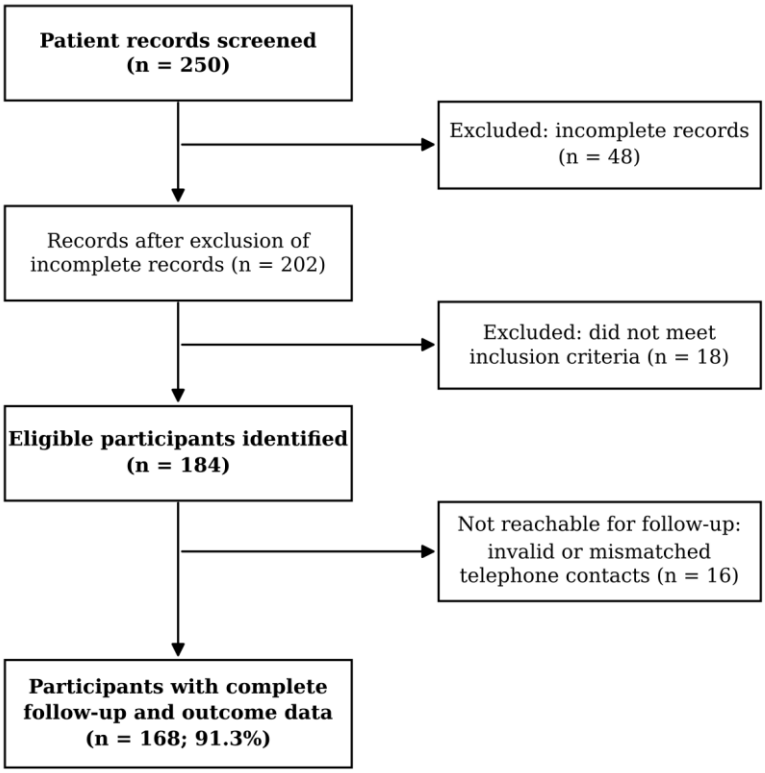


Figure 4.1. Participants screening and enrolment process of the study

4.2 Characteristics of the Participants

The sociodemographic characteristics of the 168 participants are presented in Table 4.2. The mean age was 34 ± 5 years, with 75 (44.6%) participants aged 35 years or older, the largest single age group. The mean body mass index was 27.0 ± 4.8 kg/m²; 54 (32.1%) participants were overweight and 48 (28.6%) were obese, so that 102 (60.7%) were overweight or obese.

Table 4.2: Sociodemographic Characteristics of Women with Infertility Who Underwent Myomectomy at JOOTRH (N = 168)

Characteristic	Category	n (%)
Age group	< 30 years	43 (25.6)
	30–35 years	50 (29.8)
	≥ 35 years	75 (44.6)
	Mean ± SD	34 ± 5
	Median (IQR)	35 (29–38)
Body mass index (kg/m²)	Normal	66 (39.3)
	Overweight	54 (32.1)
	Obese	48 (28.6)
	Mean ± SD	27.0 ± 4.8
	Median (IQR)	26.4 (23.1–30.5)

Note. SD = standard deviation; IQR = interquartile range. BMI categories (WHO): normal 18.5–24.9; overweight 25.0–29.9; obese ≥ 30.0 kg/m².

The reproductive and clinical characteristics of the participants are presented in Table 4.3. Most women had secondary infertility (129, 76.8%), and 71 (42.3%) had been infertile for five years or more. Ninety (53.6%) reported a previous pregnancy loss and 96 (57.1%) had undergone previous uterine surgery. Tubal patency had not been assessed by hysterosalpingography in 130 (77.4%) women, and a male-partner fertility assessment was documented for only 83 (49.4%) couples. Ninety-five (56.5%) women used contraception for a period after surgery, for a median of 6 months (IQR 3–9)

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Table 4.3: Reproductive and Clinical Characteristics of Women with Infertility Who Underwent Myomectomy at JOOTRH (N = 168)

Characteristic	Category	n (%)
Parity	Nulliparous	85 (50.6)
	Primiparous	59 (35.1)
	Multiparous	24 (14.3)
Type of infertility	Primary	39 (23.2)
	Secondary	129 (76.8)
Duration of infertility (years)	< 5	97 (57.7)
	≥ 5	71 (42.3)
History of pregnancy loss	Yes	90 (53.6)
	No	78 (46.4)
Previous uterine surgery	Yes	96 (57.1)
	No	72 (42.9)
HSG assessment	Bilateral blockage	17 (10.1)
	Unilateral blockage	5 (3.0)
	Normal tubal patency	16 (9.5)
	Not assessed	130 (77.4)
Menstrual regularity	Regular	90 (53.6)
	Irregular	78 (46.4)
Polycystic ovary syndrome	Yes	2 (1.2)
	No	166 (98.8)
Male-partner fertility assessment	Yes	83 (49.4)
	No	85 (50.6)
Frequency of intercourse (weekly)	< 1	41 (24.4)
	1–2	48 (28.6)
	≥ 3	37 (22.0)
	Not disclosed	42 (25.0)
Post-operative contraceptive use	Yes	95 (56.5)
	No	73 (43.5)
Duration of contraceptive use, months (n = 95)	Median (IQR)	6 (3–9)
	Mean ± SD	6 ± 4

Note. HSG = hysterosalpingography; IQR = interquartile range; SD = standard deviation.

4.3 Reproductive Outcomes Within Two Years After Myomectomy

The reproductive outcomes within two years of myomectomy are shown in Table 4.4. Of the 168 women, 54 (32.1%) conceived within two years of surgery and 114 (67.9%) did not.

Table 4.4: Reproductive Outcomes Within Two Years of Myomectomy Among Women with Infertility at JOOTRH (N = 168)

Reproductive outcome	n (%)
Conceived within two years	54 (32.1)
Did not conceive within two years	114 (67.9)
Total	168 (100.0)

Note. Percentages are of the whole cohort.

The outcomes of the 54 pregnancies are shown in Table 4.5. Live birth occurred in 34 women, 63.0% of those who conceived and 20.2% of the whole cohort. Fifteen (27.8%) pregnancies ended in miscarriage, 3 (5.6%) were ongoing at the time of follow-up and 2 (3.7%) were ectopic pregnancies.

Table 4.5: Pregnancy Outcomes Among Women Who Conceived Within Two Years of Myomectomy at JOOTRH (n = 54)

Pregnancy outcome	n (%)
Live birth	34 (63.0)
Miscarriage	15 (27.8)
Ongoing pregnancy	3 (5.6)
Ectopic pregnancy	2 (3.7)
Total	54 (100.0)

Note. Percentages are of the women who conceived.

4.4 Patient-Related Factors Associated with Conception

The bivariate associations between patient-related characteristics and conception are presented in Table 4.6. Among the patient-related characteristics assessed, only previous uterine surgery demonstrated a statistically significant association with conception ($p = .037$): 24 of 96 women (25.0%) with previous uterine surgery conceived, compared with 30 of 72 women (41.7%) without previous uterine surgery. Conception was not significantly associated with age group, body mass index, parity, type or duration of infertility, previous pregnancy loss, HSG findings, menstrual regularity, frequency of intercourse or post-operative contraceptive use.

Table 4.6: Association Between Patient-Related Characteristics and Conception Among Women with Infertility Who Underwent Myomectomy at JOOTRH (N = 168)

Characteristic	Category	Conceived n (%)	Did not conceive n (%)	p
Age (years)	< 30	11 (25.6)	32 (74.4)	.259
	30–35	14 (28.0)	36 (72.0)	
	≥ 35	29 (38.7)	46 (61.3)	
Body mass index	Normal	20 (30.3)	46 (69.7)	.408
	Overweight	15 (27.8)	39 (72.2)	
	Obese	19 (39.6)	29 (60.4)	
Parity	Nulliparous	23 (27.1)	62 (72.9)	.319
	Primiparous	23 (39.0)	36 (61.0)	
	Multiparous	8 (33.3)	16 (66.7)	
Type of infertility	Primary	14 (35.9)	25 (64.1)	.706
	Secondary	40 (31.0)	89 (69.0)	
Duration of infertility (years)	< 5	35 (36.1)	62 (63.9)	.267
	≥ 5	19 (26.8)	52 (73.2)	
History of pregnancy loss	Yes	27 (30.0)	63 (70.0)	.636
	No	27 (34.6)	51 (65.4)	
Previous uterine surgery	Yes	24 (25.0)	72 (75.0)	.037*
	No	30 (41.7)	42 (58.3)	
HSG assessment	Bilateral blockage	4 (23.5)	13 (76.5)	.817
	Unilateral blockage	2 (40.0)	3 (60.0)	
	Normal tubal patency	6 (37.5)	10 (62.5)	
	Not assessed	42 (32.3)	88 (67.7)	
Menstrual regularity	Regular	30 (33.3)	60 (66.7)	.850
	Irregular	24 (30.8)	54 (69.2)	
Frequency of intercourse (weekly)	< 1	15 (36.6)	26 (63.4)	.471
	1–2	16 (33.3)	32 (66.7)	
	≥ 3	8 (21.6)	29 (78.4)	
	Not disclosed	15 (35.7)	27 (64.3)	
Post-operative contraceptive use	Yes	32 (33.7)	63 (66.3)	.748
	No	22 (30.1)	51 (69.9)	

Note. Values are n (%) within each category. p from Pearson's chi-square test. * p < .05.

Table 4.7 presents the crude (univariable) logistic regression of patient-related factors associated with conception following myomectomy, the preliminary step of the regression analysis that provides the crude odds ratios against which the adjusted estimates in Table 4.8 are compared. Women with a history of previous uterine surgery were less likely to conceive than those without previous uterine surgery: 24 of 96 women (25.0%) with previous uterine surgery conceived, compared with 30 of 72 women (41.7%) without, corresponding to 53% lower odds of conception (crude OR 0.47, 95% CI 0.24–0.90, p = .023). The p-value differs slightly from that in Table 4.6 because Table 4.6 reports Pearson's chi-square test, whereas Table 4.7 reports the Wald test of the regression coefficient. No statistically significant associations were observed between conception and age, body mass index, type or duration of infertility, history of pregnancy loss, HSG findings, menstrual regularity, frequency of intercourse or post-operative contraceptive use. The wide confidence intervals observed for the HSG categories should be interpreted with caution because of the small number of participants in these groups (5–17 women per category).

Table 4.7: Crude (Univariable) Logistic Regression of Patient-Related Factors Associated with Conception Following Myomectomy at JOOTRH (N = 168)

Variable	Category	Crude OR	95% CI	p
Age group	< 30	1.00 (Ref.)	–	–
	30–35	1.13	0.45–2.89	.793
	≥ 35	1.83	0.82–4.32	.151
BMI category	Normal	1.00 (Ref.)	–	–
	Overweight	0.86	0.40–1.95	.762
	Obese	1.51	0.69–3.31	.304
Type of infertility	Primary	1.00 (Ref.)	–	–
	Secondary	0.80	0.38–1.74	.567
Duration of infertility	< 5 years	1.00 (Ref.)	–	–
	≥ 5 years	0.65	0.33–1.25	.203
Previous pregnancy loss	No	1.00 (Ref.)	–	–
	Yes	0.82	0.42–1.55	.523
Previous uterine surgery	No	1.00 (Ref.)	–	–
	Yes	0.47	0.24–0.90	.023*
HSG status	Normal	1.00 (Ref.)	–	–
	Bilateral block	0.51	0.11–2.29	.386
	Unilateral block	1.11	0.12–8.75	.920
	Not assessed	0.80	0.28–2.47	.677
Menstrual regularity	Irregular	1.00 (Ref.)	–	–
	Regular	1.12	0.59–2.17	.723
Intercourse frequency (weekly)	< 1	1.00 (Ref.)	–	–
	1–2	0.87	0.36–2.09	.748
	≥ 3	0.49	0.17–1.29	.151
	Not disclosed	0.96	0.40–2.37	.934
Contraceptive use	No	1.00 (Ref.)	–	–
	Yes	1.18	0.61–2.29	.626

Note. OR = odds ratio; CI = confidence interval; Ref. = reference category. p from the Wald test. * p < .05.

Table 4.8 presents the multivariable logistic regression of patient-related factors associated with conception following myomectomy. After adjustment for age, duration of infertility, body mass index and type of infertility, women with a history of previous uterine surgery had approximately 53% lower odds of conceiving within two years than those without previous uterine surgery (AOR 0.47, 95% CI 0.23–0.94, p = .034). This is a clinically important difference: previous uterine surgery was common in this cohort (57.1%) and was associated with roughly half the odds of conception. None of the other patient-related factors (age group,

duration of infertility, body mass index or type of infertility) demonstrated a statistically significant association with conception; their confidence intervals were wide, so clinically important effects of these factors cannot be excluded.

Table 4.8: Multivariable Logistic Regression of Patient-Related Factors Associated with Conception Following Myomectomy at JOOTRH (N = 168)

Variable	Category	AOR	95% CI	p
Previous uterine surgery	No	1.00 (Ref.)	–	–
	Yes	0.47	0.23–0.94	.034*
Age group	< 30	1.00 (Ref.)	–	–
	30–35	0.95	0.35–2.62	.926
	≥ 35	1.46	0.58–3.81	.426
Duration of infertility	< 5 years	1.00 (Ref.)	–	–
	≥ 5 years	0.72	0.34–1.51	.391
BMI category	Normal	1.00 (Ref.)	–	–
	Overweight	1.02	0.42–2.45	.966
	Obese	1.80	0.77–4.28	.174
Type of infertility	Primary	1.00 (Ref.)	–	–
	Secondary	0.70	0.25–1.94	.497

Note. AOR = adjusted odds ratio; CI = confidence interval; Ref. = reference category. Seven parameters; 54 events (7.7 events per parameter). * p < .05.

4.5 Fibroid and Intraoperative Factors Associated with Conception

The fibroid and intraoperative characteristics of the cohort are summarised in Table 4.9. The median number of fibroids removed was 8 (IQR 6–10), the median diameter of the largest fibroid was 8 cm (IQR 5–10) and the median uterine size was 20 weeks (IQR 18–22). Intramural fibroids were the most common predominant location (52, 31.0%), and endometrial cavity distortion was documented in 82 (48.8%) women. Most procedures involved an estimated blood loss of 500 mL to less than 1,000 mL (122, 72.6%), perioperative blood transfusion was given to 158 (94.0%) women, the endometrial cavity was entered in 94 (56.0%) procedures, and post-operative complications were recorded in 119 (70.8%) women.

Table 4.9: Fibroid and Intraoperative Characteristics of Women with Infertility Who Underwent Myomectomy at JOOTRH (N = 168)

Characteristic	Category	n (%)
Number of fibroids removed	Median (IQR)	8 (6–10)
	Mean ± SD	8 ± 4
Largest fibroid diameter (cm)	Median (IQR)	8 (5–10)
	Mean ± SD	8 ± 3
Uterine size (weeks)	Median (IQR)	20 (18–22)
	Mean ± SD	20 ± 4
Fibroid location	Intramural	52 (31.0)
	Subserosal	43 (25.6)
	Submucosal	40 (23.8)
	Mixed	33 (19.6)
Endometrial cavity distortion	Yes	82 (48.8)
	No	86 (51.2)
Pre-operative haemoglobin (g/dL)	8.0–10.9	91 (54.2)
	11.0–11.9	37 (22.0)
	≥ 12.0	40 (23.8)
Estimated blood loss (mL)	< 500	40 (23.8)
	500 to < 1,000	122 (72.6)
	≥ 1,000	6 (3.6)
Perioperative blood transfusion	Yes	158 (94.0)
	No	10 (6.0)
Endometrial cavity entry	Yes	94 (56.0)
	No	74 (44.0)
Post-operative complications	Yes	119 (70.8)
	No	49 (29.2)

Note. IQR = interquartile range; SD = standard deviation.

Table 4.10 presents the bivariate associations between fibroid and intraoperative characteristics and conception following myomectomy. None of the fibroid-related or intraoperative variables demonstrated a statistically significant association with conception (all $p > .05$). For example, conception occurred among 14 (35.0%) women with submucosal fibroids, 16 (30.8%) with intramural fibroids, 11 (25.6%) with subserosal fibroids and 13 (39.4%) with mixed fibroids, although these differences were not statistically significant ($p = .607$). Similarly, estimated blood loss, endometrial cavity entry, post-operative complications and endometrial cavity distortion were not significantly associated with conception.

Table 4.10: Association Between Fibroid and Intraoperative Characteristics and Conception Following Myomectomy at JOOTRH (N = 168)

Variable	Category	Conceived (n = 54)	Did not conceive (n = 114)	p
Fibroid location	Submucosal	14 (35.0)	26 (65.0)	.607
	Intramural	16 (30.8)	36 (69.2)	
	Subserosal	11 (25.6)	32 (74.4)	
	Mixed	13 (39.4)	20 (60.6)	
Endometrial cavity distortion	Yes	24 (29.3)	58 (70.7)	.539
	No	30 (34.9)	56 (65.1)	
Pre-operative haemoglobin (g/dL)	8.0–10.9	31 (34.1)	60 (65.9)	.845
	11.0–11.9	11 (29.7)	26 (70.3)	
	≥ 12.0	12 (30.0)	28 (70.0)	
Estimated blood loss (mL)	< 500	14 (35.0)	26 (65.0)	.901
	500 to < 1,000	38 (31.1)	84 (68.9)	
	≥ 1,000	2 (33.3)	4 (66.7)	
Endometrial cavity entry	Yes	28 (29.8)	66 (70.2)	.568
	No	26 (35.1)	48 (64.9)	
Post-operative complications	Yes	37 (31.1)	82 (68.9)	.785
	No	17 (34.7)	32 (65.3)	

Note. Values are n (%) within each category unless stated otherwise. p from Pearson's chi-square test for categorical variables and the Mann–Whitney U test for continuous variables.

Table 4.11 presents the crude (univariable) logistic regression of fibroid and intraoperative factors associated with conception following myomectomy. None of the fibroid-related or intraoperative factors demonstrated a statistically significant association with conception (all p > .05). Larger fibroid size was associated with lower odds of conception, with each one-centimetre increase in the diameter of the largest fibroid corresponding to an estimated 10% reduction in the odds of conception (crude OR 0.90, 95% CI 0.79–1.00, p = .055), although this association did not reach statistical significance. Similarly, the number of fibroids removed, uterine size, fibroid location, endometrial cavity distortion, pre-operative haemoglobin level, estimated blood loss, endometrial cavity entry (crude OR 0.78, 95% CI 0.41–1.50, p = .462) and post-operative complications (crude OR 0.85, 95% CI 0.42–1.74, p = .650) were not significantly associated with conception. Estimates for some variables were

accompanied by wide confidence intervals, indicating limited precision because of small numbers within certain categories.

Table 4.11: Crude (Univariable) Logistic Regression of Fibroid and Intraoperative Factors Associated with Conception Following Myomectomy at JOOTRH (N = 168)

Variable	Category	Crude OR	95% CI	p
Number of fibroids removed	Per fibroid	0.95	0.86–1.04	.258
Largest fibroid diameter (cm)	Per cm	0.90	0.79–1.00	.055
Pre-operative uterine size (weeks)	Per week	0.94	0.86–1.03	.182
Fibroid location	Mixed	1.00 (Ref.)	–	–
	Intramural	0.68	0.27–1.72	.415
	Submucosal	0.83	0.31–2.16	.699
	Subserosal	0.53	0.20–1.41	.202
Endometrial cavity distortion	No	1.00 (Ref.)	–	–
	Yes	0.77	0.40–1.48	.436
Pre-operative haemoglobin	≥ 12 g/dL	1.00 (Ref.)	–	–
	11–11.9 g/dL	1.00	0.37–2.63	.979
	8–10.9 g/dL	1.47	0.56–4.00	.648
Estimated blood loss	< 500 mL	1.00 (Ref.)	–	–
	500 to < 1,000 mL	0.84	0.40–1.82	.651
	≥ 1,000 mL	0.93	0.12–5.40	.936
Endometrial cavity entry	No	1.00 (Ref.)	–	–
	Yes	0.78	0.41–1.50	.462
Post-operative complications	No	1.00 (Ref.)	–	–
	Yes	0.85	0.42–1.74	.650

Note. OR = odds ratio; CI = confidence interval; Ref. = reference category. Continuous variables were modelled per unit increase. p from the Wald test.

Table 4.12 presents the multivariable logistic regression of fibroid and intraoperative factors associated with conception following myomectomy. After adjustment for the other variables in the model, larger diameter of the largest fibroid was associated with lower odds of conception: each one-centimetre increase was associated with an approximately 15% reduction

in the odds of conception (AOR 0.85, 95% CI 0.72–0.997, p = .048). Across the observed interquartile range of 5 to 10 cm, this corresponds to a potentially clinically meaningful difference. However, the association is borderline, the upper confidence limit lies close to 1, and the crude association did not reach statistical significance, so the estimate is imprecise and should be interpreted with caution. Fibroid number, fibroid location, endometrial cavity entry and post-operative complications were not significantly associated with conception (all p > .05). The relatively wide confidence intervals observed for several categorical variables indicate limited precision.

Table 4.12: Multivariable Logistic Regression of Fibroid and Intraoperative Factors Associated with Conception Following Myomectomy at JOOTRH (N = 168)

Variable	Category	AOR	95% CI	p
Largest fibroid diameter (cm)	Per cm	0.85	0.72–0.997	.048*
Number of fibroids removed	Per fibroid	1.01	0.84–1.20	.943
Fibroid location	Mixed	1.00 (Ref.)	–	–
	Submucosal	0.81	0.30–2.21	.681
	Intramural	0.66	0.25–1.76	.407
	Subserosal	0.58	0.20–1.68	.218
Endometrial cavity entry	No	1.00 (Ref.)	–	–
	Yes	0.98	0.41–2.40	.967
Post-operative complications	No	1.00 (Ref.)	–	–
	Yes	1.84	0.69–5.05	.224

Note. AOR = adjusted odds ratio; CI = confidence interval; Ref. = reference category. Continuous variables were modelled per unit increase. Post-operative complications were included as an intervening variable (Section 3.12). Seven parameters; 54 events (7.7 events per parameter). * p < .05.

4.6 Time to Confirmed Pregnancy

Table 4.13 summarises the time to conception among the 54 women who conceived following myomectomy. The median time to conception was 14.0 months (IQR 9.25–17.75), indicating

that half of these women conceived between approximately 9 and 18 months after surgery. The mean time to conception was 13.6 ± 6.0 months, with conception occurring as early as 3 months and as late as 24 months after myomectomy. These figures describe only the women who conceived and are not an estimate for the whole cohort; the time to conception for the whole cohort, which accounts for women who did not conceive, is presented in the survival analysis that follows.

Table 4.13: Time to Conception Among Women Who Conceived Within Two Years of Myomectomy at JOOTRH (n = 54)

Time to conception (months)	Value
Mean ± SD	13.6 ± 6.0
Median	14.0
Interquartile range	9.25–17.75
Minimum	3
Maximum	24

Note. n = 54 women who conceived. SD = standard deviation.

Table 4.14 presents the life-table analysis of time to conception following myomectomy. In this analysis, "survival" denotes the probability of remaining non-pregnant, and women who had not conceived were censored at their last follow-up. The cumulative probability of conception increased progressively throughout the 24-month follow-up period, with the greatest increase observed between 7 and 18 months after surgery. By the end of follow-up, the actuarial cumulative probability of conception was 35.0%. This figure differs from the crude conception rate of 32.1% (54/168) reported in Table 4.4: the crude rate treats every woman as observed for the full 24 months, whereas the actuarial estimate accounts for censored observations. Correspondingly, the number of women at risk of conception declined from 168 at baseline to 59 at the start of the final interval as participants conceived or were censored.

Table 4.14: Life Table of Time to Conception Following Myomectomy at JOOTRH (N = 168)

Time interval (months)	Number at risk	Number conceived	Survival probability	Cumulative conception (%)
0	168	0	1.00	0.0
0–3	167	1	0.99	1.0
4–6	161	7	0.95	5.0
7–12	145	15	0.86	14.0
13–18	115	19	0.75	25.0
19–24	59	12	0.65	35.0

Note. Survival probability = probability of remaining non-pregnant; cumulative conception = 1 − survival probability. Women who had not conceived were censored at their last follow-up.

Further assessment of time to conception is illustrated by the Kaplan–Meier curve in Figure 4.2. The probability of remaining non-pregnant declined steadily across the 24-month follow-up period, indicating that conceptions occurred throughout follow-up rather than clustering at any single interval. Because fewer than half of the cohort conceived, the Kaplan–Meier median time to conception was not reached; the median of 14 months reported above therefore refers only to the women who conceived.

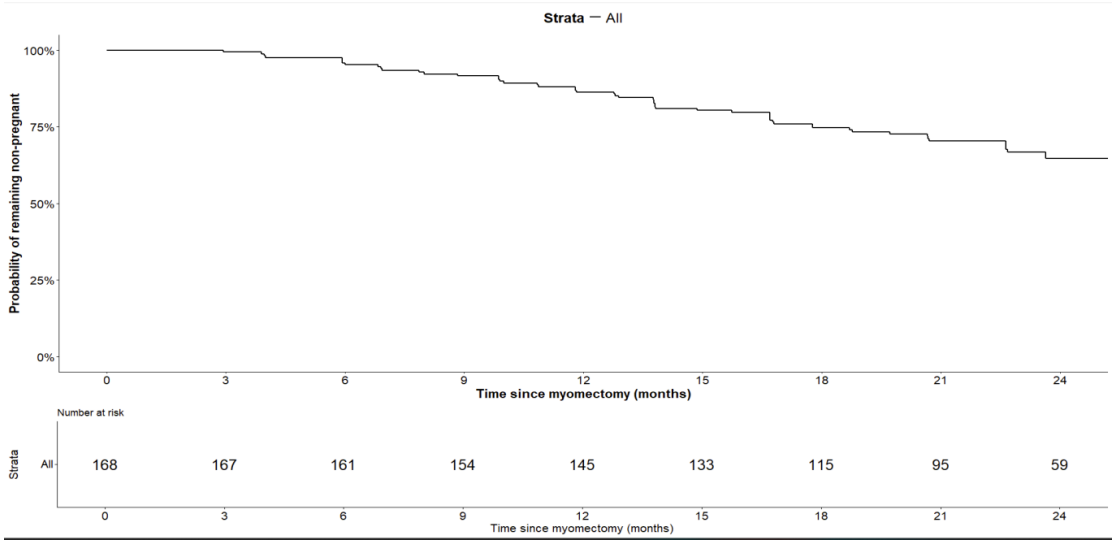


Figure 4.2: Kaplan–Meier Curve of Time to Confirmed Pregnancy Following Myomectomy

Table 4.15 presents the multivariable Cox proportional-hazards regression analysis of factors associated with time to conception following myomectomy. After adjustment for the other variables in the model, women with a history of previous uterine surgery had a 50% lower rate of conception during follow-up than those without previous uterine surgery (aHR 0.50, 95% CI 0.27–0.93, p = .029). Each one-centimetre increase in the diameter of the largest fibroid was associated with an estimated 13% reduction in the rate of conception over time (aHR 0.87, 95% CI 0.76–1.00, p = .051), but this association did not reach statistical significance. Age group, fibroid location and endometrial cavity entry were also not significantly associated with time to conception (all p > .05). The proportional-hazards assumption was assessed using Schoenfeld residuals and was satisfied for the final model.

Table 4.15: Cox Proportional-Hazards Regression of Factors Associated with Time to Conception Following Myomectomy at JOOTRH (N = 168)

Variable	Category	aHR	95% CI	p
Previous uterine surgery	No	1.00 (Ref.)	–	–
	Yes	0.50	0.27–0.93	.029*
Age group	< 30	1.00 (Ref.)	–	–
	30–35	0.99	0.42–2.34	.989
	≥ 35	1.65	0.75–3.64	.212
Largest fibroid diameter (cm)	Per cm	0.87	0.76–1.00	.051
Fibroid location	Mixed	1.00 (Ref.)	–	–
	Submucosal	0.73	0.31–1.71	.465
	Intramural	0.73	0.33–1.66	.457
	Subserosal	0.65	0.27–1.59	.343
Endometrial cavity entry	No	1.00 (Ref.)	–	–
	Yes	0.82	0.45–1.51	.531

Note. aHR = adjusted hazard ratio; CI = confidence interval; Ref. = reference category. Proportional-hazards assumption assessed using Schoenfeld residuals and satisfied. Eight parameters; 54 events (6.75 events per parameter). * p < .05.

CHAPTER FIVE

DISCUSSION

5.1 Introduction

This chapter discusses the principal findings of the study in the light of their biological plausibility and the existing global, regional and local evidence, and considers their implications for clinical practice in resource-limited settings. Four main findings are discussed: approximately one-third of women conceived within two years of myomectomy, and most of those who conceived had a live birth; previous uterine surgery was associated with both a lower likelihood of conception and a slower time to conception; and larger fibroid size was associated with lower odds of conception, although this estimate was imprecise. To the researcher's knowledge, this is among the first studies to characterise these outcomes among women with infertility in western Kenya. The discussion also considers how incomplete pre-operative fertility evaluation and limited access to assisted reproductive technology may have shaped outcomes that could otherwise be attributed to surgery alone.

5.2 Reproductive Outcomes Within Two Years After Myomectomy

In this cohort, 54 of 168 women (32.1%) conceived within two years of myomectomy, and the actuarial cumulative probability of conception, which accounts for censored follow-up, was 35.0% at 24 months. Conception was therefore achieved by a meaningful minority of women but was far from assured, and it occurred less often than many published series would predict. This tempered finding is clinically important because it positions myomectomy in this setting as a worthwhile but not curative intervention, and it cautions against the optimistic expectations that may be conveyed to patients before surgery. Because the study had no comparison group of women who did not undergo surgery, these figures describe the proportion of women who

conceived after myomectomy; they cannot be used to estimate the effect of myomectomy itself on fertility.

Placed against the wider evidence, the result lies at the lower end of the reported range. Globally, a recent literature review reported an overall clinical pregnancy rate of approximately 58% after myomectomy (Gnanachandran et al., 2023), and a systematic review of fertility-preserving treatments found that myomectomy was associated with the highest pooled pregnancy rate among the available options, at 75.6% (Khaw et al., 2020). Regionally, the closest comparator, a tertiary-hospital study in Addis Ababa, Ethiopia, reported a pregnancy rate of 56.7% (Jeldu et al., 2021). Locally, directly comparable Kenyan data are scarce, which is precisely the gap this study addresses. The conception rate observed here is therefore best understood not as an outlier but as the lower end of a wide spectrum shaped by population and case mix.

A particularly relevant comparison concerns ancestry. The same review reported markedly lower conception after myomectomy among women of African ancestry than among Caucasian women (24.3% versus 63.5%) (Gnanachandran et al., 2023). The rate of 32.1% observed in this entirely African cohort is consistent with that disparity. This should not be read as a fixed biological ceiling; rather, it reflects the factors that operate in this setting: a heavier fibroid burden, earlier and more symptomatic disease, a higher background prevalence of tubal and male-factor infertility, and more limited access to complete fertility evaluation and assisted reproduction.

Several mechanisms plausibly account for the comparatively modest rate. First, this cohort reflects real-world practice at a referral hospital rather than a selected fertility-clinic population, and so includes women with a poorer baseline prognosis; the fibroid burden was heavy, with a median of eight fibroids removed and a median uterine size of 20 weeks. Second, and most importantly, the pre-operative fertility work-up was frequently incomplete: tubal patency had

not been assessed by hysterosalpingography in 77.4% of women, and a male-partner assessment was documented for fewer than half of the couples. Because uterine fibroids are the sole cause of infertility in only 2–3% of cases, unrecognised tubal, ovulatory and male-factor infertility, which carry a high regional burden in sub-Saharan Africa, are likely to have limited conception in a substantial proportion of women irrespective of the surgery (Abebe et al., 2020; Don et al., 2023). Third, more than half the cohort used contraception for a period after surgery, reducing the time during which conception was possible. These factors suggest that the modest conception rate reflects the clinical realities of the setting.

The crude conception rate does not account for women with shorter follow-up, whereas the Kaplan–Meier estimate, which adjusts for this through censoring, yielded a higher cumulative probability of about 35%; the crude figure therefore slightly understates the probability of conception within two years. All conceptions observed occurred within 24 months, which is consistent with international evidence that most conceptions after myomectomy occur within the first two years and supports the two-year outcome window used in this study (Margueritte et al., 2021). Finally, the miscarriage rate of 27.8% among women who conceived is consistent with the high pre-operative prevalence of previous pregnancy loss in this cohort (53.6%), and is a reminder that achieving conception is not the same as achieving a live birth; 34 women (63.0% of those who conceived, and 20.2% of the whole cohort) had a live birth.

5.3 Patient-Related Factors Associated with Conception

Among the patient-related characteristics examined, a woman's surgical history mattered more than her demographic profile. Women with a history of previous uterine surgery had roughly half the odds of conceiving within two years of myomectomy (AOR 0.47), and this finding was consistent with the Cox model, in which they conceived at about half the rate over time (aHR

0.50). Because previous uterine surgery was common in this cohort (57.1%), this is a clinically significant finding for pre-operative counselling.

Several biological, surgical and clinical explanations may account for this association. Biologically, previous uterine surgery is a recognised cause of pelvic and intrauterine adhesions, which can impair fertility by distorting the endometrial cavity, obstructing or distorting the fallopian tubes and altering the relationship between the tube and the ovary, or by interfering with implantation (Bortoletto et al., 2022). Surgically, a prior uterine procedure adds to the trauma of the index myomectomy: repeat incisions into previously operated myometrium increase cumulative tissue injury and the likelihood of dense adhesions, and may compromise myometrial integrity and uterine perfusion. Clinically, previous uterine surgery, particularly a previous myomectomy, may also identify women with recurrent or more extensive fibroid disease and a longer history of infertility, in whom the overall prognosis for conception is poorer.

This finding is consistent with the wider literature. Globally, systematic reviews of fertility after non-hysteroscopic myomectomy have identified adhesion formation and the extent of uterine surgery as recurring influences on subsequent fertility (Orlando et al., 2021), and the risk of intrauterine adhesions after myomectomy is well documented (Bortoletto et al., 2022). Regionally, the Addis Ababa cohort similarly found that surgical and fibroid-burden characteristics influenced the pregnancy rate after myomectomy (Jeldu et al., 2021). Locally, no comparable Kenyan data were identified. The agreement across settings is plausibly explained by the shared mechanism of adhesion formation, which operates regardless of population. The magnitude of the effect observed here may, however, be larger than in high-income series because of the high proportion of women with a prior uterine operation in this cohort and the reliance on open surgery, which is associated with more adhesion formation than minimally invasive approaches.

Maternal age, one of the most consistently reported determinants of fertility after myomectomy in high-income series, was not significantly associated with conception in this study, nor were body mass index or the duration and type of infertility (Donnez et al., 2024; Orlando et al., 2021). Statistical power depends on the size of the effect being examined: with 54 conception events, the study was able to detect a large effect such as the roughly halved odds associated with previous uterine surgery, but had limited ability to detect the smaller effects that are plausible for age or body mass index. The relatively narrow age distribution of the cohort further reduced the contrast available to demonstrate an age effect. These results are therefore best described as associations not demonstrated in this sample, rather than as evidence that these factors are unimportant, and larger studies are needed before age and body mass index are discounted in this setting.

5.4 Fibroid and Intraoperative Factors Associated with Conception

Among the fibroid and intraoperative factors, fibroid size was the characteristic associated with conception: after adjustment, each additional centimetre in the diameter of the largest fibroid was associated with approximately 15% lower odds of conceiving (AOR 0.85, 95% CI 0.72–0.997). This direction of effect is consistent with substantial evidence that larger fibroids exert a greater negative effect on fertility, with a threshold of roughly 3–4 cm often cited as clinically important (Donnez et al., 2024; Metwally et al., 2020). The mechanism is well described: larger fibroids are more likely to distort the endometrial cavity, impair endometrial receptivity and disturb uterine contractility, each of which can reduce implantation and early pregnancy maintenance.

This finding should nevertheless be interpreted with caution. The crude association did not reach statistical significance (crude OR 0.90, p = .055), the adjusted estimate is borderline, with an upper confidence limit close to 1, and the model was based on 54 events. The fibroid model

also adjusted for post-operative complications, which occur after surgery and may lie on the pathway between fibroid characteristics and conception, so that the adjusted estimate for fibroid size may be affected by this adjustment. Reassuringly, the Cox model, which did not include post-operative complications, produced a very similar estimate for fibroid size (aHR 0.87, 95% CI 0.76–1.00), although this too did not reach statistical significance. The finding is therefore best interpreted as a consistent but imprecise association between larger fibroid size and lower likelihood of conception, which requires confirmation in larger prospective studies, rather than as an established determinant.

The absence of an association with fibroid location and endometrial cavity entry deserves critical comment, because it appears to conflict with literature identifying cavity-distorting and submucosal fibroids as the most detrimental to fertility, and with a systematic review reporting that fewer fibroids and the absence of cavity distortion were among the factors most consistently linked to reproductive outcome (Orlando et al., 2021; Turkgeldi et al., 2024). Two explanations may reconcile this. First, the number of events was too small to detect associations within location subgroups, so the null result may reflect limited power. Second, fibroid size may have captured part of the effect otherwise attributable to location, because larger fibroids are more likely to involve or distort the cavity. The lack of association with cavity entry is itself consistent with evidence that intraoperative cavity breach does not necessarily reduce conception, provided that adhesion formation is avoided (Bortoletto et al., 2022). The finding is also relevant to surgical approach: because the large and multiple fibroids typical of this setting frequently necessitate an open procedure, myomectomy by laparotomy remains the pragmatic option, and existing evidence suggests that the operative route has a limited independent effect on conception once fibroid burden is accounted for.

5.5 Time to Confirmed Pregnancy

Analysing the timing rather than merely the occurrence of conception added a clinically useful dimension. The cumulative probability of conception rose steadily to about 35% by 24 months, and the median time to conception among the women who conceived was 14 months (IQR 9–18). Because fewer than half of the cohort conceived, the Kaplan–Meier median was not reached, so the 14-month median describes only the women who conceived. This profile supports advising women to expect conception, if it occurs, over a one-to-two-year horizon rather than immediately after surgery, and it justifies a follow-up period of at least two years when evaluating reproductive outcomes. It is consistent with the systematic review by (Margueritte et al., 2021), which reported a median interval of 13.3 months from myomectomy to pregnancy, despite the differences in population and surgical approach between that review and the present study.

The Cox model reinforced the finding on surgical history: women with previous uterine surgery conceived at approximately half the rate over time (aHR 0.50, 95% CI 0.27–0.93). The consistency of this factor across two different modelling approaches, logistic regression for whether conception occurred and Cox regression for how quickly it occurred, makes it less likely that the association is a chance finding and strengthens the inference that previous uterine surgery is a genuine determinant of reproductive outcome in this population. Larger fibroid diameter showed the same direction of effect on the rate of conception but did not reach statistical significance (aHR 0.87, 95% CI 0.76–1.00, p = .051). The most reasonable interpretation is not that fibroid size is irrelevant to timing, but that the study had limited power to confirm an effect of this size.

5.6 Implications for Practice

Interpreted as a whole, the findings carry several practical implications for resource-limited settings. First, about one-third of women in this cohort conceived within two years of myomectomy, and about two-thirds of those who conceived had a live birth. Where assisted reproductive technology is largely unavailable, myomectomy remains a justifiable uterus-conserving option for women with fibroid-associated infertility, but counselling should be individualised and realistic, explicitly acknowledging the poorer prognosis of women with previous uterine surgery and possibly of those with large fibroids, and a conception horizon that extends up to two years.

Second, the high proportion of women operated on without a complete fertility evaluation is itself a modifiable problem: assessing tubal patency and male-partner factors before myomectomy would identify non-fibroid causes of infertility that may have limited conception in many women in this cohort. Third, counselling should extend beyond conception to the pregnancy itself: myomectomy is associated with recognised, if uncommon, obstetric risks, including uterine rupture and placental complications, so women who conceive warrant closer antenatal surveillance and individualised delivery planning (Gnanachandran et al., 2023). Fourth, the consistency of the association with previous uterine surgery argues for careful surgical technique and adhesion-reduction strategies in women with a prior uterine procedure. These implications should be read alongside the limitations of the study.

CHAPTER SIX

CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

1. Approximately one-third (32.1%) of women with fibroid-associated infertility conceive within two years following myomectomy at JOOTRH, and 63.0% of those who conceive achieve a live birth. This provides a locally derived estimate of reproductive outcomes that was previously undocumented at this facility.
2. Previous uterine surgery is the only patient-related factor associated with reduced odds of conception within two years of myomectomy, whereas age, body mass index and the duration and type of infertility show no significant association with conception in this population.
3. Larger fibroid diameter is associated with lower odds of conception after adjustment, although the estimate is imprecise and requires confirmation; fibroid location, endometrial cavity entry and the other intraoperative factors show no clear association with conception.
4. The cumulative probability of conception reaches approximately 35% within 24 months following myomectomy, compared with a crude conception rate of 32.1%, and previous uterine surgery is associated with a slower time to confirmed pregnancy.

6.2 Strengths of the Study

1. This is among the first studies to describe reproductive outcomes following myomectomy among women with infertility in western Kenya, addressing a genuine gap in locally relevant evidence.

2. All eligible women operated on over the five-year procedure window were included rather than a sample, which maximised the available data and reduced selection bias at the identification stage.
3. Reproductive outcomes were ascertained through direct follow-up interviews in addition to record review, capturing conception and pregnancy events that would not have been documented in hospital files alone.
4. The analysis combined logistic regression with time-to-event methods (Kaplan–Meier and Cox regression), allowing both the occurrence and the timing of conception to be examined while accounting for variable follow-up; the proportional-hazards assumption of the Cox model was assessed and met.

6.3 Limitations and Delimitations

The following limitations were encountered when interpreting these findings; each was addressed, where possible, through a corresponding delimitation.

1. The study was retrospective, and data depended in part on the completeness and accuracy of hospital records, raising the possibility of information bias and missing data. This was delimited by restricting the study to a single tertiary facility with a structured records system and by supplementing record review with direct follow-up interviews, allowing key reproductive outcomes to be verified or completed at source.
2. Reproductive outcomes were partly self-reported during interviews conducted up to seven years after surgery, so recall bias may have affected the accuracy of reported dates of conception and pregnancy outcomes. This was delimited by asking participants in advance to have relevant documents, such as antenatal booklets and discharge summaries, available, and by cross-checking reported information against medical records.

3. Sixteen eligible women could not be included because their contact details were invalid or they could not be reached, introducing potential loss-to-follow-up bias. This was delimited by attempting to include all eligible women rather than a sample, and by reporting the losses at each stage of the participant flow so that the extent of the bias is transparent.

4. The pre-operative fertility work-up was frequently incomplete. Most participants had secondary infertility (76.8%) and 42.3% had been infertile for five years or more, both of which increase the likelihood of tubal disease, yet tubal patency was not assessed in 77.4% of women and a male-partner assessment was not documented for 50.6% of couples. Evaluation of male-factor and tubal-factor infertility was beyond the scope of this study and these factors could not be adjusted for; undetected tubal or male factors may account for part of the non-conception observed, so the conception rate may underestimate what is achievable with complete pre-operative evaluation.

5. The number of conception events (n = 54) limited the statistical power of the multivariable models and the number of parameters that could be estimated reliably, raising the risk of type II error and of imprecise estimates. This was delimited by restricting each adjusted model to a small set of predictors chosen on the basis of crude associations and established evidence, by reporting events per parameter, and by interpreting results through their effect sizes and confidence intervals.

6. The study was a single-arm cohort without a comparison group of women who did not undergo myomectomy. It can therefore describe the proportion of women who conceived after surgery and the factors associated with conception, but it cannot estimate the effect of myomectomy itself on fertility.

7. Nutritional status was assessed only through body mass index, and dietary factors and psychosocial stress, which may influence fertility, are not documented in gynaecological records and could not be assessed retrospectively. The completeness of fibroid removal was taken from operation notes, and residual fibroids were not systematically documented.

8. All myomectomies in the study were performed by laparotomy, because laparoscopic myomectomy was not performed for women with infertility at JOOTRH during the study period. The findings therefore apply to myomectomy performed by laparotomy and should not be extrapolated to laparoscopic or hysteroscopic myomectomy.

6.4 Recommendations

Based on the findings of this study, the following recommendations are made:

1. Clinicians should provide comprehensive pre-operative and post-operative fertility counselling to women undergoing myomectomy, including realistic, locally derived expectations: about one-third of women conceive within two years of surgery, and about two-thirds of those who conceive achieve a live birth.

2. Women with a history of previous uterine surgery should undergo thorough pre-operative fertility assessment and individualised counselling, as prior uterine surgery is associated with a lower and slower likelihood of conception following myomectomy.

3. Women presenting with large uterine fibroids should be evaluated without undue delay and considered for timely surgical intervention, since larger fibroid size may reduce the likelihood of conception following myomectomy; this recommendation should be revisited as more precise evidence becomes available.

4. Women should be followed for up to 24 months after myomectomy to monitor reproductive outcomes, and those with a history of previous uterine surgery should

receive closer follow-up and early referral for further fertility evaluation if conception is delayed.

5. A complete pre-operative fertility work-up, including assessment of tubal patency and partner semen analysis, should be undertaken before myomectomy is performed for infertility, so that coexisting causes of infertility are identified and addressed.

6.5 Suggestions for Future Studies

1. Multicentre prospective cohort studies involving diverse healthcare settings should be conducted to validate these findings, to estimate the conception rate after myomectomy with greater precision, and to improve generalisability to women undergoing myomectomy in Kenya and similar resource-limited settings.
2. Future research should evaluate the long-term reproductive and obstetric outcomes following myomectomy, including subsequent pregnancies, mode of delivery, uterine rupture and neonatal outcomes, to provide comprehensive evidence on maternal and fetal prognosis after surgery.
3. Prospective studies with complete pre-operative fertility evaluation, including tubal patency, male-partner assessment, ovarian reserve, nutritional status and psychosocial stress, are needed to confirm the associations of previous uterine surgery and fibroid size with conception, and to detect factors such as age and body mass index that the present study may have been underpowered to demonstrate.
4. Studies with a comparison group, such as women managed expectantly or with assisted reproduction, are needed to estimate the effect of myomectomy itself on fertility in this setting.
5. Future research should examine the mechanism by which previous uterine surgery reduces conception, including the role of intrauterine and pelvic adhesions and the

influence of the number and type of prior procedures, and should evaluate adhesion-reduction interventions in this higher-risk group.

REFERENCES

Abebe, M. S., Afework, M., & Abaynew, Y. (2020). Primary and secondary infertility in Africa: systematic review with meta-analysis. *Fertility Research and Practice*, *6*(1), 20. https://doi.org/10.1186/s40738-020-00090-3

Bortoletto, P., Keefe, K. W., Unger, E., Hariton, E., & Gargiulo, A. R. (2022). Incidence and risk factors of intrauterine adhesions after myomectomy. *F&S Reports*, *3*(3), 269–274. https://doi.org/10.1016/j.xfre.2022.05.007

Bulun, S. E., Yin, P., Wei, J., Zuberi, A., Iizuka, T., Suzuki, T., Saini, P., Goad, J., Parker, J. B., Adli, M., Boyer, T., Chakravarti, D., & Rajkovic, A. (2025). Uterine fibroids. *Physiological Reviews*, *105*(4), 1947–1988. https://doi.org/10.1152/physrev.00010.2024

Carranza-Mamane, B., Havelock, J., & Hemmings, R. (2015). The management of uterine fibroids in women with otherwise unexplained infertility. *J Obstet Gynaecol Can*, *37*(3), 277–288. https://doi.org/10.1016/S1701-2163(15)30232-4

Don, E. E., Mijatovic, V., & Huirne, J. A. F. (2023). Infertility in patients with uterine fibroids: a debate about the hypothetical mechanisms. *Human Reproduction*, *38*(11), 2045–2054. https://doi.org/10.1093/humrep/dead194

Donnez, J., Taylor, H. S., Marcellin, L., & Dolmans, M.-M. (2024). Uterine fibroid–related infertility: mechanisms and management. *Fertility and Sterility*, *122*(1), 31–39. https://doi.org/10.1016/j.fertnstert.2024.02.049

Gnanachandran, C., Penketh, R., Banzal, R., & Athauda, P. (2023). Myomectomy Benefits, Risks, Long-Term Outcomes, and Effects on Fertility and Pregnancy Outcomes: A Literature Review. *Journal of Gynecologic Surgery*, *39*(4), 151–157. https://doi.org/10.1089/gyn.2022.0127

Jeldu, M., Asres, T., Arusi, T., & Gutulo, M. G. (2021). Pregnancy Rate after Myomectomy and Associated Factors among Reproductive Age Women Who Had Myomectomy at Saint Paul's Hospital Millennium Medical College, Addis Ababa: Retrospective Cross-Sectional Study. *International Journal of Reproductive Medicine*, *2021*, 1–6. https://doi.org/10.1155/2021/6680112

Khaw, S. C., Anderson, R. A., & Lui, M. (2020). Systematic review of pregnancy outcomes after fertility-preserving treatment of uterine fibroids. *Reproductive BioMedicine Online*, *40*(3), 429–444. https://doi.org/10.1016/j.rbmo.2020.01.003

Lebovitz, O., Orvieto, R., James, K. E., Styer, A. K., & Brown, D. N. (2019). Predictors of reproductive outcomes following myomectomy for intramural fibroids. *Reproductive BioMedicine Online*, *39*(3), 484–491. https://doi.org/10.1016/j.rbmo.2019.04.130

Margueritte, F., Adam, C., Fauconnier, A., & Gauthier, T. (2021). Time to conceive after myomectomy: should we advise a minimum time interval? A systematic review. *Reproductive BioMedicine Online*, *43*(3), 543–552. https://doi.org/10.1016/j.rbmo.2021.05.016

Metwally, M., Raybould, G., Cheong, Y. C., & Horne, A. W. (2020). Surgical treatment of fibroids for subfertility. *Cochrane Database of Systematic Reviews*, *2020*(1). https://doi.org/10.1002/14651858.CD003857.pub4

Morhason-Bello, I. O., & Adebamowo, S. N. (2022). Epidemiology of uterine fibroid in black

African women: A systematic scoping review. *African Journal of Reproductive Health*, *26*(2), 10–25.

Mumo, J., Christine, A., Ogot, V., Njoki, N., Marube, A., Grace, L., & Kiplagat, J. (2024). Prevalence and Management of Uterine Fibroids among Women of Reproductive Age at Jaramogi Oginga Odinga Teaching and Referral Hospital, Kisumu. *East African Journal of Health and Science*, *7*(2), 141–149. https://doi.org/10.37284/eajhs.7.2.2507

Munro, M. G., Critchley, H. O. D., Broder, M. S., & Fraser, I. S. (2011). FIGO classification system (PALM- COEIN) for causes of abnormal uterine bleeding in nongravid women of reproductive age. *International Journal of Gynecology & Obstetrics*, *113*(1), 3–13. https://doi.org/10.1016/j.ijgo.2010.11.011

Muteshi, C., & Chesire, A. (2025). Approach to evaluation and management of male infertility in Sub- Saharan Africa. *International Journal of Gynecology & Obstetrics*, *169*(3), 913–920. https://doi.org/10.1002/ijgo.16196

Orlando, M., Kollikonda, S., Hackett, L., & Kho, R. (2021). Non-hysteroscopic Myomectomy and Fertility Outcomes: A Systematic Review. *Journal of Minimally Invasive Gynecology*, *28*(3), 598-618.e1. https://doi.org/10.1016/j.jmig.2020.10.006

Penzias, A., Azziz, R., Bendikson, K., Falcone, T., Hansen, K., Hill, M., Jindal, S., Kalra, S., Mersereau, J., Reindollar, R., Shannon, C. N., Steiner, A., Tanrikut, C., Taylor, H., & Yauger, B. (2021). Obesity and reproduction: a committee opinion. *Fertility and Sterility*, *116*(5), 1266–1285. https://doi.org/10.1016/j.fertnstert.2021.08.018

Sefah, N., Ndebele, S., Prince, L., Korasare, E., Agbleke, M., Nkansah, A., Thompson, H., Al-Hendy, A., & Agbleke, A. A. (2023). Uterine fibroids — Causes, impact, treatment, and lens to the African perspective. In *Frontiers in Pharmacology* (Vol. 13). Frontiers Media S.A. https://doi.org/10.3389/fphar.2022.1045783

Turkgeldi, E., Kalkan, U., & Ata, B. (2024). Uterine fibroids & infertility: which fibroids should be removed?—a narrative review. *Gynecology and Pelvic Medicine*, *7*, 26–26. https://doi.org/10.21037/gpm-22-29

Won, S., Hwang, J. Y., Lee, N., Kim, M., Kim, M. K., Kim, M.-L., Yun, B. S., Seong, S. J., & Jung, Y. W. (2021). Anti-Müllerian hormone level may predict successful pregnancy after adenomyomectomy in patients with infertility due to adenomyosis. *Medicine*, *100*(21), e26075. https://doi.org/10.1097/MD.0000000000026075

World Health Organization. (2023, April 4). *1 in 6 people globally affected by infertility*. World Health Organization. https://doi.org/10.1093/hropen/hoad007

APPENDICES

Appendix 1: Verbal Consent Form (English)

Study title: Reproductive Outcomes Among Infertile Female Patients Who Have Undergone Myomectomy at JOOTRH, Kisumu, Kenya: A Retrospective Cohort Study

Principal investigator: Christine Atolo Onyango, MMed student in Obstetrics and Gynaecology, Maseno University

Script to be read to the participant:

Hello, my name is _____. I am calling on behalf of Christine Atolo Onyango, a postgraduate student at Maseno University conducting a study at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH).

I am carrying out a research study to understand the factors that affect reproductive outcomes among women who have had a myomectomy because of infertility. We are looking at patients who had this surgery between January 2019 and January 2024.

You are being asked to take part in this study because you had a myomectomy at JOOTRH, and we believe your medical information can help us learn more about reproductive outcomes after this procedure.

Please note:

- This study is retrospective, meaning that we will collect data from your medical records and ask you a few questions about any pregnancy after your surgery.
- No physical procedures or tests will be performed on you.
- Your name and identity will be kept strictly confidential.
- You will not receive any payment, but there is also no cost or risk to you.

- Participation is completely voluntary. You are free to say no now or to withdraw your consent at any time without any consequences.
- The interview will be recorded for documentation purposes, and the call is expected to take about 10 minutes.

If you have any questions, I will be happy to answer them.

Do you give verbal consent for your medical records to be included in this study and to answer a few questions? [Wait for response: Yes / No]

If the participant says yes: Thank you. I will record your consent, and no personal identifiers will be used in our reporting.

Documentation for researcher (to be completed):

Name of participant (optional): _____

Verbal consent given: ☐ Yes ☐ No

Date of consent: ___/___/_____

Signature of researcher obtaining consent: _____

Name of researcher: _____

Appendix 2: Verbal Consent Form (Kiswahili)

Jina la utafiti: Matokeo ya Uzazi kwa Wagonjwa Waliokuwa na Ugumba na Waliofanyiwa Upasuaji wa Kuondoa Uvimbe wa Mfuko wa Uzazi (Myomectomy) Katika JOOTRH, Kisumu, Kenya

Mtafiti mkuu: Christine Atolo Onyango, Mwanafunzi wa MMed katika Obstetrics and Gynaecology, Chuo Kikuu cha Maseno

Maelezo ya kusomwa kwa mshiriki:

Habari, jina langu ni _____. Ninapiga simu kwa niaba ya Christine Atolo Onyango, mwanafunzi wa shahada ya juu katika Chuo Kikuu cha Maseno, anayefanya utafiti katika Hospitali ya Rufaa ya Mafunzo ya Jaramogi Oginga Odinga (JOOTRH).

Tunachunguza mambo yanayoathiri matokeo ya uzazi kwa wanawake waliokuwa na ugumba na wakafanyiwa upasuaji wa kuondoa uvimbe wa mfuko wa uzazi (myomectomy). Tunatafuta taarifa kutoka kwa wagonjwa waliofanyiwa upasuaji huo kati ya Januari 2019 na Januari 2024.

Unaombwa kushiriki kwa sababu ulifanyiwa upasuaji huo katika JOOTRH, na tunaamini taarifa zako za matibabu zinaweza kusaidia kuelewa vyema matokeo ya uzazi baada ya upasuaji.

Tafadhali fahamu yafuatayo:

- Utafiti huu ni wa kuangalia nyuma (retrospective); tutachukua taarifa kutoka kwa rekodi zako za hospitali na kukuuliza maswali machache kuhusu ujauzito wowote baada ya upasuaji.
- Hakutakuwa na vipimo wala matibabu yoyote kwako.
- Jina na utambulisho wako vitahifadhiwa kwa usiri mkubwa.

- Hutapokea malipo yoyote, lakini pia hakuna gharama wala hatari yoyote kwako.
- Kushiriki ni kwa hiari kabisa. Unaweza kukataa sasa au kujiondoa wakati wowote bila madhara yoyote.

Ikiwa una maswali yoyote, nitafurahi kuyajibu.

Je, unatoa ridhaa ya maneno kuruhusu taarifa zako za hospitali zitumike katika utafiti huu na kujibu maswali machache? [Subiri jibu: Ndiyo / Hapana]

Kama mshiriki atasema Ndiyo: Asante. Nitarekodi ridhaa yako, na hakuna kitambulisho cha kibinafsi kitakachotumika katika ripoti yetu.

Kwa matumizi ya mtafiti:

Ridhaa ya maneno imetolewa: ☐ Ndiyo ☐ Hapana

Tarehe: ___/___/_____

Sahihi ya mtafiti: _____

Appendix 3: Data Abstraction Tool

Study title: Reproductive Outcomes Among Infertile Female Patients Who Have Undergone Myomectomy at JOOTRH, Kisumu, Kenya

Study ID: _____ File number: _____

Date abstracted: ____/____/2026 Abstractor: _____ Patient contact: _____

Source: ☐ File ☐ Theatre register ☐ Laboratory report ☐ Ultrasound ☐ Telephone follow-up

PART A: RECORD REVIEW

Section 1: Eligibility and identification

Meets inclusion criteria: ☐ Yes ☐ No Date of myomectomy: ____/____/____ Year of surgery: _____

Type of surgery: ☐ Abdominal (open)

Section 2: Baseline patient characteristics (Objective 2)

Age at myomectomy (years): _____ Height (cm): _____ Weight (kg): _____ BMI (kg/m²): _____

Gravidity: _____ Parity: _____ Type of infertility: ☐ Primary ☐ Secondary

Duration of infertility (months/years): _____ Previous pregnancy loss: ☐ Yes ☐ No

Previous uterine surgery: ☐ Yes ☐ No

Section 3: Other infertility factors (descriptive)

Tubal assessment done: ☐ Yes ☐ No Tubal status: ☐ Normal ☐ Unilateral block ☐ Bilateral block ☐ Not recorded

Ovulatory status: ☐ Ovulatory ☐ Anovulatory ☐ Not recorded PCOS diagnosis: ☐ Yes ☐ No Endometriosis diagnosis: ☐ Yes ☐ No

Male partner assessed: ☐ Yes ☐ No Semen analysis: ☐ Normal ☐ Abnormal ☐ Not recorded

Prolactin (if available): _____ TSH (if available): _____ FSH/AMH (if available): _____

Section 4: Fibroid characteristics (Objective 3)

Number of fibroids removed: _____ Largest fibroid size (cm): _____ Uterine size (weeks): _____

Predominant location: ☐ Submucosal ☐ Intramural ☐ Subserosal ☐ Mixed Cavity distortion documented: ☐ Yes ☐ No

Pre-operative haemoglobin (g/dL): _____

Section 5: Intraoperative and post-operative details (Objective 3)

Estimated blood loss (mL): _____ Blood transfusion required: ☐ Yes ☐ No Entry into endometrial cavity: ☐ Yes ☐ No

Post-operative complications: ☐ Yes ☐ No (specify) _____

PART B: FOLLOW-UP INTERVIEW

☐ Verbal consent obtained before proceeding Date of interview: ____/____/____

Section 6: Post-myomectomy exposure

Resumed sexual intercourse after surgery: ☐ Yes ☐ No Average frequency per week: ☐ < 1 ☐ 1–2 ☐ ≥ 3 ☐ Not stated

Contraception after surgery: ☐ Yes ☐ No If yes, duration (months): _____

Fertility treatment after surgery: ☐ None ☐ Ovulation induction ☐ IUI ☐ IVF

Section 7: Reproductive outcomes within two years (Objective 1)

Conceived after myomectomy: ☐ Yes ☐ No If yes, months after surgery: _____ Date of confirmed pregnancy: ____/____/____

Pregnancy confirmation: ☐ Ultrasound ☐ Urine test ☐ Both Outcome: ☐ Live birth ☐ Miscarriage ☐ Ectopic ☐ Ongoing

Gestational age at outcome (weeks): _____ Mode of delivery: ☐ SVD ☐ Caesarean section ☐ Assisted Multiple pregnancy: ☐ Yes ☐ No

Section 8: Time to confirmed pregnancy (Objective 4)

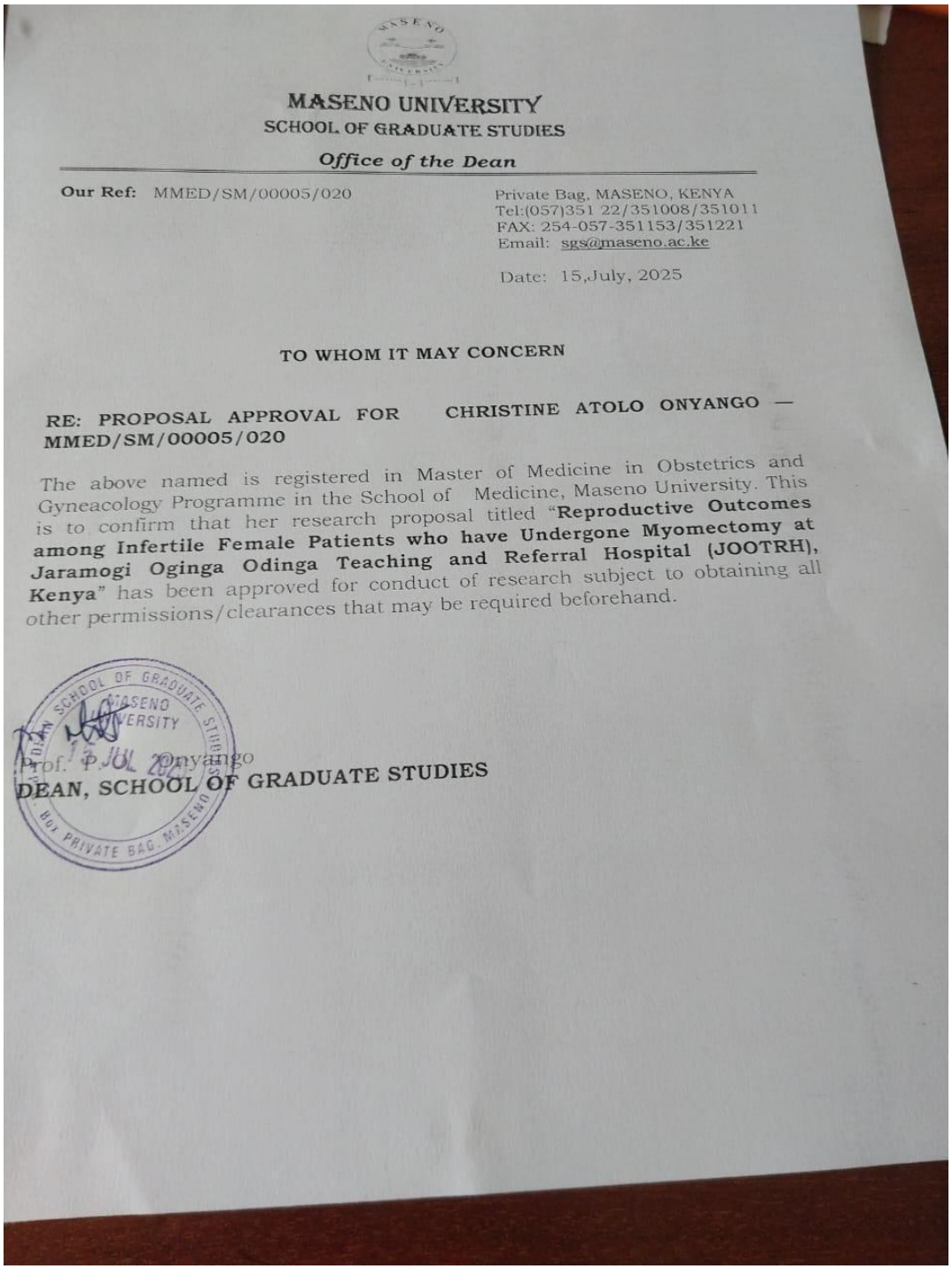
Date of myomectomy (start time): ____/____/____ Date of confirmed pregnancy (event date): ____/____/____

If no pregnancy, still trying: ☐ Yes ☐ No Date of last contact (censor date): ____/____/____

Follow-up duration (months): _____ Censored: ☐ Yes ☐ No

Coding guide (SPSS): Yes = 1; No = 0; Not recorded = 99. Location: 1 = Submucosal, 2 = Intramural, 3 = Subserosal, 4 = Mixed. Pregnancy outcome: 1 = Live birth, 2 = Miscarriage, 3 = Ectopic, 4 = Ongoing.

Appendix 4: School of Graduate Studies Proposal Approval



MASENO UNIVERSITY
SCHOOL OF GRADUATE STUDIES
Office of the Dean

Our Ref: MMED/SM/00005/020

Private Bag, MASENO, KENYA
Tel:(057)351 22/351008/351011
FAX: 254-057-351153/351221
Email: sgs@maseno.ac.ke

Date: 15,July, 2025

TO WHOM IT MAY CONCERN

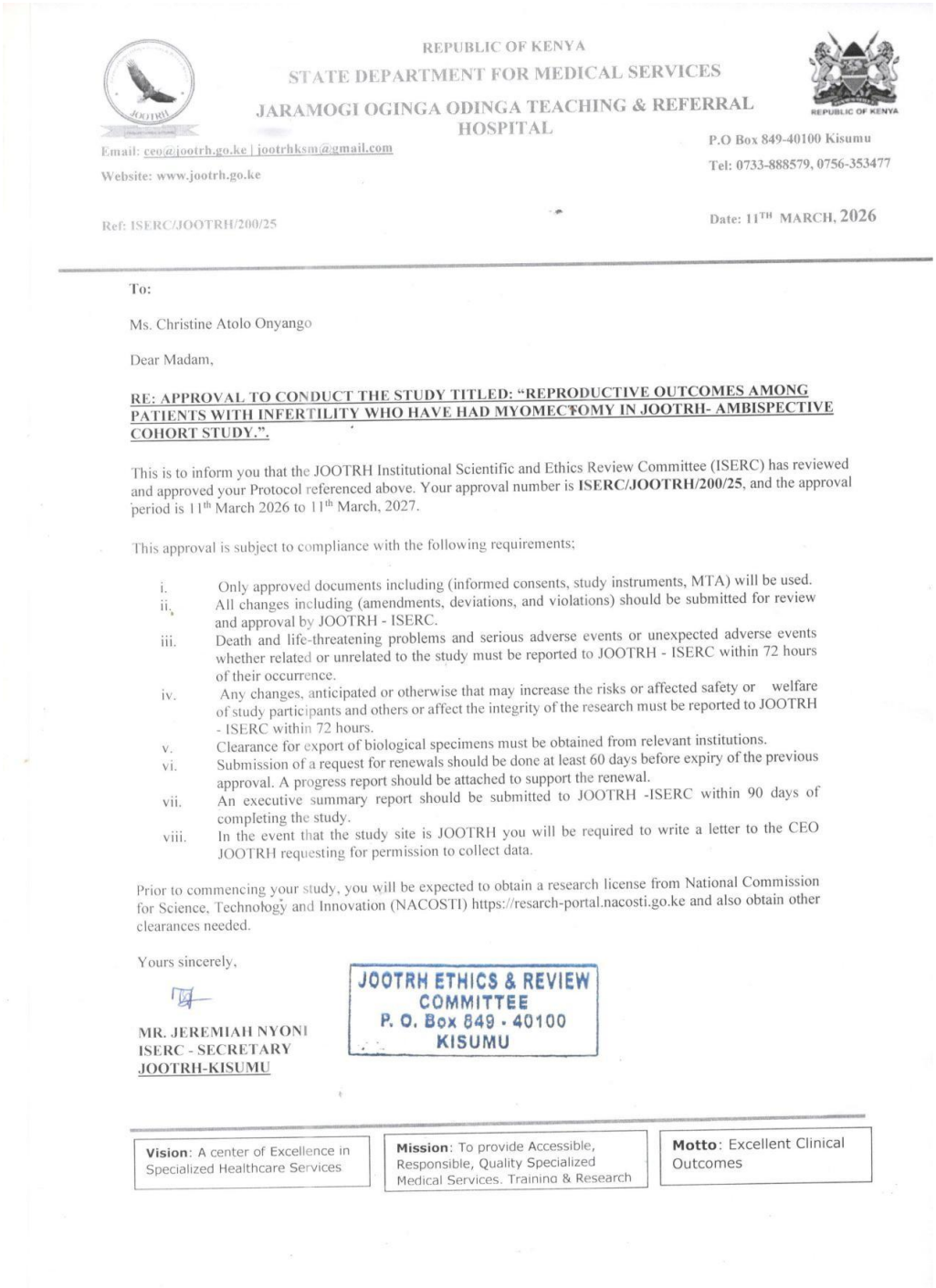
RE: PROPOSAL APPROVAL FOR CHRISTINE ATOLO ONYANGO — MMED/SM/00005/020

The above named is registered in Master of Medicine in Obstetrics and Gyneacology Programme in the School of Medicine, Maseno University. This is to confirm that her research proposal titled "**Reproductive Outcomes among Infertile Female Patients who have Undergone Myomectomy at Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), Kenya**" has been approved for conduct of research subject to obtaining all other permissions/clearances that may be required beforehand.

SCHOOL OF GRADUATE STUDIES MASENO UNIVERSITY P.O. BOX PRIVATE BAG, MASENO

Prof. P. O. Onyango
DEAN, SCHOOL OF GRADUATE STUDIES

Appendix 5: ISEREC Ethical Approval



REPUBLIC OF KENYA

STATE DEPARTMENT FOR MEDICAL SERVICES

JARAMOGI OGINGA ODINGA TEACHING & REFERRAL HOSPITAL

REPUBLIC OF KENYA

Email: ceo@jootrh.go.ke | jootrhksm@gmail.com

Website: www.jootrh.go.ke

P.O Box 849-40100 Kisumu

Tel: 0733-888579, 0756-353477

Ref: ISERC/JOOTRH/200/25

Date: 11TH MARCH, 2026

To:

Ms. Christine Atolo Onyango

Dear Madam,

RE: APPROVAL TO CONDUCT THE STUDY TITLED: "REPRODUCTIVE OUTCOMES AMONG PATIENTS WITH INFERTILITY WHO HAVE HAD MYOMECTOMY IN JOOTRH- AMBISPECTIVE COHORT STUDY.":

This is to inform you that the JOOTRH Institutional Scientific and Ethics Review Committee (ISERC) has reviewed and approved your Protocol referenced above. Your approval number is **ISERC/JOOTRH/200/25**, and the approval period is 11th March 2026 to 11th March, 2027.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) should be submitted for review and approval by JOOTRH - ISERC.
iii. Death and life-threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to JOOTRH - ISERC within 72 hours of their occurrence.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to JOOTRH - ISERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewals should be done at least 60 days before expiry of the previous approval. A progress report should be attached to support the renewal.
vii. An executive summary report should be submitted to JOOTRH -ISERC within 90 days of completing the study.
viii. In the event that the study site is JOOTRH you will be required to write a letter to the CEO JOOTRH requesting for permission to collect data.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://resarch-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

JOOTRH ETHICS & REVIEW COMMITTEE
P. O. Box 849 - 40100
KISUMU

MR. JEREMIAH NYONI
ISERC - SECRETARY
JOOTRH-KISUMU

Vision: A center of Excellence in Specialized Healthcare Services

Mission: To provide Accessible, Responsible, Quality Specialized Medical Services, Training & Research

Motto: Excellent Clinical Outcomes

Appendix 6: JOOTRH Authorisation to Collect Data

REPUBLIC OF KENYA

STATE DEPARTMENT FOR MEDICAL SERVICES

JARAMOGI OGINGA ODINGA TEACHING & REFERRAL HOSPITAL

REPUBLIC OF KENYA

Email: ceo@jootrh.go.ke | jootrhksm@gmail.com
Website: www.jootrh.go.ke
Ref: ST/2A/VOL.VI

P.O Box 849-40100 Kisumu
Tel: 0733-888579, 0756-353477

Date: 12TH MARCH ,2026

To:

Mr. Christine Atolo

Dear Madam,

RE: PERMISSION TO COLLECT DATA

On the strength of the approval letter from our Institutional Scientific and Ethical Review Committee for your proposal titled "Reproductive Outcomes Among Patients with Infertility Who Have Had Myomectomy in Jootrh- Ambispective Cohort Study.'' **Ref: ISERC/JOOTRH/ 200/25.**

I take this opportunity to grant you permission to collect data from Jaramogi Oginga Odinga Teaching and Referral Hospital between 12th March, 2026 to 12th March, 2027.

Thank you.

Yours Sincerely

CHIEF EXECUTIVE OFFICER
JARAMOGI OGINGA ODINGA TEACHING & REFERRAL HOSPITAL (JOOTRH)
12 MAR 2026
P.O BOX 849 - 40100, KISUMU

DR. JOSHUA CLINTON OKISE, PhD
Ag. CHIEF EXECUTIVE OFFICER
JOOTRH-KISUMU

Vision: A center of Excellence in Specialized Healthcare Services

Mission: To provide Accessible, Responsible, Quality Specialized Medical Services, Training & Research

Motto: Excellent Clinical Outcomes

Appendix 7: NACOSTI Research Licence

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **952387**

Date of Issue: **10/April/2026**

RESEARCH LICENSE



This is to Certify that Dr.. CHRISTINE ATOLO ONYANGO of Maseno University, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Kisumu on the topic: REPRODUCTIVE OUTCOMES AMONG INFERTILE FEMALE PATIENTS WHO HAVE UNDERGONE MYOMECTOMY AT JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL(JOOTRH), KISUMU, KENYA. for the period ending : 10/April/2027.

License No: **NACOSTI/P/26/4186815**

952387

Applicant Identification Number

Ag. Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

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See overleaf for conditions