

A Multicenter Collaboration to Assess the Safety of Laparoscopic Ventral Rectopexy

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BACKGROUND: Concerns have been raised regarding the potential risk of mesh complications after laparoscopic ventral rectopexy.

OBJECTIVE: This study aimed to determine the risk of mesh and nonmesh morbidity after laparoscopic ventral rectopexy and to compare the safety of synthetic meshes with biological grafts.

DESIGN: This was a retrospective review.

SETTINGS: The study used data collated from prospective pelvic floor databases in 5 centers (3 in the United Kingdom, 1 in Australia, and 1 in Italy).

PATIENTS: All of the patients undergoing laparoscopic ventral rectopexy over a 14-year period (1999–2013) at these centers were included in the study.

MAIN OUTCOME MEASURES: The primary outcome was mesh morbidity, classified as vaginal erosion, rectal erosion, rectovaginal fistula, or perineal erosion. Secondary outcomes were nonmesh morbidity.

RESULTS: A total of 2203 patients underwent surgery; 1764 (80.1%) used synthetic mesh and 439 (19.9%)

used biological grafts. There were 2 postoperative deaths (0.1%). Forty-five patients (2.0%) had mesh erosion, including 20 vaginal, 17 rectal, 7 rectovaginal fistula, and 1 perineal. Twenty-three patients (51.1%) required treatment for minor erosion morbidity (local excision of stitch/exposed mesh), and 18 patients (40.0%) were treated for major erosion morbidity (12 laparoscopic mesh removal, 3 mesh removal plus colostomy, and 3 anterior resection). Erosion occurred in 2.4% of synthetic meshes and 0.7% of biological meshes. The median time to erosion was 23 months. Nonmesh complications occurred in 11.1% of patients.

LIMITATIONS: This was a retrospective study including patients with minimal follow-up. The study was unable to determine whether patients will develop future erosions, currently have asymptomatic erosions, or have been treated in other institutions for erosions.

CONCLUSIONS: Laparoscopic ventral rectopexy is a safe operation. Mesh erosion rates are 2% and occasionally require resectional surgery that might be reduced by the use of biological graft. An international ventral mesh registry is recommended to monitor mesh problems and to assess whether type of mesh has any impact on functional outcomes or the need for revisional surgery for nonerosion problems.

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Laparoscopic ventral rectopexy (LVR) is a surgical technique that is used increasingly to treat external rectal prolapse (full thickness extrusion of the

rectum outside the anus) and in patients with functional bowel disorders, including obstructive defecation and fecal incontinence, who have been identified to have internal rectal prolapse (a folding of the full thickness of the rectal wall that occurs on straining to defecate that does not protrude outside the anus).¹ The surgery involves anterior mobilization of the rectum down to the pelvic floor, followed by fixing the rectum up to the sacral promontory using either a synthetic surgical mesh or biological graft.² To date, evidence from colorectal centers across the world has demonstrated the technique to be both effective and safe.²⁻⁵

The use of surgical mesh in the repair of pelvic organ prolapse (POP) has, however, raised concerns. This follows an association between the placement of mesh transvaginally in gynecologic practice for both POP and stress urinary incontinence with serious complications including mesh erosion (US Food and Drug Administration public health notification, July 13, 2011).⁶ Indeed, the use of all medical devices within the body has come under intense scrutiny. Concerns have been raised over their current assessment and the regulation of implanted devices, with a call made by the Royal College of Surgeons of England for mandatory databases for all surgical implants and associated techniques.⁷

The aim of this article was to assess the safety of LVR, including determining the risk of postoperative mesh and nonmesh morbidity and comparing the safety of synthetic mesh with biological grafts. The primary outcome measured was mesh morbidity; the secondary outcome was nonmesh morbidity.

PATIENTS AND METHODS

An international collaboration of specialist colorectal pelvic floor centers was undertaken to enable significant case numbers to be analyzed and an adequate comparison of mesh types made. Operative and clinical data were collated from prospective pelvic floor databases used by 5 institutions (3 in the United Kingdom: Oxford Pelvic Floor Centre, North Bristol National Health Service Trust Frenchay Hospital, and Queen Elizabeth Hospital; 1 from Australia: Royal Brisbane and Women's Hospital; and 1 from Italy: University of Rome Tor Vergata). Each institution had independently created their prospective database and regime for data input. To minimize bias, all of the surgeries performed within each institution were included and collated into 1 database. The data interpreted within this study, therefore, include patients who have been reported previously by the individual centers.^{3-5,8-17}

The indication for patients undergoing LVR was at the discretion of individual center practice. However, 4 of the 5 centers included within this study were involved in the creation of a published consensus for LVR with standardized indications for surgery,¹⁸ and, as such, practice was consistent among all of the centers.

Surgery

In all of the institutions, LVR was performed using the operative technique as described previously by D'Hoore et al.¹⁹ In brief, after an inverted-J incision of the peritoneum on the right side of the rectum from the sacral promontory to the cul-de-sac of the rectovaginal pouch, the anterior rectum is dissected down to the pelvic floor and then fixed to the sacral promontory using either a synthetic mesh or biological graft. There is no posterior dissection, and the lateral ligaments are left intact. Biological grafts used in our study were porcine dermal collagen (Permacol; Covidien, Dublin, Ireland) or porcine small intestinal submucosa-derived collagen (Biodesign; Cook Medical, Bloomington, IN). Synthetic meshes used were polypropylene, polyester, and titanium-coated polypropylene. The choice of mesh used and postoperative care depended on individual surgeon preference. Follow-up was performed within the outpatient setting at 3 months and every 12 months thereafter (universally across the institutions), with open access should there be any issue. This routinely included rigid sigmoidoscopy/proctoscopy but only vaginal speculum examination if symptomatic. Any patients who developed symptomatic complications were assessed as soon as they presented.

Data Collection

Data from each center was collated onto 1 central database. Data recorded included patient demographics (sex, age, and ASA score), degree of rectal prolapse (internal, external, or none), operation details (date of operation and mesh used), and postoperative complications. Mesh erosions were classified as vaginal erosion, rectal erosion, rectovaginal fistula (RVF), or perineal erosion. Duration of time from operation to identification of mesh morbidity was recorded, as was the definitive treatment required. Mesh morbidity was considered minor if treatment required local excision of exposed mesh or removal of sutures. Major mesh morbidity was classified as need for removal of mesh, bowel defunctioning, or resection. All other postoperative complications were recorded and assessed as nonmesh morbidity.

Statistical Analysis

Statistical analysis was performed with SPSS version 17.0 (SPSS Inc, Chicago, IL). Quantitative data are expressed as median \pm SD (range). Mann-Whitney *U* test was used to analyze unpaired 2-group nonparametric data and Kruskal-Wallis tests when comparing more than 2 groups. To compare incidence of mesh erosion according to prolapse, mesh type, and institution, a time-to-event analysis was performed using the Kaplan-Meier method. The log-rank test was performed to compare probability curves between meshes. HRs with 95% CIs were calculated for the risk of mesh erosion development according to synthetic mesh

type using Cox regression analysis. A p value of <0.05 was taken to denote a significant difference.

RESULTS

Between September 1999 and March 2013, 2203 LVRs were performed in the 5 participating centers (Oxford = 1179, Bristol = 674, Gateshead = 137, Brisbane = 164, and Rome = 49). At point of analysis, median length of time since operation was 36 months (range, 0–162 months).

Patient Demographics

A total of 2051 patients (93%) were women. The median patient age was 59 ± 16 years (range, 15–82 years). Patient ASA grades were as follows: 1, 567 (42.9%); 2, 550 (41.6%); 3, 200 (15.1%); and 4, 4 (0.3%). A total of 569 patients (28.0%) underwent LVR for external rectal prolapse and 1389 (68.5%) for internal rectal prolapse, and 71 (3.5%) had no rectal prolapse (49 for rectocele, 21 for vault prolapse, and 1 for sigmoidocele).

Operation Details

A total of 1764 (80.1%) LVRs were performed using a synthetic mesh and 439 (19.9%) were performed using a biological graft. The synthetic meshes used were polypropylene (1325 patients (60.1%)), titanium-coated polypropylene (160 patients (7.2%)), and polyester (279 patients (12.7%)). The biological grafts used were porcine dermal collagen (309 patients (14.0%)) and porcine small intestinal submucosa (130 patients (5.9%); Table 1). Individual center mesh usage is demonstrated in Figure 1. In March 2013, the median length of follow-up within the registry since synthetic mesh LVR operation was 38 months (range, 0–162 months), whereas the median length of follow-up within the registry since biological graft LVR operation was 26 months (range, 0–68 months).

Mesh Morbidity

A total of 45 patients (2.0%) developed a mesh erosion, including 20 vaginal erosions (1.0%), 17 rectal erosions (0.8%), 7 RVFs (0.3%), and 1 perineal erosion (0.1%). All of the patients who developed mesh erosions were women; the median patient age was 54 years (range, 23–86 years). Patient ASA grades were as follows: 1, 30 (67%); 2, 9 (20%); 3, 6 (13%); and 4, 0 (0%). Mesh erosions were more frequently associated with surgery for internal rectal prolapse than external prolapse (39/1389 internal rectal prolapse patients (2.8%); 6/569 external rectal prolapse patients (1.1%); $p = 0.02$). No other patient demographics correlated with a risk of developing mesh erosion. Median time from operation to identification of mesh erosion was 23.0 ± 18.5 months (range, 2.0–78.0 months; Fig. 2). Seven patients (15.6%) presented early with erosions within 6 months of surgery (3 vaginal, 2 rectal, 1 RVF, and 1 peri-

TABLE 1. Mesh types used and mesh erosions rates after laparoscopic ventral rectopexy

Mesh frequency (%)		Mesh erosions frequency, n
Synthetic, N = 1764 (80.1%)	Polypropylene, n = 1325 (60.1%)	23
	Polyester, n = 279 (12.7%)	18
	Titanium-coated polypropylene, n = 160 (7.2%)	1
	Total = 42	
Biological, N = 439 (19.9%)	Porcine dermal collagen, n = 309 (14.0%)	3
	Porcine intestine submucosa, n = 30 (5.9%)	0
	Total = 3	

neal). Three of these patients (1 vaginal and 2 rectal) had a stitch sinus with no evidence of mesh exposure. A total of 34 erosions (75.6%) had developed within 36 months of follow-up. Two patients presented with erosions 60 months after surgery (441 patients within the study had had follow-up for ≥ 60 months).

Mesh Type

Of the 45 mesh erosions, 42 (93%) involved a synthetic mesh (23 polypropylene, 18 polyester, and 1 titanium-coated polypropylene). This equates to 2.4% (42/1764) of all patients with a synthetic mesh having been identified as having a mesh erosion at time of analysis. Calculating the survival probability using the Kaplan-Meier method identified synthetic erosion rates at 1 year of 0.4%, at 2 years of 1.1%, and at 5 years of 2.3%. There were 3 patients with erosion after use of the biological graft (0.7% (3/439) of all biological cases at time of analysis). Biological erosion rates at 1 year were 0.5%, at 2 years 0.7%, and at 5 years 0.7%. All 3 of the biological erosions involved porcine dermal collagen graft. However, this includes 2 stitch sinuses (1 rectal and 1 vaginal) in which there was exposure of nonabsorbable Ethibond sutures with no evidence of direct mesh exposure. The third biological erosion was a perineal erosion. Synthetic mesh was not significantly associated with an increased incidence of erosion compared with biological graft (Fig. 3A).

When assessing synthetic meshes independently, polyester was associated with an increased risk of erosion ($p = 0.00006$; Fig. 3B). The HRs for risk of mesh erosion using polyester compared with polypropylene and titanium-coated polypropylene were 4.09 (95% CI, 2.16–7.73) and 2.96 (95% CI, 0.38–23.28). Polyester mesh was only used in 1 institution (Bristol), and when comparing mesh erosion rates between centers, Bristol was associated with higher erosion rates ($p = 0.016$). However, when patients with polyester mesh were excluded, there were no significant differences in institution erosion rates. Median time to mesh erosion identification was 27.0 ± 18.1 months

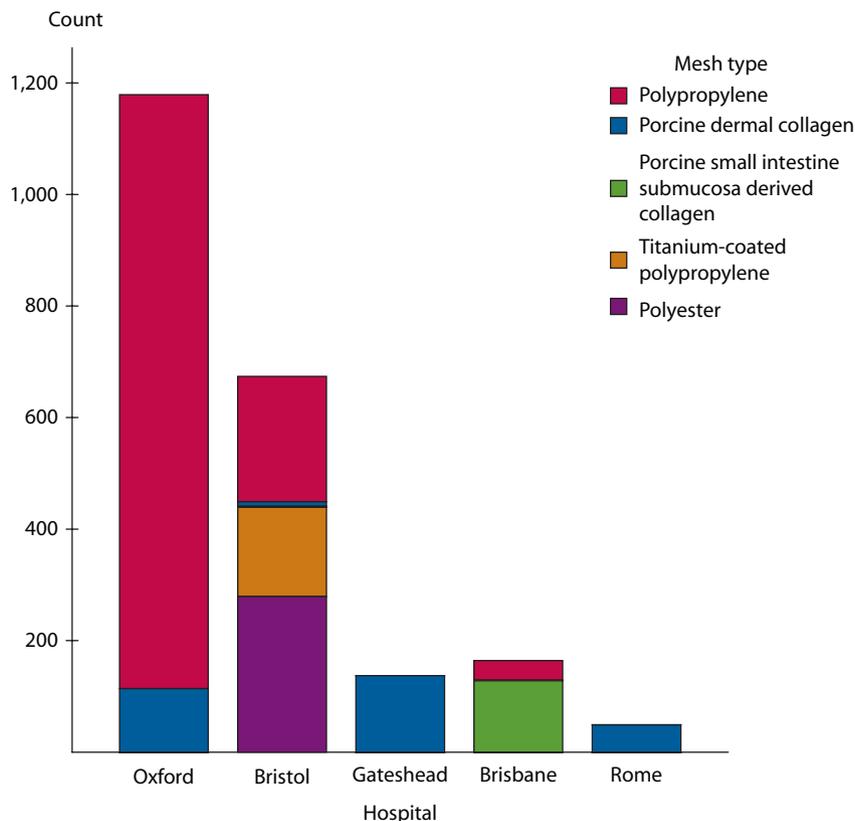


FIGURE 1. Mesh type used for laparoscopic ventral rectopexy in each individual center.

(range, 2.0–78.0 months) for synthetic mesh and 2.5 ± 6.1 months (range, 2.0–14.0 months) for biological graft.

Treatment of Mesh Erosion

Figure 4 summarizes the definitive management delivered in treating patients with mesh erosions. A total of 23 patients (51.1%) have undergone treatment for minor erosion morbidity (local excision of stitch/exposed mesh) without further intervention required. Twelve patients had local excision of stitch/mesh from the vagina, 9 from the rectum, and 1 from the perineum. Rectal mesh excision was performed under direct vision or using transanal endoscopic microsurgery (3 patients). The median length of follow-up within the registry after local excision is 15.5 ± 25.8 months (range, 1.0–101.0 months).

Eighteen patients (40%) required treatment for major erosion morbidity (12 laparoscopic mesh removal, 3 mesh removal plus colostomy, and 3 laparoscopic ultralow anterior resection). All of the ultralow anterior resections required a temporary defunctioning loop ileostomy. One patient with a vaginal erosion and 1 with a rectal erosion had initially been treated with local excision of mesh but went on to have laparoscopic removal of mesh within a year. Median length of follow-up within the registry after major erosion morbidity is 18.0 ± 14.3 months (range, 1.0–48.0 months). None of these patients have had any further

surgical intervention. Four patients have undergone examination under anesthesia without further intervention.

Nonmesh Morbidity

Thirty-day mortality after LVR was 0.1%. Two patients died from sepsis after a perforated viscus postsurgery (1 involving perforated diverticular disease postsurgery and the other because of a small-bowel enterotomy). A total of 11.1% of patients had a nonmesh complication postsurgery; 5.6% had a surgical complication, and 5.4% had a medical complication (Table 2). A significant proportion of complications arose from port site complications (1.4% had port site hernia incidence, 1.3% had port site infection/hematoma). Urinary retention postsurgery was 1.9%, and the risk of urinary tract infection was 1.0%. Postoperative pain was the most common complication (2.8%). It was most frequently localized to port sites but was also seen intra-abdominally, in the perineum/perianally, in the pelvis, or in the sacrum (Table 3). The majority (40/55 (73%)) were successfully treated with analgesics. However, 6 underwent examination under anesthesia and diagnostic laparoscopy requiring division of adhesions in 2 patients and division of a port suture in another. Four patients received pudendal nerve blocks for perineal pain, and 4 required treatment for anal fissures. Sacral osteomyelitis was confirmed in 1 patient, as was lumbar discitis in another.

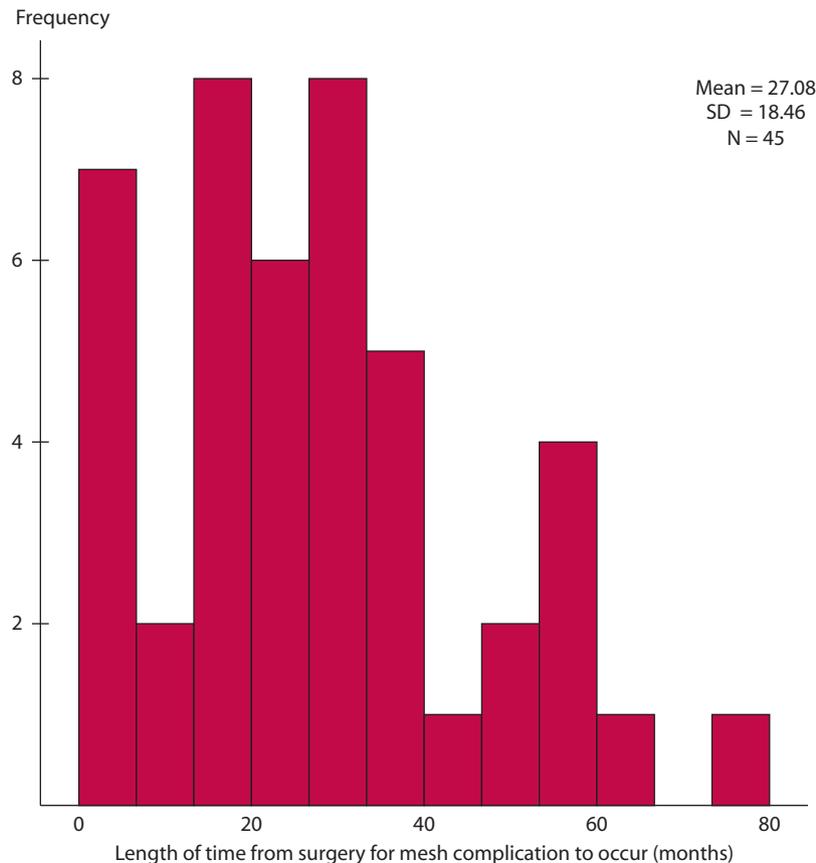


FIGURE 2. Length of time from laparoscopic ventral rectopexy operation until diagnosis of mesh erosion (months).

DISCUSSION

LVR has become an accepted treatment option for both external and internal rectal prolapse.¹⁸ It has also been applied to rectocele, enterocele, and vaginal vault prolapse.²⁰ Through an international collaboration of 5 specialist pelvic floor centers, this study has been able to demonstrate that LVR is a safe operation. The risk of developing mesh erosion is 2.0%, nonmesh complication rate is 11.0%, and 30-day mortality rate is 0.1%.

This study has follow-up data from more than 2200 patients performed over a 14-year period. This was necessary to gain an accurate picture of complication rates in light of the fact that the occurrence of events after LVR is uncommon.²¹ It must be noted that this study is reliant on the accurate recording of data within each institution. There is, therefore, a risk of variability in the accuracy of outcome recording, plus some complications may be lost to follow-up because of treatment at other centers. However, in an attempt to minimize bias and give as broad a picture as possible, all of the patients from each institution were included within this study even if this meant that follow-up for certain patients was short.

The use of mesh in the treatment of POP has raised serious concerns regarding the safety and effectiveness

when placed transvaginally.⁶ However, the mesh fixation in LVR is more analogous to that seen in sacrocolpopexy (paravaginal mesh fixation). The 2% mesh erosion rates seen in this study are equivalent to outcomes identified in a systematic review of sacrocolpopexy (erosion rates of 0%–12%),²² supporting the consensus that they are comparable techniques in terms of mesh safety and should not be considered in the same category of risk as transvaginal mesh.

Mesh erosion in female pelvic floor reconstruction has been linked with synthetic materials and, in particular, has been related to the pore size of the material used. Type I meshes with a pore size >75 μm have been associated with reduced risk as opposed to those with smaller pores (types II–IV; type II mesh is defined as mesh pore size <10 μm , type III <10 μm macroporous with microporous components, and type IV <1 μm).²³ Patient factors including poorly controlled diabetes mellitus, tobacco use, previous pelvic irradiation, vaginal estrogen status, and previous surgery were also linked with increased erosion risk.²³ To date, the evidence regarding the risk of mesh erosion after LVR has been limited. A systematic review of 13 observational studies including 866 patients identified an erosion rate of <1.0%, with no difference identified

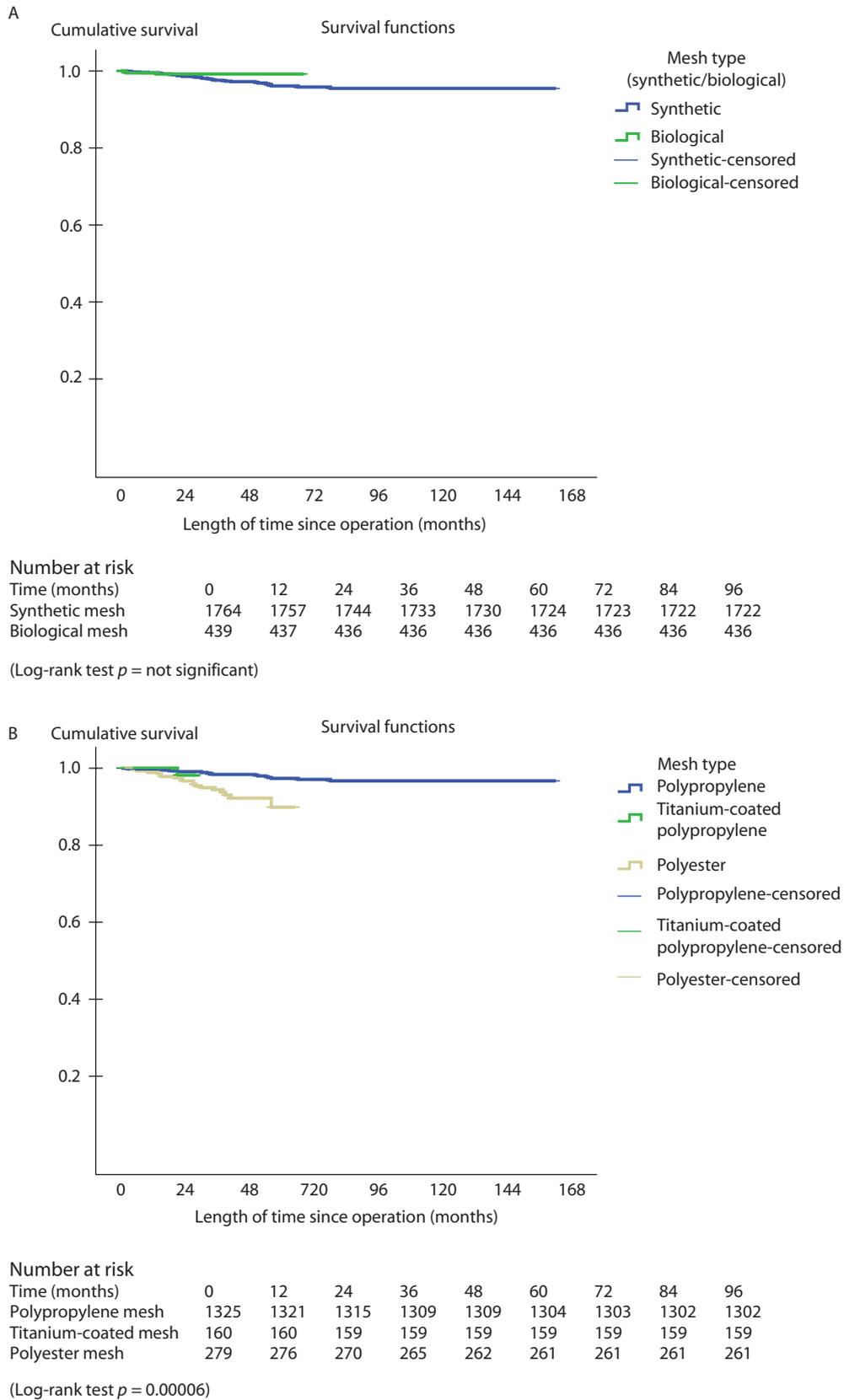


FIGURE 3. A, Comparison of the incidence of mesh erosion after laparoscopic ventral rectopexy (LVR) between synthetic and biological mesh. B, Comparison of the incidence of mesh erosion after LVR between different synthetic meshes.

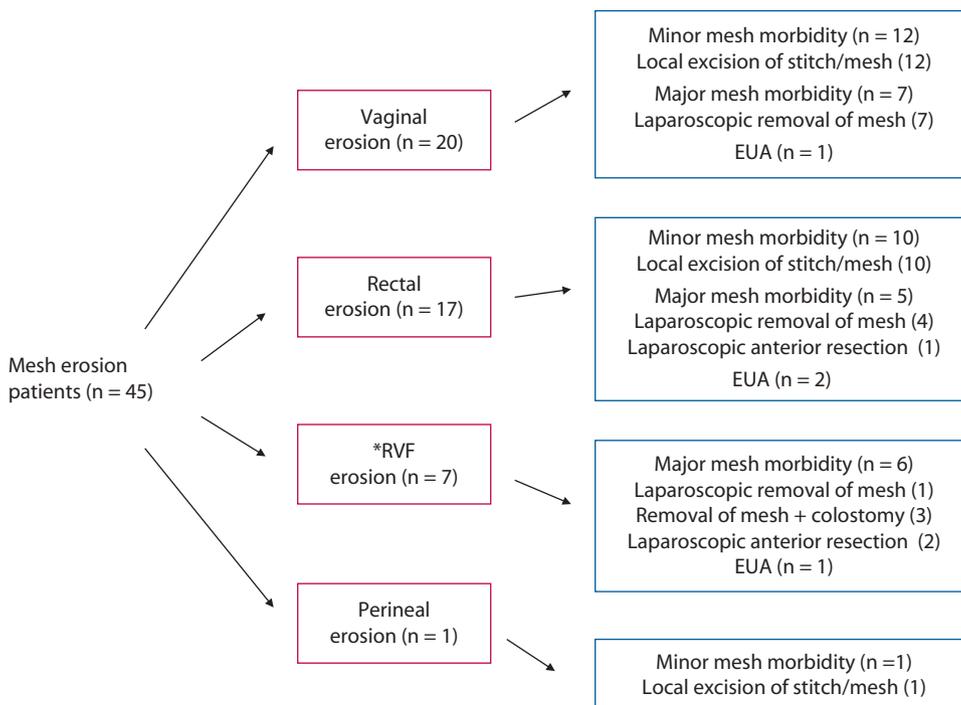


FIGURE 4. Summary of the management of patients experiencing mesh erosion. RVF = rectovaginal fistula; EUA = examination under anesthesia.

between synthetic and biological mesh (0.7% vs 0%).²¹ The choice of mesh used in LVR has been dependent on a balance of many factors, including cost, operative failure/recurrence, requirement for revisional surgery, and risk of prosthetic-related complication. Without conclusive evidence to date regarding the optimal mesh

for LVR, mesh choice has been left to individual surgeon preference. Different institutions within this study have used different meshes, and the authors accept that this may lead to a bias when interpreting results. However, in light of the standardization of practice within the centers and the large numbers of patients involved, we believe that this article offers significant evidence regarding LVR safety.

This study identified that polyester mesh was associated with a significantly higher incidence of mesh erosion compared with both polypropylene and titanium-coated polypropylene. It is noted that polyester meshes were only used within 1 institution (Bristol) and, thus, the higher erosion rates associated with polyester could reflect differences in surgical practice. However, the technical aspects of the procedure were identical among all of the centers, and when patients with polyester mesh were excluded, there were no statistical differences in institutional mesh erosion rates. We hypothesize that polyester erosions are a function of the “antigenicity” of polyester, inducing a host reaction and producing a sterile abscess, which, through pressure necrosis, then discharges at the weakest point—the suture. We therefore recommend that polyester should not be used for LVR but believe that alternative synthetic meshes still are appropriate for use in patients requiring uncomplicated surgery. Although there was no statistically significant difference in mesh erosion rates when comparing synthetic and biological mesh with respective mesh erosion rates, we believe that biological implants should be considered when treating young/adolescents, women of reproductive age, di-

TABLE 2. Nonmesh postoperative complications after laparoscopic ventral rectopexy

Complication	Frequency, n (%)
Surgical complication	
Port site hernia	27 (1.4)
Port site infection/hematoma	26 (1.3)
Pelvic hematoma	10 (0.5)
Urinary retention	37 (1.9)
Perforated viscus	8 (0.4)
Small-bowel obstruction/ileus	6 (0.3)
Subcutaneous emphysema	3 (0.2)
Vaginal bleed/discharge	3 (0.2)
Musculoskeletal	2 (0.1)
Intersphincteric abscess	1 (0.1)
Medical complication	
Urinary infection	19 (1.0)
Respiratory infection	6 (0.3)
Cardiovascular	12 (0.6)
Venous thrombotic event	2 (0.1)
Neurological	4 (0.2)
Pain	55 (2.8)
Pyrexia of unknown origin	5 (0.2)
Diarrhea	6 (0.3)
Constipation	7 (0.4)
Duodenal ulcer	2 (0.1)

TABLE 3. Postoperative pain after laparoscopic ventral rectopexy

Site of postoperative pain	Frequency, n (%)
Port site	14 (0.7)
Intra-abdominal	11 (0.6)
Perineum/perianally	10 (0.5)
Pelvic	7 (0.4)
Sacral	7 (0.4)
Back	3 (0.2)
Thigh	2 (0.1)
Neck	1 (0.1)

abetics, smokers, patients with a history of previous pelvic radiation and IBD, or if there is an intraoperative breach of the rectum or vagina.¹⁸ This article has not examined the question of whether synthetic meshes are more durable than biological grafts in terms of clinical outcomes.

When considering the 3 biological graft erosions identified in these data, it is significant that 2 of the patients involved a stitch sinus with the presence of nonabsorbable suture (Ethibond) within the rectum or vagina. We therefore suggest the use of an absorbable suture to secure the mesh to the rectum to avoid this problem. Indeed, we hypothesize that the etiology of a significant proportion of erosions is the result of exposure of nonabsorbable sutures to the rectal or vaginal lumen acting as a nidus for infection and the progressive exposure of mesh. It is accepted that ideally a randomized prospective study would be required to provide clarification of the risk of erosion according to mesh type. However, the incidence of erosion is so low that we believe that collaboration and creation of a prospective mesh registry would be a more pragmatic approach. The National Pelvic Floor Society of Great Britain and Ireland is in the process of setting up a Web-based database that will address these issues, creating an online registry for all meshes placed at LVR that will be available free of charge to international collaborators.

This is a retrospective, observational study with a median follow-up time of 36 months. It is not possible to determine whether any patients will develop erosions in the future or already have erosions but are currently asymptomatic. However, the majority of patients (75.6%) had mesh erosions diagnosed within 36 months of surgery, and only 2 patients (4.4%) were newly identified to have erosions 60 months after surgery. This suggests that, if mesh erosion is going to occur, it is likely to be symptomatic within 3 years of the operation and that the risk of erosion reduces if asymptomatic beyond this point.

A proportion of erosion patients (11.1%) presented with erosions within a short space of time after surgery. It is likely that surgical technical error, such as unrecognized rectal or vaginal injury or too-deep placement of fixation sutures, was responsible for such erosions. Indeed, 3 patients required removal of stitch sinuses only without any mesh exposed. LVR is a technically demanding procedure,

and we recommend that it be performed only by trained colorectal surgeons with significant laparoscopic experience and an interest in pelvic floor surgery.¹⁸

Treating mesh complications after LVR can be challenging, and is optimally managed in a tertiary referral center.²⁴ A significant proportion of erosions can be treated with local excision of mesh or suture, as was performed in 51.1% of patients in this study. However, a number of patients will have major mesh morbidity requiring greater surgical intervention, particularly if there is an RVF. The majority can be successfully treated with laparoscopic mesh removal, but some will require a diverting stoma or even resectional surgery, which is technically demanding.²⁵

The review of nonmesh morbidity demonstrated that the procedure is safe and can be performed on both elderly and young patients with minimal complication, which is consistent with previously published work.³ It is of note that the incidence of port site hernia was >1% and led to significant complications in certain patients. It has been recognized previously that patients with prolapse are at higher risk of hernia development, possibly because of collagen weaknesses,²⁶ and we advocate that 10-mm ports be avoided where possible when performing LVR.¹⁸

LVR is generally a well-tolerated procedure with minimal postoperative pain. However, a proportion (2.8%) of patients did experience significant pain. The majority of these can be treated with simple analgesics, but if symptoms persist or are not controlled, the etiology of the pain must be determined, because it may ultimately require some form of surgical intervention, and septic complications, including pyogenic spondylodiscitis, must be excluded.²⁶

CONCLUSION

The data from more than 2200 patients undergoing LVR in this study demonstrate that it is a safe operation with a risk of mesh erosion of 2%. However, this is only an observation at 1 point in time, and we believe that regular follow-up and analysis are required for definitive risk assessment and conclusions to be made. We propose that an international mesh registry is the best way to regulate and assess outcomes after LVR, thereby ensuring patient safety and guiding best practice. It is the responsibility of colorectal surgeons with a specialist interest in pelvic floor disorders to work together and drive this objective forward. Transparency in techniques performed, prosthetics used, and clinical outcomes will result in the optimum safety and care for patients.

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