

Biological Meshes in complex anterior abdominal wall reconstructions and hernia repair in contaminated fields

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Abstract

Objective: Anterior abdominal wall hernia repair can be challenging especially in contaminated fields. A retrospective study was done aiming to examine the recurrence and wound complications following use of biological mesh in anterior abdominal wall hernia repairs at our institutions. The study also aimed at identifying any correlation in results with respect to different types and locations (onlay/inlay/sublay etc.) of mesh.

Method: A retrospective study. Patients were identified from the operating theatre database. Data were collected from operating theatre records and medical records of the patients. Data included patient demographics age, gender, body mass index, medical comorbidities, ASA (American Society of Anaesthesiologists) grade, indication for operation, details of operation, type of biological mesh, plane of implantation of biological mesh, complications and duration of post-operative follow up.

All adult (age over 16 years) patients who required usage of biological mesh in anterior abdominal wall hernia repairs and reconstructions, as elective or emergency, from Jan 2008 to August 2012 at Glan Clwyd Hospital and from August 2012 to November 2016 at University Hospital of North Durham, were included in this study. The study included those complex parastomal hernia repairs with or without re-siting of stomas where biological meshes were used. Moreover this study also included those complex laparostomy cases where biological meshes were used for the closure of anterior abdominal wall. Further follow up of patients was dictated by the clinical needs of patients. Data were analysed using Microsoft Excel® and IBM Statistical Programme for Social Sciences (SPSS) version 21. Continuous variables were expressed as mean, standard deviation and range. Categorical variables were described with numbers and percentages. Comparison between variables was analysed with non-parametric Mann-Whitney U and Wilcoxon Signed Rank test. A P-value of less than 0.05 was considered to be significant. Cox regression model was used to analyse the survival rates.

Results: Data were collected from operating theatre and medical records of patients. The recurrence and wound complications were objectively defined. Data were analysed. Fifty-eight procedures were performed in 54 patients (F:M 1:1) with a mean age of 62 years (range 23-83 years), mean BMI was 30 ± 7.769 . The mean follow up was 10.28 months ± 9.541 . There was a recurrence rate of 22.5% (13) & wound complication rate of 42.5% (25). Although there was increased incidence of wound complications and recurrence with use of Permacol in sublay and intraperitoneal location of biological mesh but there was no statistically significant correlation among the recurrence, wound complication, type of mesh and its position (Mann-Whitney U and Wilcoxon Signed Rank test).

Conclusion: It was concluded that biological meshes can be used safely and effectively as an alternative to traditional non-biological mesh products for abdominal wall reconstructions in the setting of contaminated fields.

Keywords: Biological mesh, contaminated abdominal wall hernia, contaminated abdominal wall reconstruction.

Introduction:

Anterior abdominal wall hernia repair is a com-

monly performed surgical procedure. It can be very challenging especially in previously scarred

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and contaminated fields.¹ Various techniques have been used in the past for repair of anterior and incisional hernias such as simple suture repair, Mayo technique and Keele repair etc.² Nuttall described rectus muscle transplantation in 1926 which involved releasing the muscles at their origins, crossing them and suturing them to the opposite pubic bone.³ The search for an optimal and ideal repair of anterior and incisional hernias have brought us to the era where several types of synthetic meshes are being used for repair of such hernia. The current dilemma of the surgical world is the use of synthetic non absorbable meshes in contaminated or potentially contaminated fields where they are prone to infection. Such non-absorbable meshes can result in complicated fistula formation if they get infected. Therefore the use of non-absorbable synthetic meshes in contaminated fields has been discouraged.⁴

Biological meshes were introduced in surgery more than a decade ago as an alternative to synthetic meshes.⁵ Derived from bovine, porcine and human sources, these are typically collagen-based and treated to remove cellular elements. Some biomaterials are cross linked additionally to delay the degradation of the collagen by collagenases.^{6,7}

There are only cohort studies, case reports, and descriptive case series in the literature about the use of biological meshes in anterior abdominal wall hernias. There are no case-matched studies or prospective randomized control trials in the peer-reviewed medical literature on the use of biological tissue grafts for incisional hernia repair in humans.⁵ High quality randomised control trials are difficult to conduct in this field due to variation in the patient demographics, disease characteristics, hvarying degree of contamination of operative fields and cost of these meshes. Hence it is felt that there is still a need to add more data and share the experience from different institutions so that future systematic reviews and meta-analyses may help in making evidence based decisions about these costly meshes. The primary aim of this study was to examine the recurrence and wound complications due to the

usage of biological mesh in anterior abdominal wall hernia repairs and reconstructions at our institutions. The study also aimed at identifying any variation in results with respect to different types of mesh. Another secondary aim of this study was to see any difference in outcome with regards to a variation in usage of such prosthesis at different locations in abdominal wall (onlay/inlay/sublay etc).

Materials and Methods:

It was a retrospective study. Patients were identified from the operating theatre database. All patients were treated at Glan Clwyd Hospital, Bodelwyddan and University Hospital North of Durham, large district general hospital in north Wales and Northeast of England, by surgical teams with special interests in lower gastrointestinal and upper gastrointestinal surgery. Data were collected from operating theatre records and medical records of the patients. Data included patient demographics including age, gender, body mass index, medical co-morbidities, ASA (American Society of Anaesthesiologists) grade, indication for operation, details of operation, type of biological mesh, plane of implantation of biological mesh, complications and duration of post-operative follow up.

All adult (age over 16 years) patients who required usage of biological mesh in anterior abdominal wall hernia repairs and reconstructions, as elective or emergency, from Jan 2008 to August 2012 at Glan Clwyd Hospital and from August 2012 to November 2016 at University Hospital of North Durham, were included in this study. The study included those complex parastomal hernia repairs with or without resiting of stomas where biological meshes were used. Moreover this study also included those complex laparostomy cases where biological meshes were used for the closure of anterior abdominal wall.

The study did not include those patients where biological mesh had been used in other types of hernias.

Routine follow-up consisted of clinical assess-

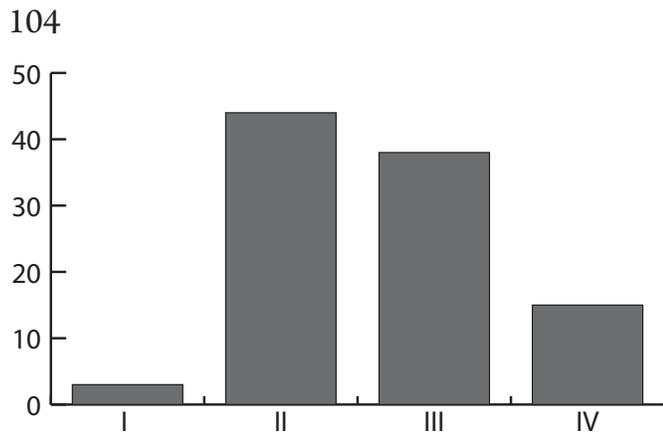


Figure 1: ASA grading of the patients

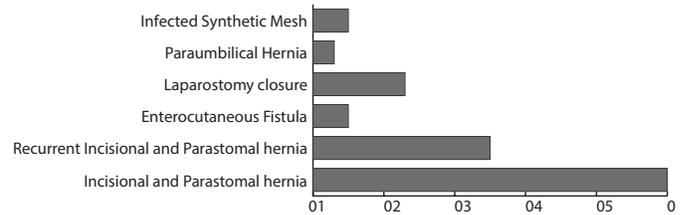


Figure 2: Diagnosis /Indications for use of biological mesh

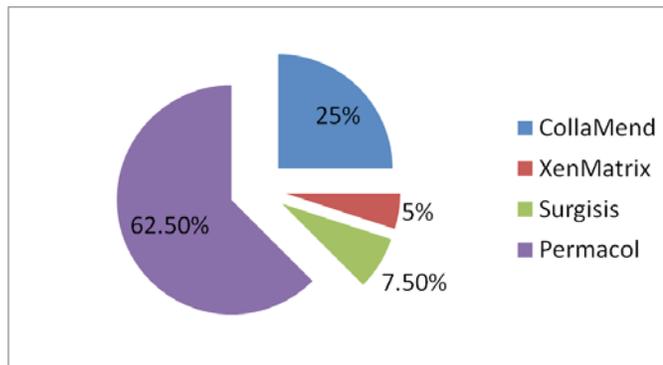


Figure 3: Types of mesh used

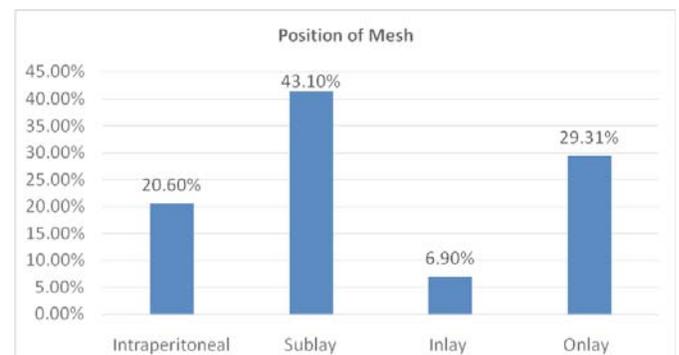


Figure 4: Location of Mesh in Anterior Abdominal Wall

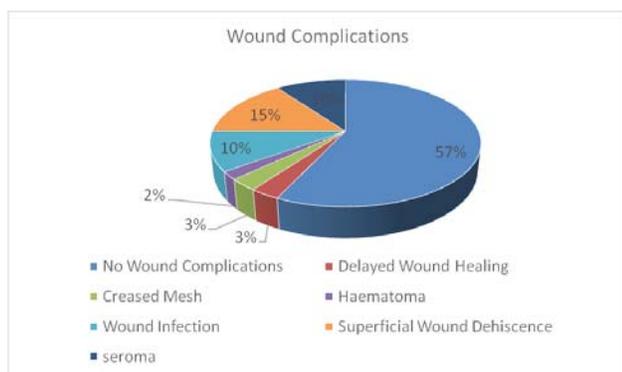


Figure 5: Wound complications

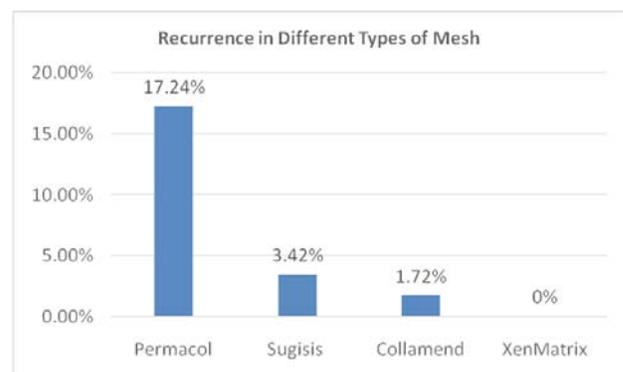


Figure 6: Recurrence in Different Types of Mesh

ment and physical examination in six weeks or earlier depending upon the clinical needs. A radiological investigation e.g. CT scan was performed only if clinical suspicion of recurrence or of any other complication warranted it. Further follow up of patients was dictated by the clinical needs of patients.

For the purposes of this study, seroma was defined as an identifiable collection of fluid in the

operative area, clinically and proven on imaging, may or may not necessarily requiring a radiological or surgical intervention to resolve.

Wound infection was defined as an erythema, swelling with purulent discharge from wound with or without systemic features of acute inflammatory response. which was treated with or without antibiotics, local measures or general measure (e.g. vacuum suction dressings,

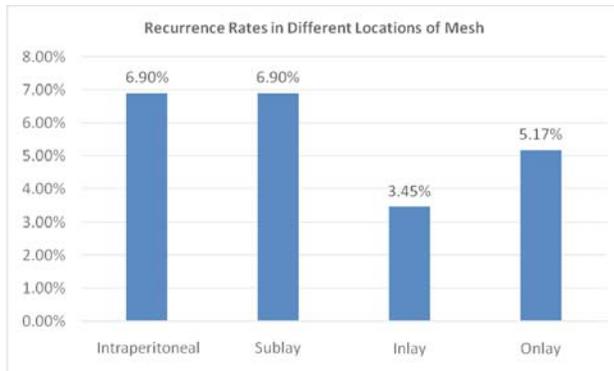


Figure 7: Recurrence Rates in Different Locations of Mesh

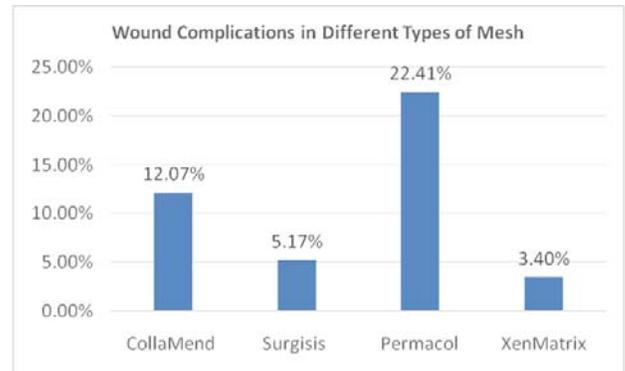


Figure 8: Wound Complications in Different Types of Mesh

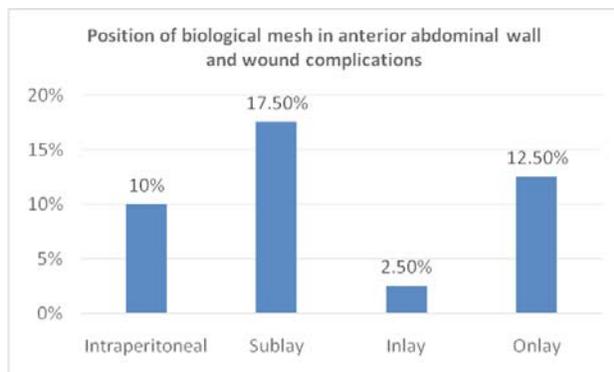


Figure 9: Position of biological mesh in anterior abdominal wall and wound complications

unplanned or early removal of clips/stiches to facilitate drainage of inflammatory fluid, debridement, prolonged antibiotics etc.)

Wound dehiscence was defined as separation of the layers of a surgical wound partial or complete which required local measures such as negative pressure dressing or debridement under general anaesthesia.

Recurrence was defined as a bulge or hernia of any size present at the site of a previous repair, diagnosed by clinically and imaging study regardless of patient symptoms.

Data were analysed using Microsoft Excel and IBM Statistical Programme for Social Sciences (SPSS) version 21. Continuous variables were expressed as mean, standard deviation and range. Categorical variables were described with numbers and percentages. Comparison between variables was analysed with non-parametric

Mann-Whitney U and Wilcoxon Signed Rank test. A P-value of less than 0.05 was considered to be significant. Cox regression model was used to analyse the survival rates.

Results:

A total of 58 procedures were performed in 54 patients where biological meshes were used for reconstruction of anterior abdominal wall during the study period. There were 29 men and 29 women. The age of these patients ranged from 23-83 years with a mean of 62 years.

The mean body mass index (calculated as weight in kilograms divided by the square of height in meters) of these patients was 29.86±7.769 (SD) (range 18-65). ASA grade for 44% of the patients was II. Fig 1

Incisional and parastomal hernia with contamination of the operative fields was the diagnosis in 50% of procedures. Recurrent parastomal and incisional hernia with contamination of operative planes was the cause of use of biological mesh in 26% of patients. Figure 2 shows in detail the diagnosis in these patients.

The size of abdominal wall defects was not accurately recorded in operation notes. There were 67.24% (39) procedures performed electively whereas 32.7% (19) were performed as an emergency. The mean hospital stay for elective cases was 11.26±9.134 (SD) (range 0-35) days whereas the mean hospital stay in emergency cases was 25±18.960 (SD) (range 8-73) days. The combined hospital stay ranged from 0-73

days with a mean of 15.73 ± 14.447 days.

The biological mesh which was used predominantly was Permacol (62.07%, 36). The other types of mesh which were used included CollaMend (25%, 15), Surgisis (6.90%, 4) and XenMatrix (5.17%, 3). Fig. 3.

These meshes were used in at various planes in abdominal wall such as intraperitoneal (20.69%, 12), Sublay (43.10%, 25), inlay (6.90%, 4) and onlay (29.37%, 17) positions. Fig 4.

There were no wound complications in 56.90% (33). Seroma was seen 10.34% (6), superficial wound dehiscence occurred in 15.52% (9) and wound infection occurred in 10.34% (6). Fig. 5

In the group of patients which were complicated by seroma four cases were treated conservatively with success. Seroma was refractory to radiological drainage in two patients and required drainage under general anaesthetics.

Wound infection occurred in 10.34% of cases (6). Five patients were treated conservatively while one patient required debridement under general anaesthesia. Wound dehiscence occurred in 15.52% (9) of the wounds. Three cases were treated with negative pressure suction dressing with complete healing while six cases required debridement in operating theatre. One patient with haematoma underwent successful ultrasound guided drainage of haematoma. One patient with creased mesh required local exploration and made a good recovery.

Urinary tract infection and urinary retention and diarrhoea due to *Clostridium difficile* infection occurred in one patient each. One procedure was complicated by kink in diversion ileostomy which caused intermittent obstruction. This required remobilisation of ileostomy four weeks later.

There was an overall recurrence rate of 22.4% (13), 3.4% (2) in emergency cases and 18.97% (11) in elective cases. The mean follow up was 10.28 months ± 9.541 (SD) (range 0-50 months). Subgroup analysis of types of mesh

and recurrence showed a recurrence of 17.24% (10) for Permacol, 3.43% (2) for Sugisis and 1.72% (1) Collamend. These differences were not statistically significant (Mann-Whitney U test, $p > 0.406$). Figure 6.

Subgroup analysis of locations of mesh and recurrence showed a recurrence of 6.90% (4) each for intraperitoneal and sublay positions whereas 3.45% (2) for inlay and 5.17% (3) for onlay positions. This difference was not significant (Mann-Whitney U test, $p > 0.444$). Figure 7.

Subgroup analysis of wound complications with respect to type of mesh showed an overall wound complication rate of 43.1% (25) with Permacol 22.4%, CollaMend 12.07%, Surgisis 5.17% and XenMatrix 3.4%. This difference was not significant (Wilcoxon Signed Rank test, $p > 0.070$). Figure 8.

Subgroup analysis of wound complications with respect to location of mesh showed an overall complication rate of 43.1% with 10% for intraperitoneal, sublay 17.5%, Inlay 2.5% and onlay 12.5%. Figure 9. This difference was not significant (Wilcoxon Signed Rank test, $p > 0.123$).

Anterior rectus sheath was closed in 55% (32) whereas it was not possible to close the sheath or mesh was in onlay position in 45% (26) cases. There was a recurrence rate of 13% when rectus sheath was closed and 10% when it was not closed. Again this did not reach to a statistical significance (Mann-Whitney U test, $p > 0.475$). However there was a significant difference in wound complications when anterior rectus sheath was closed (Mann-Whitney U test, $p < 0.049$).

There was a 30 day mortality of 6.9% (4) but an overall mortality of 15% (6) over the duration of study period. Although there was an overall mortality of 15.5% (69) in this group of patients but none of the death was related to usage of biological mesh.

Discussion:

The concept of using biologic tissue for struc-

tural repair of abdominal wall defects is nearly a century old. The credit of this concept goes to Otto Loewe who used autologous dermal graft in seven patients.^{8,9} He harvested full thickness skin grafts and then removed their epidermis by scraping them with a knife to obtain the dermis. He used these dermal grafts to repair five hernias, an extensor pollicis longus tendon and to correct a retroverted uterus. Bio-prosthetic meshes are a diverse and expanding class of mesh materials. The examples of these mesh include AlloDerm™, Allomax™, Collamend™, FlexHD™, FortaGen™, Peri-Guard™, Permacol™, Strattice™, Surgisis™, Tutopatch™, Veritas™, XenMatrix™.

Once implanted, there is ingrowth of fibrovascular tissue and repopulation of host cells into these scaffolds provided by such meshes. As a result of this in growth of fibrovascular tissue and repopulation of host cells such mesh are resistant to infection when placed in potentially contaminated fields.¹⁰ Our study examines the use of biological mesh in the management of complex abdominal wall defects at our institutions. The number of total procedures performed in this study is comparable to other studies in literature, though there are some studies of bigger size than this.⁵ About 58% of the procedures were performed at ASA III or more. The mean BMI of 30 indicates a group of patients with obesity, a compounding factor to add not only in the difficulty of procedure but also suboptimal tissue quality as well. The majority of these patients have had a variety of other procedures in the past such as laparotomy, bowel resection, creation of stomas, abdominal aneurysm repairs etc. A quarter of these patients had recurrent incisional or parastomal hernias.

The indications for use of these meshes were varied including incisional hernia, enterocutaneous fistulas, ventral hernias, laparostomy closures following damage control surgery for intrabdominal catastrophe where the operating surgical team found fascial closure difficult without insertion of biological mesh. These cases posed complex surgical management scenarios. All cases involved repair and reconstruc-

tion of anterior abdominal wall in contaminated and in some cases infected fields. As such cases pose a relative contraindication to the use of non-biological prosthetic meshes hence biological meshes were used as preferred by operating surgeons.

Diaz-Siso et al. have reported mortality of 5% in their case series. Similar results have been suggested by the Bellows et al in their recent review as well.^{11,5} Our study shows 30 day mortality of 7% (4) with an overall mortality of 15.5% (9) over the duration of study period but none of the death was related to usage of biological mesh.

The causes of mortality in our series included pulmonary embolism, pneumonia, leukaemia, heart failure due to morbid obesity, metastatic disease and small bowel leak.

Johnson et al, in their review paper, have highlighted an important issue of definition of recurrent hernia versus abdominal wall laxity in such cases where biological meshes have been used for reconstruction of abdominal wall.¹² A clear definition of recurrence of hernia was followed in our study i.e. a bulge or hernia of any size present at the site of a previous repair, diagnosed by clinically and confirmed with imaging regardless of patient symptoms. The reported incidence of recurrence in various studies varies from 0-100% with an overall weighted recurrence rate of 15.2%.⁵ The overall recurrence rate in our study was 22.5%. There were 25% of cases with recurrent incisional hernias in our series and we think this might have skewed the result slightly. Chavarriaga et al in their case series reported a recurrence of 44.4%.¹³ Similar high rates of recurrences have been reported in other studies.^{14,15} Surgical site occurrences following use of biological meshes include infection, haematoma, seroma, pain, bulging, abdominal wall laxity, superficial dehiscence, fistula, skin necrosis, mesh reaction/rejection, poor mesh integration, mesh disintegration, flap necrosis etc. Bellow et al in their recent systematic review of literature suggests a rate of 52.8% wound site occurrences with the use of biological meshes.⁵ The overall rate of surgical site occurrences in our study was

43%. The wound infection rate in our study was 10%. Maurice et al have reported a wound infection rate of 35%, non-infectious wound complications 44% and recurrence of 41%. In a recent review of literature by Slater et al infection occurred in 15.9% (95% CI, 9.8-23.2) but only led to graft removal in 4.9% of cases.¹⁶ These authors were sceptical about the capability of resistance to infection by biological meshes but they suggested that the biologic graft could nearly always be salvaged. Seroma formation is an important complication following incisional hernia repairs. The exact details of pathophysiological processes underlying the seroma formation are still not very clear. Bernatchez et al have stated that seroma formation occurs as a consequence of the inflammatory foreign body reaction with monocytes and macrophages involved at the interface of connective tissue and implant. These monocytes and macrophages produce a variety of cytokines, which regulate and control the local immune response, wound healing and scar formation.¹⁷ Klink et al found several distinct differences between the composition of drainage liquid and seroma fluid, suggesting that seroma formation cannot be a continuation of drainage liquid.¹⁸ The incidence of seroma formation following incisional hernia repair can be seen in 30% of cases.¹⁹ Seromas are usually asymptomatic but can require surgical or radiological intervention in some cases for pain and infection. Promahac et al reported a seroma rate of 21% in their study.²⁰ The seroma rate in our series is 10% which is comparable to other studies. The anatomic plane of the inlay mesh inset has direct implications on the degree of incorporation at the mesh-musculofascial interface.²¹ Some authors prefer to avoid bio-prosthesis in direct contact with peritoneum or preperitoneal fat.²¹ Biological meshes can be used in onlay position which is technically easier to perform but it is not recommended as a primary option. This technique has its inherent mechanical disadvantage against the intrabdominal pressure. In addition, the seroma rate is at least theoretically higher when the mesh is placed in the subcutaneous plane.²¹ However the rate of post-operative wound occurrences or wound complications in

our study seems to correlate with closure of anterior rectus sheath. This difference in result as compared to other studies is not clear.

There are some situations where an onlay mesh repair may be the only safe option, as is the case when it is impractical to re-enter a hostile abdomen or when it is not safely possible to define the anatomy of abdominal wall in previously scarred tissues. The findings of our study show a recurrence 5% for onlay mesh repair. This figure appears to be better than the recurrence rate of intraperitoneal repair (8%) and sublay repair 8%, but this difference is statistically not significant ($p > 0.444$). Similarly, the rate of wound complications in onlay repair group is 12.5% while that for sublay repair is 17.5%. This difference is again not significant statistically ($p > 0.123$). We think that these results may be spurious and might have been misled by the smaller number of patients in onlay group (30%).

The predominant type of mesh which has been used in our study was Permacol (62%). This study shows a recurrence rate of 18% for Permacol mesh which seems to be higher than other types. But this difference is statistically not significant ($p > 0.406$). This trend may also be explained by the smaller number of patients in other types of meshes.

The seroma rate in our study was 10%. We think that a policy of keeping the drain in situ for a longer time period in our department may have contributed to achieve this result.

Our study is limited by the heterogeneity in types of mesh and different types of repairs. There are a number of variables factors in this study and therefore interpretation of specific covariates and their individual impact on outcomes is difficult and probably not feasible.

Another limitation of this study is duration in follow up. The mean follow up in our study is 10.28 months which is comparable with other current studies.^{20,22} But this duration is relatively shorter for interpretation of recurrence and a further review of these results may help to clarify

the recurrence better in future.

Conclusion:

In conclusion, this study demonstrates the safety of various types of biological meshes in complex anterior abdominal wall reconstructions and repairs of hernia defects. There is an acceptable rate of recurrence and rate of complication as compared with the current literature. Further larger studies comparing different types of biological meshes with analysis of long-term outcomes are required to assess the durability of this repair, although the short term results are encouraging.

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Role and contribution of authors:

Dr Syed Mansoor Yousuf, FRCSI, Department of Surgery, University Hospital of North Durham, United Kingdom, did concept, analysis, data collection and final layout.

Dr Fayyaz Akbar, FRCS, Department of Surgery, The Royal Shrewsbury Hospital, Mytton Oak Road, Shrewsbury, did write-up, data collection, and layout

Dr Iain Bain, FRCS, Department of surgery, University Hospital of North Durham, United Kingdom, did data collection, reviewing and final approval.

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