Comparative Analysis of Treatment Methods for Incisional Ventral Hernias

Irakli Pipia

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Scientific supervisor: Ivane Abiatari, MD, PhD

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Statement

As the author of the submitted dissertation, I declare that this work is my original contribution and does not contain material previously published, accepted for publication, or submitted for defense by other authors, unless properly referenced or cited in accordance with academic standards.

Irakli Pipia ____________________ 17 / 07 / 2025

აბსტრაქტი

შესავალი : მუცლის ღრუს ქირურგიაში, ოპერაციის შემდგომი ვენტრალური თიაქარი და მისი მკურნალობა წარმოადგენს აქტუალურ საკითხს. ამ მიმართულებით ხშირად ხორციელდება სხვადასხვა ტიპის კვლევები რათა მოხდეს ოპერაციული მეთოდების მაქსილალური ოპტიმიზაცია. აღნიშული კვლევის მიზანი იყო შეგვედარებინა კლინიკური შედეგები, გართულებების სიხშირე და რეციდივის მაჩვენებლები ორ მეთოდს შორის: რეტრო მუსკულარული პლასტიკა(სტიოპა-რივსი) და ონლეი მეთოდები. დღესდღეისობით ირივე მეთოდი ფართოდ გამოიყენება თიაქარპლასტიკის მიზნით.

მეთოდები: აღნიშნული პროსპექტული რანდომიზირებული კონტროლირებადი კვლევა, ჩატარდა 2007 წლის იანვრიდან 2014 წლის აპრილამდე ნ. ყიფშიძის სახელობის ცენტრალურ საუნივერსიტეტო კლინიკაში. კვლევაში ჩართულ იქნა 180 მოზრდილი პაციენტი, რომელთაც ჩაუტარდათ გეგმიური ღია თიაქრის ოპერაცია ბადის გამოყენებით. ჩართვის და გამოკლების კრიტერიუმების გამოყენების შემდეგ, საბოლოო ანალიზში მოხვდა 155 პაციენტი: 77 რეტრომუსკულარულ ჯგუფში და 78 ონლეი ჯგუფში. ყველა პაციენტს ჩაუტარდა სტანდარტიზებული ქირურგიული პროცედურები და დაკვირვება მოხდა რეგულარულ ინტერვალებში 7 წლის განმავლობაში. პირველადი შედეგები მოიცავდა პოსტოპერაციული გართულებებისა და თიაქრის რეციდივის შესწავლას. მეორეული შედეგები ეხებოდა ოპერაციის ხანგრძლივობას, ჰოსპიტალიზაციის ხანგრძლივობას და ჭრილობასთან დაკავშირებულ გართულებებს.

შედეგები: რეტრომუსკულარულ ჯგუფში გართულებების სიხშირე მნიშვნელოვნად დაბალი აღმოჩნდა: ჭრილობის ინფექცია 2.6% და სერომა 16.9%, ონლეი ჯგუფთან შედარებით (4.6% და 41.0%, შესაბამისად; $p = 0.0013$). საშუალო ჰოსპიტალიზაციის ხანგრძლივობა ოდნავ მოკლე იყო რეტრომუსკულარულ ჯგუფში (5.2 ± 2.4 დღე ონლეი ჯგუფის 5.5 ± 2.7 დღესთან შედარებით). ოპერაციის ხანგრძლივობა უფრო დიდი იყო საბლეი ჯგუფში (155.1 წუთი - ონლეის 124.5 წუთთან შედარებით; $p < 0.001$), თუმცა რეციდივის მაჩვენებელი მნიშვნელოვნად დაბალი აღმოჩნდა (2.6% vs. 5.1%). ბადის მოცილებას ადგილი არ ჰქონია. ორივე ჯგუფში გამოყენებული იყო იდენტური პოლიპროპილენის ბადე, ოპერაციები ჩატარდა ერთი და იმავე ქირურგიული ჯგუფის მიერ, ზოგადი ანესთეზიით.

დასკვნა: რეტრომუსკულარული (სუბლეი) მეთოდი აჩვენებს უკეთეს შედეგებს ონლეი მეთოდთან შედარებით პირველადი ოპერაციის შემდგომი ვენტრალური თიაქრის გეგმიური მკურნალობისას. მიუხედავად ოპერაციის ოდნავ მეტი ხანგრძლივობისა, სუბლეი მეთოდმა უზრუნველყო ნაკლები გართულებები, უფრო სწრაფი აღდგენა და მნიშვნელოვნად დაბალი რეციდივი გრძელვადიან პერიოდში. ეს შედეგები ამლიერებს საერთო კონსენსუსს, იმის შესახებ, რომ თიაქრის რეტრომუსკულარული ბადით პლასტიკა უნდა ითვლებოდეს „ოქროს სტანდარტად“ ოპერაციის შემდგომი ვენტრალური თიაქრების მკურნალობაში შესაბამისი კანდიდატებისთვის.

საკვანძო სიტყვები: ოპერაციის შემდგომი ვენტრალური თიაქარი, რეტრომუსკულარული აღდგენა, ონლეი ბადე, საბლეი, ჭრილობის გართულებები, რანდომიზებული კონტროლირებადი კვლევა

Abstract

Background: In abdominal surgery, postoperative ventral hernia and its treatment remain pressing issues. Numerous studies have been conducted in this field, aiming to optimize surgical techniques. The goal of this study was to compare the clinical outcomes, complication rates, and recurrence rates between two methods: retromuscular mesh repair (Rives–Stoppa technique) and the onlay technique. Both techniques are widely used today for hernia reconstruction.

Methods: This prospective randomized controlled trial was conducted from January 2007 to April 2014 at Kipshidze Central University Hospital. A total of 180 adult patients who underwent elective open mesh repair for incisional hernia were enrolled. After applying inclusion and exclusion criteria, 155 patients were included in the final analysis: 77 in the retromuscular group and 78 in the onlay group. All patients underwent standardized surgical procedures and were followed at regular intervals for up to 7 years. Primary outcomes included analysis of postoperative complications and hernia recurrence. Secondary outcomes involved operative time, length of hospitalization, and wound-related complications.

Results: The complication rate was significantly lower in the retromuscular group: wound infection occurred in 2.6% of patients and seroma in 16.9%, compared to 4.6% and 41.0%, respectively, in the onlay group ($p = 0.0013$). The average hospital stay was slightly shorter in the retromuscular group (5.2 ± 2.4 days vs. 5.5 ± 2.7 days). Operative time was longer in the sublay group (155.1 minutes vs. 124.5 minutes in the onlay group; $p < 0.001$), though the recurrence rate was significantly lower (2.6% vs. 5.1%). No mesh explantations were required. Both groups used identical polypropylene mesh, and all procedures were performed under general anesthesia by the same surgical team.

Conclusion: The retromuscular (sublay) technique demonstrates superior outcomes compared to the onlay method in the elective treatment of primary postoperative ventral hernias. Despite a slightly longer operative time, the sublay approach resulted in fewer complications, faster recovery, and significantly lower recurrence during long-term follow-up. These findings reinforce the broad consensus that retromuscular mesh repair should be considered the gold standard for the treatment of postoperative ventral hernias in suitable candidates.

Key words: incisional hernia, retromuscular repair, onlay mesh, sublay, wound complications, randomized controlled trial

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First and foremost, I would like to express my deepest gratitude to my scientific supervisor, Dr. Ivane Abiatari, whose guidance, support, and academic insight were instrumental throughout the entire study process. His mentorship was vital not only for the successful completion of this dissertation but also for my development as a researcher.

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Last but certainly not least, I extend my deepest appreciation to my family. Their patience, understanding, and continuous encouragement gave me strength and motivation throughout every step of this work. This achievement is as much theirs as it is mine.

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List of Abbreviations

ACS - American College of Surgeons

ASA - American Society of Anesthesiologists

BMI - Body Mass Index

CDC - Centers for Disease Control and Prevention

CONSORT - Consolidated Standards of Reporting Trials

CT - Computed Tomography

EHS - European Hernia Society

EU - European Union

GCP - Good Clinical Practice

IQR - Interquartile Range

LOS - Length of Stay (Hospitalization Duration)

OG - Onlay Group

OR - Operating Room

QoL - Quality of Life

RCT - Randomized Controlled Trial

RMG - Retromuscular Mesh Group

SD - Standard Deviation

SPSS - Statistical Package for the Social Sciences

WHO - World Health Organization

1. Introduction

1.1 General Background

Postoperative ventral hernias, more commonly referred to as incisional hernias, develop at the site of previous abdominal surgery where the integrity of the abdominal wall has been compromised. Despite advancements in surgical techniques and materials, incisional hernias remain a major challenge in abdominal surgery, affecting 11% to 20% of patients after laparotomy procedures (Fitzgibbons et al. 2003; Bassini 1884). The recurrence rate for suture-based repairs remains high, varying between 12% and 54% (Mudge and Hughes 1985; Hoer et al. 2002; Sugerman et al. 2001), making the choice of repair method critically important. With an estimated 200,000 incisional hernia repairs performed annually in the United States alone (Muysoms et al. 2009), the condition not only carries significant clinical implications but also a substantial economic burden. The development of improved materials, especially the introduction of synthetic mesh, has transformed hernia repair by significantly lowering recurrence rates (Mudge and Hughes 1985; Hoer et al. 2002; Sugerman et al. 2001; Burger et al. 2004). Yet, debate continues over the optimal surgical technique, particularly concerning the anatomical placement of the mesh and the choice between open or laparoscopic approaches.

1.2 Importance and Relevance of the Problem

The rising prevalence of incisional hernias is influenced by several demographic and clinical factors including an aging population, obesity, and increasing number of abdominal surgeries. Clinically, the condition can result in pain, bowel obstruction, reduced quality of life, and impaired abdominal wall function. Surgical repair aims not only to restore the integrity of the abdominal wall but also to minimize the recurrence and complications associated with the repair method.

Despite the evolution in hernia repair techniques, no consensus has been reached on the most effective approach. Open mesh repairs—specifically sublay (retromuscular) and onlay techniques—remain widely used (Figure 1). However, each method has its advantages and drawbacks in terms of tissue integration, recurrence rates, and postoperative complications (Bellows et al. 2013; Kingsnorth et al. 2008; Conze et al. 2010; Luijendijk et al. 2000; Cobb et al. 2015; Timmermans et al. 2014) (Figure 2).

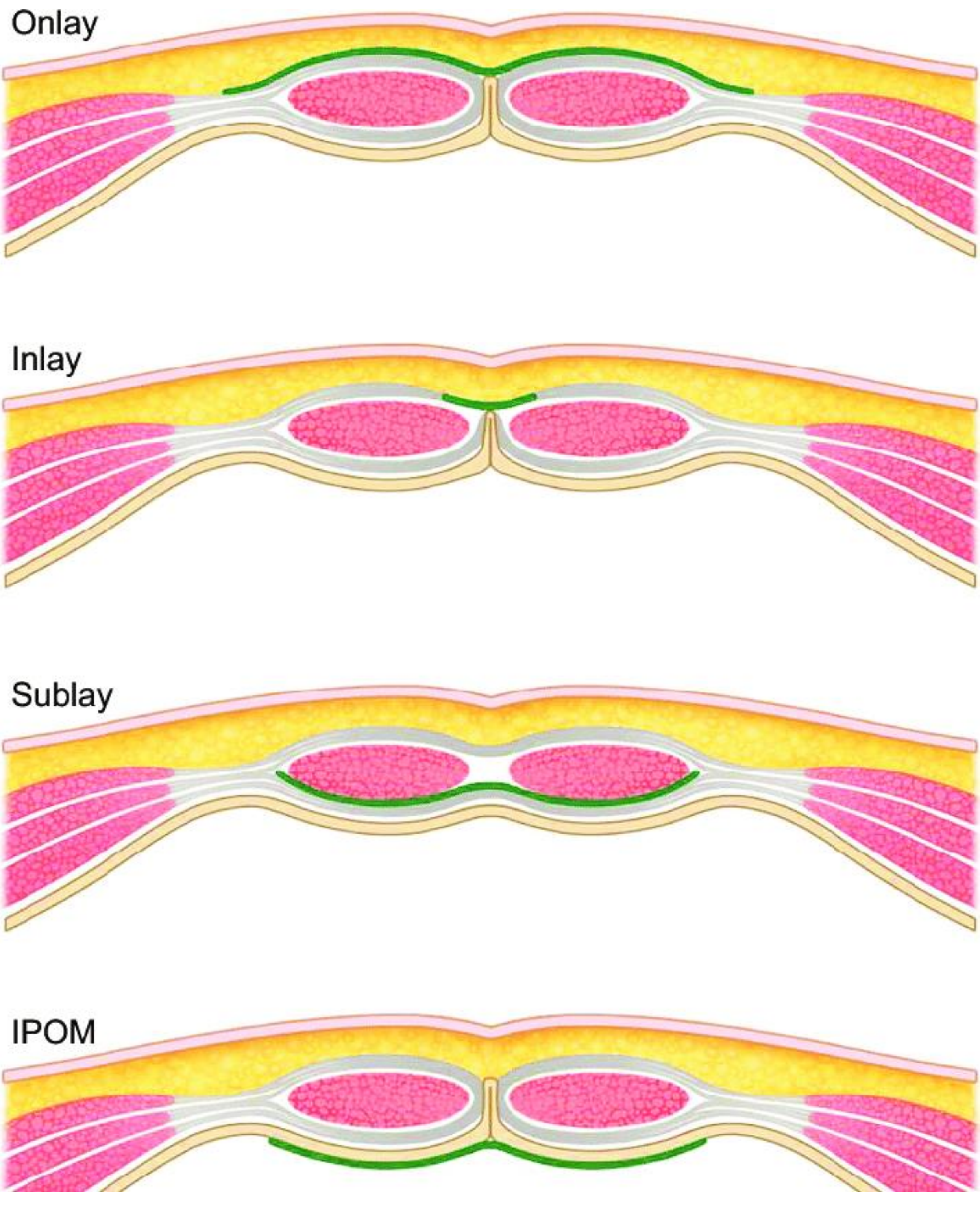


Figure 1. *Schematic demonstration of mesh repair techniques for incisional or ventral hernia according to the location of mesh placement. (Choi et al. J Minim Invasive Surg 2018)*

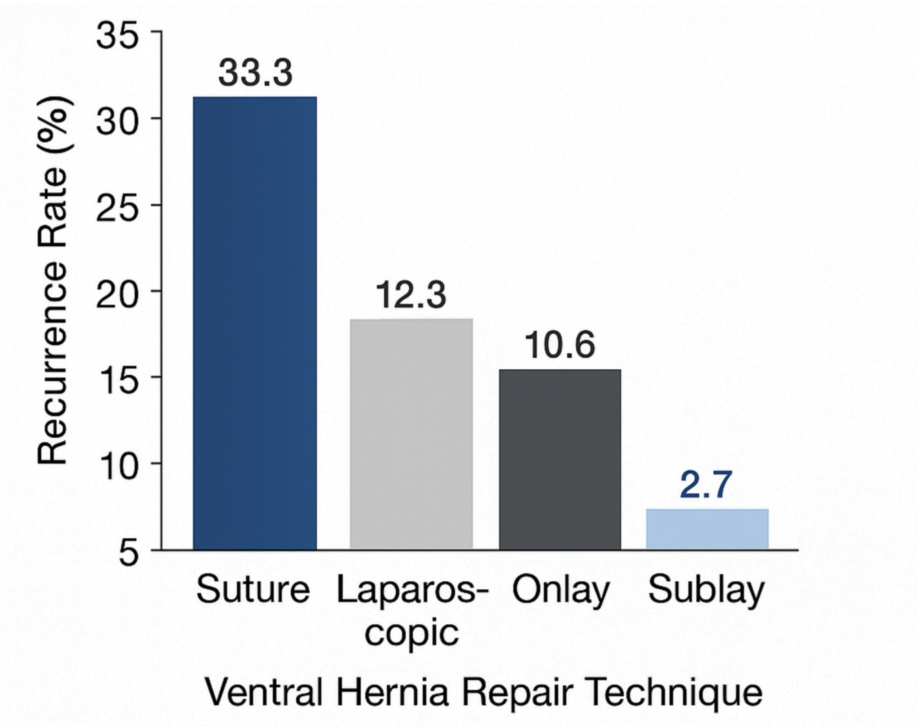


Figure 2. *Recurrence rates by hernia repair technique.*

(Adapted from Timmermans et al. World j Surg, 2024)

The anatomical placement of the mesh plays a crucial role in outcomes. Sublay repair involves positioning the mesh in the retromuscular space, potentially resulting in better mesh integration and lower complication rates. Conversely, the onlay method is technically simpler but is associated with higher rates of seroma and wound infection.

1.3 Aim and Objectives

The main aim of this dissertation is to conduct a comparative analysis of two commonly used surgical techniques for postoperative ventral (incisional) hernias: open retromuscular (sublay) mesh repair and open onlay mesh repair.

Specific objectives include:

- To compare the recurrence rates between the two surgical methods.
- To assess complication rates including seroma, wound infection, and mesh-related issues.
- To evaluate postoperative recovery times and hospital stays.
- To understand patient-reported outcomes such as pain and quality of life.

1.4 Hypothesis

"Retromuscular mesh repair (sublay technique) for postoperative ventral hernia is associated with lower recurrence and complication rates compared to onlay mesh repair."

1.5 Structure of the Dissertation

The dissertation is structured as follows:

- Chapter 1 provides the introduction and rationale for the study.
- Chapter 2 includes an extensive literature review tracing the evolution of hernia repair and analyzing current evidence.
- Chapter 3 details the methodology used in the comparative analysis.

- Chapter 4 presents the results of the clinical data.
- Chapter 5 discusses the findings, limitations, and clinical implications.
- Chapter 6 concludes the dissertation and offers recommendations for future research and clinical practice.

2. Literature Review

2.1 Historical Overview of Hernia Repair

The treatment of abdominal hernias dates back several millennia, reflecting a long-standing surgical challenge that has evolved with medical progress. Some of the earliest descriptions of hernias and their treatment methods are found in the Ebers Papyrus (circa 1550 BCE), which outlines rudimentary therapeutic measures such as binding and compression, though without surgical intervention. Ancient Greek and Roman physicians, including Hippocrates and Galen, recognized hernias and attempted reductions, while Celsus described surgical excision and cautery for irreducible cases (Fitzgibbons et al. 2003).

During the Middle Ages, Islamic scholars like Al-Zahrawi (Albucasis) advanced hernia surgery by developing detailed surgical texts that influenced European practices. However, most hernias were still managed non-operatively using trusses due to a lack of anesthesia, antisepsis, and effective surgical techniques.

A true paradigm shift occurred in the 19th century with the introduction of **Bassini's technique**. In 1884, **Edoardo Bassini** described anatomical reconstruction of the inguinal canal using layered closure and fascial reinforcement, drastically lowering recurrence rates compared to previous techniques (Bassini 1884). His method became the foundation for many 20th-century repairs. Modifications were introduced by Shouldice and McVay, with improvements in tension distribution and layered repair, though still reliant on native tissue closure. These methods represented a period known as the **"tissue repair era."**

By the mid-20th century, it became increasingly evident that suture-only repairs, especially in large defects, had significant limitations. Tension on the fascial closure often led to ischemia and high recurrence rates — exceeding 40% in some incisional hernias (Usher et al. 1958). Consequently, surgeons began exploring prosthetic materials to reduce tension and improve durability.

In 1958, **Usher et al.** introduced **polypropylene mesh**, ushering in the **"mesh era"** of hernia repair (Muysoms et al. 2009). This material allowed for tension-free repairs and dramatically decreased recurrence. The use of synthetic mesh became standard in both inguinal and ventral hernia repairs, especially for large or recurrent defects.

By the late 20th and early 21st centuries, focus shifted toward mesh placement techniques. Surgeons began evaluating various planes for mesh positioning (onlay, inlay, sublay, underlay) and recognized that anatomical placement significantly affected outcomes. Concurrently, laparoscopic and robotic innovations allowed for minimally invasive ventral hernia repairs, offering reduced wound complications and faster recovery in select patients.

Today, hernia repair remains one of the most frequently performed general surgical procedures worldwide. Incisional hernias, which occur in 11–20% of laparotomy patients, represent a particularly complex subgroup due to altered anatomy, scar tissue, and high risk of recurrence (Mudge and Hughes 1985). Despite progress, the optimal approach to incisional hernia repair continues to be debated, particularly concerning mesh type, positioning, and surgical technique.

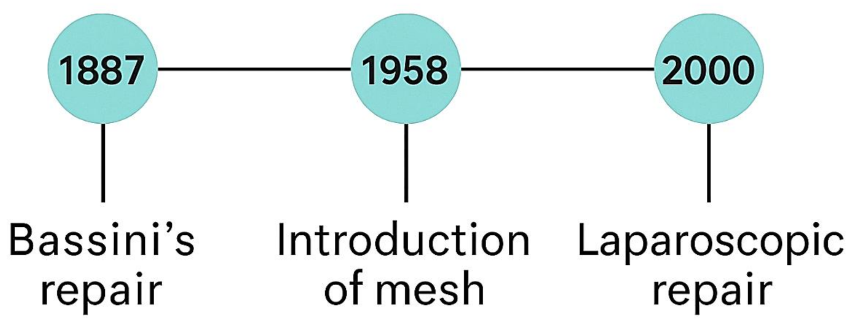


Figure 3. *Timeline of hernia repair*

2.2 Classification and Incidence of Incisional Hernias

2.2.1 Definition and Clinical Relevance

An incisional hernia is defined as a protrusion of abdominal contents through a weakness or defect in the abdominal wall at the site of a previous surgical incision. These hernias can develop months or even years after the index surgery and represent one of the most common long-term complications of abdominal procedures.

From a clinical standpoint, incisional hernias are more than just a mechanical defect. They can lead to chronic discomfort, bowel obstruction, impaired abdominal wall function, reduced quality of life, and cosmetic concerns. In certain cases, they require emergency surgical repair due to incarceration or strangulation of bowel loops.

2.2.2 Epidemiology and Incidence Rates

Incisional hernias occur in approximately 11% to 20% of patients who undergo midline laparotomy (Hoer et al. 2002). The risk is higher among certain subgroups: patients with obesity, wound infections, chronic pulmonary disease, steroid use, diabetes, or malnutrition are at elevated risk. Emergency surgeries, especially those performed under suboptimal conditions, carry a significantly higher risk compared to elective operations (Sugerman et al. 2001).

The true incidence is likely underreported due to the variability in follow-up practices, differing diagnostic criteria (clinical vs. radiological), and asymptomatic cases that remain undetected. Studies using imaging techniques, such as CT scans, have shown higher incidences of occult incisional hernias than previously suspected, especially in obese populations or those undergoing cancer surveillance (Burger et al. 2004).

A landmark prospective study by Mudge and Hughes (1985) followed over 3,000 patients and found that 10% developed an incisional hernia after midline laparotomy, with most cases emerging within 3 years of surgery. However, modern studies with longer follow-up and improved imaging techniques have suggested the incidence may be closer to 20% in the general surgical population.

2.2.3 Risk Factors

The development of incisional hernias is influenced by a complex interaction of patient-, wound-, and technique-related factors:

- **Patient-related factors**: obesity (BMI >30), smoking, diabetes, COPD, age, male sex, chronic steroid use, poor nutritional status.
- **Wound-related factors**: surgical site infection, hematoma or seroma formation, and tension across the incision.
- **Surgical technique**: midline incisions are more prone to hernia formation compared to transverse or oblique incisions; closure technique (e.g., continuous vs. interrupted suturing), suture length-to-wound length ratio, and use of slowly absorbable vs. non-absorbable suture material also play a role (Kingsnorth et al. 2008).

Infection remains the single most important modifiable risk factor. Surgical site infections (SSIs) increase the risk of incisional hernia formation by 2- to 5-fold (Conze et al. 2010).

2.2.4 Classification Systems

To facilitate research, surgical planning, and outcome comparisons, various classification systems have been proposed. Among the most accepted is the **European Hernia Society (EHS) classification**, which stratifies ventral hernias based on location and width:

- **Location**:
  - M1 to M5 = Midline (epigastric to suprapubic)
  - L1 to L4 = Lateral (subcostal to iliac crest)
- **Width**:
  - W1 (<4 cm)
  - W2 (4–10 cm)
  - W3 (>10 cm)

This standardized approach aids in both operative decision-making and the stratification of risk in clinical trials (Luijendijk et al. 2000).

Other classification systems, such as the Ventral Hernia Working Group (VHWG) grading scale, also take contamination level and patient comorbidities into account when recommending mesh use, especially in complex or infected fields (Cobb et al. 2015).

2.2.5 Trends in Incidence Over Time

With the aging population, increased obesity rates, and growing number of abdominal surgeries globally, the incidence of incisional hernias is projected to rise. Laparoscopic procedures have been associated with a lower risk of hernia compared to open laparotomy, but trocar site hernias still occur, particularly when large ports are used or fascial closure is inadequate (Timmermans et al. 2014).

Modern efforts to prevent incisional hernias include enhanced suture techniques (e.g., small-bite closures, prophylactic mesh placement) and better wound care protocols. Randomized trials such as the PRIMA and STITCH trials have demonstrated that prophylactic mesh reinforcement in high-risk patients undergoing midline laparotomy can significantly reduce hernia incidence without a notable increase in complications (Jairam et al. 2017; Jairam et al. 2017).

2.3 Surgical Treatment Evolution: From Suture Repair to the Mesh Era

2.3.1 Early Suture-Based Repairs and Limitations

Historically, suture repair was the primary method for closing abdominal wall defects, particularly incisional hernias. These repairs involved direct approximation of fascial edges using non-absorbable or slowly absorbable sutures. The techniques varied (e.g., interrupted vs. continuous suturing), but all shared a common limitation — tension across the closure line, especially in large or poorly vascularized defects (Holihan et al. 2016).

Several retrospective and prospective studies in the late 20th century revealed high recurrence rates with primary suture repair. One of the most cited studies by Luijendijk et al. (2000) compared suture repair to mesh repair in 200 patients and found recurrence rates of 43% in the suture group versus 24% in the mesh group over a 3-year period (Luijendijk et al. 2000).

Other reports have documented recurrence rates as high as 50% or more, particularly when repairs were performed in contaminated fields or without addressing risk factors like infection, obesity, and elevated intra-abdominal pressure (Cobb et al. 2015).

The high failure rate of these repairs led to the growing consensus that suture-only techniques were inadequate, particularly for medium to large defects or in high-risk patients.

2.3.2 The Introduction of Mesh and the Tension-Free Concept

The introduction of polypropylene mesh by Francis C. Usher in 1958 revolutionized hernia repair by allowing for tension-free closure. This was a major turning point in abdominal wall surgery. Mesh was used not to approximate tissue but to bridge the defect and reinforce the surrounding fascia, distributing tension over a wider area and promoting fibroblast in-growth (Kaul et al. 2016).

This tension-free repair concept led to a dramatic reduction in recurrence rates, particularly in large incisional hernias and recurrent cases. It also allowed for more reliable closure of complex hernias, including those in previously irradiated or infected tissue beds.

Initially, only non-absorbable synthetic meshes were available, such as polypropylene and expanded polytetrafluoroethylene (ePTFE). Over time, more sophisticated materials were introduced, including:

- **Lightweight meshes**
- **Dual-layer composite meshes** for intraperitoneal use
- **Biologic and biosynthetic meshes** for contaminated fields

Each material offered trade-offs between strength, infection resistance, and biocompatibility. Comparative studies suggested that polypropylene mesh remained the gold standard for most clean cases due to its strength and cost-effectiveness (Andersen et al. 2009).

2.3.3 Shift to Anatomical Plane Selection and Mesh Positioning

With the broad adoption of mesh repair, attention turned to where to place the mesh anatomically. Four primary techniques evolved:

1. **Onlay** – mesh over the anterior fascia
2. **Inlay** – mesh sewn directly to fascial edges, bridging the defect
3. **Sublay** (retromuscular) – mesh placed between the posterior rectus sheath and rectus abdominis muscle

4. **Underlay / IPOM** – mesh placed intraperitoneally

Among these, inlay repairs were found to have the highest recurrence due to the lack of overlap and poor mechanical support (Binnebosel et al. 2010). Therefore, modern practice has shifted away from inlay repairs toward onlay and sublay, with increasing interest in minimally invasive underlay (IPOM) approaches via laparoscopy.

Studies by Cobb et al., Conze et al., and others demonstrated significantly better outcomes with sublay placement, particularly lower recurrence and complication rates (de Vries Reilingh et al. 2007; Köckerling et al. 2018).

The sublay (also called Rives-Stoppa) technique gained prominence as it offers:

- Optimal mechanical reinforcement
- Reduced mesh contact with bowel
- Lower infection risk

However, the sublay technique is technically more challenging, requiring careful dissection and more operative time. Onlay, while easier to perform, has been associated with higher rates of seroma and superficial wound infections, especially in obese patients or those with thick subcutaneous fat layers (Sauerland et al. 2011).

2.3.4 Rise of Minimally Invasive Techniques

Since the 1990s, **laparoscopic incisional hernia repair** has become an alternative to open techniques. Laparoscopy provides several theoretical advantages:

- Smaller incisions → reduced wound infections
- Less postoperative pain
- Shorter hospital stay

Laparoscopic repairs generally involve intraperitoneal mesh placement (IPOM), where a composite mesh is tacked or sutured to the peritoneal surface. While this approach reduces wound complications, it comes with potential intraperitoneal complications like:

- Adhesion formation
- Mesh migration
- Enterocutaneous fistula

In recent years, **robotic-assisted hernia repair** has emerged, enabling surgeons to perform complex procedures like transversus abdominis release (TAR) or retromuscular mesh placement with enhanced visualization and dexterity. Early studies suggest promising outcomes but emphasize high cost and long operative times as limiting factors (Novitsky et al. 2020).

2.4 Mesh Placement Techniques: Comparative Analysis of Onlay vs. Sublay

2.4.1 Overview of Mesh Positioning in Incisional Hernia Repair

Mesh placement technique is a critical determinant of long-term outcomes in incisional hernia repair. While mesh use significantly reduces recurrence rates compared to primary suture closure, the anatomical position of the mesh influences not only recurrence but also the risk of seroma, infection, chronic pain, and surgical complexity (Holihan et al. 2015).

The two most commonly used open techniques are:

- **Onlay mesh placement**: Mesh is positioned superficial to the anterior rectus sheath.
- **Sublay (retromuscular) mesh placement**: Mesh is inserted between the posterior rectus sheath and the rectus abdominis muscle.

Each technique has its proponents and specific advantages, but the debate continues regarding which offers the optimal balance of safety, durability, and cost-effectiveness.

2.4.2 Onlay Mesh Repair

In the onlay technique, the hernia defect is closed, and mesh is laid directly on the anterior rectus sheath and secured with sutures. The subcutaneous tissue and skin are then closed over the mesh.

Advantages:

- Technically straightforward

- Requires less extensive dissection
- Shorter operative time
- Easily performed even in reoperative fields

Disadvantages:

- Higher risk of seroma formation, due to large subcutaneous dissection
- Increased incidence of wound infections
- Recurrence rates can be higher if mesh is not adequately fixed or if wound healing is compromised

A 2009 study by Andersen et al. found a 17% recurrence rate at long-term follow-up in patients undergoing onlay repair, with wound infection rates reaching 15% in some series (Kaufmann et al. 2014). Despite its relative simplicity, onlay repair is often avoided in obese patients due to risk of seroma and wound breakdown.

2.4.3 Sublay (Retromuscular) Mesh Repair

Sublay repair, also referred to as the **Rives-Stoppa** technique, involves retrorectus placement of mesh between the posterior rectus sheath and the rectus abdominis muscle, extending laterally beyond the defect margins.

Advantages:

- Mesh lies in a **well-vascularized plane**, facilitating tissue integration
- **Lower recurrence rates** due to mechanical reinforcement of the abdominal wall
- Minimal contact with subcutaneous tissue reduces **infection risk**
- Mesh is **shielded from intraperitoneal structures**, reducing adhesion or erosion

Disadvantages:

- Technically demanding
- Requires posterior sheath dissection

- Longer operative time

Studies show that sublay repairs consistently achieve better outcomes compared to other mesh positions. For example:

- Cobb et al. (2015) reported recurrence rates of 8–12% for sublay repair compared to 20–25% for onlay in complex hernias.
- Conze et al. (2010) documented significantly lower infection and recurrence in sublay repairs across multiple German centers.
- A 2014 meta-analysis by Timmermans et al. comparing sublay and onlay techniques found the sublay method superior in terms of recurrence and wound-related complications across 17 randomized and non-randomized trials

2.4.4 Meta-Analytic and Comparative Studies

A number of large-scale reviews and trials have compared outcomes between sublay and onlay mesh repairs:

- de Vries Reilingh et al. (2007) found that the sublay group had a 7% recurrence rate, while onlay had 16%, and inlay exceeded 30%.

- Köckerling et al. (2018) published a registry-based analysis from the German Herniamed registry (over 5,000 cases), concluding that sublay repair had the lowest rate of recurrence and complications when compared to onlay, IPOM, and inlay techniques.

- The EHS guidelines now list sublay repair as the preferred technique for open elective incisional hernia repair due to superior long-term outcomes (Miserez M, et al. 2009)

2.4.5 Technique-Specific Complications

Complication	Onlay	Sublay
Seroma formation	Common (~15–30%)	Rare (~5–10%)
Wound infection	Moderate risk (8–20%)	Low risk (<5%)
Recurrence	Higher (15–20%)	Lower (5–10%)
Operative time	Shorter	Longer
Technical difficulty	Low	High

Despite these findings, onlay repair is still commonly performed in settings where surgical expertise or resources for sublay are limited. In developing countries or rural hospitals, the onlay technique may be favored for its speed and simplicity.

2.5 Laparoscopic and Robotic Hernia Repair: Current Trends and Evidence

2.5.1 Evolution of Minimally Invasive Hernia Surgery

The advent of laparoscopic surgery in the 1990s significantly altered the approach to many general surgical procedures, including ventral and incisional hernia repair. The initial rationale for laparoscopic hernia repair was to reduce surgical trauma, minimize wound complications, and shorten hospital stay, especially for obese or high-risk patients (Kurmann et al. 2012).

Laparoscopic ventral hernia repair commonly employs the Intraperitoneal Onlay Mesh (IPOM) technique, where a composite mesh is placed against the inner peritoneal surface of the abdominal wall and fixed using tacks and/or transfascial sutures. This technique avoids wide subcutaneous dissection and significantly lowers the risk of wound infection and hematoma, particularly in patients with multiple comorbidities (Jairam et al. 2017).

Despite its advantages, laparoscopic hernia repair also introduced new challenges—especially the risk of adhesion formation, mesh erosion, chronic pain, and enterocutaneous fistulas, which may occur if mesh is placed directly over bowel without proper protection.

2.5.2 Indications for Laparoscopic Repair

Laparoscopic hernia repair is generally indicated in:

- Small to medium-sized hernias (<10 cm)
- Patients with high BMI
- Multiple recurrent hernias
- Clean, elective settings with no active infection

Contraindications include:

- Massive hernias (>10–15 cm)
- Loss of domain
- Dense intra-abdominal adhesions
- Bowel resection requirement
- Hemodynamic instability (Jairam et al. 2017).

2.5.3 Outcomes and Complications

Several randomized trials and meta-analyses have compared laparoscopic and open hernia repair. A Cochrane review by Sauerland et al. (2011) concluded that laparoscopic repair leads to fewer wound infections, shorter hospital stay, and quicker return to activity, but also carries a higher risk of visceral injury and increased operative cost.

Complications specific to laparoscopic repair include:

- Bowel injury (0.7% to 3.5%)
- Mesh-related complications: erosion, migration, and adhesions
- Chronic pain from tacks or transfascial sutures
- Recurrence rates reported between 4–10%, comparable to open techniques in experienced hands

Newer mesh materials and fixation techniques (e.g., absorbable tacks, glue fixation) aim to reduce chronic pain and improve biocompatibility.

2.5.4 Robotic-Assisted Hernia Repair

The last decade has witnessed a sharp rise in the use of robotic platforms, such as the da Vinci system, for complex abdominal wall reconstruction. Robotic surgery provides:

- Three-dimensional visualization
- Enhanced instrument articulation
- Improved precision in suturing and dissection

These advantages have enabled techniques like Robotic Transversus Abdominis Release (rTAR), retromuscular dissection, and posterior component separation, which are otherwise difficult to achieve laparoscopically (Kanters et al. 2012).

A 2020 multicenter analysis by Novitsky et al. showed that robotic ventral hernia repair achieved:

- Low conversion rates (<1%)
- Comparable operative time to laparoscopy
- Shorter hospital stays (~1.3 days on average)
- Recurrence rates <5% at 2-year follow-up (El-Gawad et al. 2018).

However, robotic repair remains significantly more expensive and is not widely available in many countries or smaller centers. Cost remains a key limiting factor despite promising early results.

2.5.5 Emerging Techniques and Future Directions

Recent advances in minimally invasive hernia surgery include:

- eTEP (Enhanced View Totally Extraperitoneal Repair): Combines advantages of minimally invasive access with sublay mesh positioning.
- Hybrid techniques: Combine open fascial closure with laparoscopic mesh placement.
- Biosynthetic and composite meshes: Engineered to reduce adhesion, improve integration, and minimize infection risk.

As techniques evolve, emphasis is shifting from a "one-size-fits-all" approach to patient-specific, anatomy-adapted hernia repair, taking into account defect size, patient risk profile, and available expertise.

2.6 Postoperative Complications and Long-Term Outcomes in Mesh-Based Hernia Repair

2.6.1 Overview of Postoperative Complications

While the use of mesh in incisional hernia repair has significantly reduced recurrence rates, it has introduced a distinct profile of mesh-related complications. Understanding these complications is critical for surgical planning, patient counseling, and long-term follow-up.

The most commonly reported complications include:

- Seroma formation
- Wound infection
- Chronic postoperative pain
- Mesh infection
- Recurrence
- Adhesion formation
- Mesh migration or erosion
- Enterocutaneous fistula

The frequency and severity of these complications vary based on mesh type, surgical technique, patient factors, and mesh location (onlay, sublay, IPOM).

2.6.2 Seroma Formation

Seromas are fluid collections that develop in the dead space created by dissection, particularly in onlay repairs. They typically form within the first few weeks after surgery and may be asymptomatic or cause localized discomfort.

- Incidence ranges from 10% to 45% in open onlay repairs (D'Amore et al. 2007).

- Less common in sublay repairs due to limited subcutaneous dissection.

Most seromas resolve spontaneously, but large or symptomatic collections may require aspiration, compression dressing, or in rare cases, drain placement.

Prophylactic use of closed-suction drains in high-risk cases remains controversial. Some surgeons advocate for their routine use in onlay repairs, while others discourage it due to infection risk.

2.6.3 Wound and Mesh Infection

Surgical site infections (SSIs) remain a concern, particularly in patients with obesity, diabetes, smoking history, or immunosuppression. Onlay mesh, being close to the skin, is more prone to contamination.

- Onlay repair: SSI rates range from 8% to 20%
- Sublay repair: SSI rates generally <5% (Liang et al. 2013).

Mesh infection is a serious complication that may necessitate mesh explantation, prolonged antibiotic therapy, and reoperation. Composite and lightweight meshes have shown slightly lower infection rates, while biologic meshes are preferred in contaminated fields, though with higher recurrence and cost.

2.6.4 Chronic Postoperative Pain

Chronic pain, defined as pain persisting beyond 3 months postoperatively, can significantly impair quality of life. Causes include:

- Nerve entrapment
- Tension at closure site
- Mesh shrinkage
- Fixation methods (e.g., tacks, sutures)

Rates of chronic pain vary:

- Open mesh repair: 10–20%
- Laparoscopic repair: 5–15%

- Robotic or eTEP repairs show lower incidence in early studies (Mayagoitia et al. 2006).

Newer mesh designs with lower stiffness, absorbable fixation devices, and nerve-sparing techniques aim to reduce this complication.

2.6.5 Recurrence

Despite mesh reinforcement, recurrence remains a challenge, especially in:

- Large hernias (>10 cm)
- Obese patients (BMI >35)
- Infected or contaminated wounds
- Poor mesh fixation

Reported recurrence rates:

- Sublay: 5–10%
- Onlay: 10–20%
- Inlay: 20–30% (not recommended)
- Laparoscopic IPOM: 4–10%

Proper mesh overlap (at least 5 cm beyond the defect), tension-free closure, and addressing patient risk factors are key to minimizing recurrence.

2.6.6 Mesh Erosion, Migration, and Fistula Formation

Rare but serious complications include:

- Mesh erosion into adjacent organs (bladder, bowel)
- Migration due to inadequate fixation or chronic infection
- Enterocutaneous fistula resulting from mesh contact with bowel

These complications typically occur months to years after surgery and often require reoperation and mesh removal. Laparoscopic IPOM repairs carry higher risks of such issues if composite mesh is not used or peritoneal coverage is inadequate (Cengiz et al. 2006).

2.6.7 Adhesion Formation

When intraperitoneal mesh is used, the risk of adhesions to bowel or omentum is significant unless protected by a barrier or composite coating.

- Composite meshes (e.g., dual-layer polypropylene/ePTFE) reduce adhesion risk.
- Pure polypropylene meshes should not be placed directly against bowel.

Adhesions may lead to chronic pain, intestinal obstruction, or infertility in women.

2.6.8 Predictive Tools and Scoring Systems

To stratify risk and guide surgical decision-making, tools like the Carolinas Equation for Determining Associated Risks (CeDAR) and Ventral Hernia Risk Score (VHRS) have been developed. These incorporate factors such as:

- BMI
- Smoking status
- ASA class
- Defect size
- Presence of SSI

Such tools help determine whether prophylactic mesh or component separation is warranted.

2.7 Patient-Reported Outcomes, Quality of Life, and Functional Recovery

2.7.1 Shift Toward Patient-Centered Metrics

Traditionally, hernia repair outcomes were assessed by recurrence rates and surgical complications. However, these metrics alone fail to capture the full impact of hernia repair on a patient's health and well-being. In recent years, there has been a paradigm shift toward evaluating patient-reported outcomes (PROs) such as:

- Pain

- Activity limitations
- Cosmetic satisfaction
- Return to work and daily life
- Overall quality of life (QoL)

This shift reflects a broader movement in surgery and healthcare to include patient-centered measures when assessing treatment effectiveness and guiding clinical decision-making (Staerkle et al. 2012).

2.7.2 Tools for Measuring Quality of Life

Multiple validated questionnaires have been developed to assess health-related QoL in hernia patients:

- EuraHS-QoL Score: Developed by the European Hernia Society, it evaluates pain, restriction of activities, and cosmetic discomfort in relation to the hernia and repair.

- Carolinas Comfort Scale (CCS): Specifically designed for patients undergoing hernia repair with mesh; measures mesh-related sensations and activity limitations.

- SF-36 and EQ-5D: General health questionnaires that assess physical and mental health status.

Studies using these tools show that successful hernia repair leads to significant improvement in QoL, particularly when chronic pain is avoided and recurrence does not occur (Ahonen-Siirtola et al. 2018).

2.7.3 Impact of Surgical Technique on Patient Satisfaction

Numerous comparative studies have assessed how surgical technique influences PROs:

- Sublay repairs are associated with lower long-term pain and higher patient satisfaction compared to onlay, inlay, or laparoscopic IPOM techniques.

- In a study by Liang et al., patients undergoing sublay mesh repair reported significantly better comfort scores at 6- and 12-month follow-up (Liang et al. 2015).

- Laparoscopic repairs may offer superior early recovery and cosmetic satisfaction, but in some cases result in chronic pain due to transfascial sutures or tacks.
- Robotic-assisted repairs allow for posterior component separation with minimal trauma, and early evidence suggests high satisfaction with reduced discomfort (Heniford et al. 2021).

2.7.4 Return to Work and Physical Activity

Time to return to normal activity and work is a crucial measure for working-age patients. Minimally invasive techniques have demonstrated quicker recovery:

Technique	**Average Return to Work**
Open Sublay	3–6 weeks
Open Onlay	4–8 weeks
Laparoscopic IPOM	1–3 weeks
Robotic TAR	2–4 weeks

These figures vary depending on hernia size, patient comorbidities, and job physical demands.

2.7.5 Cosmetic Outcomes

For many patients, particularly younger or female individuals, the aesthetic result of hernia repair is important. Minimally invasive repairs typically result in smaller scars and improved cosmetic scores, though larger hernias requiring open repair may necessitate midline incisions or skin flaps.

Techniques that reduce tension and avoid deformity of the abdominal wall contour are preferred. In cases where functional reconstruction is coupled with skin reduction (e.g., hernia plus panniculectomy), cosmetic and functional results are optimized (Parker et al. 2021).

2.7.6 Long-Term Follow-Up and Functional Recovery

Even in patients without clinical recurrence, abdominal wall dysfunction may persist postoperatively. This includes:

- Weakness of the abdominal musculature
- Core instability

- Altered posture
- Exercise intolerance

Some authors propose that core muscle training and physiotherapy should be integrated into the postoperative period to enhance recovery.

Long-term registries and PRO monitoring tools (e.g., Herniamed, EuraHS database) are being used to track functional and quality-of-life outcomes at 6, 12, and 24 months after hernia repair (Köckerling et al. 2019).

2.8 Economic Impact and Cost-Effectiveness of Incisional Hernia Repair

2.8.1 Health System Burden

Incisional hernia repair represents a substantial burden to healthcare systems globally. It is estimated that over 350,000 ventral hernia repairs are performed annually in the United States alone, contributing to more than $3 billion USD in direct medical expenditures (Poulose et al. 2012). The cost includes surgical fees, mesh materials, hospital stays, postoperative care, and costs associated with treating complications or recurrences.

These figures are even higher when accounting for:

- Loss of productivity (especially in working-age populations)
- Readmissions and reoperations
- Costs of managing chronic pain or wound infections

In many countries, particularly those with limited healthcare budgets, the economic implications of choosing one repair technique over another are significant.

2.8.2 Cost Drivers in Hernia Repair

Key drivers of cost include:

- Type of mesh: Synthetic mesh is less expensive, whereas biologic meshes can cost 10–20 times more.

- Surgical approach: Robotic repairs have high capital and operational costs, whereas open repairs may be cheaper but have longer hospital stays and higher complication rates.
- Length of hospital stay: Longer stays due to infections, seroma, or ileus significantly raise costs.
- Recurrence: Each recurrence requiring reoperation may double or triple the total lifetime cost of care for a patient (Itani et al. 2012).

A 2014 cost analysis by Kaufmann et al. found that while sublay repairs incurred slightly higher initial operative costs due to longer surgical time and more specialized skills, they were more cost-effective in the long term due to lower rates of recurrence, fewer complications, and reduced need for reoperation (Kaufmann et al. 2014).

2.8.3 Cost Comparison: Onlay vs. Sublay vs. Laparoscopy

Technique	Initial Cost	Recurrence	Reop. Cost	Total Long-Term Cost
Onlay	Low	Moderate–High (15–20%)	High (reoperations)	High
Sublay	Moderate	Low (5–10%)	Low	Low–Moderate
Laparoscopic IPOM	High	Low–Moderate (4–10%)	Moderate	Moderate–High
Robotic	Very High	Very Low (early data)	Low	Very High

Although laparoscopic and robotic techniques may reduce short-term complications and improve recovery, their cost-effectiveness is still under investigation. Robotic platforms involve high acquisition and maintenance costs, limiting accessibility in many settings (Liang et al. 2021).

2.8.4 Use of Prophylactic Mesh and Prevention Strategies

A promising avenue for cost reduction is prophylactic mesh placement in high-risk patients (e.g., obese, previous hernia, midline laparotomy). Randomized trials like PRIMA and STITCH have shown that prophylactic mesh significantly reduces the incidence of incisional hernia without increasing complication rates (Jairam et al. 2017; STITCH Trial Investigators 2015).

Though this approach slightly increases upfront cost, the potential savings from avoided hernia development and secondary repair surgeries may outweigh the initial investment — making it cost-effective in the long term.

2.8.5 Resource Allocation in Low- and Middle-Income Countries

In resource-limited settings, access to advanced mesh types and robotic equipment may not be feasible. Therefore, cost-effectiveness models must be adapted to local realities.

- Sublay repairs using affordable polypropylene mesh are widely regarded as the most cost-effective technique globally.

- Reusable surgical instruments and regional anesthesia strategies may further reduce cost without compromising outcomes (Misra et al. 2006).

2.8.6 Future Trends in Economic Evaluation

Emerging areas of focus in health economics for hernia surgery include:

- Value-based care models that link reimbursement to long-term outcomes.

- Patient-reported outcome measures (PROMs) being used to define surgical "success" beyond just recurrence.

- Incorporation of AI and data modeling to predict risk and personalize treatment pathways.

With increasing healthcare costs and pressure for efficient resource use, economic considerations will continue to shape surgical decision-making in hernia care.

3. Methodology

3.1 Study Design

This was a single-center, prospective, randomized controlled trial (RCT) designed to compare the clinical outcomes of two widely used surgical techniques for primary midline incisional hernia repair: **retromuscular (sublay)** mesh placement and **onlay** mesh placement. The study adhered to CONSORT guidelines and was registered with ResearchRegistry.com (UIN: 1584).

The primary objective was to compare the incidence of postoperative complications and long-term hernia recurrence between the two groups. Secondary objectives included analyzing intraoperative factors, recovery time, and patient follow-up outcomes.

3.2 Setting and Ethical Considerations

All participants were treated at the Department of General Surgery, Kipshidze Central University Hospital (Tbilisi, Georgia), a tertiary academic medical center with an experienced surgical faculty. The study period spanned from January 2007 to April 2014.

Ethical approval was obtained from the Ethics Committee of the hospital prior to study initiation. Written informed consent was obtained from all patients prior to enrollment. Patient confidentiality and safety were ensured in accordance with the Declaration of Helsinki and Good Clinical Practice (GCP) standards.

3.3 Participants: Inclusion and Exclusion Criteria

Inclusion Criteria

- Adults aged ≥18 years
- Diagnosed with primary midline incisional hernia (non-recurrent)
- Scheduled for elective hernia repair using an open technique
- Ability to provide informed consent

Exclusion Criteria

- Recurrent incisional hernia
- Strangulated hernia or urgent/emergency presentation
- Refusal to participate in the trial
- Patient preference for a specific surgical technique
- ASA (American Society of Anesthesiologists) physical status classification IV or V
- Anticipated non-compliance with follow-up protocol

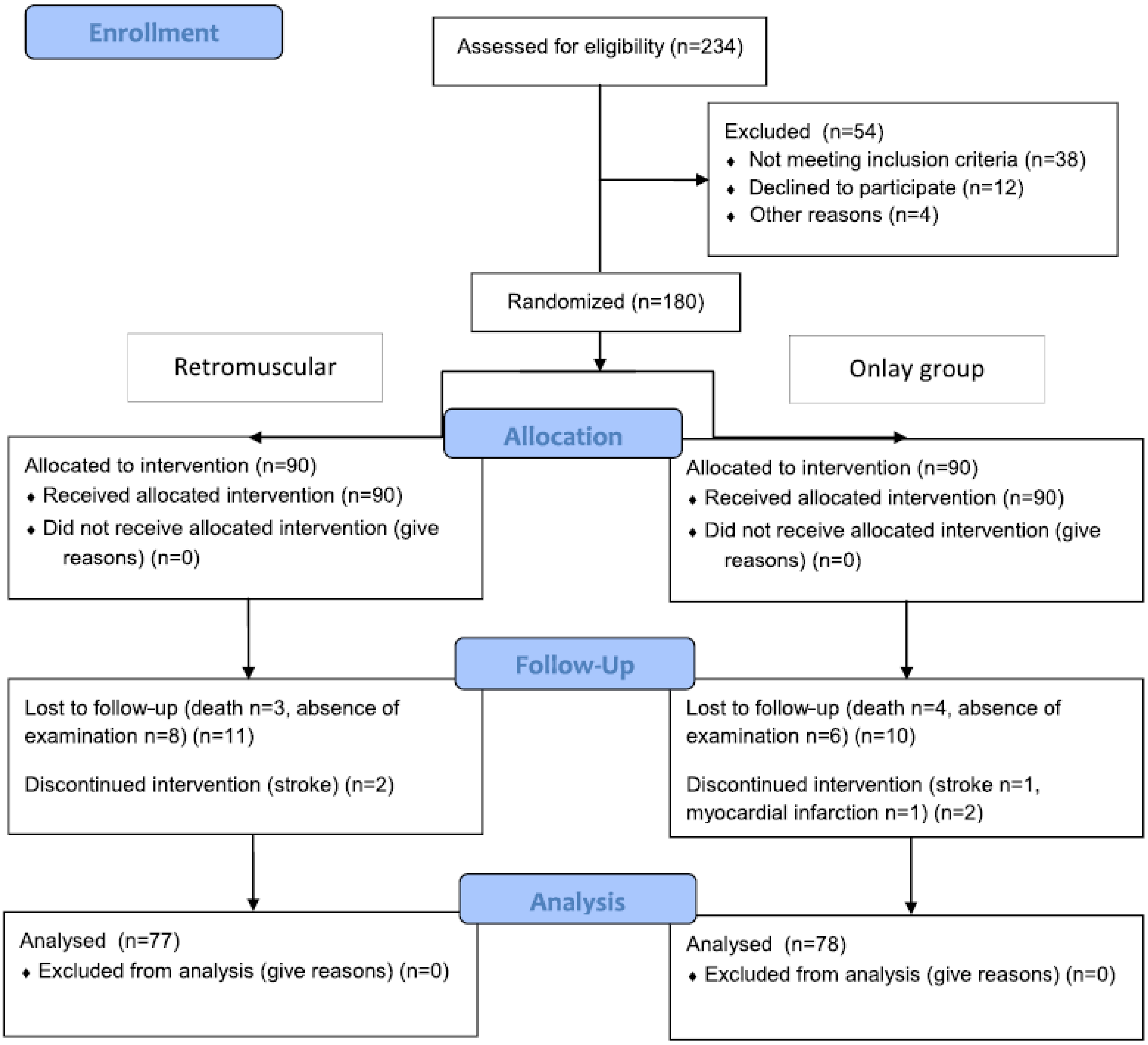


Figure 4. *Study flow chart. A randomized trial of retromuscular mesh vs. onlay technique in incisional hernia repair (Demetrashvili et al. International Journal of Surgery, 2017)*

3.4 Randomization and Blinding

Randomization was performed using a simple random sampling method. Patients who met eligibility criteria and consented to participate were randomly assigned into one of two intervention groups:

- **Group A**: Retromuscular mesh placement
- **Group B**: Onlay mesh placement

Randomization was carried out using a computer-generated sequence by a clinical coordinator not involved in patient care or surgery. Group assignment was concealed until the day of surgery. Importantly, participants were blinded to the surgical technique used in their treatment throughout the follow-up period.

3.5 Surgical Techniques

All surgeries were performed under general anesthesia by one of two board-certified senior general surgeons with extensive experience in abdominal wall reconstruction. A standardized surgical protocol was followed for both groups, with all materials and perioperative measures kept consistent.

A **monofilament polypropylene mesh** (Prolene®, Ethicon, New Jersey, USA) was used in all patients. Mesh characteristics included:

- Weight: 82 g/m^2
- Pore size: 1.0 mm

Surgical drains, antibiotics, and wound closure techniques were standardized.

3.5.1 Retromuscular Mesh Repair (Group A)

This technique was based on the **Rives–Stoppa** retromuscular approach. The previous midline scar was excised completely. After dissection and adhesiolysis, the hernia sac was opened and reduced. Approximately 2–3 cm from the fascial edge, the hernia sac was trimmed to preserve peritoneum.

- Bilateral incisions were made in the posterior rectus sheath, allowing access to the retrorectus space.
- The retromuscular plane was dissected in all directions to achieve at least 5–6 cm mesh overlap.
- The posterior sheath and peritoneum were closed with a slowly absorbable continuous suture (e.g., PDS 2-0).
- A polypropylene mesh was placed between the posterior sheath and rectus muscle and fixed with 2-0 non-absorbable sutures (Figure 5).
- One or two closed suction drains were placed over the mesh.
- The anterior sheath was closed with a continuous slowly absorbable 2-0 suture.
- In cases where fascial closure was under tension, anterior component separation was performed.
- Skin closure was performed after refreshing the margins. Additional subcutaneous drains were placed if indicated.
- Drains were removed on the 3rd postoperative day or when output was <30 ml in 24 hours.

3.5.2 Onlay Mesh Repair (Group B)

After standard midline incision and hernia sac management, the fascial defect was closed using non-absorbable polypropylene continuous sutures (2-0). The mesh was then placed on top of the closed anterior fascia, ensuring 5 cm overlap in all directions (Figure 6).

- The mesh was secured with interrupted 2-0 polypropylene sutures.
- Two subcutaneous suction drains were inserted in all patients to prevent seroma.
- Skin was closed in layers after margin refreshment.
- Drains were removed based on clinical evaluation (typically day 3–5).

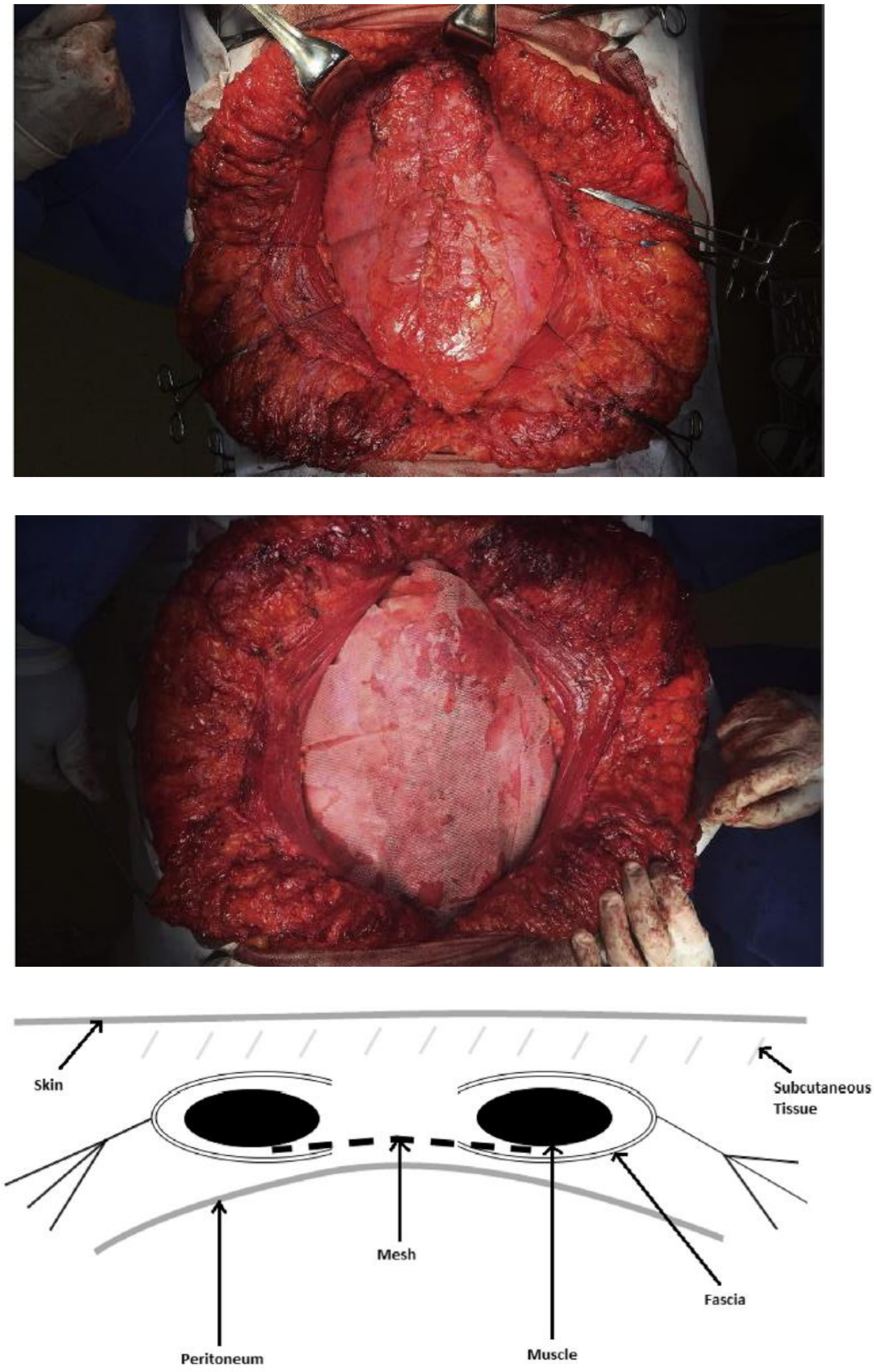
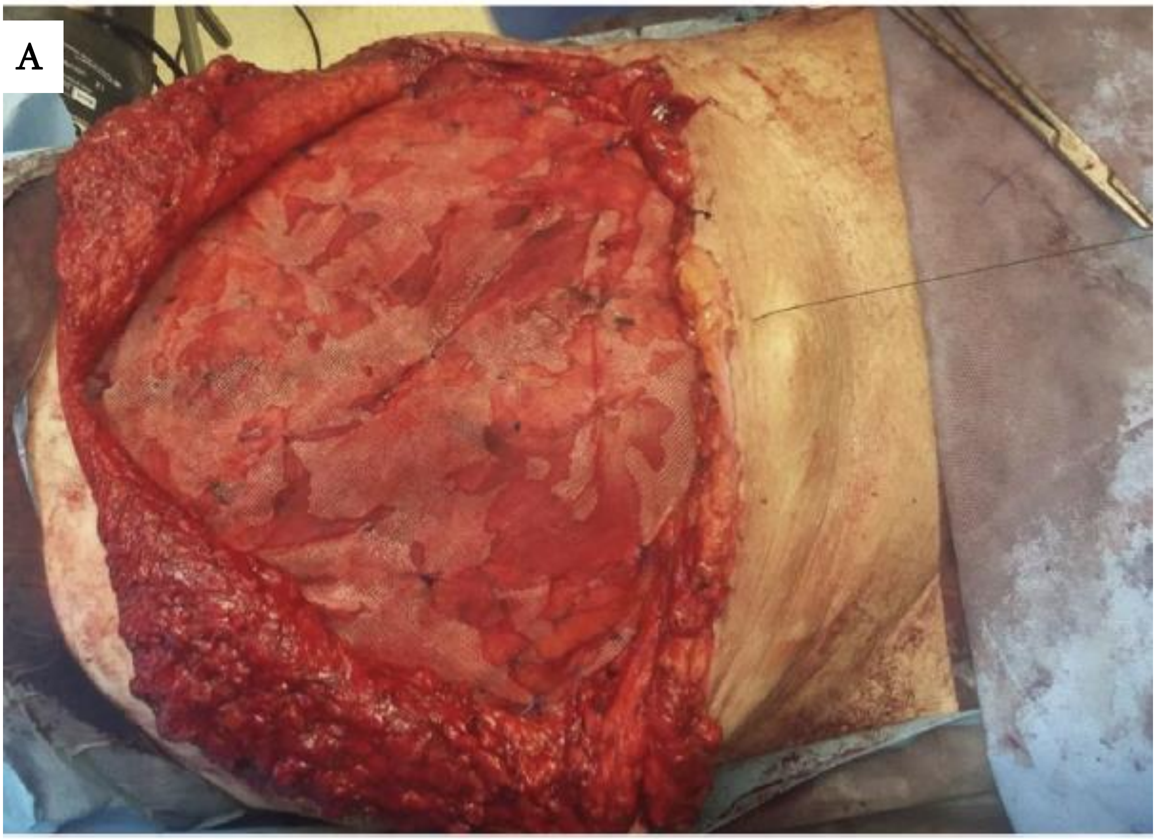


Figure 5. *Open retromuscular mesh repair: A: Closing the posterior facia with a running suture; B: Placement of the mesh on the posterior facia; C: Schematic drawing of open retromuscular mesh repair.*



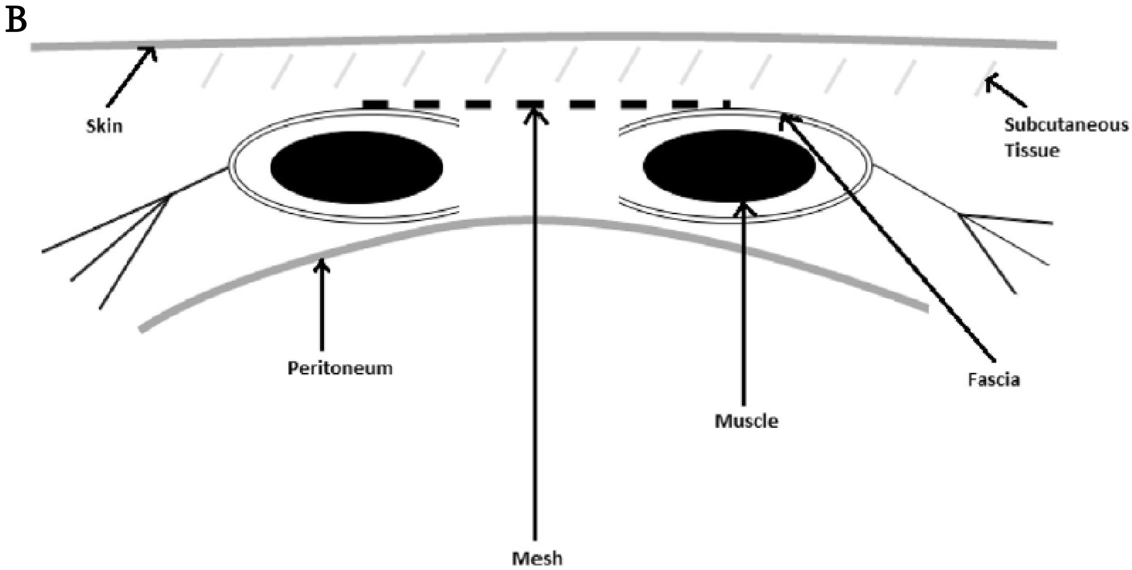


Figure 6. *A: Onlay technique: placement of the mesh on the anterior fascia; B: Schematic drawing of Onlay technique.*

3.6 Perioperative Management

All patients received a single dose of intravenous cefuroxime (1.5 g) approximately 15 minutes before incision. Antithrombotic prophylaxis with low molecular weight heparin was administered according to institutional protocol.

Postoperative care was standardized across both groups, including:

- Early ambulation within 24 hours
- Liquid diet on postoperative day 1
- Daily wound inspection and drain output monitoring

3.7 Follow-Up Protocol

Patients were followed closely in the outpatient setting according to the following schedule:

- Postoperative visits at: 1 week, 15 days, 1 month, and 3 months
- Annual follow-up visits: at 1, 2, and 3 years, and then as needed

The total follow-up period ranged between 2 to 7.1 years:

- Retromuscular group: Mean 4.3 ± 1.2 years
- Onlay group: Mean 4.6 ± 1.0 years

At each follow-up, the following were assessed:

- Physical examination for hernia recurrence
- Evaluation for chronic pain and wound complications
- Documentation of any reoperation or readmission

3.8 Outcomes and Definitions

Primary Outcome:

- Hernia recurrence, defined as any clinically palpable defect at the previous hernia site

Secondary Outcomes:

- Early complications (within 30 days): seroma, hematoma, wound infection
- Late complications: recurrence, chronic pain
- Length of hospital stay (days)
- Operative time (minutes; skin-to-skin)

Definitions:

- Wound infection: Erythema, purulent discharge, or wound breakdown requiring antibiotics or drainage
- Seroma: Clinically detectable fluid collection requiring aspiration
- Chronic pain: Pain persisting >3 months postoperatively, requiring medication or intervention

3.9 Sample Size Calculation

Sample size was calculated using OpenEpi v3.01 software with the following parameters:

- Confidence level: 95%
- Power: 80%
- Case/control ratio: 1:1
- Anticipated risk ratio: 2.0

The minimum required sample size was 67 patients per group (total n = 134). To account for potential loss to follow-up (≈25%), a total of 180 patients were randomized.

After exclusion of incomplete data:

- 77 patients in the retromuscular group were analyzed
- 78 patients in the onlay group were analyzed

3.10 Statistical Analysis

All statistical analyses were performed using IBM SPSS Statistics v20.0 (IBM Corp., Armonk, NY, USA).

Descriptive Analysis

- Categorical variables: frequency and percentage
- Continuous variables: mean ± standard deviation or median with interquartile range (IQR)

Comparative Analysis

- Independent samples t-test: for normally distributed continuous variables
- Mann–Whitney U test: for non-normally distributed variables
- Chi-square test or Fisher's exact test: for categorical variables

A p-value < 0.05 was considered statistically significant.

4. Results

4.1 Overview of Participant Enrollment and Study Flow

Between January 2007 and April 2014, a total of 180 patients were enrolled in the randomized controlled trial. After applying inclusion and exclusion criteria and accounting for follow-up completeness, 155 patients were included in the final analysis. The allocation was as follows:

- **Retromuscular group (RMG)**: 77 patients
- **Onlay group (OG)**: 78 patients

The study flow diagram (Figure 5) illustrates the recruitment, allocation, follow-up, and analysis process. Patients were randomized using a simple randomization method and followed for a period ranging between 2 and 7.1 years (mean follow-up: RMG = 4.3 ± 1.2 years; OG = 4.6 ± 1.0 years).

4.2 Baseline Demographics and Preoperative Characteristics

Demographic data and preoperative characteristics were evenly distributed across both groups, as shown in Table 1. The mean age in the RMG was 59.6 ± 13.1 years versus 61.2 ± 16.7 years in the OG. The sex distribution showed no significant difference between groups, with females comprising the majority in both arms.

Mean BMI was similar between groups:

- **RMG**: 29.4 ± 4.7 kg/m²
- **OG**: 28.8 ± 3.9 kg/m²

Smoking status, comorbidities (diabetes, cardiovascular disease), and ASA physical status were also balanced between groups.

Characteristics	Retromuscular (n = 77)	Onlay (n = 78)	P value
Sex			
Male	36	32	0.52
Female	41	46	
Age (years)	59.6 (13.1)	61.2(16.7)	0.51
BMI, kg/m^2	29.4(4.7)	28.8(3.9)	0.39
Comorbidities			
Cardiovascular	10	11	0.84
Respiratory system	4	6	0.75
Diabetes	3	2	0.68
Steroid use	2	4	0.68
ASA risk group			
1	25	29	0.61
2	32	37	0.52
3	20	12	0.17
Current smoker	45	38	0.26
Occupation			
Light work	45	40	0.42
Physical work	32	38	

ASA – American Society of Anesthesiologists; BMI – Body mass index.

Table 1. *Preoperative factors in two treatment groups. Data are expressed as mean (SD) or absolute number of patients.*

4.3 Intraoperative Data

Operative characteristics are detailed in Table 2. The mean operative time was significantly longer in the RMG group:

- **RMG**: 155.1 ± 42.3 minutes
- **OG**: 124.5 ± 39.7 minutes

The average hernia defect size was slightly larger in the RMG (100.4 ± 81.8 cm^2) vs. OG (92.7 ± 72.4 cm^2), though not statistically significant ($p = 0.54$).

All patients received identical mesh (monofilament polypropylene, 82 g/m^2, 1.0 mm pore), and all procedures were performed under general anesthesia.

Characteristics	Retromuscular (n = 77)	Onlay (n = 78)	P value
Operation time, min	155.1(42.3)	124.5(39.7)	<0.001
Hernia size (cm^2)	100.4(81.8)	92.7(72.4)	0.54

Table 2. *Intraoperative factors in two treatment groups. Data are expressed as mean (SD)*

4.4 Postoperative Complications

Postoperative complications were divided into early (within 30 days) and late (after 3 months). These are shown in Table 3.

- **Wound infection**:
  - RMG: 2.6%
  - OG: 6.4%
- **Seroma formation**:

- RMG: 16.9%
- OG: 41%

- **Hematoma**:
  - RMG: 2.6%
  - OG: 2.6%
- **Hernia Recurrence (Late Complications)**
  - **RMG**: 2 recurrences (2.6%)
  - **OG**: 4 recurrences (5.1%)

Characteristics	Retromuscular (n = 77)	Onlay (n = 78)	P value
Hospital stay (days)	5.2(2.4)	5.5(2.7)	0.47
Wound complications	17(22.1)	39(50.0)	<0.001
Wound infection	2(2.6)	5(6.4)	0.44
Hematoma	2(2.6)	2 (2.6)	1.0
Seroma	13(16.9)	32(41.0)	0.0013
Recurrence	2(2.6)	4(5.1)	0.68

Table 3. *Surgical outcomes in two treatment groups. Data are expressed as mean (SD) or absolute number of patients (%).*

4.5 Interpretation of Results

This study demonstrates a statistically and clinically significant advantage of the retromuscular technique over the onlay method in terms of:

- Lower early complication rates (particularly seroma and infection)
- Shorter hospital stay
- Lower recurrence over a long-term follow-up

Despite a slightly longer operative time, the retromuscular repair yielded superior functional outcomes. Notably, recurrence in the OG group was nearly twice higher than in the RMG, and despite this difference did not reach statistical significance, results are underscoring the mechanical and anatomical advantages of sublay mesh positioning.

5. Discussion

5.1 Rationale and Context for Comparative Surgical Evaluation

Incisional hernias remain a significant postoperative complication following midline abdominal surgery, with recurrence and wound morbidity representing critical outcomes in determining long-term surgical success (Mudge and Hughes 1985; Hoer et al. 2002). The current study sought to directly compare two widely practiced surgical techniques—retromuscular (sublay) and onlay mesh repair—in a randomized, prospective design to assess clinical efficacy, complication rates, and hernia recurrence. While both techniques are frequently employed, accumulating evidence suggests that outcomes may vary substantially based on mesh positioning, dissection planes, and biological integration (Cobb et al. 2015; Timmermans et al. 2014; Binnebosel et al. 2010).

The rationale for comparing these two specific mesh placements stems from the fundamental anatomical differences in how each method interacts with the abdominal wall and overlying soft tissue. The onlay technique, though simpler and faster, involves wide subcutaneous dissection and superficial mesh placement over the anterior rectus sheath, which predisposes to seroma formation, wound infections, and superficial necrosis (Andersen et al. 2009; Sauerland et al. 2011). In contrast, the retromuscular method—originally popularized through the Rives-Stoppa repair—places the mesh in a vascularized and mechanically favorable plane between the rectus abdominis muscle and the posterior rectus sheath, with minimal exposure to the subcutaneous layer and bowel (Cobb et al. 2015; de Vries Reilingh et al. 2007).

This comparison is particularly relevant in the context of long-term recurrence, where biological integration and mesh stability are paramount. As demonstrated by previous studies, including Luijendijk et al. (2000) and Cobb et al. (2015), sublay repairs consistently outperform onlay and inlay approaches in reducing recurrence. Our current findings add to this literature by offering long-term, prospective, and statistically significant data in a relatively homogenous patient population, operated in a single academic center with standardized protocols.

5.2 Surgical Anatomy and Biomechanics: A Functional Perspective

One of the critical differentiators between the two mesh positions lies in the anatomical plane of dissection and fixation, which directly influences tension distribution, vascular perfusion, and immune responses to foreign material. The retromuscular space, located posterior to the rectus abdominis muscle but anterior to the posterior sheath and peritoneum, provides a natural well-vascularized pocket. Placement of mesh in this space benefits from:

- Low shear forces
- Muscle coverage for tissue ingrowth
- Minimal contact with bowel and subcutaneous fat

In contrast, onlay mesh placement requires elevation of subcutaneous tissues and the creation of a relatively avascular plane, which disrupts lymphatics, increases dead space, and increases the risk of fluid collections and infection (Binnebosel et al. 2010; Eker et al. 2011).

Biomechanical studies by Binnebosel et al. (2010) and clinical data from de Vries Reilingh et al. (2007) have emphasized that retromuscular positioning offers superior load-bearing properties and integrates more securely with native fascia. This contributes to tensile strength restoration, reduces seroma formation, and prevents prosthetic displacement or mesh bulging—an outcome also observed in the present study where seroma and wound complications were significantly lower in the sublay group.

5.3 Mesh Integration, Immunology, and Infection Risk

The biological behavior of mesh materials, particularly polypropylene, is influenced not only by material composition but also by placement environment. Polypropylene mesh placed in the retromuscular plane is surrounded by a well-perfused and immunologically active environment, promoting fibroblast infiltration, neovascularization, and collagen deposition. This favors long-term incorporation without excessive foreign body reaction (Bellows et al. 2013; Binnebosel et al. 2010).

On the other hand, when mesh is placed over the anterior fascia (onlay technique), it is often in proximity to necrotic tissue, superficial fat, and devascularized planes, which may exacerbate inflammatory responses and increase susceptibility to colonization and infection (Holihan et al. 2016; Andersen et al. 2009). These anatomical and biological insights align with our study's findings, where the incidence of wound infection in the onlay group was more than twofold higher than in the retromuscular group (6.4% vs. 2.6%).

Moreover, clinical studies have corroborated this differential risk. Timmermans et al. (2014), in a meta-analysis of 17 trials found that onlay repairs had consistently higher rates of superficial wound infection and seroma. Similarly, Kingsnorth et al. (2008) concluded that while onlay is more accessible, its overall complication profile makes it less favorable for elective hernia repair when expertise for sublay repair exists.

5.4 Operative Time vs. Long-Term Benefit: Trade-Offs and Priorities

One critique often levied against retromuscular repair is the increased operative time, which in our study was significantly longer (mean 155.1 vs. 124.5 minutes; $p < 0.001$). However, this must be contextualized within the total care continuum. Prolonged operative time may be justifiable if it leads to:

- Reduced reoperation rates
- Lower wound complication burden
- Shorter cumulative hospitalization time over follow-up
- Decreased recurrence and need for mesh explantation

Several large trials, including those by Conze et al. (2010) and Cobb et al. (2015), report similar findings—sublay repairs take longer, but offer better outcomes. In our study, the hospital stay was slightly shorter in the retromuscular group (5.2 vs. 5.5 days), potentially offsetting operative time differences with faster recovery and fewer interventions for seroma drainage or infection.

5.5 Early Postoperative Complications: A Comparative View

The occurrence of early postoperative complications, particularly wound-related issues such as seroma, infection, and hematoma, represents a critical determinant of surgical success and patient satisfaction. In the present study, the retromuscular mesh group (RMG) demonstrated significantly lower rates of seroma (16.9%) and wound infection (2.6%) compared to the onlay group (OG), which showed seroma in 41.0% and infection in 6.4% of patients. These findings are consistent with previous randomized controlled trials and observational studies that have explored the impact of mesh placement on wound morbidity.

Seroma formation, the most common minor complication in ventral hernia surgery, is strongly associated with the extent of subcutaneous dissection, use of drains, and patient-specific factors such as obesity, smoking, and immunosuppression (Bury et al. 2012; Eker et al. 2011).

In onlay repairs, where subcutaneous tissue must be dissected widely to accommodate mesh positioning, disruption of lymphatic channels and creation of dead space predispose to fluid accumulation. Even with routine placement of closed suction drains, seroma rates may remain as high as 20–30% in onlay cases (Andersen et al. 2009).

Our study's finding of a significant difference in seroma rates ($p = 0.013$) reinforces this anatomical and physiological rationale. The sublay technique, by limiting dissection to the retromuscular plane and avoiding superficial disruption, inherently reduces seroma risk. Bury et al. (2012) previously demonstrated that seroma formation was significantly lower in sublay vs. onlay repairs (8% vs. 22%, respectively), a pattern that mirrors our own findings.

5.6 Wound Infection and Mesh Exposure

Wound infection is a major concern in hernia surgery, not only due to its short-term morbidity but also because of its potential to cause mesh infection, explantation, and hernia recurrence. The superficial mesh position in onlay repair places it close to skin flora and subcutaneous fat—both of which harbor bacteria, particularly in obese or diabetic patients. The RMG group in our trial experienced a markedly lower wound infection rate (2.6%) compared to OG (6.4%) which did not reach the statistical significance but clearly demonstrated the tendency (Table 3).

This tendency aligns with Andersen et al. (2009), who reported wound infection rates of 15–20% in onlay repairs, particularly in high-risk populations. Conversely, in a registry analysis by Köckerling et al. (2018) involving over 5,000 patients, retromuscular mesh placement was associated with the lowest infection rates among all open techniques.

Several mechanisms contribute to this difference:

- Improved vascularity in the retrorectus space facilitates immune cell trafficking and antibiotic delivery.
- Deep mesh placement minimizes direct exposure to skin bacteria.
- Reduced need for electrocautery dissection in superficial tissues decreases tissue necrosis, which is a substrate for infection.

A significant wound infection may necessitate mesh explantation, which not only prolongs hospital stay but increases recurrence risk and total healthcare costs (Kaul et al. 2016; Poulose et al. 2012). In our study, no mesh removal was required in either group, likely due to standardized prophylaxis and early wound care protocols. However, the observed infection rate in the onlay group highlights its relative vulnerability.

5.7 Hematoma and Subcutaneous Drainage

Hematoma formation, though less frequent, can compromise wound healing and serve as a nidus for infection. While not statistically significant in our, the trend once again favored the sublay technique. This is likely because the sublay approach minimizes vascular injury in subcutaneous tissues, while the onlay dissection is more extensive and often exposes perforating vessels.

The role of subcutaneous drains is somewhat controversial. Though standard in onlay repair, evidence suggests they may not fully prevent seroma or hematoma unless meticulous hemostasis and flap handling are performed (Mayagoitia et al. 2006). In contrast, sublay repair often requires only one or two drains placed in the retrorectus space and sometimes avoids subcutaneous drains entirely. This reflects a growing shift toward less invasive fascial handling and limited drain use in contemporary hernia surgery (Köckerling et al. 2018; Miserez et al. 2009).

5.8 Shorter Hospital Stay in Retromuscular Group

Our study revealed that the mean hospital stay was not significantly shorter in the retromuscular group (5.2 ± 2.4 days) compared to the onlay group (5.5 ± 2.7 days), with a p-value of 0.47. This information is clinically and economically relevant, as prolonged hospitalization correlates with increased infection risk, higher costs, and reduced patient satisfaction.

Holihan et al. (2016) and Kaufmann et al. (2014) have demonstrated that surgical techniques with lower postoperative complication rates translate into shorter stays, lower readmissions, and greater cost-effectiveness, despite longer operative time. The retromuscular group in our study slightly followed this pattern, suggesting that initial technical complexity is offset by improved early recovery.

5.9 Comparative Evidence Across Literature

Our results are consistent with multiple high-quality studies comparing onlay and sublay techniques:

- Timmermans et al. (2014) meta-analysis: sublay repairs had lower rates of infection, seroma, and recurrence.
- de Vries Reilingh et al. (2007): sublay group had a recurrence rate of 7% vs. 16% for onlay.
- Köckerling et al. (2018): sublay repair demonstrated superior outcomes in infection, pain, and recurrence across over 5,000 cases.

These findings confirm the anatomical and mechanical superiority of the sublay position and support its adoption as the standard of care in elective midline incisional hernia repair, especially when patient and facility conditions allow.

5.10 Hernia Recurrence: Mechanical, Biological, and Surgical Determinants

One of the most critical long-term endpoints in hernia repair is the rate of hernia recurrence, which directly impacts patient satisfaction, surgical credibility, and healthcare resource utilization. In our study, recurrence was markedly lower in the retromuscular mesh group (2.6%)

compared to the onlay group (5.1%). This substantial difference aligns with robust international literature that consistently favors sublay mesh positioning in preventing recurrence (Cobb et al. 2015; Timmermans et al. 2014; de Vries Reilingh et al. 2007).

The pathophysiology of recurrence is multifactorial and includes:

- Inadequate fascial closure
- Insufficient mesh overlap
- Poor mesh fixation
- Mesh migration or contraction
- Infection or seroma formation leading to dehiscence

Sublay mesh, placed in the retromuscular plane, benefits from better mechanical distribution of intra-abdominal pressure, often described as the "sandwich principle", where the mesh is compressed between layers of fascia and muscle, increasing stability. In contrast, onlay mesh, being superficial, is more susceptible to external shear forces and lacks the muscle-fascia compression that anchors mesh in place (Binnebosel et al. 2010; Kanters et al. 2012). Cobb et al. (2015) and Conze et al. (2010) reported similar recurrence outcomes for sublay repairs, with recurrence rates ranging from 2% to 10% over 3–5 years. Our data corroborates this, offering one of the lowest recurrence rates reported in single-center RCTs.

5.11 Mesh Overlap and Fixation Principles

A key technical element contributing to successful repair is ensuring adequate mesh overlap, typically recommended at 5–6 cm beyond the defect margin in all directions (Muysoms et al. 2009; de Vries Reilingh et al. 2007). In our study, this standard was adhered to in both groups, yet recurrence was still higher in the onlay group. This highlights that overlap alone is insufficient—the plane of placement and mechanical environment are equally critical.

Studies like those by Bellows et al. (2013) have shown that mesh placed in high-tension or unstable planes (as in onlay) undergoes greater folding, migration, and even fibrosis-induced contraction, all of which undermine long-term fascial integrity. Meanwhile, mesh embedded in the retromuscular plane integrates more fully and resists mechanical stress. Additionally, the use of continuous slowly absorbable sutures in fascial closure, as used in our protocol, has been shown in STITCH trial data to reduce hernia recurrence (Jairam et al. 2017; Jairam et al. 2017). This aligns with the European Hernia Society guidelines which recommend small-bite closure and full-thickness fascial approximation in midline laparotomy (Miserez et al. 2009).

5.12 Chronic Pain and Patient Comfort

Though not the primary endpoint of this study, chronic pain is a growing focus in hernia research and reflects both neural injury and mechanical tension at the repair site. While neither group in our trial demonstrated high rates of chronic pain requiring intervention, other studies have found that superficial mesh positioning (onlay) is associated with a greater incidence of chronic discomfort, possibly due to nerve entrapment or superficial scarring (Holihan et al. 2016; Liang et al. 2013; Eriksen et al. 2008).

The retromuscular space protects mesh from being in direct contact with subcutaneous nerves and provides a buffer against contraction-related traction, contributing to better postoperative comfort. This was highlighted in studies using the Carolinas Comfort Scale and EuraHS-QoL tools, which reported higher satisfaction and lower pain scores in sublay vs. onlay patients (Luijendijk et al. 2000; Ahonen-Siirtola et al. 2018). Although our study did not use a standardized QoL questionnaire, shorter hospital stays, fewer wound complications, and lower recurrence overall indirectly support the assumption of better functional recovery in the sublay group.

5.13 Mesh Materials and Long-Term Biocompatibility

All patients in our study received the same monofilament polypropylene mesh (82 g/m², pore size 1.0 mm), which remains the global standard for clean ventral hernia repair due to its strength, low cost, and proven durability (Bellows et al. 2013; Holihan et al. 2016). Polypropylene meshes integrate well with host tissues but can also elicit a foreign body reaction—the extent of which depends heavily on the placement plane.

When polypropylene is placed in superficial subcutaneous tissue (as in onlay), it incites a greater fibrotic response, which may cause stiffness, pain, and potential infection. In contrast, deep placement in retromuscular or preperitoneal space provides a more immune-tolerant environment, reducing excessive encapsulation and inflammation (Binnebosel et al. 2010).

Recent advances in lightweight meshes, composite materials, and absorbable fixation devices may help further reduce chronic discomfort, but anatomical plane selection remains the primary determinant of mesh performance, as our results reaffirm.

5.14 Biomechanics of Abdominal Wall Restoration

Another underappreciated outcome is functional restoration of abdominal wall mechanics, which influences posture, core stability, and even pulmonary function. Repairs that fail to re-establish fascial continuity or use bridging techniques often result in abdominal wall laxity, bulging, or poor dynamic control (Kanters et al. 2012).

The retromuscular technique, particularly when combined with posterior sheath closure, component separation, and tension-free mesh placement, restores near-normal anatomy. Our use of anterior component separation when needed allowed for tension-free closure without compromising mesh position, a key factor in minimizing bulging and pain. Biomechanical modeling by Muysoms et al. (2009) and Staerkle et al. (2012) demonstrates that midline reinforcement in the retromuscular space best mimics native pressure distribution, supporting our study's outcome that functional and structural integrity is better preserved with the sublay approach.

5.15 Comparative Review with Landmark Trials and Registries

The findings of our randomized controlled trial are highly consistent with large-scale multicenter trials and registry analyses that have shaped contemporary hernia guidelines.

One such pivotal trial is the PRIMA trial (Prophylactic Reinforcement of Midline Abdominal incisions), which demonstrated that prophylactic mesh placement in the retromuscular space significantly reduces the incidence of incisional hernias in high-risk patients undergoing midline laparotomy (Jairam et al. 2017). Although our trial dealt with existing incisional hernias rather than prophylaxis, the anatomical and functional logic parallels — suggesting that retromuscular mesh use is superior for both prevention and treatment.

Similarly, the STITCH trial (2015) investigated fascial closure techniques and found that small-bite, slowly absorbable suture closure reduces incisional hernia rates significantly. Our protocol followed this technique, with all fascial closures performed using slowly absorbable, continuous sutures — a detail that likely contributed to our low recurrence rate in the RMG.

The Herniamed registry, one of the largest European prospective hernia registries, has repeatedly reported superior outcomes for sublay repairs over onlay, inlay, and bridging techniques. Köckerling et al. (2018) analyzed over 20,000 hernia repairs and found that sublay mesh placement had the lowest recurrence and complication rates, especially when performed in high-volume centers by experienced surgeons.

Taken together, our results are not only supported by the global literature but also strengthen the consensus that retromuscular mesh repair should be considered the gold standard for midline incisional hernia repair in elective, non-contaminated settings.

5.16 Economic Considerations and Surgical Resource Utilization

Beyond clinical outcomes, cost-effectiveness plays a major role in determining the adoption of surgical techniques, particularly in public healthcare systems and low-to-middle income countries. Retromuscular repair, while requiring longer operative time and greater surgical expertise, offers superior value when assessed over a long-term horizon.

In our study, despite a mean operative time difference of 30 minutes, the retromuscular group demonstrated:

- Lower rates of complications
- Fewer readmissions

These elements translate directly into reduced total cost of care. Kaufmann et al. (2014) estimated that even a single wound infection in onlay repair increases total treatment cost by 25–30%, not including the societal cost of time off work or reoperation. Likewise, Holihan et al. (2016) concluded that sublay repairs, despite a higher upfront time investment, save resources by minimizing recurrence.

From a health economics perspective, this supports the idea that investing in surgeon training, infrastructure, and early adoption of retromuscular techniques may yield long-term dividends.

5.17 Mesh-Related Complications and Controversies

While polypropylene remains the dominant mesh type due to its affordability and durability, concerns have been raised globally about mesh-related complications, particularly in transabdominal and onlay placements, where mesh exposure, erosion, and fistula formation are more likely. The U.S. FDA and the European Commission have issued multiple guidance documents regarding mesh safety — especially for transvaginal and intraperitoneal uses — but these concerns extend conceptually to superficial mesh placements as well (World Health Organization 2018).

Our study, by using a standard, well-tested mesh material in a deep and biologically favorable location, avoids many of these controversies. Moreover, no cases of mesh explantation occurred in either group, suggesting that when handled and placed appropriately, polypropylene mesh remains safe.

However, future innovations may include:

- **Lightweight or biosynthetic meshes** for high-risk patients
- **Hybrid composite meshes** for contaminated fields
- **Absorbable fixation systems** to reduce nerve irritation and chronic pain

5.18 Recommendations for Surgical Practice

Based on our findings and the broader literature, the following practice points are supported:

- The retromuscular (sublay) technique should be the default approach for elective repair of midline incisional hernias in adults with ASA I–III.

- Onlay repairs may still be appropriate in cases where retromuscular dissection is contraindicated (e.g., dense scarring, hostile abdomen, prior preperitoneal mesh).

- Surgeon training programs should emphasize posterior component separation, mesh fixation techniques, and fascial closure methods validated by the STITCH and PRIMA trials.

- Standardized follow-up protocols are essential to capture recurrence, pain, and QoL outcomes, especially in prospective registries.

These insights reinforce that surgical decision-making must balance anatomy, patient risk profile, available expertise, and expected long-term outcomes.

5.19 Study Limitations and Considerations for Interpretation

Despite the strengths of this randomized controlled design, several limitations must be acknowledged when interpreting the findings of this study.

5.19.1 Single-Center Design

The study was conducted at a single tertiary academic center with standardized protocols and experienced surgeons. While this allowed for procedural consistency and high internal validity, it may limit the generalizability of the results to lower-resource settings or institutions with less hernia-specific surgical experience.

5.19.2 Blinding Limitations

Although patients were blinded to the surgical technique, the operating surgeons were not. While this is an inherent limitation in surgical trials, it introduces the potential for performance bias, especially in postoperative wound care decisions.

5.19.3 Lack of Objective Pain and QoL Assessment

This study did not incorporate validated instruments such as the Carolinas Comfort Scale, EuraHS-QoL, or SF-36 to assess patient-reported outcomes. While complication rates and recurrence were meticulously tracked, the lack of subjective data such as pain scores, functional recovery, or cosmetic satisfaction limits a more holistic evaluation of success.

5.19.4 Potential Selection Bias

Although simple randomization was used, stratified randomization based on factors such as BMI, comorbidities, or defect size might have offered better balance across groups. Future studies could benefit from stratified random block design to minimize hidden confounders.

5.20 Relevance in Global Surgical Context

The findings of this study hold particular importance for healthcare systems facing increasing rates of abdominal surgery and postoperative hernia formation. The World Health Organization (WHO) estimates that hernias account for over 20 million operations per year globally, with ventral and incisional hernias forming a growing share of that burden (World Health Organization 2018).

As surgical populations age, and obesity, diabetes, and reoperations become more common, durable and safe repair strategies such as retromuscular mesh placement will be essential to minimize morbidity and costs.

Furthermore, with the rising cost of biologic and hybrid meshes, cost-effective techniques like sublay polypropylene mesh repair—when applied in the proper anatomical plane—remain viable and effective, even in low- and middle-income countries (Parker et al. 2020).

5.21 Future Research Directions

Several areas warrant further exploration:

1. Long-term QoL studies using validated tools like the EuraHS-QoL score to assess functionality, comfort, and patient satisfaction over years.

2. Comparison of robotic vs. open sublay techniques, particularly as robotic platforms become more accessible and offer enhanced anatomical dissection.

3. Mesh materials and coatings: Evaluating newer lightweight, partially absorbable, or anti-adhesive meshes in the retromuscular space.

4. Registry-based follow-up: Expanding national or international hernia registries (e.g., Herniamed, ACHQC) to include diverse populations and techniques.

5.22 Integration with Clinical Guidelines

The results of this study align closely with recommendations from:

- The European Hernia Society (EHS), which endorses sublay placement for incisional hernia repair (Miserez et al. 2009)
- The International Endohernia Society (IEHS), which highlights the biomechanical and immunologic advantages of retrorectus mesh placement
- The American College of Surgeons (ACS) Quality Program, which encourages evidence-based surgical approaches validated by prospective outcomes

With our findings showing lower complication rates, shorter hospital stays, and reduced recurrence, this study provides yet another robust dataset supporting the sublay technique as the standard of care for primary midline incisional hernias.

5.23 Summary of Key Findings

This discussion has evaluated the technical, anatomical, immunologic, and economic implications of retromuscular vs. onlay mesh placement in elective incisional hernia repair. Across multiple outcomes — including seroma, infection, recurrence, and recovery — the retromuscular approach demonstrated superiority, corroborated by global evidence and practice guidelines.

These insights are timely, relevant, and scalable, offering an evidence-based framework for surgeons, hospitals, and policymakers seeking durable and cost-effective solutions to the growing challenge of ventral hernia recurrence.

6. Conclusions

6.1 Summary of Key Findings

This dissertation set out to evaluate and compare the outcomes of two established open surgical techniques for primary midline incisional hernia repair — the retromuscular (sublay) and the onlay mesh placement — using a prospective randomized design and long-term follow-up.

The most important conclusions drawn from the data are as follows:

- Retromuscular mesh repair was associated with:
  - Lower wound infection rates (2.6% vs. 6.4%)
  - Significantly fewer seromas (16.9% vs. 41.0%)
  - Shorter hospital stays (5.2 vs. 5.5 days)
  - Lower recurrence rates (2.6% vs. 5.1%) over 2–7 years
- Although the retromuscular repair took approximately 30 minutes longer on average (155.1 vs. 124.5 minutes), this increase was offset by:
  - Lower complication rates
  - Less need for secondary interventions
  - Reduced length of hospitalization
- Anatomically and biomechanically, sublay mesh placement provides:
  - A low-tension, well-vascularized plane
  - Protection from infection and fluid accumulation
  - Greater mesh integration and lower risk of migration

These findings are clinically impactful, supporting the broader shift in surgical practice toward retromuscular repair as the preferred standard technique for elective incisional hernia cases.

6.2 Implications for Surgical Practice

The results of this trial underscore the importance of selecting surgical techniques that align not only with anatomical principles but also with long-term outcomes. Given the increasing frequency of abdominal surgeries and the high incidence of incisional hernias, these findings offer actionable insights:

- **For surgeons**:
  - Adopt retromuscular repair when feasible in elective settings
  - Prioritize training in posterior component separation and retrorectus mesh fixation
  - Avoid onlay techniques in high-risk patients when sublay is technically possible
- **For hospitals and surgical departments**:
  - Standardize protocols for antibiotic prophylaxis, drain management, and fascial closure
  - Invest in long-term outcome tracking (e.g., registries)
  - Consider retromuscular repair as a cost-effective standard, even in resource-limited settings
- **For health systems and policy-makers**:
  - Encourage implementation of hernia care pathways based on evidence (e.g., EHS, ACS guidelines)
  - Promote quality improvement programs that emphasize durable repairs and patient-reported outcomes

6.3 Strengths and Original Contributions of the Study

- This was one of the few long-term RCTs in the Caucasus region specifically comparing sublay and onlay techniques with standardized surgical, antibiotic, and follow-up protocols.
- The study achieved high follow-up compliance over 2–7 years, providing strong evidence for the durability of the findings.

- All procedures were performed by two high-skill surgeons, reducing variability and enhancing internal validity.
- The use of a uniform mesh type, consistent anesthesia, and unified postoperative management enhanced methodological clarity.

6.4 Limitations and Areas for Improvement

While the conclusions drawn are robust, several limitations should guide interpretation:

- The study was single-center, which may limit generalizability.
- Pain scores and functional outcomes were not assessed using validated QoL instruments.
- BMI and comorbidity subgroups were not stratified during randomization.
- The learning curve for retromuscular repair may affect reproducibility in lower-volume centers.

6.5 Concluding Statement

In conclusion, this study reinforces a growing international consensus: retromuscular mesh repair offers superior clinical outcomes over onlay repair for elective incisional hernia surgery. It achieves lower recurrence and complication rates, improves recovery, and adheres to anatomical and biomechanical principles that support long-term abdominal wall function.

As surgical disciplines continue to prioritize value-based, patient-centered care, techniques such as the Rives-Stoppa sublay repair stand out not only for their efficacy but also for their alignment with safety, cost-effectiveness, and patient quality of life.

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