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Original Research Article

Two-year prospective single-arm multicenter study results of clinical safety and performance of synthetic Parietene™ DS composite mesh in ventral hernia repair

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ABSTRACT

Background: In ventral hernia surgery, using synthetic meshes is the standard of care to provide additional support to weakened or damaged tissues. This study aimed to assess clinical safety and performance of the synthetic Parietene™ DS composite mesh in ventral hernia repair.
Methods: This is a prospective, single-arm, multicenter study including adults undergoing intraperitoneal onlay mesh repair for ventral hernias using Parietene™ DS composite mesh. Patients were enrolled at 6 US sites and evaluated at discharge and 1, 3, 12, and 24 months postoperatively. Primary endpoint was hernia recurrence at 12 months; secondary endpoints included hernia recurrence at 1, 3 and 24 months, adverse device effects and patient quality of life (QoL). Surgeon satisfaction with mesh was also assessed.
Results: A total of 125 patients were included in this study: 70 treated for primary hernias and 55 for incisional hernias; 68 patients underwent laparoscopy, 56 robotic and 1 open surgery. Only 4 (3.3%) hernia recurrences were reported, all within 12 months. No additional recurrences occurred at 24 months. No significant differences were found in hernia recurrence incidence between hernia type or surgery approach sub-groups. No adverse events related to mesh were reported. Patients experienced significant improvement in QoL at 12- and 24-month post-surgery compared to baseline and 1 month. For >95% of procedures, surgeons rated handling, deployment, and introduction of the mesh as easy or very easy.
Conclusions: Parietene™ DS composite mesh use in ventral hernia repair assures a safe profile, low hernia recurrence rate and improvement in patient QoL.

Keywords: Ventral hernia, Primary hernia, Incisional hernia, Hernia repair, Polypropylene mesh, Synthetic mesh

INTRODUCTION

A ventral hernia is defined as a "hernia of the abdominal wall excluding the inguinal area, pelvic area and diaphragm" that can occur spontaneously (primary hernia) or following a surgical incision (incisional hernia).[1] In the U.S. alone, up to 30-45% of the annually performed laparotomies cause incisional hernias.[2]

Surgery (open, laparoscopic, or robotic) is often considered the first-choice treatment in hernia repair: it has been estimated that every year, about 2 million ventral hernia procedures are performed worldwide.[1,3]

Meshes are used during surgical procedures to provide additional support to weakened or damaged tissues. Their distinctive textile structure and ability for tissue ingrowth ensure a strong and long-term reinforcement of soft tissues. Depending on the type of surgery, meshes can be implanted either in an intraperitoneal position or outside of the abdominal cavity, using onlay, sublay or retrorectus/preperitoneal techniques to place mesh outside the abdominal cavity. Mesh can also be placed in the intraperitoneal position. For ventral hernia repair, the European and American Hernia Society (EHS/AHS) guidelines advise sublay mesh placement in either retrorectus or preperitoneal location.[1]

Meshes can be synthetic, biosynthetic, or biologic. The use of synthetic mesh is considered the standard of care for ventral hernia repair.[4] Polypropylene is one example of a commonly employed material for synthetic mesh in non-contaminated fields.[1]

Parietene™ DS composite mesh (Medtronic) is constructed from polypropylene-based textile presenting a macroporous texture on the parietal side to encourage tissue ingrowth and reinforce the abdominal wall, and a synthetic continuous resorbable film on the visceral side to help minimise tissue attachment.

Our 2-year prospective multicenter study was conceived with the intent to evaluate the clinical safety and performance of Parietene™ DS composite mesh in the context of primary and incisional ventral hernia repair.

METHODS

Study population

Patients (≥18 years at the time of consent) undergoing intraperitoneal onlay mesh repair (IPOM) for primary and incisional ventral hernias using Parietene™ DS composite mesh were enrolled in the study. Written informed consent (ICF)-approved by a properly constituted institutional review board (IRB)-was obtained from subjects at the time of subject screening in the study. Preoperative exclusion criteria included: BMI >45, subject undergoing emergency surgery, subject pregnant or planning to become pregnant during the study participation period, subject unable or unwilling to comply with the study requirements or follow-up schedule, subject with comorbidities that, in the opinion of the investigator, will not be appropriate for the study or the subject has an estimated life expectancy of less than 6 months, the subject has participated in another investigational drug or device research study within 30 days of enrollment, and subject has a parastomal hernia. Intraoperative exclusion criteria included: subject's hernia repair is in a contaminated or infected site as assessed by the investigator (Exclude CDC wound class 2-4), subject is undergoing "bridging" repair technique with the mesh placed in an "inlay" position, surgeon is unable to completely remove existing mesh from prior surgery, surgeon overlays 2 meshes, and subject receives any mesh other than Parietene™ DS composite mesh.

Study design and endpoints

This is a prospective, single-arm, multicenter, observational study conducted in 6 US hospitals from 2018 to 2022 (ClinicalTrials.gov NCT03495154). One hundred and twenty-five (125) male or female subjects were planned to be enrolled. To minimise enrollment bias, enrollment was not to exceed 40 subjects per site.

This is the first study aiming to evaluate the clinical performance and safety of the new Parietene™ DS composite mesh.

The study's primary endpoint was to assess the incidence of hernia at 12 months following mesh implantation. The evaluation of hernia recurrence - defined as a "clinically manifested bulge or a protrusion exacerbated by a Valsalva maneuver" -was performed during a physical examination and confirmed per site standard of care, if necessary. Secondary endpoints included incidence of hernia recurrence at 1, 3 and 24 months; incidence of adverse device effects (ADEs) intra-operatively, at discharge, within 1 month, 3 months, 12 months, and 24 months following mesh use. ADE was defined as any adverse event associated with the use of an investigational medical device, including both device- and/or procedure-related events, regardless of its severity. Other secondary endpoints were the assessment of time to hernia recurrence, time to ADEs occurrence (from surgery time-point), and QoL evaluated pre-operatively and at 1, 12 and 24 months post-operatively.

Besides study endpoints, we also evaluated the surgeon's satisfaction with the mesh.

Carolinas comfort scale™

Patient QoL was assessed pre-operatively and at 1, 12 and 24 months post-operatively by using the Carolinas Comfort Scale™ -a validated disease-specific questionnaire developed for patients undergoing hernia repair. Each question is scored on a scale ranging from 0 to 5, with 0 indicating no symptoms and 5 indicating disabling symptoms. Hence, a lower score indicates a better patient QoL.

Patient visits

Patients were evaluated at discharge and 1-month, 3-month, 12-month, and 24-month post-operatively. All follow-up visits were originally planned as in-person visits. However, due to the COVID-19 pandemic, they

were conducted remotely when needed, following an IRB-approved protocol addendum. Remote and in-person clinical assessments were performed at the discretion of the Principal Investigator (PI) based on the current single institution COVID-19 procedures. Remote visits relied on the subject self-reporting key symptoms of recurrence. When a suspected hernia was identified during a remote visit, the patient was instructed to return to the clinic or hospital to perform an in-person clinical assessment. Protocol deviations were required to be reported when a patient was evaluated for their follow-up visit without a physical examination.

Device

Parietene™ DS composite mesh (Medtronic) (Figure 1) is designed to be placed in an intraperitoneal site by a laparoscopic (both traditional and robotically assisted) or open approach. The mesh is composed of a permanent 2-D non-absorbable monofilament macroporous polypropylene textile on the parietal side and a fully absorbable synthetic film on the visceral side. While the polypropylene macroporous side is designed to be placed over the abdominal wall to ensure a long-term reinforcement of soft tissues, the continuous absorbable film is designed to minimise tissue attachment to the mesh in case of direct contact with the viscera. The macroporous textile provides the strength required to withstand biomechanical stresses throughout the healing period while allowing for tissue ingrowth. As the textile integrates, host tissue ingrowth is intended to provide strength to the repair. The synthetic film is made of an absorbable synthetic copolymer of glycolide, caprolactone, trimethylene carbonate, and lactide, which degrades within 105 days by hydrolysis. This polymer has been clinically used since 2002 in the absorbable suture Caprosyn™ (Medtronic). The film is adhered to the textile using a binding agent localised on the textile fibers. A violet central marking and additional dots are positioned on the mesh to help center and orient it. Two non-absorbable pre-placed sutures are tied to the mesh to help with side differentiation. These pre-placed sutures are Surgipro™ sutures, which are manufactured by Medtronic and have been used in clinics for more than 20 years.

Name:	Parietene™ DS composite mesh
Manufacturer:	Medtronic PLC
Device indication:	Reinforcement of the abdominal wall soft tissue where weakness exists. Ventral hernia repairs.
Material composition:	2-D textile non-absorbable monofilament polypropylene A film composed of an absorbable synthetic polymer Absorbable polycaprolactone used for the binding agent and the markings Two pre-placed sutures made from polypropylene and polyethylene
Shape and size:	Available in different shapes (rectangular with rounded edges and circular) and sizes. If necessary, the mesh can be trimmed to an appropriate size or shape.
Transparent:	Yes
Surgery indications:	To be placed in an intraperitoneal site by a laparoscopic (both traditional and robotically assisted) or open approach.

Figure 1: Parietene™ DS composite mesh.

The figure shows a picture of the Parietene™ DS composite mesh (image has been provided by the manufacturer) and its main features.

The combination of violet markings for precise positioning and repair (distinctive to this mesh), sutures for aiding in facial recognition, and mesh transparency makes Parietene™ DS composite mesh unique.

These features enhance mesh handling and positioning, potentially leading to high mesh satisfaction and favourable clinical outcomes.

Statistics

Statistical analysis presented here was performed on the full analysis set, including any subject enrolled and receiving the study device, representing the primary analysis population. Continuous variables were summarised using counts, means, standard deviations, medians, minimum and maximum. Categorical variables were summarised using frequencies and percentages. Statistical analysis was performed using SAS version 9.4.

Several comparative analyses were performed by hernia type (primary hernia versus incisional hernia) on overall subjects and on a subgroup of subjects with robotically assisted laparoscopic repair. Results of subjects operated with robotically assisted laparoscopic repair were compared with subjects operated with a traditional laparoscopic procedure. The following statistical tests were used: Pearson Chi-square test or Exact test (as appropriate) for categorical data; Student t-test or Wilcoxon rank sum test if assumptions of the t-test were not verified for continuous data.

Kaplan-Meier (KM) estimates and survival plots for the evaluation of time to ADEs occurrence (from surgery time-point) will be drawn according to hernia type and surgical approach.

Determination of sample size

Sample size has been determined based on an acceptable level of accuracy for the estimated rate of hernia recurrence at 12 months (primary endpoint). Previous studies with similar study indications, population, and design have reported the incidence of hernia recurrence at 12 months to range from 3.5% to 5.2%.[5,6] There were 95% confidence intervals obtained from incidence rates between 3.5% and 5.2% with n=100 subjects. Precision of the recurrence rates ranged from ±3.6% to ±4.4% as the recurrence rate increased. The study anticipated an attrition rate of 20% at 12 months, so 125 subjects were targeted for enrollment in this study.

RESULTS

Patients

Between June 2018 and June 2021, 145 patients were screened at 6 US sites. Four patients were identified as preoperative screen failures, 10 withdrew before surgery, and 6 were screen failures during surgery. A total of 125 patients were then enrolled and included in the final analysis set (Figure 2).

Enrolled population had a mean age of 58.0±12.31 years and a mean BMI of 33.2±4.82 kg/m^2 (Table 1), with 88 (70.4%) patients having a BMI ≥30 and 12 (9.6%) a BMI ≥40. Seventy-four (59.2%) patients were male (Table 1). Patients also presented other important risk factors for developing ventral hernias-such as tobacco use (n=58, 46.4%), diabetes mellitus (n=16, 12.8%), and immunocompromission (n=2, 1.6%) (data not shown).

In total, seventy patients (56%) were treated for primary hernias and 55 (44%) for incisional hernias. Sixty-eight patients (54%) underwent the traditional laparoscopic approach, 56 (45%) under the robotically assisted approach and 1 patient had open surgery. Fifteen (12%) subjects were treated for recurrent hernias (all incisional) (Table 1).

There was no statistical difference between the demographics of any of the surgical sub-groups.

One hundred sixteen (92.8%) out of 125 patients presented comorbidities, the most common being obesity (n=81, 64.8%), hypertension (n=62, 49.6%), hyperlipidemia (n=24, 19.2%), gastroesophageal reflux disease (n=19, 15.2%), diabetes mellitus (n=16, 12.8%), and hyperthyroidism (n=16, 12.8%) (Table 1). Overall, ninety-eight (78.4%) patients had a surgical history, mainly abdominal surgery - the most common being hernia repair (n=36, 28.8%) (Table 1).

Patient visits

Of the 125 enrolled subjects, 118 (94.4%) completed the 12-month follow-up, and 103 (82.4%) completed the 24-month follow-up (Figure 2). Around 20% of visits were performed remotely (7.3% at 1 month; 11% at 3 months; 21.2% at 12 months, and 34% at 24 months), with the majority occurring at 12- and 24-month follow-up visits (n=25 and n=35, respectively). Physicians confirmed that remote visits did not affect their ability to accurately assess hernia occurrences.

Hernia recurrence

Overall, four hernia recurrences were reported within 12 months in 120 analysed subjects (3.3%, CI 1.0%-8.5%). Patients who completed the 1-month and 3-month timepoints did not experience any hernia recurrence (0.0%, CI 0.0%-2.9% and 0.0%, CI 0.0%-3.0%; respectively). No additional hernia recurrence occurred at 24 months (3.8%, CI 1.2%-9.6%) (Table 2).

Three out of the four patients who experienced hernia recurrence underwent reoperation.

In subjects who had hernia recurrence, the defects during the hernia operation had a mean area of 18.2±15.20 cm^2 compared to repairs where no recurrence occurred, in which the defect area was 14.6±23.10 cm^2 (data not shown).

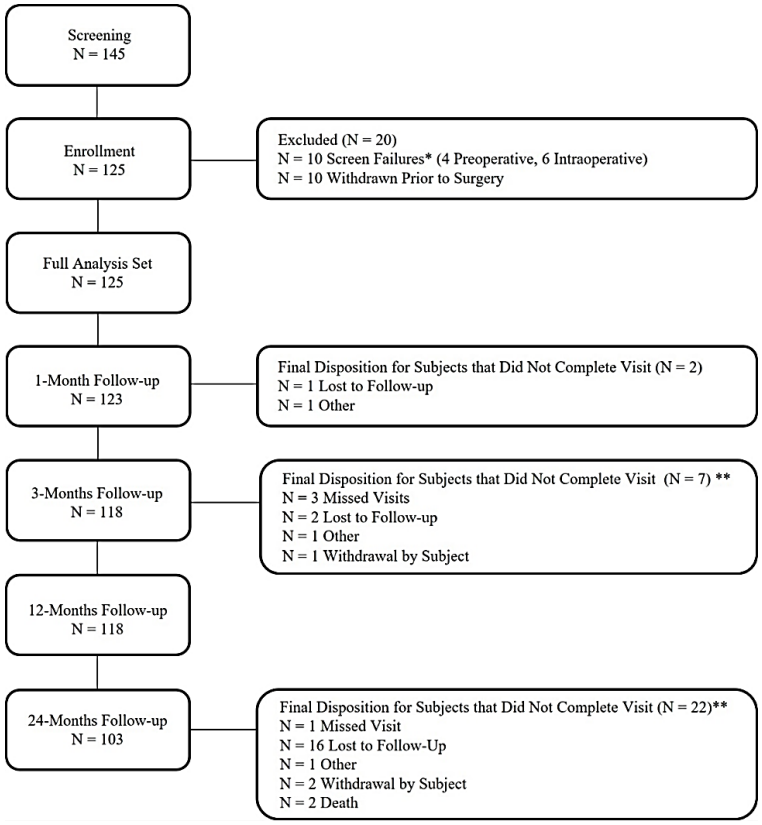

Figure 2: Flow chart of patient inclusion in the study.

The figure depicts a visual overview of the study design and provides information about the number of included and excluded patients, as well as reasons for exclusion. * Subjects who provided study consent but were ultimately determined to be ineligible due to the pre-defined inclusion or exclusion criteria were considered a screen failure. ** The number of subjects who did not complete the visit is derived from the Full Analysis Set. Note: At 12-months follow-up, n=2 patients missed the visit (indicated in the picture as "Lost to Follow-up") but were able to attend the 24-months follow-up visit. These 2 patients were successively included in the hernia recurrence analysis for both 12- and 24-months timepoints (total n=120 subjects).

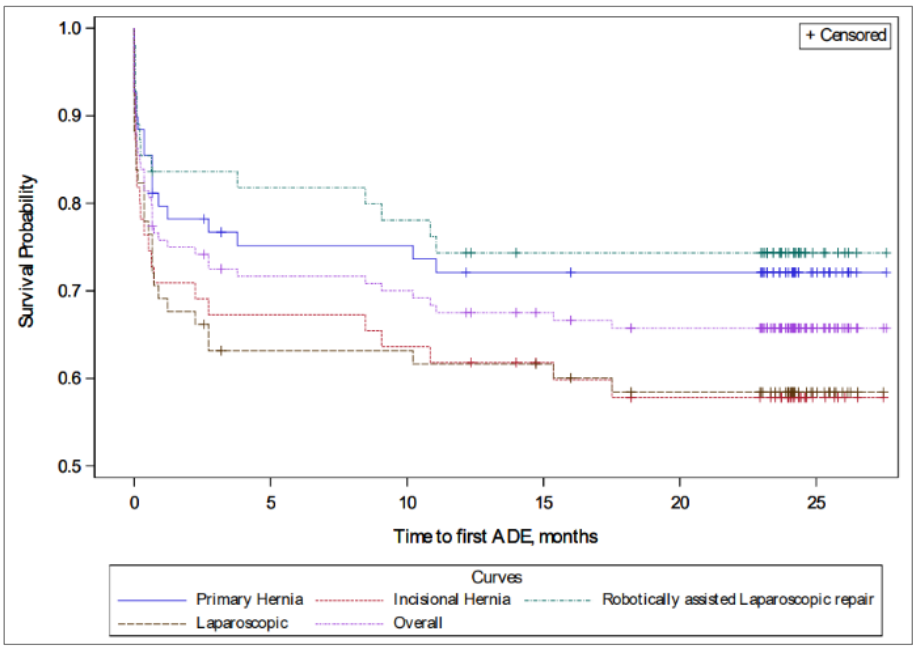

Figure 3: Time to ADE occurrence.

The Kaplan-Meier curve for the survival rates of patients reporting ADE occurrence over the 24-months post mesh implantation is shown. The curves were performed for the overall patients group and by hernia type and surgical approach, respectively.

Table 1: Patient disposition, demographics, and baseline characteristics.

Variables	Overall, (n=125)	Hernia type			Surgical approach			
		Primary, (n=70)	Incisional, (n=55)	P values primary vs incisional	Robotic, (n=56)	Laparoscopic, (n=68)	Open, (n=1)	P values robotic vs laparoscopic
Age (in years)	58.0±12.31	54.7±11.80	62.2±11.73	<0.001	57.9±10.58	58.4±13.57	41.0±0	0.855
Male	74 (59.2%)	56 (80.0%)	18 (32.7%)	<0.001	33 (58.9%)	41 (60.3%)	0 (0.0%)	0.877
BMI, kg/m²	33.2±4.82	32.7±4.62	33.7±5.06	0.256	33.1±4.62	33.3±5.05	32.0±0	0.809
Medical history								
Obesity	81 (64.8%)	42 (60.0%)	39 (70.9%)	0.205	35 (62.5%)	45 (66.2%)	1 (100%)	0.670
Hypertension	62 (49.6%)	31 (44.3%)	31 (56.4%)	0.180	29 (51.8%)	32 (47.1%)	1 (100%)	0.600
Hyperlipidemia	24 (19.2%)	13 (18.6%)	11 (20.0%)	0.840	6 (10.7%)	18 (26.5%)	0 (0.0%)	0.027
Gastroesophageal reflux disease	19 (15.2%)	9 (12.9%)	10 (18.2%)	0.410	11 (19.6%)	8 (11.8%)	0 (0.0%)	0.226
Diabetes mellitus	16 (12.8%)	7 (10.0%)	9 (16.4%)	0.290	9 (16.1%)	7 (10.3%)	0 (0.0%)	0.340
Hypothyroidism	16 (12.8%)	6 (8.6%)	10 (18.2%)	0.110	5 (8.9%)	11 (16.2%)	0 (0.0%)	0.231
Obstructive sleep apnea	14 (11.2%)	5 (7.1%)	9 (16.4%)	0.105	6 (10.7%)	8 (11.8%)	0 (0.0%)	0.854
Sleep apnea	12 (9.6%)	6 (8.6%)	6 (10.9%)	0.660	6 (10.7%)	6 (8.8%)	0 (0.0%)	0.723
Postmenauposal	11 (8.8%)	3 (4.3%)	8 (14.5%)	0.058	6 (10.7%)	5 (7.4%)	0 (0.0%)	0.542
Heart disease	10 (8.0%)	4 (5.7%)	6 (10.9%)	0.333	5 (8.9%)	5 (7.4%)	0 (0.0%)	0.754
Other	91 (72.8%)	46 (65.7%)	45 (81.8%)	0.045	37 (66.1%)	53 (77.9%)	1 (100%)	0.140
Repair for recurrent hernia	15 (12.0%)	0 (0.0%)	15 (27.3%)	<0.001	12 (21.4%)	2 (2.9%)	1 (100%)	0.001
Surgical history	98 (78.4%)	43 (61.4%)	55 (100%)	<0.001	40 (71.4%)	57 (83.8%)	1 (100%)	0.096
Previous hernia surgery	36 (28.8%)	9 (12.9%)	27 (49.1%)	<0.001	20 (35.7%)	15 (22.1%)	1 (100%)	0.093

Table 2: Hernia recurrence rate in the study population (n=125) during the follow-up period.

Hernia recurrence rate at follow-up	Overall subjects, (n=125)	Primary hernia, (n=70)	Incisional hernia, (n=55)	Robotically assisted laparoscopic repair, (n=56)	Traditional laparoscopic repair, (n=68)
Visits within 1 month*	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	(0.0%-2.9%)	(0.0%-5.2%)	(0.0%-6.5%)	(0.0%-6.5%)	(0.0%-5.3%)
Visits within 3 months*	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
	(0.0%-3.0%)	(0.0%-5.2%)	(0.0%-6.5%)	(0.0%-6.6%)	(0.0%-5.3%)
Visits within 12 months*	4 (3.3%)	2 (3.1%)	2 (3.6%)	2 (3.7%)	2 (3.1%)
	(1.0%-8.5%)	(0.2%-11.2%)	(0.3%-13.0%)	(0.3%-13.3%)	(0.2%-11.2%)
Visits within 24 months	4 (3.8%)	2 (3.3%)	2 (4.3%)	2 (4.1%)	2 (3.6%)
	(1.2%-9.6%)	(0.3%-12.0%)	(0.4%-15.3%)	(0.4%-14.5%)	(0.3%-12.8%)

*Hernia recurrences are assessed within 1, 3 or 12 months. When a recurrence occurs at a specific timepoint, it is also reported in the following one. Of the total 125 subjects included in the study, 120 were considered for the primary endpoint analysis (12-months follow-up), 124 subjects were included in the 1-month analysis, 123 subjects were included in the 3-months and 106 in the 24-months analysis.

Table 3: ADEs occurrences features.

ADEs events**	Overall, (n=60)	Hernia type			Surgical Approach			
		Primary, (n=26)	Incisional, (n=34)	P values* primary vs incisional	Robotic, (n=17)	Laparoscopic, (n=43 ADEs)	Open, (n=0)	P values* robotic vs laparoscopic
Intra-operative ADE	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	NA	NA
Peri-operative ADE	14 (23.3%)	5 (19.2%)	9 (26.5%)	0.511	6 (35.3%)	8 (18.6%)		0.190
ADE within 1-month	41 (68.8%)	19 (73.1%)	22 (64.7%)	0.490	10 (58.8%)	31 (72.1%)		0.319
ADE within 3-month	44 (73.3%)	20 (76.9%)	24 (70.6%)	0.582	10 (58.8%)	34 (79.1%)		0.193
ADE within 12-month	55 (91.7%)	24 (92.3%)	31 (91.2%)	1	16 (94.1%)	39 (90.7%)		1
ADE within 24-month	60 (100.0%)	26 (100.0%)	34 (100.0%)	1	17 (100.0%)	43 (100.0%)		1
		Hernia type			**Surgical approach**			
Subjects with ADEs**	**Overall, (n=125)**	**Primary, (n=70)**	**Incisional, (n=55)**	**P values* primary vs incisional**	**Robotic, (n=56)**	**Laparoscopic, (n=68)**	**Open, (n=1)**	**P values* robotic vs laparoscopic**
Subjects with the intra-operative ADE	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA
Subjects with peri-operative ADE (from surgery through discharge)	14 (11.2%)	5 (7.1%)	9 (16.4%)	0.105	6 (10.7%)	8 (11.8%)	0 (0.0%)	0.854
Subjects with at least 1 ADE occurring within 1-month	31 (24.8%)	15 (21.4%)	16 (29.1%)	0.325	9 (16.1%)	22 (32.4%)	0 (0.0%)	0.037
Subjects with at least 1 ADE occurring within 3-month	34 (27.2%)	16 (22.9%)	18 (32.7%)	0.218	9 (16.1%)	25 (36.8%)	0 (0.0%)	0.010
Subjects with at least 1 ADE occurring within 12-month	40 (32.0%)	19 (27.1%)	21 (38.2%)	0.189	14 (25.0%)	26 (38.2%)	0 (0.0%)	0.117
Subjects with at least 1 ADE occurring within 24-month	42 (33.6%)	19 (27.1%)	23 (41.8%)	0.085	14 (25.0%)	28 (41.2%)	0 (0.0%)	0.058

*P values for comparison between hernia groups or surgical approach are from chi-square or Fisher exact tests.
**ADEs events occurring at a specific timepoint are also reported in the following one.

No statistically significant differences were found in hernia recurrence between any of the hernia type sub-groups (2 hernia recurrences per each group: 3.3% [CI 0.3%-12.0%] primary; 4.3% [CI 0.4%-15.3%] incisional) or surgical type sub-groups (2 hernia recurrences per each group: 3.6% laparoscopic [0.3%-12.8%]; 4.1% robotic [CI 0.4%-14.5%]) (Table 2) (p=1).

No significant associations with previously published risk factors for hernia recurrence (e.g., hernia size, comorbidities) or surgical features (e.g., mesh overlap, type of mesh fixation, facial closure) were found. Since the most common comorbidity among the study population was obesity, we have further investigated its possible association with the hernia recurrence rate. A specific analysis was performed on the sub-group of patients with a BMI≥30 and showed no statistically significant correlation between obesity and hernia recurrence rate (p=1) (data not shown). In the opposite trend compared to what the literature reports, age ≤60 years was the only factor that approached statistical significance (p=0.055) using the Fisher Exact statistical test (data not shown).

Adverse device effects

Overall, 60 ADEs occurred in the study: a total of 14 events (23.3%) occurred peri-operatively, 41 (68.8%) within 1 month, 44 (73.3%) within 3 months, 55 (91.7%) within 12 months, and 60 (100%) within 24 months (Table 3). No statistically significant differences were found across hernia type/surgical approach sub-groups.

Patients did not report any ADEs intra-operatively, while 14 patients (11.2%) reported at least one ADE peri-operatively (from surgery through discharge), 31 (24.8%) within 1 month, 34 (27.2%) within 3 months, 40 (32%) within 12 months, and 42 (33.6%) within 24 months (Table 3). Fourteen (25%) out of the 56 patients undergoing robotically assisted hernia repair experienced a total of 17 ADEs, while 28 (41.2%) of the 68 patients undergoing traditional laparoscopic repair experienced 43 ADEs (p=0.058). At both 1- and 3-month follow-up, patients in the robotic approach group had statistically significant fewer ADEs as compared to those in the laparoscopic group (9 vs 22, p=0.037 and 9 vs 25, p=0.010; respectively) (Table 3). A more in-depth analysis showed that n=8 ADEs were uniquely related to robotic surgery and n=23 were uniquely related to laparoscopy. However, the statistical analysis showed no significant difference between the two groups (p=0.080). No statistically significant difference was found in patients experiencing ADEs across the hernia type sub-groups (Table 3).

The majority of the occurred ADEs (n=39, 65%) were considered to be non-serious events (data not shown). The most common complications included seroma (n=12, 9.6%), hernia recurrence (n=4, 3.2%), and surgical site infection (n=3, 2.4%) (Supplementary data, Table 1). One device deficiency was reported, which was a mesh fracture observed during a hernia reoperation and thought likely secondary to the mesh fixation technique used during the initial hernia repair (as confirmed by surgeon).

Importantly, the relationship assessment of each ADE to procedure and/or device showed that no ADEs were uniquely related to the device (Supplementary data, Table 2). The majority of ADEs (n=46) were assessed as unlikely or not related to the device, whereas 17 ADEs were assessed as causal or possible related to the device with no events assessed as probable related to the device (data not shown).

A completed list of ADEs that occurred within the study is reported in supplementary data, Table 1.

Time to hernia recurrence and time to ADEs occurrence

Time to hernia recurrence (from surgery time-point) was evaluated following the Parietene™ DS composite mesh in ventral hernia repair using Kaplan-Meier (KM) analysis. The overall hernia recurrence-free rate over the 24-month post-procedural observational period was 96.7%. There were no observed differences in hernia recurrences between primary and incisional hernia, and between robotic and laparoscopic surgical approaches (p=0.8655 and p=0.8372, respectively).

Time to ADEs occurrence (from surgery time-point) was also evaluated using the Kaplan-Meier analysis. The overall ADEs recurrence-free rate over the 24-month post-procedural observational period was 66.13%. Survival curves for time to ADEs occurrence were presented for the overall group and then by hernia type and surgical approach, respectively. The sample size was not powered to detect differences between sub-groups. The differences observed between primary ventral and incisional hernias (p=0.1057) and between robotic and laparoscopic approaches (p=0.0651) were not found to be statistically significant (Figure 3).

Patient QoL

Patient QoL was evaluated pre-operatively and at 1-, 12-, and 24-month post-operatively using the Carolinas Comfort Scale™ (CCS). The analysis of the CCS mean scores revealed an important statistically significant improvement (=decrease) in both patient pain and movement limitations at 12- and 24-month post-surgery, as compared to baseline (pre-operatively) and 1 month (p<0.001) (Figure 4). At 1-month follow-up, the mean CCS scores for both pain and movement limitations showed no statistically significant variation as compared to baseline (p=0.151 and p=0.545, respectively). Patients also experienced an overall statistically significant reduced sensation of mesh at 12- and 24-month post-surgery, as compared to 1 month postoperatively (mesh was not implanted at baseline) (p<0.001) (Figure 4).

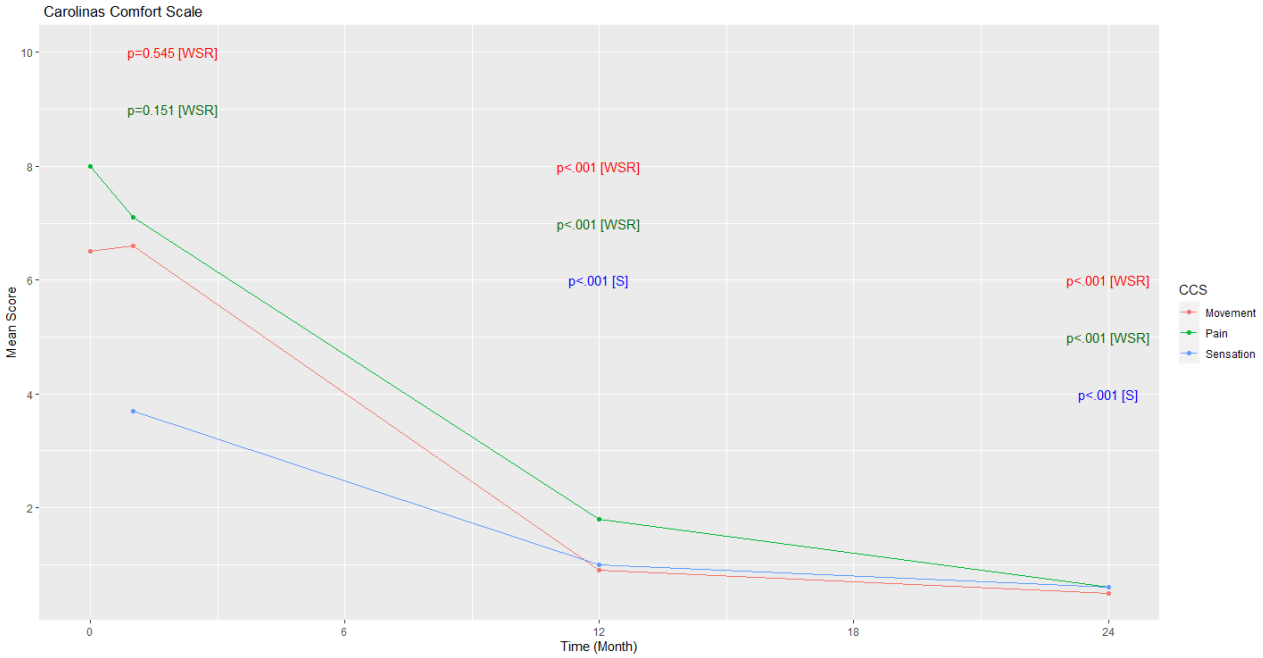

Figure 4: Carolina comfort scale (CCS) overall scores in study population (n=125) during follow-up period.

Mean patient CCS scores for movement limitations (red line), patient pain (green line), and sensation of mesh (blue line) were assessed pre-operatively and at 1, 12 and 24 months post-operatively. At baseline, sensation of mesh was not available since the device was not implanted pre-operatively. P values have been calculated per each timepoint, compared to baseline (0 month) or 1-month overall CCS Score, using paired T test [PTT], Wilcoxon Signed Rank test [WSR] or Sign Test [S] for paired data.

Surgery results

Mean operative time was 80 minutes. For both primary and incisional hernia procedures, robotic surgery showed a significantly longer operative time compared to the laparoscopic technique (70 min vs 49 min and 121 min vs 92 min, respectively. P<0.05). The operative time of the only open surgery for incisional hernia was 151 minutes.

Seventy (56.0%) procedures were primary ventral hernias (60 umbilical, 9 epigastric, 2 spigelian), while 52 (41.6%) were incisional midline and 3 (2.4%) incisional lateral hernias. Fifteen (12.0%) procedures were performed for the repair of recurrent hernias (15 incisional, 12 repaired robotically and 2 laparoscopically).

One hundred ten (88.0%) of the hernias were reducible, 15 (12.0%) were incarcerated hernias, and none were strangulated hernias. Bowel resection was not required in any of the operations. Defects had a mean defect area of 14.3±22.5 cm^2. Although primary hernias were smaller, on average, than incisional hernias, there were no significant differences between the primary or incisional surgical sub-groups.

One hundred twenty-two (97.6%) subjects had a mesh overlap greater than or equal to 5cm, while none were less than 3cm, and fascial closure occurred in 109 (87.2%) subjects (n=67 [61.5%] with absorbable sutures and n=43 [39.5%] with permanent sutures). Robotic procedures allowed surgeons to perform a higher number of facial closures as compared to laparoscopic procedures, for both primary and incisional hernia procedures (100% vs 85% and 100% vs 64.3%, respectively. P<0.05). During mesh fixation, 29 (23.2%) subjects had pre-placed sutures used, and 75 (60%) patients had other sutures placed, of which 52 (69.3%) were absorbable and 23 (30.7%) were permanent. Tacks were used in 68 (54.4%) subjects, of which 4 (5.9%) were permanent and 64 (94.1%) were absorbable, requiring a mean use of 52.5±17.8 tacks. No subjects had biosurgical agents used for mesh fixation. The latter details were not pre-specified by the protocol, allowing surgeons to follow the IFU on-label for all fixations.

The mean length of hospital stay was 0.7±1.69 days and there was no significant difference between the surgical sub-groups.

Surgeon satisfaction

Surgeons rated their experience handling the mesh, deploying the mesh, and introducing the mesh into the working cavity as easy or very easy in 95.2%, 97.6%, and 99.2% of procedures, respectively. Surgeons could choose between the following rating categories: very difficult, difficult, easy and very easy-allowing them to make their subjective judgment based on their clinical experience.

The 99.2% of surgeons rated the mesh as either transparent or very transparent, 40% used the mesh's

violet markings to center and orient the mesh, 19.2% used marking dots for overlap management, and 50.4% reported using trans fascial sutures to position mesh.

DISCUSSION

Incisional hernias are an increasingly common complication after surgical intervention.[7] Although the exact causes are not completely clear, there are several well-known modifiable patient factors that influence hernia recurrence. The patient's high intra-abdominal pressure impacts the efficacy of hernia repair as it adds additional force on the repair through exertion on the abdominal wall. It has been previously reported that a lower BMI (specifically a BMI<40) is associated with reduced hernia recurrence rates.[8] Moreover, factors that delay wound healing (such as smoking, immunosuppression, and diabetes) increase the risk of hernia recurrence.[9]

The use of synthetic meshes is a well-established approach to reduce the rate of hernia recurrence after surgery. When selecting a type of mesh, the surgeon should consider its related properties including tensile strength, porosity, tissue ingrowth/incorporation, infection resistance, and placement. All of these factors must be considered as part of the operative decision-making on mesh choice, fixation and even whether or not to use mesh.

Expanded polytetrafluoroethylene (ePTFE) has high tensile strength, but it weakly incorporates into the abdominal wall.[10] Once implanted, a capsular layer is formed around ePTFE-composed mesh, preventing vascular ingrowth into the mesh. As a result, this makes the device highly susceptible to infections that are unlikely to clear with antibiotics.[11,12]

Polypropylene is a synthetic polymer of plastic that has been used in operations for over 50 years. It can be manufactured to increase the tensile strength as needed and promotes a high rate of tissue ingrowth.[12] However, dense adhesions can form to the mesh and possible enteric fistulas can occur. Mesh with exposed synthetic material, in particular microporous material, should not be placed in the intra-abdominal location due to the risk of enteric fistula formation.[10]

Parietene™ DS composite mesh is a new macroporous polypropylene monofilament textile that provides good tensile strength while also allowing good tissue integration.

Although still under discussion, several studies confirm that the macroporous/monofilament structure also ensures a lower risk of developing infections as compared to microporous/multifilament meshes. According to Brown and Finch, macrophages and neutrophils are unable to enter the small pores of microporous meshes (such as ePTFE) thus increasing the risk of infection.[10]

The addition of an absorbable film (derived of glycolide, caprolactone, trimethylene carbonate, and lactide) allows safe placement within the abdominal cavity.

We investigated the clinical safety and performance of Parietene™ DS composite mesh in ventral primary and incisional hernia repair procedures performed with the IPOM technique.

Overall complications were low, the most common being seroma (n=13, 10.4%), hernia recurrence (n=4, 3.2%) and surgical site infection (n=4, 2.4%). They were all within the nationally reported outcomes. Moreover, a recent analysis done by the Americas Hernia Society Quality Collaborative (AHSQC) showed a very similar complication profile.[13] Only one device deficiency was reported, due to a central mesh failure.

Importantly, while the hernia recurrence rate described in previous studies on predicate composite device (Proceed™ Surgical mesh, Ethicon, Somerville, NJ, USA) ranges from 3.5 to 5.2% at 1-year follow-up, we reported a lower rate of 3.3%-which is of particular note considering that at baseline the study population presented several risk factors for hernia recurrence (such as tobacco use [46.4%], diabetes mellitus [12.8%] and immunocompromission [1.6%]).[5,6]

Our study was not powered to detect statistically significant differences between hernia type or surgery type sub-groups; thus, a larger sample size may be needed to better determine trends not demonstrated in this analysis.

Surgeons were highly satisfied with the mesh used in this study, finding it easy to handle, deploy and introduce into the abdominal cavity. Nearly all the surgeons thought the mesh was either transparent or nearly transparent, which further facilitates the ease of use during the procedure by ensuring it is placed in the appropriate location with adequate overlap of the edges of the hernia defect. There are several features (violet central marking and measurement markings) designed to aid in the deployment of the Parietene™ DS composite mesh. We found that 40% used the mesh's violet markings to center and orient the mesh, whereas 19% used the marking dots for overlap management.

The mesh did not require any deviation from a surgeon's established technical preference for the procedures. The fixation method for this study was done at the discretion of the surgeon, but this has been shown to have no effect on patient-reported pain and morbidity.[14]

This study also showed that, using Parietene™ DS composite mesh, patients experienced an overall post-operative improvement in the CCS QoL, which is comparable to results obtained in other hernia repair studies using the same scale.[15-17]

Patient enrollment occurred during the COVID-19 pandemic, resulting in some follow-up (about 20%) conducted remotely. Recent literature has shown that remote visits are a reliable method to assess hernia recurrence and would not significantly impact hernia recurrence endpoints, being more likely to result in overreporting of hernia recurrence rather than underreporting.[18-20]

The positive clinical outcomes obtained within this study-particularly the low hernia recurrence and complication rates in patients with comorbidities and risk factors for hernia recurrence-highlight the importance of carefully choosing a performant mesh but also of evaluating the entire surgical context in which it will be used. In this regard, following the manufacturer's instructions and good clinical practice established by international guidelines is crucial. Parietene™ DS composite mesh is designed to be placed in an intraperitoneal site and is not recommended for bridging repair technique with the mesh placed in an inlay position. In this study, all patients underwent the IPOM technique, and no bridging repair was performed. Similarly, we followed the protocol study recommendations in ensuring a minimum of 5 cm mesh overlap beyond the edges of the defect, which is also in agreement with the EHS/AHS guidelines indications.[1]

CONCLUSION

In conclusion, the Parietene™ DS composite mesh can be used as a valid alternative to the other available composite meshes to perform safe and effective ventral hernia repair in patients (including those with high-risk factors for hernia recurrence) undergoing intraperitoneal mesh placement performed via open, laparoscopic or robotic surgical procedures. Also, Parietene™ DS composite mesh use shows a significant improvement in patient QoL and a high level of satisfaction by surgeons.

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