

Hernia

 Springer

The World Journal of Hernia
and Abdominal Wall Surgery

Abstract Book

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P89

Spectrum of clinical presentation and disease association in complex para-oesophageal herniaeP. Mackenzie¹, J.O. Brewer^{1,2}, R. Dean³, S.A. Wajed^{1,3}¹Royal Devon and Exeter Hospital, Upper GI Surgery, Exeter, United Kingdom, ²University of Exeter, Exeter, United Kingdom, ³Peninsula College of Medicine and Dentistry, Exeter, United Kingdom

Background: The aetiology and pathogenesis of complex (giant) para-oesophageal herniae is a topic of debate. Often described as the “great mimic”, it presents in a non-uniform way, and its disease associations not fully understood.

We set out to identify primary reason for referral to a specialist benign upper GI unit, associated secondary symptoms and relevant associated medical conditions.

Methods: A retrospective analysis of patients who underwent laparoscopic repair of large and complex para-oesophageal hernia was performed utilizing the prospectively maintained oesophago-gastric database at the Royal Devon and Exeter Hospital between October 2004 and December 2013.

Primary presenting complaint and associated symptoms were analysed and associated degenerative medical conditions correlated.

Results: 121 cases were identified, including 17 emergencies; 34 Male (median age 67, range 26-82), 76 Female (median age 76, range 52-91). 4 patients were excluded due to poor documentation.

Primary reasons for referral included; obstructive symptoms such as Chest/Abdominal Pain, Dysphagia, Nausea and Vomiting, Early Satiety (n=61, 52.1%), reflux symptoms including Heart Burn and Volume Regurgitation (n=33, 28.2%), respiratory symptoms characterised by Shortness of Breath and Cough (n=12, 10.3%) and Anaemia or Weight loss (n=11, 9.4%).

Nearly all patients (n=113, 96.6%) reported symptoms consistent with episodes of oesophageal obstruction, regardless of their primary presenting complaint.

Prevalence of degenerative conditions in our cohort included; diverticular disease (n=31, 26.5%), abdominal wall hernias (n=17, 14.5%), osteoarthritis (n=29, 24.8%), rectocoeles (n=4, 3.4%), cystocoeles (n=12, 10.3%).

Conclusions: Obstructive symptoms appear to form the mainstay of the clinical presentation.

There is increased frequency of para-oesophageal herniae amongst females, typically presenting in the eighth decade of life.

We have observed a higher incidence of degenerative conditions compared to the general population. Along with para-oesophageal herniation, these are known to increase in prevalence with age, although the exact aetiology remains a matter of uncertainty.

P90

Polypropylene prosthesis in a composite form is colonized by different cell types involved in abdominal wall repairG. Muzio¹, M. Oraldi¹, E. Paiuzzi¹, V. Festa², F. Festa³, A. Chiaravalloti⁴, C. Buemi⁴, R.A. Canuto¹¹Università degli Studi di Torino, Clinical Biological Sciences, Turin, Italy, ²Università degli Studi di Torino, Surgical Sciences, Turin, Italy, ³Maria Vittoria Hospital, Turin, Italy, ⁴Dipro Medical Devices s.r.l., San Mauro Torinese, Italy

Background: Proliferative phase is a crucial step in wound healing, including abdominal wall repair. In this case it takes around three weeks and aims to the regeneration of different abdominal wall tissues and extracellular matrix components, mainly collagen. Different cell types are involved, i.e. fibroblasts, epithelial and mesothelial cells. Other than proliferation, molecular mediators produced by these cells are important modulators of essential processes, as inflammation and angiogenesis. In this view, the ability of prosthesis for hernia repair to promote cell proliferation and specific activity, could be important in improving healing. This research investigated the growth of different cell types on polypropylene composite prosthesis.

Methods: The CMC prosthesis (DIPROMED srl), comprised of two polypropylene layers, one macroporous light meshes (parietal side) and one thin transparent film (visceral side), was used. Human fibroblasts BJ, keratinocytes NCTC 2544, and mesothelial cells isolated from omentum specimens (approved protocol by Ethics Committee) were seeded on CMC (meshes side) or on film. NCTC cells were seeded only on CMC since epithelium should colonized only this prosthesis side. At different experimental times, cell growth and viability were examined.

Results: Counting the number of cells present on CMC and in culture medium evidenced that all cell types well grown on CMC and that no induction of cell death (neither necrosis nor apoptosis) occurred. Interestingly, the evaluation of cells on film alone showed that fibroblasts did not colonized this layer whereas the number of mesothelial cells increased during the time.

Conclusion: The results evidenced that CMC is well colonized by all cell types when cells are seeded on parietal side, whereas the growth on film facing the visceral side seems to be selective. In particular, the observation that mesothelial cells and not fibroblasts colonize the film indicate that CMC can favour peritoneum regeneration, avoiding abdominal adherence formation.

P130**Long-time experience with double layers polypropylene composite prosthesis in laparoscopic hernioplasty: five years follow-up**

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Background: A critical analysis of the main issues and results of laparoscopic treatment was made by a cohort study conducted using laparoscopic approach in the ventral and incisional hernia repair.

Methods: From June 2008 to June 2013 at the S. Giovanni Battista Hospital in Turin, 110 patients were underwent laparoscopic hernioplasty for ventral or incisional hernia. The incisional hernia rate was 72,8%, instead the rest of patients (27,2%) had ventral hernia. The prosthesis used were not-absorbable, different materials, composite meshes, fixed with glue, clips or both. The 51% of patients are treated with CMC, polypropylene double layers composite mesh (DIPROMED srl-Turin, Italy); whereas the 49% with other marketed prostheses (OTHERS). Surgical complications are classified as peri or intra-operative and postoperative, whereas disease recurrence was recorded separately. Follow-up time was between 6 and 60 months. The results were analyzed through "MedCalc" software, using χ^2 test to examine all data and ANOVA One-way analysis of variance for the continuous variables study.

Results: At long follow-up, there were good results with 3 recurrences observed using OTHERS, instead CMC didn't show any recurrence. No postoperative mortality, no wound infection or systemic complications were presented. The complication rate was determined using the recurrences and the complications occurred. All the patients characteristics are statistically analyzed. The results showed a significant trend between the number of defects and post-operative complications: these were higher in patients with multiple defects.

Conclusion: Patients underwent laparoscopic hernioplasty with CMC, had experienced no recurrence and less pain thanks to good tolerance of biomaterial, good handling, ease to fixing and transparency. The evidence was given by a 2,7% recurrence rate in our study. The results are comparable with other studies, in addition to count on the follow-up of longer period. The results confirmed that laparoscopic surgery is an efficient approach in hernioplasty.

P131**Patient reported outcome measurements (PROM) and incisional hernia repair**

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Background: The repair of incisional midline hernias should be performed with a mesh, but the surgical techniques are associated with different panoramas of complications. The patient characteristics demand consideration when recommending surgery. We analysed our RCT to discern the value of preoperative clinical facts related to patient reported surgical outcome.

Methods: The patients of an RCT (PROLOVE trial) on open (OHR) versus laparoscopic (LHR) midline incisional hernia repair were analysed at one year. Four outcomes were used in the binary logistic

regression: event-free recovery, hernia recurrence, satisfied patient, and scoring above median in the norm based SF-36 Physical Composite Score (PCS, norm 50 SD10). Crude, unadjusted, odds ratios (OR) were calculated for clinical predictors: type of surgery, sex, age, BMI, ASA, recurrence, hernia width, smoking, diabetes, heart condition, lung condition, use of steroids, anticoagulants, NSAIDs and insulin, which all were regarded as significant if $p < 0.05$.

Results: After one year 124 (61 LHR, 63 OHR) patients remained for analysis. In total 75% reported an event-free recovery, 5% developed a recurrence, 90% reported satisfaction and the PCS was median 53.2. Favouring an event-free recovery the OR for males were 2.95 (1.16-7.51) and for LHR 3.10 (1.29-7.45). For recurrence no predictors were significant, but hernia width over 5 cm was at the rim (OR 4.59, 0.80-26.3, $p < 0.086$). No significant predictors were identified for patient satisfaction. The only predictor favouring PCS above median was no risk factors present OR 3.31 (1.53-7.16), where the dominant contributor was diabetes 0.18 (0.04-0.84).

Conclusion: Only a few clinical predictors for the PROMs reached significance. LHR was favoured for an event-free recovery only. The wide confidence intervals of several predictors suggest power lacking in this material to clearly support further predictors.

P132**Surgical treatment of ventral hernias in conjunction with morbid obesity**

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The aim: To improve the treatment results in patients with morbid obesity with ventral hernias by developing criteria for choosing the optimal method of hernioplasty and abdominoplasty.

Material and methods: Conducted a retrospective and prospective analysis of results of surgical treatment of 496 patients with ventral hernias.

Morbid obesity 1-4 degree observed at 426 (86%) patients. Ptosis of the abdominal wall is marked in 38 (77.7%) obese patients: 1 degree - 200 (52.1%) of the patients of the 2nd degree - 104 (27.1%) patients, 3 degree - 67 (17.2%) patients, 4 degree - 14 (3.6%) people. An accompanying pathology of the cardiovascular system met 172 (34.7%) patients ventral hernias. Among 426 (86%) of patients with adiposity 310 (73%) had extending down stomach shape. All patients with large and giant ventral hernias (W3, W4) 54 (10.8%) conducted a study of Central hemodynamics method of compression oscillotometry.

Results: All 54 patients with morbid obesity and BMI over 50 kg/m² performed bilio-pancreatic diversion. Combined methods of hernioplasty were used in 17 (31.5%) patients. The maximum level of intra-abdominal pressure (IAP) was 23.6 mm RT. Confidence interval was 20.2-21.3 mm RT ($p < 0.05$). The initial level of IAP was 12.2 ± 0.7 mm RT. century, after the hernioplasty IPA was 21.3 ± 2.3 mm RT. In early postoperative complications have developed 28 (11.3%) patients with ventral hernias W3 W4. Specific complications reported in 6 (9.7%) patients, including seroma 3 (5.7%), surgical site infection - 2 (2.8%), the marginal necrosis of the skin - 1 (1.2%) patients. Non-specific complications were observed in 2 (1.6%) people. There were no lethal outcomes.

Conclusions: Thus, the correction of underlying diseases and differentiated approach to the choice of method for reconstruction of the anterior abdominal wall after bariatric surgery in patients with over obesity and ventral hernias can achieve good aesthetic and functional results of surgical treatment.

P180**Recurrences and adhesions after Physiomesh implantation – Closer to understanding the mechanisms**M. Pawlak¹, M. Śmietański¹, K. Bury²¹*Ceynowa Hospital, General Surgery, Wejherowo, Poland, ²Medical University of Gdansk, Cardiac and Vascular Surgery, Gdansk, Poland*

Background: Long-term mesh related complications are increasingly reported as using synthetic meshes has become the gold standard for almost every abdominal wall defect. In this study we would like to share our experiences with the use of Physiomesh in the IPOM operation and to draw attention to the particularly important complication appearing in the observed group of patients. Using our theoretical models we also try to explain the mechanism behind it.

Methods: In last 3 years almost 100 Physiomesh implants were used for IPOM repair in our department. 72 were included into the database and monitored in the postoperative period. Recurrences and other symptoms requiring hospital readmission were noted and analysed. Reasons and mechanisms of recurrence, time and place of its occurrence and intraabdominal adhesion formation on the mesh were described.

Results: In the minimum 6-months follow-up 4 patients were readmitted to the hospital due to recurrence and one due to subileus like symptoms. All the patients were reoperated. In all cases dense adhesions were found on the majority of the mesh surface. In all cases recurrence were present in the long axe of the mesh in the line of PDS stripe built into the mesh. Tackers were still presented in the abdominal wall fascia, showing the rupture mechanism of connection failure. Recurrences occurred after 6 months, at the time point when stiff PDS stripe underwent degradation.

Conclusions: Stiffness of the mesh in PDS axe could be an independent factor causing recurrences. Special attention must be paid when fixing the mesh in this line. The phenomenon of adhesions is not explicable in the light of our study, still must be a topic of further investigation.

P181**Ultrasound bio microscopy (UBM) and scanning acoustic microscopy (SAM) for the assessment of hernia mesh integration – A comparison to standard histology in an experimental model**A.H. Petter-Puchner¹, S. Gruber-Blum¹, J. Brand¹, R.H. Fortelny¹, H. Redl¹, K. Raum²¹*Ludwig Boltzmann Institute, Vienna, Austria, ²Charité, Berlin, Germany*

Introduction: Mesh integration is a key parameter for reliable and safe hernia repair. So far, its assessment is based on histology obtained from rare second look operations or experimental research. Therefore, non-invasive high resolution imaging techniques would be of great value. Ultrasound bio- (UBM) and scanning acoustic microscopy (SAM) have shown potential in the imaging of hard and soft tissues. This experimental study compared the detection of mesh integration, foreign body reaction and scar formation in UBM/SAM with standard histology.

Materials and methods: 10 titanized polypropylene meshes were implanted in rats in a model of onlay repair. 7 days postOP animals were sacrificed and samples were paraffin embedded for histology (H&E, cresyl-violet) or processed for post mortem UBM/SAM. The observation period was uneventful and meshes appeared well integrated.

Results: Relocation of neighbouring cross sectional levels could easily be achieved with the 40 mHz UBM, whereas the spatial resolution of approximately 8 µm of the 200 MHz UBM system images was comparable to standard histology (2.5-5 x magnification).

Conclusion: This study demonstrates that UBM/SAM is a superior tool to assess hernia mesh integration non-invasively. UBM/SAM offers additional information on biomechanical properties, eg elasticity, which are not accessible by histology.

P182**CMC composite mesh: biological characterization, proteomic analysis and anisotropy as reference study for “MES-STAR” Manunet II – European research project**I. Guerrazzi¹, L. Comelli¹, C. Buemi², A. Chiaravalloti², C. De Maria³, R. Caruso⁴, A. Cecchetti¹, C. Domenici¹, S. Rocchiccioli¹, G. Vozzi³, F. Vozzi¹¹*CNR, Institute of Clinical Physiology, Pisa, Italy, ²Dipromed Medical Devices s.r.l., San Mauro Torinese, Italy, ³University of Pisa, Interdepartmental Research Center “E. Piaggio”, Pisa, Italy, ⁴CNR, Institute of Clinical Physiology, Milan, Italy*

Background: Several commercial products are available for abdominal wall hernia treatment and industries work to improve the implant success. To achieve this goal it is fundamental understand the biological response to prosthesis by host and the biomechanical features of natural tissue that the prosthesis should mimic.

Methods: CMC composite mesh (Dipromed) was seeded with Human BJ Fibroblast to test cytotoxicity and cell growth trend during 21 days. The inflammatory profile (IL-6 and IL-10 ELISA assay) was quantified as also the collagen type I and type III production was highlighted with immunohistochemistry. Mechanical studies were performed to evaluate properties of CMC mesh (anisotropy, Young modulus). A proteomic study was performed to analyse Extra Cellular Matrix (ECM) content. Zimography was used to measure activity of Metalloproteinase (MMP) 2 and 9.

Results: Material is biocompatible (90% viability), with a good cell growth on macroporous polypropylene layer. The inflammatory profile shows an initial secretion of anti-inflammatory IL-10 and a final increase of pro-inflammatory IL-6. Immunocytochemistry highlighted an increase of Collagen type III respect to type I. CMC presents an anisotropy similar to that of natural tissue. The proteomic analysis shows a rising amount of ECM protein content (collagens, fibronectin, laminin). MMPs are both up-regulated when in contact to mesh.

Conclusion: The CMC mesh shows a good cellular growth, indicating a satisfying rate of cell adhesion, confirmed by high rate of therapy hernia success. The preliminary data of proteomic analysis highlights the heterogeneous families of ECM released proteins, useful for future development studies. The increase of IL-6 cytokine, Collagen type III and MMPs are all elements to take in account for new product development. All these elements must be take in account as decision making in the MES-STAR research project.

P183

Advanced design with FEM modelling and mechanical characterisation to develop functional hernia prosthesis: an innovative approach developed in MES-STAR European project

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Background: Nowadays more than 166 different types of prosthesis are on the market, making it rather difficult to choose that it is appropriate for the different clinical cases. The aim of this study is to show how the combination of Finite Element Modeling analysis and mechanical characterization can help in the advanced design of mesh commonly used to repair defects to the abdominal wall.

Methods: This research has been performed on Clear Mesh Composite (CMC) produced by Dipromed s.r.l. This prosthesis is composed of two different components. The first element is a polypropylene film with an average thickness of $50 \pm 5 \mu\text{m}$, performed in an elliptic shape that can have different sizes depending on the defect present in abdominal wall. The second element is a monofilament woven mesh called Evolution with an average thickness of $460 \pm 5 \mu\text{m}$. Film and mesh are sawed with a polypropylene wire. Each part and the whole prosthesis has been modeled using Ansys software and also experimentally tested using Instron device.

Results: The results of FEM analysis show that the stress and the strain on the mesh are uniformly distributed without generating critical points. Only in the CMC prosthesis there is just an increased load in the contact points between mesh and film, that it is normal, because it is important to ensure a strong bond between the two parts that compose it. The comparison with experimental test performed on CMC prosthesis and on each of its parts shows that there is a good fitting between them. Moreover its anisotropy is similar to that of natural abdominal wall.

Conclusion: With this study we showed that the use of FEM analysis combined with mechanical characterization is a valid approach to select and design an advanced and functional prosthesis, as CMC demonstrated to be.

P184

Influence of topography, stiffness and anisotropy in the tissue integration and absence of adhesion of a totally polypropylene clear mesh composite: a reference study for MES-STAR European project

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Background: The tissue integration and the formation of adhesions in the repair of abdominal wall defects seem to depend upon the topology and the mechanical features of the prosthesis. In this study we will analyse how the surface morphology, the stiffness and anisotropy of a material (polypropylene, PP) used for the realization of hernia prosthesis influence tissue repair ability, prevent and minimize the formation of adhesions, and to promote tissue ingrowth.

Methods: Two series of *in vivo* studies were performed. In the first, two types of PP meshes were compared to determine the good possibility for tissue integration, a lightweight macroporous mesh (Evolution-Dipromed srl, Italy) and a heavyweight microporous mesh. In the second *in vivo* study, the new Clear Mesh Composite (CMC) (Dipromed) was compared with a PP planar film, with the aim to demonstrate how the mechanical properties and the topology of a prosthesis influence tissue integration with the abdominal wall and minimize adhesion with internal organs. In both studies, the prosthesis was implanted in Wistar rats and histological analysis and the mechanical characterization of tissue coupled with the implanted meshes were performed.

Results: Lightweight macroporous mesh showed better host tissue ingrowth in comparison to heavyweight one. CMC prosthesis showed no adhesions to the viscera and no strong foreign body reaction. Moreover the mechanical tests indicated that it presented an elasticity and anisotropy index more similar to that of natural tissue.

Conclusions: The change of topology and mechanical features of a PP hernia prosthesis allows to modulate the repair ability of a surgical mesh. Macroporous mesh gives better results in terms of tissue integration. The CMC prosthesis reveals to be a promising device for treatment of abdominal hernias because the macroporous mesh side promotes tissue ingrowth and the smooth film does not adhere to viscera.

P185

Bovine versus porcine acellular dermal matrix: a comparison of mechanical properties

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Background: Porcine and bovine acellular dermal matrices (PADM and BADM, respectively) are the most commonly used biologic meshes for ventral hernia repair. A previous study suggests a higher rate of intraoperative device failures using PADM than BADM. We hypothesize that this difference is, in part, related to intrinsic mechanical properties of the matrix substrate and source material. The following study directly compares these two matrices to identify any potential differences in mechanical properties that may relate to clinical outcomes.

Methods: Sections of PADM (Strattice, Lifecell) and BADM (SurgiMend, TEI Biosciences) were subjected to a series of biomechanical tests, including suture retention, tear strength, and uniaxial tensile strength. Results were collected and compared statistically.

Results: In all parameters, BADM exhibited a superior mechanical strength profile compared to PADM of similar thickness. Increased BADM thickness correlated with increased mechanical strength. In suture tear-through testing with steel wire, failure of the steel wire occurred in the 4 mm – thick BADM whereas the matrix material failed in all other thicknesses of BADM and PADM.

Conclusions: Before implantation, BADM is inherently stronger than PADM at equivalent thicknesses, and considerably stronger at increased thicknesses. These results corroborate clinical data from a previous study in which PADM was associated with a higher intraoperative device failure rate. Although numerous properties of ADM contribute to clinical outcomes, surgeons should consider initial mechanical strength properties when choosing acellular dermal matrices for load-bearing applications such as hernia repair.