A novel biosynthetic scaffold mesh reinforcement affords the lowest hernia recurrence in the highest-risk patients

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Abstract

Introduction

Patients with higher postoperative infection risk undergoing ventral hernia repair (VHR) have limited options for mesh use. Biosynthetic mesh is intended to utilize the durability of synthetic mesh combined with the biocompatibility of biologic mesh. We sought to assess the outcomes of a novel biosynthetic scaffold mesh for VHR in higher risk patients over a 12-month postoperative period.

Methods

Two cohorts of 50 consecutive patients who underwent VHR with TELA Bio OviTex biosynthetic or synthetic mesh were retrospectively compared. Endpoints included surgical site occurrence (SSO), readmission rate, and hernia recurrence following VHR at 12 months postoperatively.

Results

OviTex mesh placement was associated with higher risk Ventral Hernia Working Group (VHWG) distribution and more contaminated CDC wound class distribution compared to synthetic mesh placement (VHWG grade 3: 68% vs. 6%, $p < 0.001$; CDC class > I: 70% vs. 6%, $p < 0.001$). Additionally, concomitant procedures were performed more often with OviTex mesh placement than synthetic mesh placement (70% vs 10%, $p < 0.001$). The OviTex mesh performed comparably to synthetic mesh in terms of incidences of SSO (36% vs 22%, $p = 0.19$), readmission rates (24% vs

14%, $p = 0.31$), and hernia recurrence (6% vs 12%, $p = 0.74$). On further evaluation, patients who developed SSO with OviTex mesh ($n = 18$) had a 17% hernia recurrence whereas those with synthetic mesh ($n = 11$) had an associated 55% hernia recurrence ($p = 0.048$).

Conclusions

The OviTex biosynthetic mesh was used in higher risk patients and performed similarly to synthetic mesh in regards to rate of SSO, readmissions, and hernia recurrence. Furthermore, patients who developed SSO with Ovitex mesh were significantly less likely to have hernia recurrence than those with synthetic mesh. Overall, the data suggest that biosynthetic mesh is a more desirable option for definitive hernia repair in higher risk patients.

Keywords

Ventral hernia repair
Biosynthetic hybrid mesh
Contaminated ventral hernia repair
Synthetic mesh
TELA bio OviTex

Abbreviations

VHR	Ventral hernia repair
VHWG	Ventral Hernia Working Group
CDC	Centers for Disease Control and Prevention
BMI	Body mass index
SSO	Surgical site occurrence
LOS	Length of stay
CPT	Current procedural terminology

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Cabo, Mexico and the 2019 Americas Hernia Society Meeting in Las Vegas, NV, USA.

Several variables must be considered when selecting mesh to augment ventral hernia repair (VHR). Understanding patient comorbidities, potential for infection, and how the material will incorporate at a cellular level will increase success and avoid surgical morbidity. Universal criteria for material selection include but are not limited to non-carcinogenicity, chemical inertness, resistance to mechanical stress, sterility, unresponsiveness to body and tissue fluids, limitation of foreign-body reactions, modifiability in size, and non-allergenicity [1]. In addition to material considerations, sound clinical reasoning must be applied to aspects such as patient comorbidities, social history, and infection risk when contemplating mesh use in hernia repair. In order to better risk-stratify patients in predicting surgical site occurrences (SSO), the Ventral Hernia Working Group (VHWG) created a classification system for incisional hernias [2]. More recently, Kanters et al. devised a modified VHWG classification system to improve the accuracy of predicting SSO after open hernia repair [3]. Increased SSO risk is associated with higher hernia grades in the classification system.

With evolving technology and techniques, the selection of mesh seems almost limitless. Traditionally, the selection had been between synthetic or biologic materials, each containing respective strengths and weaknesses. As an overview, synthetic materials such as polypropylene, polyester, or expanded polytetrafluoroethylene (ePTFE) generally maintain higher tensile strength yet carry a higher infection risk with regards to foreign-body reactions such as chronic inflammation, fibrosis, abdominal wall stiffness, and fistulas [4, 5, 6]. Biologic mesh derived from human, bovine, or porcine tissue addresses foreign-body infection risks yet are scrutinized for high cost and lack of strength leading to higher hernia recurrence as the graft is resorbed over time [4, 5, 6]. With the strengths and weaknesses of these materials at the extremes of a continuum, patients with higher risk of infection assume the risk yet may not achieve the benefit of each category of mesh. Therefore, new approaches and material amalgamation are required for improved outcomes.

Biosynthetic, and/or hybrid, mesh are comprised of long-term absorbable synthetic materials or are meshes that incorporate both biologic and synthetic components, which have been shown to be effective in clean contaminated and contaminated wounds [6, 7, 8]. The principal goal of hybrid mesh is to establish a scaffold for tissue ingrowth in addition to maintaining integrity with a permanent synthetic support. This category of mesh is designed to stimulate fibroblast migration in addition to cell signaling cascades, leading to neovascularization and deposition of collagen [6, 7, 8]. One such biosynthetic option is the TELA Bio OviTex Reinforced Bioscaffolds. The reinforced bioscaffold consists of layers of biologic tissue consisting of ovine rumen that is interwoven with a monofilament polypropylene. The biologic component allows for reduced foreign body responses, decreased inflammation, and enhancement of host tissue remodeling while the interwoven synthetic filament allows for increased strength and lower hernia recurrence. There is no literature describing outcomes of high-risk ventral hernia repair utilizing OviTex biosynthetic mesh, thus we sought to assess the surgical outcomes in this patient population. The aims of this study were to assess the SSO, hernia recurrence, and hospital readmission rates with respect to higher risk patients receiving OviTex biosynthetic mesh.

Methods

Patient population

All patients were identified using CPT procedural codes corresponding to open VHR using either TELA Bio OviTex biosynthetic or synthetic meshes. All synthetic meshes used were microporous, low-weight, composite-type polypropylene-based mesh with an absorbable barrier. Patients underwent surgery at either Indiana University Health Methodist or University Hospitals during the 2017 calendar year. Cases from multiple surgeons of multiple specialties were included, including one trauma surgeon, one plastic surgeon, and three gastrointestinal surgeons. Data were collected from retrospective chart review and readmissions, clinic visits, and complications were documented in a 12-month post-operative period. Patients were stratified

using the modified VHWG grading classification (Fig. 1) and CDC wound classifications I–IV (Fig. 2). Exclusion criteria included patients less than 18 years of age, patients receiving biologic or other forms of biosynthetic mesh other than OviTex, and patients who were lost to follow-up. IRB approval was obtained for this study.

Fig. 1

Modified VHWG classification system as defined by Kanters et al. [3]

Modified Ventral Hernia Working Group Grading System		
Grade 1	Grade 2	Grade 3
Low Risk	*Co-morbidities*	*Contaminated*
Low risk of complications No history of wound infection	Smoking Obesity Diabetes Immunosuppression Previous wound infection	Clean contamir Contaminated Active infection

Fig. 2

Surgical wound classification grades as defined by the CDC

Class I ***Clean***	An uninfected operative wound in which no inflammation is encou and the respiratory, alimentary, genital, or uninfected urinary trac entered. In addition, clean wounds are primarily closed and, if nec drained with closed drainage. Operative incisional wounds that fo nonpenetrating (blunt) trauma should be included in this category meet the criteria.
Class II ***Clean-contaminated***	An operative wound in which the respiratory, alimentary, genital, urinary tracts are entered under controlled conditions and withou unusual contamination. Specifically, operations involving the biliar appendix, vagina, and oropharynx are included in this category, pr no evidence of infection or major break in technique is encounter
Class III ***Contaminated***	Open, fresh, accidental wounds. In addition, operations with majo in sterile technique (e.g., open cardiac massage) or gross spillage f gastrointestinal tract, and incisions in which acute, nonpurulent inflammation is encountered are included in this category.
Class IV ***Dirty-infected***	Old traumatic wounds with retained devitalized tissue and those t involve existing clinical infection or perforated viscera. This definit suggests that the organisms causing postoperative infection were in the operative field before the operation.

Outcomes

Individual data on each patient were collected including age, gender, BMI, ethnicity, comorbidities, tobacco use (current or past), hospital LOS (index and total), past surgical history, hernia size, repair method, and concomitant surgeries. Endpoints of interest included SSO, readmission rate, and hernia recurrence at more than 12 months post-operatively. An SSO was defined as any defect within the midline incision including abscess, seroma, dehiscence, hematoma, or cellulitis.

Statistical analyses

Statistical analysis was performed using SPSS software, version 24 (IBM corporation; Armonk, NY) and R, version 3.5.2 (R Foundation for Statistical Computing) to identify significant differences between two 50-patient cohorts receiving either OviTex biosynthetic or poly-propelene synthetic meshes. Categorical data were displayed as percentages and continuous data presented as averages with standard deviations. Categorical data were analyzed using a 2×2 contingency table with a two-tailed Fisher's Exact Test (FET). Continuous data were analyzed with unpaired *t*-tests. Statistical significance was defined as $p < 0.05$.

Results

Biosynthetic vs. synthetic outcomes

Two cohorts of 50 consecutive patients who underwent VHR with OviTex biosynthetic or synthetic mesh were compared (Table 1). No biosynthetic mesh patients were lost to follow-up, meanwhile five synthetic mesh patients did not have 12 months follow-up and were excluded. Of the patients receiving OviTex biosynthetic mesh, the majority of patients were female (58%), mean age of 55 ± 14 years, and mean body mass index (BMI) of 34 ± 6 kg/m^2. Mean defect size was 124 ± 63 cm^2, with 68% requiring component separation. Primary fascial closure was achieved in 92% of cases and location of mesh included underlay (68%), sublay (20%), and onlay (12%). Concomitant procedures were performed in 70% of patients. VHWG distribution included grade 2 (32%) and grade 3 (68%). Wound class distribution included CDC class I (30%), II (44%), III (10%), and IV (16%). SSO were seen in 36% of patients, which included seroma ($n = 5$), abscess/deep SSI ($n = 8$), and wound drainage/dehiscence ($n = 5$). Average LOS distribution in days included ICU (1) and total (11). Rate of readmission was 24% and hernia recurrence rate was 6% ($n = 3$). Open VHR with synthetic mesh group had a similar mean age and BMI. Mesh location included underlay (62%), sublay (34%), and onlay (4%). Wound class consisted CDC class I (94%), II (4%), and III (2%); VHWG included grade 2 (94%) and grade 3 (6%). Postoperative occurrences included 22% SSO, 14%

readmission rate, and 12% ($n = 6$) hernia recurrence, which were comparable to that of the OviTex mesh cohort. OviTex mesh was associated with a significantly higher VHWG distribution, higher CDC wound classification, and longer length of stay compared to synthetic mesh. An attempt was made to match preoperative and operative variables of contemporary patients but was unsuccessful due to the lack of patients with synthetic mesh and VHWG grade 3, thus we reported consecutive patient data.

Table 1

Comparison of patient data receiving OviTex TELA Bio mesh vs. synthetic mesh

	OviTex TELA Bio	**Synthetic mesh**	***p* value**
N	50	50	
Gender	21 M (42%) 29 F (58%)	27 M (54%) 23 F (46%)	0.32
Age (years)	55 ± 14	52 ± 12	0.25
BMI (kg/m^2)	34 ± 6	33 ± 7	0.45
VHWG grade	2 (32%) 3(68%)	2 (94%) 3 (6%)	< 0.001* < 0.001*
CDC wound class	I (30%) II (44%) III (10%) IV (16%)	I (94%) II (4%) III (2%) IV (0%)	< 0.001* < 0.001* 0.20 0.006*
Repair method	Open	Open	
Mesh location	Underlay (68%) Sublay (20%) Onlay (12%)	Underlay (62%) Sublay (34%) Onlay (4%)	0.68 0.18 0.27
Concomitant surgeries	70%	10%	< 0.001*
Avg. hospital LOS (days)	11	2	< 0.001*
SSO	36%	22%	0.19
Readmission rate	24%	14%	0.31
Hernia recurrence	6%	12%	0.74
Statistical significance was $p < 0.05$ and denoted by *			

Surgical site occurrences (SSO) outcomes

Data from both cohorts with respect to patients who developed SSO are found in Table 2. The OviTex cohort with SSO ($n = 18$; 36%) consisted mostly of VHWG grade 3 (61%) and CDC wound class III (61%). Concomitant

procedures were performed in 67% of these patients, and the average hospital LOS was 11 days. On the other hand, the synthetic cohort with SSO ($n = 11$; 22%) consisted of mostly VHWG grade 2 (91%) and CDC wound class I (91%). Only 9% underwent concomitant procedures, and the average LOS was 3 days. Most notably, only 17% of patients with OviTex mesh who developed SSO also developed hernia recurrence, in contrast to 55% of patients with synthetic mesh and SSO ($p = 0.048$).

Table 2

Comparison of patient data receiving OviTex TELA Bio mesh vs. synthetic mesh who sustained a surgical site occurrence (SSO)

	OviTex SSO	**Synthetic SSO**	***p* value**
N	18 (36%)	11 (22%)	0.187
Gender	2 M (11%) 16 F (89%)	7 M (64%) 4 F (36%)	0.010*
Age (years)	49 ± 14	47 ± 11	0.648
BMI (kg/m^2)	35 ± 7	34 ± 9	0.893
VHWG grade	2 (39%) 3 (61%)	2 (91%) 3 (9%)	0.008* 0.008*
CDC wound class > I	61%	9%	0.008*
Tobacco use	78%	73%	1.0
Mesh location	Underlay (56%) Sublay (33%) Onlay (11%)	Underlay (73%) Sublay (27%) Onlay (0%)	0.449 1.0 0.512
Concomitant surgeries	67%	9%	0.006*
Avg. hospital LOS (days)	11	3	< 0.001*
Readmission rate	61%	64%	1.0
Hernia recurrence	17%	55%	0.048*
Statistical significance was $p < 0.05$ and denoted by *			

Discussion

Ventral hernia repair remains one of the most commonly performed surgical procedures, with over 350,000 cases performed annually in the United States. The surgery unfortunately carries high rates of recurrence ranging from 10 to 32%. These recurrences can be extremely costly to both the patient and the hospital, and it has been estimated that reducing recurrence rates by even 1% could save the nation millions of dollars in healthcare costs [8, 9, 10]. Factors that can play a role in hernia recurrence include patient characteristics such as obesity, tobacco consumption, and wound contamination, as well as operative factors such as open vs. laparoscopic entry and mesh selection. As more surgical options and mesh materials become available, the best approach is often unclear and continuously evolving. This study focused on a novel biosynthetic hybrid mesh in highly comorbid patients in a single-institution retrospective review. This study in particular is one of the first to focus on the TELA Bio OviTex biosynthetic scaffold mesh in patients classified as VHWG grades 2 and 3 as compared to patients receiving synthetic mesh for VHR.

The results of the study demonstrated that surgeons at our institution were more likely to select the OviTex biosynthetic mesh over a pure synthetic mesh in higher risk patients and cases, such as those with a higher degree of wound contamination or those performed with concomitant surgeries. Despite that, the data showed no significant differences in rates of SSO, readmissions, or hernia recurrence between the two groups. Average hospital length of stay was significantly increased in the OviTex cohort. However, this may be attributed to increased usage of the mesh in higher risk patients and more involved surgeries. Most importantly, on further analysis of patients who developed SSO, the OviTex mesh demonstrated statistically significant lower rates of hernia recurrence than synthetic mesh.

Investigating safe and effective approaches to hernia repairs in high risk patients is critical for their management. Repair of a hernia is often an elective or semi-elective procedure, and in such circumstances, surgeons will attempt to optimize the patient’s medical and surgical risks. However, hernia repair is also commonly an urgent or emergent procedure when incarceration,

bowel ischemia, or acidosis/shock are involved. Pre-existing active infection or wound contamination is considered a contraindication to synthetic mesh placement, due to increased infection risk, yet primary tissue repair alone of hernia defects has been repeatedly demonstrated to be associated with higher risks of recurrence [11, 12]. Biologic meshes, on the other hand, are significantly more costly and carry a higher risk of hernia recurrence compared to synthetic mesh [4, 5, 6]**.** The results of our study are promising as they suggest that the Ovitex biosynthetic mesh could be a better option for definitive hernia repair in the highest risk cases, such as those with higher preoperative risk or increased degree of contamination.

The literature supporting the use of OviTex biosynthetic scaffold mesh in VHR is extremely limited. Lake et al. studied hybrid hernia meshes, including the OviTex resorbable bioscaffold, in rabbit bacterial inoculated models and demonstrated microbial colonization of the OviTex mesh at 7 days post-inoculation [13]. To date there have been no studies investigating the clinical significance of these findings with regards to outcomes such as mesh infection in humans. A case series by Ferzoco that focused on inguinal hernia repair with the TELA Bio OviTex mesh demonstrated no reported hernia recurrence in an average 12-month postoperative period. The patients reported no complications, including no SSO nor recurrence, as well as a decrease in post-operative pain [14]; these findings were not surprising considering the low rate of morbidity and recurrence for inguinal herniorraphy regardless of mesh selection. Our study corroborated the safety and effectiveness of the OviTex mesh for ventral hernia. Furthermore, the data reported here are the first to investigate surgical outcomes in high-risk patients undergoing open and often complex (requiring component separation) abdominal wall hernia repairs.

Several limitations exist for the study including its retrospective design at a single institution over a 1-year time period, which does not account for a selection bias in terms of mesh used by surgeons in a consecutive series of hernia repairs. An effort to limit the influence of this bias was made by collecting data from multiple surgeons across multiple specialties and

hospitals, including one trauma surgeon, one plastic surgeon, and three gastrointestinal surgeons. An attempt was also made to match the VHWG grade and CDC wound classification of contemporary cases several years before the use of OviTex; the primary limitation was that other forms of biologic mesh were used instead for these same patients with VHWG grade 3 and CDC wound classification II-IV. Data collection was performed via retrospective chart review and does not exclude the possibility of a confirmation bias; follow up at 12-months was felt to be reasonable in both groups based on clinic visits and available cross-sectional imaging. Although consecutive patients were used in data collection, considerable variance existed including multiple surgeons with varying surgical approaches as well as location of the mesh placement. The study had 100 total patients ($n = 50$ for both synthetic and biosynthetic mesh use), and thus is limited by a relatively small sample size. Further prospective, multi-center trials utilizing TELA Bio OviTex mesh for open VHR are needed to support our results. One such trial has completed enrollment and hernia repair, and 24-month follow-up is currently ongoing (NCT03074474). Overall, the optimal approach and mesh selection for complicated VHR remains unclear in the literature and requires continued investigation.

Conclusions

Although numerous categories of mesh are available for ventral hernia repair, the options become limited in severely comorbid or contaminated cases. Our data suggested that TELA Bio OviTex biosynthetic mesh is a safe option in VHWG grade 2 and 3 patients in which synthetic mesh would be contraindicated with comparable rates of SSO and hernia recurrence at 12 months follow-up. OviTex biosynthetic mesh offers durable defect reinforcement with a decreased risk for hernia recurrence in comparison to synthetic mesh options in high risk patients. Further prospective multi-center trials utilizing TELA Bio OviTex mesh for open VHR are ongoing and needed to support the validity of these results.

Publisher's Note

Compliance with ethical standards

Disclosures Mitchell J. Parker, Rachel C. Kim, Martin Barrio, Juan Socas, Lawrence R. Reed, Attila Nakeeb, Michael G. House and Eugene P. Ceppa declares that they have no conflicts of interest or financial ties to disclose.

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