BIOCOMPATIBILITY - REVOLVING ISSUE FOR BIOMATERIALS IN CONTAMINATED FIELDS: NOVEL THERAPEUTIC SOLUTIONS FOR COMPLICATED INCISIONAL HERNIAS

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Incisional hernias occur in nearly 20% of all abdominal procedures. Emergency repair is challenging and has limited the use of prosthetics in the past, especially if the operating field is contaminated to a certain degree. On the other hand, primary repair of abdominal wall defects has a high recurrence rate, ranging between 10 and 50% because of intrinsic parietal tension and myocutaneous flap necrosis. Growing interest for minimally invasive surgery and reduced hospital stay when repairing abdominal wall defects has led to research and development in the field of prosthetics that can serve those aims. Biomaterials, such as collagen impregnated meshes, seem to offer new possibilities for prosthetic repair of complicated incisional hernias, emergency incisional hernia surgery and mesh placement in contaminated fields. The article presents a retrospective study on biocompatibility and late tissue reactions, determined for complicated incisional hernias. The study relies on a 5 years' experience (2009-2013), analyzing 195 emergency prosthetic repairs for complicated incisional hernias versus 195 repairs for uncomplicated incisional hernias. The assessment of postoperative complications for the study parameters showed no significant differences between the two groups. The results promoted the development of a protocol for parietal prosthetic repair using biomaterials (collagen impregnated meshes) in complicated incisional hernias (i.e. Altemeier class III surgical wounds).

Keywords: biomaterials, biocompatibility, complicated incisional hernias

INTRODUCTION

Incisional hernias occur, according to different authors (Alaedeen *et al.*, 2007), in up to 20% of all abdominal procedures. Emergency repair of incarcerated incisional hernia with or without bowel obstruction, in potentially contaminated fields is challenging due to edematous, inflamed and friable tissues with occasional need for concurrent procedures (small bowel, colonic resections, stoma revisions or take-down) and therefore with higher rates of postoperative complications, infectious or otherwise (Davies *et al.*, 2007).

Primary repair of incisional hernias has high recurrence rates ranging between 10% and 50% primarily because of the tension created and myocutaneous flap necrosis (Burger *et al.*, 2004). Many techniques have been proposed over time to reduce tension, such as relaxing incisions and compartment release. Results are far from being optimal. In addition, large, full thickness abdominal wall defects secondary to wide resection of cancer, traumatic injuries or congenital abnormalities, cannot be closed primarily. The use of prosthetic meshes has become necessary. Along with the traditional open techniques of mesh implantation, the recent laparoscopic techniques have gained popularity because of the decrease in wound infection, recurrence rates and recovery time.

There is constantly growing interest for minimally invasive surgery and reduced length of hospital stay. This has stimulated the medical industry in the development of new materials that support these aims. Biological materials are an important component

of surgical treatment of incisional hernias. The ideal biological material must allow a perfect biological interaction with the environment in which it is implanted, and must therefore possess high biological compatibility and biodegradability. The biological materials currently on the market exhibit total resorption and are biologically compatible, carrying out four important physiological functions: adhesion, hemostasis, sealing and repair. The repair of complex contaminated abdominal wall defects is even more challenging. The fear of fibrosis, erosions, infection and fistulas with the prosthetic meshes commonly used has led engineers and doctors to investigate biological meshes. Biological grafts seem to offer a solution. Their aim is to provide a collagen and other extracellular matrix scaffold, in which the host fibroblasts can create angiogenesis and deposit new collagen. The non-synthetic nature of these products allows them to be more resistant to infections. Several biological grafts are available on the market. Their classification is based on the species of origin (allogenic, xenogenic), type of collagen matrix utilized (dermis, pericardium, intestinal submucosa), decellularization process, presence or absence of cross-linking, storage requirements (need for refrigeration, need for rehydration) (Cavallaro *et al.*, 2010). Porcine dermal collagen is now indicated in the following situations: complicated incisional hernias with septic or contaminated surgical fields, contact of the mesh with the bowel, stomal hernias, cases with associated bowel resections and anastomosis, patients with infected previously placed synthetic meshes (Armellino *et al.*, 2006).

According to the literature, the use of meshes reduces the recurrence rate but is also associated with serious complications in 10%-15% of cases. Infection, fistula, skin erosion often lead to mesh removal (Buinewicz and Rosen, 2004). Using meshes in contaminated wounds leads to removal in 50% to 90% of cases (Szczerba and Dumanian, 2003). Ideal meshes should posses proper strength, should be compatible with host tissues and have an ability to avoid infections. Many synthetic and biological mesh tissues have been proposed over time but no single material, nor newer biosynthetic mesh, has fulfilled these requirements and gained universal acceptance (Cavallaro *et al.*, 2010).

Incisional hernia repair in the setting of surgical field contamination is a delicate subject. Advocated mesh use for incisional hernia repair in order to lower recurrence rates changes in cases with contamination. The principles of repair are removal of the source of contamination and reconstruction of the abdominal wall.

Associated colonic procedures (contaminated and infected, class III-IV Altemeier classification) at the time of repair strongly discourage the use of meshes (Machairas *et al.*, 2008). The use of meshes has been discouraged by authors if open bowel is encountered during repair (Morris-Stiff and Hughes, 1998). The risk of using a foreign body (mesh) for incisional hernia repair was highlighted by Korenkov *et al.* (2002) who found high rates of chronic postoperative pain and wound infection. Some authors feel that hernia repair should be postponed and done separately if intestinal resection is required (Temudom *et al.*, 1996).

The paper presents descriptive retrospective study based on authors' recent experience with incisional hernias.

MATERIALS AND METHOD

The paper compares incisional hernia treatment and outcome in 390 patients, 195 presenting for elective surgery and 195 presenting for emergency procedures with complicated incisional hernias. The patients were all operated on by a team of surgeons

using standardized techniques (on-lay, in-lay, under-lay) and a prosthetic mesh (polypropylene, collagen impregnated composite dual-mesh) was used in all cases. Data was recorded over a period of 5 years (2009-2013) from patient charts, operative notes and follow-up records. Follow up was attempted in all cases for a period of one year.

The three types of meshes used for incisional hernia repair are shown in Table 1: synthetic polymers, composites and biological prosthesis. The prosthesis can be placed in a pre-fascial site (subcutaneous), intra-parietally (pre-peritoneal) or in an intra-peritoneal site. The choice of prosthesis thus depends on the site where it will be implanted - a reticular mesh (polypropylene or polyester) in a pre-fascial and intra-parietal sites (Chevrel or Rives procedure), a laminar (ePTFE) or a composite prosthesis intra-peritoneally since they avoid adhesion formation with the intra-abdominal viscera.

Table 1. Types of prosthetic materials for incisional hernias

Synthetic	
Non-absorbable polymers	Polypropylene
	Polyester
	Expanded polytetrafluoroethylene (ePTFE)
Absorbable synthetic polymers	
Composites	
Biologic prosthetics	Human
	Bovine, Swine

EXPERIMENTAL AND RESULTS

During the five years of the study (2009-2013), 390 patients operated for incisional hernias were evaluated preoperatively and postoperatively. The studied population consisted of 257 (65.9%) female subjects and 133 (34.1%) male subjects showing an approximately 2:1 female to male ratio. Of the 390 patients 195 presented for elective incisional hernia surgery and 195 were operated for complicated incisional hernias in an emergency setting. Mean age was comparable for both groups, 56 years old overall.

Various sites for incisional hernias were recorded, as follows: for the elective surgery group (uncomplicated incisional hernias) 112 (57.4%) cases were in the lower abdomen on the midline, 72 (37%) cases were in the upper abdomen on the midline and 11 (5.6%) cases were flank hernias; for the emergency surgery group (complicated incisional hernias) 76 (39%) cases were in the lower abdomen on the midline, 69 (35.4%) cases were in the upper abdomen on the midline, 43 (22%) cases presented with flank hernias and 7 (3.6%) cases presented with para-stomal hernias. All para-stomal hernias were considered complicated due to the inherent septic nature of the procedure regarding mesh placement. A slight overall predominance of lower midline incisional hernias was observed. Mean diameter of the abdominal wall defect observed was 7.9 cm for the uncomplicated group and 6.3 cm for the complicated group.

The 195 patients in the uncomplicated group all had clean wounds and required no additional septic procedures during surgery. The patients in the complicated group were selected so that their Altemeier wound class was no greater than class II. They presented with incarcerated hernias and problems concerning bowel integrity. Only patients without bowel necrosis that required no procedure or patients with small bowel necrosis but no spillage were selected for the study group. In the case of patients with bowel necrosis enterectomy (either mechanical or hand-sewn) was performed. No patients with colonic necrosis and associated colon resections were included. Of the 195 patients

of the complicated group, 127 presented without bowel necrosis and 68 patients presented with small bowel necrosis and required enterectomy with no spillage of bowel content. All patients in the complicated group had clean (Altemeier class I) or clean-contaminated (Altemeier class II) wounds.

ASA score for the uncomplicated group was distributed as follows: ASA I in 52 (26.4%) cases, ASA II in 78 (40%) cases and ASA III in 65 (33.3%) cases. For the complicated group of patients ASA IE was recorded in 19 (9.7%) cases, ASA IIE in 53 (27.3%) cases, ASA IIIE in 97 (49.7%) cases and ASA IVE in 26 (13.3%) cases. The procedures performed can be classified in onlay techniques (mesh placed above the aponeurosis), sublay techniques (mesh placed over the closed posterior rectus sheath) and inlay techniques (mesh placed intraperitoneally). All cases were operated in an open fashion. The meshes used for repair were monofilament polypropylene for the onlay and sublay techniques and a composite mesh impregnated with bovine collagen - polyester and absorbable hydrophilic film for the intraperitoneal technique. Mean operating time was 130 minutes for the onlay technique, 190 minutes for the sublay technique and 125 minutes for the intraperitoneal approach. Procedures were divided between the two studied groups as follows: for the uncomplicated group 113 (57.9%) onlay procedures, 46 (23.5%) sublay procedures and 36 (18.5%) intraperitoneal approaches; for the complicated group 82 (42%) onlay procedures, 51 (26.2%) sublay procedures and 62 (31.8%) intraperitoneal approaches. Of the 68 patients that required enterectomy, the abdominal wall was repaired in 53 cases with an intraperitoneal approach and in 15 cases with a sublay technique.

Mean hospital stay was 3 days for the patients in the uncomplicated group. The complicated group had a mean hospital stay of 4 days for patients that did not require enterectomy and of 6 days for patients that presented with bowel necrosis. Postoperative pain was handled adequately in both groups; bowel function return was day 2 on average for uncomplicated hernias and day 4 for complicated ones with no difference regarding bowel necrosis or not. Length of hospital stay was increased in the group with bowel necrosis and enterectomy probably due to surgeon preference.

Table 2 shows the types of complications and their occurrence. A slight increase in complication rates can be observed between the group that required enterectomy and the group that did not. Overall complication rates, however, remain comparable. Prosthesis infection was managed in all cases with mesh removal and an alternate repair without mesh was used. One year follow-up was possible in 373 patients and chronic pain and recurrence were investigated at this point. 13 patients died during the immediate postoperative period, 5 patients from the group with enterectomy, 3 from the complicated group that did not require enterectomy and 5 patients that presented with uncomplicated incisional hernias. 8 deaths were related to sepsis and 5 to pre-existing comorbidities.

Table 2. Complications following surgery

Complication	Uncomplicated incisional hernias n (%)	Complicated incisional hernias Enterectomy (-) n(%)	Enterectomy (+) n(%)
Seroma	65 (33.3%)	34 (17.4%)	41 (21%)
Hematoma	22 (11.2%)	12 (6.1%)	7 (3.6%)
Prosthesis infection	11 (5.64%)	2 (1%)	7 (3.5%)
Fistula	4 (2%)	5 (2.5%)	9 (4.6%)
Skin necrosis	2 (1%)	0	1 (0.5%)

Complication	Uncomplicated incisional hernias n (%)	Complicated incisional hernias Enterectomy (-) n(%)	Enterectomy (+) n(%)
Chronic po pain	36 (18.46%)	21 (10.7%)	17 (8.7%)
One year recurrence	27 (13.8%)	13 (6.6%)	20 (10.2%)

Various techniques for mesh placement are currently used without generalized consensus, the most common being onlay, sublay and intraperitoneal underlay. The sublay Rives-Stoppa technique has been advocated to have low infection rates but it also comes at the expense of longer operating times which could prove to be ever important in cases that require emergency surgery. Veillette *et al.* recorded mean operating times of 131 minutes for primary repair, 141 minutes for onlay procedures and 231 minutes for Rives-Stoppa (Veillette *et al.*, 2001). The present study found a clearly longer mean operating time for Rives-Stoppa recorded at 190 minutes compared to the other mesh procedures that required 130 and 125 minutes. Emergency surgery for patients with incarcerated incisional hernias and bowel obstruction sometimes places the surgeon in the setting of hemodynamically unstable patients and the time-consuming Rives-Stoppa procedure might prove costly. Our study showed a slight preference for intraperitoneal mesh placement in the setting of complicated hernias when compared with the uncomplicated group. Zafar *et al.* advocated the use of an onlay technique and an open wound treated with daily dressings until neoepithelization for contaminated wounds (Zafar *et al.*, 2012). Consensus is lacking in regards to the best technique to be used for the treatment of incisional hernias, especially in the context of wound contamination.

DISCUSSIONS AND CONCLUSIONS

The study shows that synthetic meshes are relatively safe to use in clean or clean contaminated incisional hernia repairs. It also shows that a preference to use collagen composite dual-mesh with higher rates of surgical field contamination is justified. Although complication rates are higher for clean-contaminated wounds, the overall rates do not differ from complicated to uncomplicated. A preference was noted for intraperitoneal repairs with composite meshes in the setting of clean contaminated wounds. Length of hospital stay was larger for patients with complicated hernias although not always supported by objective factors. The new additions of biological materials to the market have driven us to elaborate a protocol for mesh placement in contaminated surgical wounds (i.e. Altemeier class III). Still, mesh removal after infection and a high recurrence rate regardless of the procedure or mesh used, are problems that need to be resolved in the following period.

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