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ORIGINAL ARTICLE

Long-Term Safety and Clinical Outcomes of Filaprop™ Mesh Variants in Elective Hernia Repair: A Multicenter Study

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Abstract

Polypropylene mesh remains a fundamental material in hernia repair, with ongoing advancements in mesh design intended to enhance biocompatibility and long-term results. The Filaprop™ Mesh and Filaprop™ Mesh Soft are heavyweight and lightweight polypropylene meshes used for various hernia procedures. The existing real-world evidence about their long-term clinical performance remains scarce. The study aims to assess the safety profile and operational outcomes of Filaprop Mesh and Filaprop Mesh Soft during elective hernia surgery through a retrospective observational study conducted at various centres in India. The retrospective multicenter observational study analysed 651 patients who received hernia repair surgery with either Filaprop™ Mesh or Filaprop™ Mesh Soft. The study evaluated patient outcomes at four different time points after surgery: 1 year, 3 years, 5 years and 7 years. The primary study objectives focused on hernia recurrence rates, mesh-related adverse effects, and surgical site infections (SSI). A total of 651 patients were enrolled in the study, with a mean age of 47.83 ± 14.84 years, the majority being male (79.88%). Of these, 510 patients (78.34%) completed the 1-year follow-up. Among them, 15 patients (2.94%) experienced adverse events, including seroma in 9 patients (1.96%), surgical site infection (SSI) in 4 patients (0.78%), and combined pain with seroma in 1 patient (0.20%). Notably, no adverse events were reported in the Filaprop™ Mesh Soft group. Furthermore, no cases of hernia recurrence or chronic postoperative pain were observed beyond the first year of follow-up. The long-term safety and performance of Filaprop™ Mesh and Filaprop™ Mesh Soft were favourable, with low postoperative complications and no recurrence for seven years, supporting their ongoing use in elective hernia repair.

Keywords Polypropylene mesh · Elective hernia repair · Lightweight mesh · Heavyweight mesh

Abbreviations

AE	Adverse Event
BMI	Body Mass Index
COPD	Chronic Obstructive Pulmonary Disease
FU	Follow-Up
GCP	Good Clinical Practice
IEC	Institutional Ethics Committee
ICH	International Council for Harmonization
RWE	Real-World Evidence
SAE	Serious Adverse Event
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences

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Introduction

Hernias are defects or weaknesses in the abdominal wall through which internal tissues or organs protrude, most commonly seen in the inguinal region. Hernia repair is one of the most frequently performed surgical procedures worldwide. The hernia repair procedures are a cornerstone of general surgery worldwide, with an estimated 20 million hernia repairs performed annually [1]. The shift from suture-based techniques to prosthetic mesh has revolutionized hernia surgery, reinforced reliable abdominal walls and supported enhanced patient outcomes [2]. Since the mid-twentieth century, polypropylene mesh has become the standard material

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for hernia repair due to its mechanical strength, versatility, and compatibility with open and laparoscopic approaches [3]. The Lichtenstein tension-free repair, which was introduced in the 1980 s, made mesh-based techniques a standard for inguinal hernias [4]. Furthermore, the contemporary mesh designs offer specific solutions for different types of hernias and surgical methods, which help enhance clinical utility.

Filaprop™ Mesh and Filaprop™ soft Mesh are polypropylene-based mesh variants designed and developed by Meril Endo-surgery Pvt.Ltd, India, to address diverse hernia repair needs. The Filaprop™ Mesh is a heavy-weight monofilament mesh (~ 100 g/m^2) that supports complex hernias like significant ventral or incisional defects. Filaprop™ Mesh soft is a lightweight mesh (~ 45 g/m^2) that is more conformable and is better suited for smaller or less complex hernias.

Performing real-world analysis of the medical device is crucial for its effective clinical use. Retrospective studies are pivotal for evaluating the device's safety and performance in routine clinical settings. These types of studies could generate real-world evidence (RWE) that matches controlled trial study findings by capturing outcomes across heterogeneous patient populations and surgical practices.

The present study assessed the long-term safety and clinical performance of Filaprop™ Mesh and Filaprop™ soft Mesh in elective hernia repair across three clinical centres. The study outcomes were evaluated at 1-,3-,5-, and 7-year follow-up to assess the mesh durability, recurrence and late-onset complications under real-world surgical practices. The study aims to evaluate the safety and performance of these polypropylene mesh variants in hernia repair.

Methodology

Study Design and Setting

The study is a retrospective, multicenter, observational study conducted at three tertiary care centres: Dixit Hospital, Jeevandeep Hospital and Shreeji Hospital in India. The study aimed to assess the long-term safety and efficacy of Filaprop™ Mesh and Filaprop™ soft Mesh in patients who underwent elective hernia repair procedures.

Study Population

Data were collected from 651 patients who underwent hernia repair with either Filaprop™ Mesh or Filaprop™ soft Mesh and were included in the study from 2017 to 2024. Adult patients aged 18 and above who underwent elective hernia repair for different hernia types (inguinal, umbilical, incisional and others) were included in the study. Patients undergoing emergency hernia repair, those with active infections, contaminated fields or incomplete medical records were excluded.

Device Description

The Filaprop™ Mesh is a sterile, non-absorbable, heavyweight knitted polypropylene mesh with a 1.0 × 1.2 mm pore size and burst strength of 106.3 N/cm^2. It offers strong tensile support and is thus indicated for repairing ventral, incisional, epigastric and large recurrent hernias, especially where strong abdominal wall reinforcement is needed. The mesh comprises a wide range of sizes, ranging from 5 × 10 cm to 30 × 30 cm, and is suitable for open and laparoscopic surgical procedures. The Filaprop™ Mesh Soft is a lightweight (45 g/m^2) flexible polypropylene mesh with a pore size of 0.8 × 1.0 mm and a burst strength of 81.29 N/cm^2. Its thin profile (0.34 mm) makes it more pliable and comfortable for the patient. It is, therefore, suitable for repairing inguinal, umbilical, femoral and small primary hernias, especially in cases where foreign body sensation and chronic pain risk are clinical priorities. It is also suitable for both open and minimally invasive procedures. The meshes are sterilized with ethylene oxide and intended for elective hernia repair with soft tissue reinforcement Fig. 1.

Surgical Technique and Data Collection

All procedures were done by surgeons who are trained in mesh-based hernia repair. Mesh selection, placement and fixation (suture, tacker, or stapler) were at the discretion of the operating surgeon based on the type of hernia, patient anatomy and clinical judgment. The data was collected retrospectively through the examination of hospital records, together with follow-up logs. The study collected information about patient demographics (age, gender) and comorbidities, hernia type and surgical approach, mesh utilization, intraoperative results, postoperative complications, and hospital stay duration.

Primary and Secondary endpoints

The study's primary endpoint mainly consists of the event of postoperative complications and hernia recurrence, which includes seroma, mesh infection, bowel obstruction and postoperative pain recorded up to 1 year and recurrence assessed at 3, 5 and 7-year follow-up. In the case of secondary endpoints, which included surgical site infections (superficial, deep, or organ/space) through a 5-year postoperative hospital stay duration and device-related adverse events, including mesh infection, mechanical failure, chronic pain, adhesions and seroma.

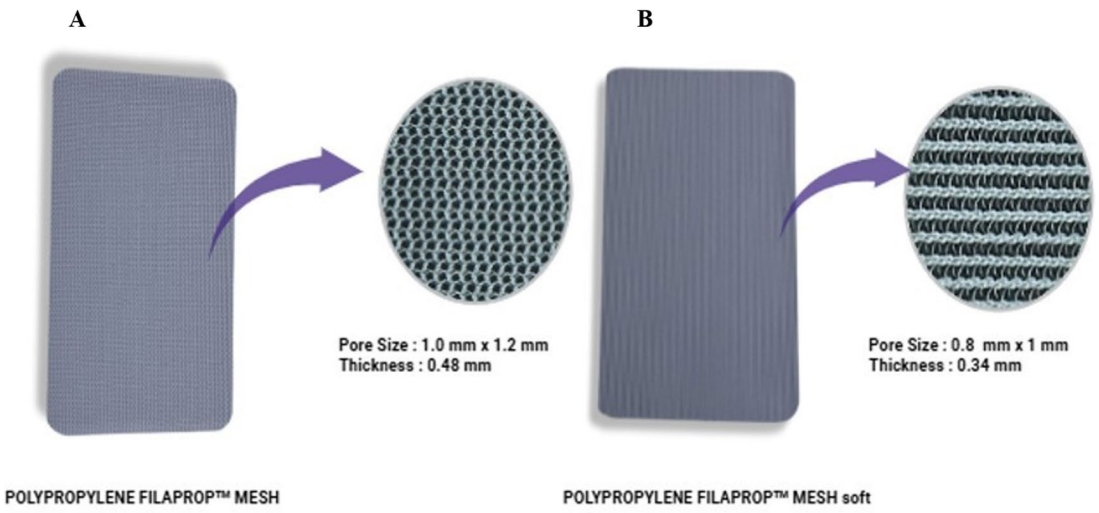

Fig. 1 Polypropylene Filaprop™ Mesh and Filaprop™ Mesh Soft with respective pore structures and dimensions. (*Figure adapted from original company image, courtesy of Meril Life Sciences Pvt. Ltd., India*)

Statistical Analysis

All the statistical analyses were performed based on the patient's data. Categorical variables were summarized by frequency distribution for each categorical component (relative frequencies and percentages). All the analyses were done using a statistical package for the social sciences (SPSS) v.20. Results were reported as mean ± standard deviation for continuous variables and as number (%) for nominal variables.

Results

The present multicentre, retrospective observational study was conducted across three healthcare institutions. A total of 651 patients underwent hernia repair surgery using either Filaprop Mesh or Filaprop Mesh Soft, with data collected and analyzed from patient records and follow-up assessments. Most procedures were performed at Jeevandeep Hospital (310, 47.62%), followed by Aastha Hospital (225, 34.56%), and Unity Hospital (116, 17.81%), respectively.

Patient Demographics and Baseline Characteristics

The study cohort mainly comprised male patients (79.88%), had an average age of 47.83 ± 14.84 years. The co-morbidities were present in 226 patients of the total of 651 patients. The most common comorbidity conditions were hypertension (22.12%) and diabetes mellitus (8.45%), followed by Chronic Obstructive Pulmonary Disease (COPD) (2.30%), which was most reported, followed by a small case of combined comorbid conditions (2.14%). Further, in terms of presenting symptoms, abdominal pain was the most frequent complaint, reported in 77.88% of the patients, while a smaller proportion experienced groin pain (1.38%) (Table 1).

Surgical History, Procedure Details, and Hernia Types

In the present cohort study, 651 hernia repair surgeries were done with either Filaprop Mesh or Filaprop Mesh Soft, as shown in Table 2. The inguinal hernia was the most frequent type of hernia repair observed in 471 patients (72.35%), followed by umbilical hernia in 126 patients (19.36%), and 20 patients (3.07%) underwent incisional hernia repair. Other types of hernias included epigastric, ventral, femoral, and hiatal hernias, which made up a small proportion of the total cases. Regarding the surgical approach, the laparoscopic approach was preferred over the open approach.

Device Utilization, Mesh Type, and Intraoperative Details

Regarding mesh utilization, 791 mesh units were implanted across all patient procedures. The Filaprop™ Mesh was most used 720 (91.02%), while the Filaprop™ Mesh soft was implanted in 71 (8.98%) of cases (Table 3). The mesh selection was based on the surgeon's discretion, hernia type, and repair technique. The most frequently used mesh sizes were 12 × 15 cm. In comparison, larger mesh sizes (30 × 30 cm and 15 × 15 cm) were used in large and complex hernias. No intraoperative complications or mesh-related adverse events were reported during the surgical procedures, and all surgeries were completed without the need for conversion or intraoperative modification.

Table 1 Patient demographics and comorbidities

Demographic Details	n (%)
Gender	
Male	520 (79.88)
Female	131 (20.12)
Race	Asian
Age, Mean ± SD	47.83 ± 14.84
Age Bifurcation	
18—35	157 (24.12)
36—53	277 (42.55)
54—71	173 (26.57)
72—89	44 (6.76)
Height, cm, Mean ± SD	165.13 ± 8.55
Weight, kg, Mean ± SD	71.81 ± 11.46
Vital Signs, Mean ± SD	
Heart Rate, bpm	82.38 ± 11.82
Systolic Blood Pressure, mmHg	129.98 ± 17.65
Diastolic Blood Pressure, mmHg	82.39 ± 10.29
Medical History	
Asthma	3 (0.46)
COPD	15 (2.30)
Diabetes	55 (8.45)
Hypertension	144 (22.12)
Hemorrhoids	1 (0.15)
Thyroids	6 (0.92)
Presenting Complaints	
Abdominal Pain	507 (77.88)
Groin Pain	9 (1.38)
Social History	
Smoking	21 (3.23)
Alcoholic	8 (1.23)

bpm beats per minute, *COPD* Chronic Obstructive Pulmonary Disease, *cm* centimeter, *kg* kilogram, *mmHg* millimeter of Mercury, *n* number of patients, *%* percentage, *SD* standard deviation.

Table 2 Hernia types, surgical history, and approach

Previous surgery details	n (%)
Abdominal operation	5 (0.77)
Hernia repair	5 (0.77)
Mesh implantation	6 (0.92)
Indication, n = 651	
Hernia Repair	
Inguinal	471 (72.35)
Epigastric	12 (1.84)
Femoral	1 (0.15)
Hiatus	17 (2.61)
Incisional	20 (3.07)
Intestinal Adhesions	1 (0.15)
Abdominal	2 (0.31)
Paramedian irreducible	1 (0.15)
Spigelian	1 (0.15)
Lumber	1 (0.15)
Umbilical	126 (19.36)
Procedural Details	**651(100)**
Type of Anaesthesia	
General	650 (99.85)
Spinal	1 (0.15)
Surgical techniques	
Laparoscopic Surgical procedure	366 (56.22)
Other fascial surgical intervention procedures	285 (43.78)
Number of Devices used	
1	513 (78.80)
2	136 (20.89)
3	2 (0.31)

The representative case related to left inguinal hernia repair using Filaprop™ mesh is shown in Fig. 2. The patient presented with a left-sided inguinal bulge (Fig. 2A). The patient underwent elective laparoscopic hernia repair, where mesh was placed at the appropriate place over the hernia defect (Fig. 2B). The postoperative evaluation showed that the surgical area remained intact without any indication of recurrence or complications (Fig. 2C). Most patients in this study followed the typical clinical course, which included positive intraoperative handling and successful postoperative results.

Hospital Discharge Outcomes and In-Hospital Safety

All 651 patients were discharged after hernia repair surgery. The mean duration of hospital stay was 67.76 ± 9.16 h, and all patients were discharged within 72 h of the procedure (Supplementary Table 1). The patients did not experience any complications during surgery or immediately after surgery, and there were no mesh-related problems during the hospital stay.

Long-Term Follow-up and Postoperative Complications

A total of 651 patients were followed up for at least 1 st year, with 510 patients (78.34%) completing the follow-up (Supplementary Table 2). A subset of these patients continued long-term follow-up, with 246 patients (37.79%) completing 3 years, 117 patients (17.97%) reaching 5 years. Three patients (0.46%) were followed up to 7 years. Fifteen adverse events (2.94%) were reported during the 1 st year follow-up period. Beyond the first year, no new cases of SSI, seroma, recurrence, mesh migration, or chronic pain were observed.

Table 3 Intraoperative mesh and procedural details

Device Specifications	n (%)
Total devices used	791
Filaprop™ Mesh Used	720 (91.02)
Filaprop Mesh Size Bifurcation, cm x cm	
5×10	44 (6.11)
6×11	59 (8.19)
7×15	80 (11.11)
10×15	114 (15.83)
12×15	124 (17.22)
12×18	66 (9.17)
15×15	105 (14.58)
15×20	59 (8.19)
15×30	46 (6.39)
30×30	23 (3.19)
Filaprop™ Mesh Soft Used	**71 (8.98)**
Filaprop™ Mesh Soft Size Bifurcation, cm x cm	
7×15	71 (100.00)
Intra-operative complication	0 (0.00)
Fixation device	PROFOUND™ N
Fixation device bifurcation	
1	513 (78.80)
2	136 (20.89)
3	2 (0.31)
PROFOUND™ N, Dimensional Sizes	
Titanium- Non-Absorbable 15 Nos	558 (70.54)
Titanium- Non-Absorbable 30 Nos	233 (29.46)

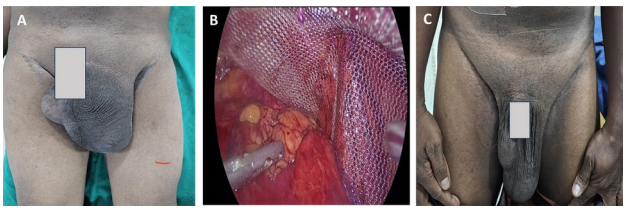

Fig. 2 (**A**-**C**). Representative clinical and intraoperative images of a patient with left inguinal hernia repair using Filaprop™ Mesh. (**A**) Preoperative image showing left-sided inguinal hernia. (**B**) Intraoperative laparoscopic view showing Filaprop™ Mesh placement over the hernia defect. (**C**) Postoperative image at follow-up demonstrating an intact surgical site with no signs of recurrence

Mesh-Specific Adverse Events at 1-Year Follow-up

Supplementary Table 3 summarizes the adverse events reported during the 1-year follow-up associated with Mesh types. A total of 15 adverse events (2.94%) were reported in patients who received implantation of Filaprop Mesh exclusively or combined with Filaprop Mesh Soft. The most recurrent adverse event among patients who received Filaprop Mesh alone was seroma, which affected 9 patients (1.76%), followed by SSI of the skin and subcutaneous tissue affecting 4 patients (0.78%), and one patient experienced both pain and seroma (0.20%). The patient who underwent mesh implantation with both types of mesh developed an additional seroma (0.20%).

Comorbidity and Symptom Profile in Patients with Adverse Events

Supplementary Table 4 illustrates the comorbidity conditions and symptom presentations in patients who experienced adverse events during a 1-year follow-up after undergoing a hernia procedure. The adverse events were reported exclusively in the Filaprop™ Mesh group, while the Filaprop™ Mesh soft group did not report any adverse events. The most common reported symptoms were abdominal pain (1.96%), while hypertension (0.20%) and diabetes (0.20%) were each noted in one patient. While some patients showed overlapping conditions, which include hypertension with abdominal pain (0.20%), hypertension with COPD (0.20%), and a combination of hypertension, diabetes, and abdominal pain (0.20%).

Discussion

Polypropylene Mesh-based procedures are considered the standard of care in hernia surgery due to their effectiveness in reducing recurrence rates [5]. Polypropylene mesh remains one of the most commonly used materials, valued for its durability and biocompatibility. Studies have indicated that the physical characteristics of polypropylene mesh, particularly pore size and filament configuration, may influence the host inflammatory response and contribute to seroma formation [6].

A total of 651 patients received Filaprop™ Mesh and Filaprop™ Mesh Soft in a multicenter, retrospective, observational study to evaluate long-term safety and clinical performance during elective hernia repair at three Indian tertiary care centers. The study provides critical real-world data about polypropylene-based meshes'durability, safety, and effectiveness at a 7-year follow-up. The present study reports an adverse event rate of 2.94% during the first year of follow-up, whereas the seroma rate is 1.96%, the SSI is 0.78%, and the combined pain and seroma rate is 0.2%, respectively. The meshes demonstrated strong long-term performance with no adverse events detected after the first year, such as recurrence, SSI, or chronic pain. The results obtained in our study support previous investigations about heavyweight polypropylene. Köckerling et. al., performed a real-world analysis through the Herniamed registry to show that heavyweight meshes resulted in 2–4% seroma and SSI

rates for incisional hernia repairs, which is consistent with our study findings of 1.76% seroma and 0.78% SSI rates with zero recurrence post 1 year [7]. The one-year recurrence rate was zero, which matched the results of Nessel et. al., who found no recurrence rate in patients who underwent incisional hernia repair during one year. The study showed that individual abdominal wall mechanics-based mesh fixation techniques produced superior long-term surgical results [8]. Further, in a study by Krpata et. al., contrasting evidence were presented through their multicenter randomized clinical trial, which showed an SSI rate of 4.8% in patients who received open retro-muscular ventral hernia repair with heavyweight polypropylene mesh despite identical surgical planes and materials [9]. The differences in infection rates demonstrate that surgical technique, patient comorbidities, and perioperative management are essential in determining infection outcomes.

The Filaprop™ Mesh Soft material was implanted in 8.98% of total cases, and the study showed excellent safety in low-tension hernia repairs because no adverse events, hernia recurrences, chronic pain, or SSI were documented during the 7-year observation period. The research agrees with the randomized clinical trial by Bringman et. al., which compared lightweight versus heavyweight meshes in Lichtenstein inguinal hernia repair and found that lightweight mesh did not affect recurrence rates but had better postoperative pain results at three years [10]. The study by Löfgren et. al., employed double-blind randomized methods to compare low-cost versus commercial lightweight meshes in Uganda and found 0.7% recurrence with low-cost mesh and 0% with commercial mesh at one year, with no significant postoperative complications [11]. Our study shows that lightweight meshes, including Filaprop™ Mesh Soft, can provide excellent long-term results with fewer postoperative complications for appropriately selected patients.

The study's cohort shows 22.12% of patients having hypertension and 8.45% showing diabetes, which reflects a real-world population with health complications that could elevate the complication risk during hernia surgery. The major presentations reported in the patients were abdominal pain (10 out of 15 patients) or combined comorbidities (e.g., hypertension, diabetes), indicating that patient-specific related complications could impact the outcomes. The study's finding is supported by Schoel et. al., who found that patients who underwent recurrent abdominal wall hernia repairs had higher rates of 30-day complications and surgical site infections, with more comorbidities such as diabetes, hypertension, COPD, and elevated BMI, which highlights the need for optimizing preoperative procedures [12]. Further, the findings of Assakran et. al., and Wilson et. al., support our statement as they have reported in their study that obesity and diabetes comorbidities lead to mesh-related complications such as surgical site infections, seromas, and wound infections, and therefore, appropriate patient selection and preoperative optimization are required for favourable hernia repair outcomes [13, 14].

Limitation

The present study presents several limitations, which are inherent to its retrospective, observational design. The absence of a comparative group (control) prevents direct comparisons between mesh types or surgical techniques. Further 1-year follow-up data were available for most patients, and long-term data were limited to a few subsets. Furthermore, patient-related study outcomes such as pain scores and quality of life were not reported. Additionally, the relatively lower number of patients who received Filaprop™ Mesh Soft also restricts the reliable statistical power to find in the given subset group.

Strength

Despite the shortcomings, this multicentred study provides a useful real-world insight related to the Filaprop™ Mesh and its Soft variant across various hernia types and surgical approaches. Further, the uniformity in surgical procedures and suture fixation across the centres reduces procedural variability. The high one-year follow-up rate strengthens the reliability of the short-term safety outcomes of mesh. Additionally, the preliminary long-term data from a small patient subset (up to 7 years) also provides a rare insight associated with mesh durability.

Conclusion

The research demonstrates that Filaprop™ Mesh and Filaprop™ Mesh Soft are both safe and effective for elective hernia repair because their low adverse event rates at one year, with no recurrences or complications beyond one year. The results of Filaprop™ Mesh match those of heavyweight polypropylene meshes for difficult hernias, demonstrating its durability and low rate of surgical site infections (SSI). The absence of adverse effects in Filaprop™ Mesh Soft matches the results of lightweight mesh studies, thus making it suitable for treating minor hernias with low probabilities of pain or infection. The research supports the continued use of both meshes in different hernia surgical procedures and offers substantial real-world data to help guide clinical practice.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s12262-025-04402-z.

Author Contributions TD, IS, and RS were responsible for study conceptualization, data collection, and manuscript preparation. KKS and RP contributed to the technical inputs related to the device and study

methodology and provided editorial assistance during manuscript drafting and review.

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

Declarations

Ethical approval and consent to participate This study was conducted in accordance with the Declaration of Helsinki, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)—Good Clinical Practice (GCP), and ISO 14155:2020 GCP standards. The Institutional Ethics Committee of Dixit Hospital approved the study prior to initiation (IEC approval letter; IEC/JAN/2025). Due to the retrospective and observational nature of the study, there was no direct intervention and modification of the patient's treatment; therefore, the ethics committee waived the informed consent.

Consent for publication Not applicable.

Conflicts of interest Kiran Kumar Shetty and Roopesh Poojary are employees of Meril, 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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