

One-Year Safety and Clinical Performance of MERINEUM™ MESH with PROFOUND™ in Hernia Repair: A Multicenter Real-World Study

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ABSTRACT

Background: MERINEUM™ MESH is a sterile, partially absorbable, dual-layer surgical mesh intended for laparoscopic ventral hernia repair and other fascial surgical interventions. This real-world post-market clinical follow-up study evaluated its safety and clinical performance over 12 months. **Methods:** This retrospective, single-arm, multicenter observational study was conducted across five centers and included patients undergoing hernia repair with MERINEUM™ MESH. The primary endpoint was hernia recurrence at 12 months, defined as the development of a new or recurrent bulge that increased in size with straining. Secondary outcomes included post-operative complications, surgical site infection (SSI), adverse events (AEs), serious AEs (SAEs), and operative time. Patient and procedural data were retrospectively collected from medical records. **Results:** A total of 141 mesh devices were implanted in 130 patients. The mean age was 54.59 ± 13.53 years, and 71.54% of patients were male. Laparoscopic repair was performed in 92.31% of patients, and the mean operative time was 80.92 ± 24.86 min. No hernia recurrence was observed during the 12-month follow-up, resulting in a 0% recurrence rate. Four patients (3.08%) developed seroma and two (1.54%) developed hematoma; all were managed conservatively and resolved. No SSIs or SAEs were reported. Two perioperative AEs were observed: post-operative abdominal distension managed conservatively and inflammation requiring mesh removal, which subsequently resolved. No additional device-related adverse reactions were reported during follow-up. **Conclusion:** MERINEUM™ MESH demonstrated a favorable safety and clinical performance profile, characterized by no clinically evident recurrence or SSI and a low incidence of conservatively managed post-operative complications. These findings support its use in hernia repair in the studied population. Larger prospective studies with longer follow-up are warranted to further establish long-term durability and safety.

Keywords: Hematoma, Hernia repair, Laparoscopic hernia repair, MERINEUM™ MESH, Mesh, Post-market clinical follow-up, Recurrence, Seroma, Surgical site infection, Ventral hernia

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INTRODUCTION

The abdominal wall is a complex multilayered structure of skin, subcutaneous tissue, muscles, fascia, and peritoneum that provides support, protects intra-abdominal organs, and maintains intra-abdominal pressure, while defects may permit protrusion of abdominal contents, resulting in hernias.^[1-3] Abdominal wall hernias are common surgical conditions associated with considerable morbidity and disability.^[4] Globally, more than 20 million hernia repairs are performed annually.^[5] Despite their high prevalence, limited awareness often leads to delayed diagnosis and presentation. Early surgical repair is recommended to prevent complications and improve outcomes.^[6,7]

The use of prosthetic mesh has become a standard approach in abdominal wall hernia repair, owing to its effectiveness in reinforcing weakened tissues and reducing recurrence compared with primary suture repair.^[8-10] However, implantation of permanent prosthetic material may be associated with foreign-body reaction, fibrosis, mesh-related stiffness, restricted abdominal wall movement, and patient discomfort.^[11] Advances in mesh technology have led to the development of partially absorbable prostheses, which may reduce the amount of permanent biomaterial remaining in the body compared with completely non-absorbable meshes such as polypropylene.^[12] Reduced permanent foreign material may help attenuate the foreign-body reaction and excessive fibrosis, potentially minimizing mesh-related stiffness, restricted abdominal wall movement, and patient discomfort.^[12]

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The evolution of minimally invasive techniques, including laparoscopic- and robotic-assisted hernia repair, has further improved hernia management by reducing tissue trauma, post-operative pain, wound-related complications, and hospital stay

while facilitating faster recovery.^[13,14] In laparoscopic ventral hernia repair, especially with intraperitoneal mesh placement, mesh design is crucial to ensure durable abdominal wall reinforcement while minimizing visceral contact.^[15]

MERINEUM™ MESH (Meril Endo Surgery Pvt. Ltd.) is a sterile, dual-layer, partially absorbable, tissue-separating surgical mesh intended for laparoscopic ventral hernia repair. It consists of a non-absorbable knitted polypropylene layer that promotes tissue ingrowth and provides reinforcement to weakened or damaged tissue, together with an absorbable, non-adhesive polylactide-caprolactone film that separates the polypropylene layer from underlying tissues and organs during healing, thereby minimizing the risk of unintended tissue attachment. PROFOUND™ A is an absorbable mesh fixation device intended for fixation of surgical mesh during hernia repair. Its use with MERINEUM™ MESH is intended to facilitate secure and controlled fixation of the mesh to the abdominal wall.^[16]

The evaluation of the safety and performance of these devices in routine clinical practice is important to complement existing clinical evidence and support continued assessment of their benefit-risk profile under real-world conditions. Therefore, this retrospective, single-arm, multi-Center, observational post-market clinical follow-up study is designed to evaluate the safety and performance of MERINEUM™ MESH with PROFOUND™ A in patients undergoing hernia repair in real-world clinical settings.

METHODS

Study Design and Population

This was a retrospective, single-arm, multicenter, observational study conducted across five participating centers. The study included patients who had undergone treatment with MERINEUM™ MESH for laparoscopic ventral hernia repair or other fascial surgical intervention procedures. Since this was a retrospective study, there were no formal exclusion criteria, and all eligible patients with complete medical records were included in the analysis.

Study Endpoints

The primary endpoint was the recurrence rate at 12 months, defined as the presence of a new or similar bulge that increased in

size on straining. The secondary endpoint included post-operative complications (such as seroma and hematoma formation) occurring from discharge to 12 months, surgical site infections (SSI) (classified as superficial, deep, or organ/space according to the Centers for Disease Control and Prevention [CDC] criteria), and operative time measured as the skin-to-skin duration, excluding anesthesia and operating room setup time.

Device Specification

MERINEUM™ MESH (Meril Endo Surgery Pvt Ltd.) is a sterile, tissue-separating dual-layered partially absorbable surgical mesh indicated for laparoscopic ventral hernia repair and other fascial surgical intervention procedures. The device is intended to provide durable reinforcement of the abdominal wall while supporting tissue integration and reducing the risk of hernia recurrence. MERINEUM™ MESH is indicated to be used for tissue reinforcement in Laparoscopic Ventral Hernia Repair and other fascial surgical intervention procedures [Figure 1].

Data Collection

Patient data were retrospectively extracted from medical records at the participating centers. Demographic characteristics, clinical history, procedural details, operative time, post-operative outcomes, recurrence, SSIs, and post-operative complications were collected. Follow-up data were reviewed for up to 12 months after the index procedure to assess the safety and performance of the device.

Sample Size Calculation

The sample size was estimated using a reported recurrence rate of 15.0% from the reference literature.^[17] Assuming a two-sided significance level (α) of 5%, 80% power, and a confidence interval with a half-width of 0.074 using the Wilson method, a minimum sample size of 103 patients was required. To enhance the robustness of the analysis, data from 130 patients were included in the study.

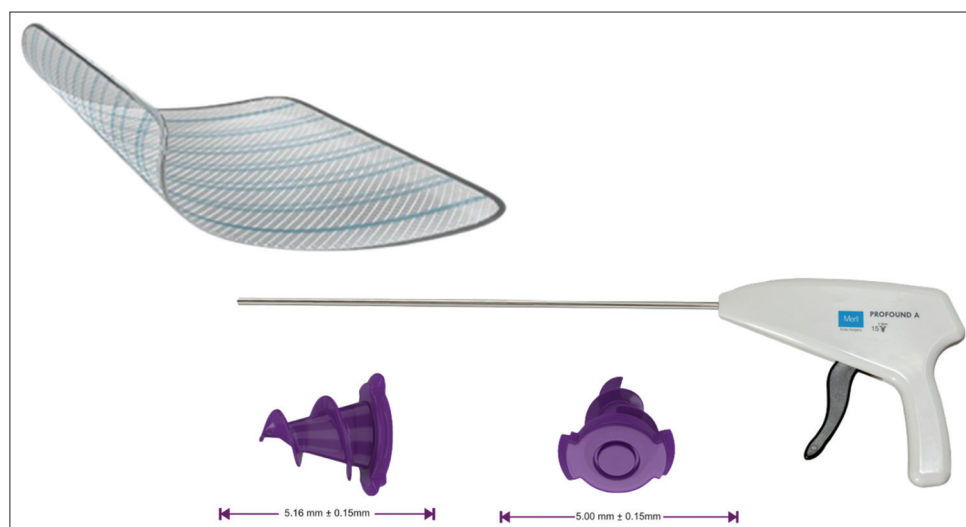


Figure 1: Schematic illustration of the MERINEUM™ MESH and PROFOUND A™

Statistical Analysis

Microsoft Excel and Statistical Package for the Social Sciences (version 27) were used for data entry, cleaning, and analysis. Continuous variables are presented as mean $\pm$ standard deviation, and categorical variables are summarized as frequencies and percentages.

RESULTS

Demographics and Baseline Characteristics

Of the 130 patients included in the study, there were 93 (71.54%) males and 37 (28.46%) females with a mean age of 54.59 ± 13.53 years. The mean body mass index and heart rate were 23.85 ± 4.25 kg/m² and 82.22 ± 8.47 bpm. The mean systolic/diastolic blood pressure was 128.63 ± 16.41 mm/Hg/ 78.66 ± 10.82 mm/Hg. There were 23 (17.69%) patients with a history of abdominal pain and 7 (5.38%) Patients with a history of groin pain [Table 1].

Procedural Characteristics

A total of 130 patients underwent hernia repair using MERINEUM™ MESH, during which 141 mesh devices were implanted. Of these, 138 (97.87%) were 15×15 cm² meshes and 3 (2.13%) were 7.6×15 cm² meshes.

Laparoscopic hernia repair was the predominant surgical approach, performed in 120 (92.31%) patients, while open hernia repair was performed in 10 (7.69%) patients. The hernia types treated included umbilical hernia (26.92%), bilateral inguinal hernia (13.08%), right inguinal hernia (12.31%), right indirect irreducible incomplete hernia treated with open hernioplasty-IPOM (12.31%), recurrent incisional hernia treated with Intraperitoneal Onlay Mesh (IPOM) (11.54%), right direct reducible complete hernia treated with R-TEP-IPOM (6.15%), left inguinal hernia (5.38%), right lumbar ventral hernia treated with IPOM (3.08%), and left indirect irreducible incomplete hernia treated with transabdominal preperitoneal (2.31%).

The mean hernia dimensions were 9.85 ± 0.87 cm for length, 4.45 ± 0.65 cm for diameter, and 8.32 ± 1.33 cm for width, corresponding to a mean hernia area of 81.93 ± 15.55 cm². General anesthesia was administered in 81.54% of patients, while 18.46% of patients received spinal anesthesia. Mesh placement was most commonly in the inguinal region (36.92%), followed by the abdominal wall (12.31%), pubic bone (12.31%), intestine (22.31%), intestine/abdominal wall (10.00%), and lumbar region (6.15%). The PROFOUND™ A mesh fixation device was used in 34.62% of patients, whereas alternative fixation devices were used in 65.38% of patients. The mean operative time was 80.92 ± 24.86 min [Table 2].

Clinical and Safety Outcomes

All hernia defects were successfully repaired using MERINEUM™ MESH, and all 130 patients completed the 12-month follow-up period. The primary endpoint, hernia recurrence, defined as the presence of a new or recurrent bulge that increased with straining, was not observed in any patient, resulting in a recurrence rate of 0%. No SAEs or deaths were reported during the index procedure or throughout the follow-up period. Two adverse events (AEs) occurred during the perioperative period: one patient

Table 1: Baseline demographic and clinical characteristics of the study population

Baseline characteristics	n=130
Age (years), mean $\pm$ SD	54.59 $\pm$ 13.53
Gender, n (%)	
Male	93 (71.54)
Female	37 (28.46)
Body mass index (kg/m ²), mean $\pm$ SD	23.85 $\pm$ 4.25
Heart rate (bpm), mean $\pm$ SD	82.22 $\pm$ 8.47
Systolic blood pressure (mmHg), mean $\pm$ SD	128.63 $\pm$ 16.41
Diastolic blood pressure (mmHg), mean $\pm$ SD	78.66 $\pm$ 10.82
Medical history, n (%)	
Hypertension	21 (16.15)
Diabetes	16 (12.31)
Smoking	11 (8.46)
Alcohol consumption	4 (3.08)
Abdominal pain	23 (17.69)
Groin pain	7 (5.38)
Chronic obstructive pulmonary disease	6 (4.62)
Others	18 (13.85)
Previous surgery details, n (%)	
Abdominal operation	7 (5.38)
Hernia repair	1 (0.77)
Mesh implantation	1 (0.77)
Others	6 (4.62)

SD: Standard deviation

Table 2: Procedural characteristics of patients undergoing hernia repair with MERINEUM™ MESH (n=130)

Operative characteristics	Value
Total number of study devices used, n	141
Total number of hernias treated, n	130
Surgical technique, n (%)	
Laparoscopic hernia repair	120 (92.31)
Open hernia repair	10 (7.69)
Type of hernia treated, n (%)	
Bilateral inguinal hernia	17 (13.08)
Umbilical hernia	35 (26.92)
Right indirect irreducible incomplete (Open hernioplasty – IPOM)	16 (12.31)
Right inguinal hernia	16 (12.31)
Right lumbar ventral hernia (IPOM)	4 (3.08)
Right direct reducible complete (R-TEP – IPOM)	8 (6.15)
Recurrent incisional hernia (IPOM)	15 (11.54)
Left inguinal hernia	3 (2.31)
Left indirect irreducible incomplete (TAPP)	7 (5.38)
Average hernia dimensions, mean $\pm$ SD	
Hernia length (cm)	9.85 $\pm$ 0.87
Hernia diameter (cm)	4.45 $\pm$ 0.65
Hernia width (cm)	8.32 $\pm$ 1.33
Hernia area (cm ²)	81.93 $\pm$ 15.55
Type of anesthesia, n (%)	
General	106 (81.54)
Spinal	24 (18.46)
Mesh location, n (%)	
Abdominal wall	16 (12.31)
Inguinal	48 (36.92)
Intestine	29 (22.31)
Intestine/Abdominal wall	13 (10.00)
Lumbar region	8 (6.15)
Pubic bone	16 (12.31)
Size of MERINEUM™ MESH, n (%)	
7.6 cm $\times$ 15 cm	3 (2.13)
15 cm $\times$ 15 cm	138 (97.87)
Mesh fixation device used, n (%)	
PROFOUND+A	45 (34.62)
Others	85 (65.38)
Operation time (min), mean $\pm$ SD	80.92 $\pm$ 24.86

TAPP: Transabdominal preperitoneal, SD: Standard deviation

experienced post-operative abdominal distension that resolved with conservative medical management, while another developed inflammation requiring removal of the MERINEUM™ MESH before discharge. During the 12-month follow-up, four patients (3.08%) developed seroma, and two patients (1.54%) developed hematoma, all of which resolved with conservative treatment. No SSIs, as defined by the CDC criteria or additional device-related adverse reactions were reported. Overall, the absence of hernia recurrence, SSI, and serious AEs (SAEs), together with the low incidence of conservatively managed seroma and hematoma, demonstrated a favorable safety and clinical performance profile of MERINEUM™ MESH over the 12-month follow-up period [Table 3].

DISCUSSION

Hernia is characterized by the protrusion of intra-abdominal contents through a defect in the anterior abdominal wall fascia. It commonly presents as a painless bulge or lump beneath the skin, which may progressively increase in size over time.^[18,19] Various surgical approaches have been developed for hernia repair, including conventional open and laparoscopic techniques. Although primary open repair, with or without mesh reinforcement, was traditionally used, laparoscopic mesh repair has become a widely accepted approach.^[20]

Surgical meshes provide additional reinforcement to weakened abdominal wall tissues and are available in a wide range of designs and materials.^[21] The development of composite meshes was aimed at addressing limitations associated with earlier-generation meshes, particularly post-operative adhesions, recurrence, infection, and tissue-related complications. Composite meshes incorporate two distinct surfaces, with one surface promoting tissue integration and the other serving as a barrier to minimize adhesion formation. They are therefore widely used in laparoscopic ventral hernia repair.^[21] However, despite their clinical benefits, mesh implantation may be associated with varying degrees of local inflammation, which can contribute to post-operative pain and discomfort.^[22]

The present real-world study evaluated the safety and performance of MERINEUM™ MESH in 130 consecutive patients undergoing hernia repair. A total of 141 study devices were utilized in these patients, with MERINEUM™ MESH being used in 45 patients in conjunction with the PROFOUND™ A mesh fixation device. At 12 months of follow-up, none of the patients developed a new or recurrent bulge that increased in size with straining, resulting in a 0% recurrence rate based on the study's predefined primary endpoint. This finding is encouraging and suggests effective mesh reinforcement during the 1st year following repair.

Post-operative complications were limited to seroma in 4 patients (3.08%) and hematoma in 2 patients (1.54%), all of which resolved with conservative management. No SSIs or additional

device-related adverse reactions were reported. The observed seroma rate was comparable to that reported by Galam *et al.*, who reported a 3.36% seroma rate and 0% recurrence at 12 months with Merigrow mesh.^[23]

The findings are also consistent with previously published outcomes for hernia mesh repair. Hopson *et al.*, reported an overall low complication rate, with seroma occurring in 10.4% of patients, hernia recurrence in 3.2%, and SSI in 2.4%.^[24] These outcomes were within nationally reported benchmarks and were similar to the complication profile reported by the Americas Hernia Society Quality Collaborative.^[25] In another retrospective single-surgeon study, Kabaoglu *et al.* evaluated 150 partially absorbable mesh repairs performed using a Totally Extraperitoneal (TEP) approach and reported a 6.0% seroma rate and a low recurrence rate of 0.67% at a median follow-up of 30 months.^[26] Although differences in surgical technique, patient populations, mesh characteristics, and follow-up duration should be considered when comparing these studies, the consistently low recurrence rates across the available evidence support the favorable clinical performance of mesh-based hernia repair.

In the present study, the mean operative time was 80.92 ± 24.86 min, indicating that the procedure could be performed within a clinically practical operative duration in the observed real-world setting. Galam *et al.* reported that all 119 patients underwent elective hernia repair, with a mean operative time of 68.07 ± 34.72 min,^[23] while Hopson *et al.* reported a mean operative time of approximately 80 min.^[24]

Two AEs were reported during the study period. One patient developed inflammation that required removal of the MERINEUM™ MESH at discharge, following which the condition was resolved. Another patient experienced abdominal distension following the intervention, which was successfully managed with medication. Similarly, Galam *et al.* reported no mesh integration failure, mesh migration, or mesh-related AEs throughout the follow-up period.^[23]

Overall, the findings from this real-world study demonstrate a favorable safety and performance profile for MERINEUM™ MESH over 12 months of follow-up. The absence of clinically evident recurrence and SSI, together with the low incidence of post-operative complications and AEs, supports the use of MERINEUM™ MESH for hernia repair in the studied patient population. These findings are encouraging; however, they should be interpreted in view of the retrospective study design, sample size, and relatively short follow-up period. Further prospective studies with larger cohorts and longer-term follow-up are warranted to confirm the durability of repair and characterize the long-term safety and clinical performance of MERINEUM™ MESH.

CONCLUSION

MERINEUM™ MESH demonstrated favorable safety and clinical performance over 12 months of follow-up. No clinically evident hernia recurrence or SSI was observed, while post-operative complications were infrequent and resolved with conservative management. The low incidence of device-related AEs and absence of SAEs further support the short-term safety of the device. Although these findings are encouraging, the retrospective design, limited sample size, and 12-month follow-up should be considered when interpreting the results. Further prospective comparative studies with larger patient populations and longer follow-up are warranted to confirm the durability and long-term clinical performance of MERINEUM™ MESH.

Table 3: Study outcomes up to 12-month follow-up

Outcomes, n (%)	Post-procedure (n=130)	Discharge (n=130)	12 Months FU (n=130)
Seroma formation	0 (0.00)	0 (0.00)	4 (3.08)
Hematoma formation	0 (0.00)	0 (0.00)	2 (1.54)
Recurrence	0 (0.00)	0 (0.00)	0 (0.00)
Surgical site infection	0 (0.00)	0 (0.00)	0 (0.00)
AE	1 (0.77)	2 (1.54)	8 (6.15)
SAE	0 (0.00)	0 (0.00)	0 (0.00)

AE: Adverse events, SAE: Serious adverse events

DATA AVAILABILITY STATEMENT

The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

AUTHOR'S CONTRIBUTIONS

KKS, JP, and PKK are employees of Meril Life Sciences Pvt. Ltd., Vapi, India, the manufacturer of the medical device evaluated in this study. Their involvement was restricted to providing technical input regarding the device, assistance with study methodology, and editorial support during manuscript preparation. They did not participate in clinical decision-making, data collection, or analysis. All other authors declare no conflicts of interest.

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