ORIGINAL ARTICLE

EXPERIMENTAL STUDY ON ANIMAL MODELS TO EVALUATE DIFFERENT MESH MATERIALS FOR INTRAPERITONEAL PROSTHESIS AND DIFFERENT WAYS OF FIXATION BY GLUES AND STAPLES

Stefano Olmi,[1] Ahmed Talha,[1,2] Giovanni Cesana,[1] Alessandro Addis,[3] CinziaDomeneghini[3]

[1]Department of Surgery, Policlinico San Marco, Zingonia-Osio Sotto (BG), Italy, [2]Department of Surgery, MRI, Alexandria University, Egypt, [3]Faculty of Veterinary Medicine, University of Milan, Italy

Correspondence to: Ahmed Talha, Email: ahmedtalha047@yahoo.com

Abstract

Summary Background Data: Feasibility of laparoscopic repair of the abdominal wall defects have been widely documented and showing good characteristics in terms of a reduction of morbidity, postoperative pain, intervention times and hospitalization, a reduction of wound complication and a further reduction of recurrences.

Objective: The aim of this study was to determine the best intraperitoneal mesh material and the best fixing device for laparoscopic repair of abdominal wall defects and, secondly, to verify its feasibility and safety.

Materials and methods: The tests were carried out on 5 pigs, in accordance with all international laws, ethics, regulations and quality criteria. In each pig we positioned 5 different meshes in each hemi-abdomen (Parietex, Hi-Tex, Proceed, Composix and Goretex) and fixing them with 5 different fixing devices (Tissucol, Glubran, Quixil, EMS and Protack). We carried out a laparoscopic second look at 15 and 30 days, and biopsies were taken for histological analysis and strength tests after pig's suppression.

Results: No intra-operative and post-operative complications were observed. The best mesh material resulted to be Parietex, Composix and then Hi-Tex, with the best reperitonalization, no adhesions, no shrinkage, no migration of the mesh and good tensile strength. Histopathological analysis confirmed a greater stability and great tissue integration.

Conclusion: This study showed that the best intraperitoneal prosthetic materials for laparoscopic repair of abdominal wall defects were Parietex, Composix and Hi-Tex, with the use of Tissucol and Quixil as fixing devices for the prosthesis.

Keywords: Laparoscopic repair, Intraperitoneal prosthesis, Dual mesh, Fixing device, Abdominal wall defect.

INTRODUCTION

The term defects of abdominal wall include a great variety of fascial defects; epigastric, umbilical, Spigelian and incisional hernias. Among these, incisional hernias are the most frequent ones, with a reported incidence of 2-20% as a complication for patients who underwent a laparotomy.[1-3] and more than 23% in patients who reported an infection of the surgical wound.[4-6]

The introduction of prosthetic materials has revolutionized the surgery of wall defects introducing the concept of tension-free repair,[7-10] decreasing the recurrence rate to less than 10%;[11-12] anyway, the need for great dissection for the positioning of the mesh contributed to increase the wound infection rate and the complications bound to the surgical wound (12%).[13- 14]

Such problems stimulated a continuous research of new techniques in abdominal wall hernioplasty. Laparoscopic treatment of abdominal wall defects is quickly evolving, showing good characteristics in terms of a reduction of morbidity, postoperative pain, intervention times and hospitalization, a reduction of wound complication and a further reduction of recurrences.[15-18]

Considering, new problems arose regarding the intraperitoneal positioning of the prosthesis, which leads to a direct contact between prosthesis and abdominal organs. This may lead to an inflammatory response towards the prosthetic material, to the formation of an adhesive syndrome[1-4] which can cause chronic pain,[5] intestinal obstruction,[6,20-21] sterility[9] and enterocutaneous fistulas.[21-22] More, intestinal adhesions may complicate future surgical procedures.[23]

Currently, the prosthetic biomaterial used more often is polypropylene,[10] reticular prosthesis which grants optimal tissue integration, relatively cheap and manageable. However, polypropylene may cause significant abdominal adherences.[11,22-23]

The necessity of a prosthesis that can avoid all these consequences lead to the introduction of expanded polytetrafluoroethylene (ePTFE) and of composite prosthesis, that promote tissue growth of abdominal wall from one side, and prevents abdominal adhesions from the other. In this case also, reduction of adhesions formation is often associated to a reduction of tissue regeneration or of an increasing in susceptibility to infection.[24-25]

Laparoscopic technique is based on prosthesis positioning in the intraperitoneal space, granting a wide overlap of the mesh on the abdominal wall defect, and fixing it by the means of biological or synthetic sealants and staples.[28-30]

However the use of staples for fixing the prosthesis can cause pain in 25.6% of patients in immediate postoperative period,[31] in 7.4% of patients after 2 months and in 1-3% after 6 months; cause of nervous entrapment can often solved with staples removal by laparoscopy.[31-32]

However, comparative characteristic of these biomaterials and differences in tensile characteristic, especially long term, have not been accurately described. In this study, our goal was to evaluate the differences among 5 different prosthetic materials, macroscopically, evaluating adhesions formation, tensile strength and shrinking; and microscopically, in term of tissue integration, reperitonalization and inflammatory response and also, evaluation of different way of fixation, making a comparison among biological and synthetic sealants and positioning of staples.

MATERIAL AND METHODS

The study was carried out on 5 pigs (Susscrofa domestics), each weighing 30-40 kg, of the same sex and about 6 months old. The animals were stabled 7 days before the operation and monitored for physical-chemical characteristics. They were treated in accordance with the policies and the principles of standard laboratory animal care and with the European Union guidelines (86/609/EEC) approved by the Italian Ministry of Health (Law 116/92).

Sedation was obtained in 10 minutes using azaperon (4 mg/kg) and midazolam (0.5 mg/kg) intramuscular.

Anaesthesia was induced with a mask sing alitane 5% and maintained, keeping the animals in a condition of spontaneous breathing, with inhalation of seforane 4% in 100% of oxygen. Intra operative analgesia was obtained with continuous infusion of fentanyl (0.03 mg/kg/h ev) and postoperative with flnixin (2 mg/kg). The animals were monitored and controlled daily during the entire study period in order to continually assess their state of health. In this context, no particular behavioural or physiological changes were noted. At the end of the predetermined period of stabling, the animals were subjected to general anaesthesia a second time to perform necessary biopsies for the anatomicopathological study. These biopsies were executed during a laparoscopic second look at 15 and 30 days, testing the fixation of the mesh and sampling the mesh for histology. A veterinarian pathologist analyzed all the samples. Still under general anaesthesia, one pig was sacrificed with potassium chloride.

Prosthesis:

Five different prosthesis were used, of 7 cm x 5 cm, each positioned in each hemi-abdomen and fixed with five different fixing devices;

- Parietex Composite® (Covidien):

  This mesh is made of polyester and coated with a hydrophilic collagen-glycerol-glycolic polyethylene film on the side facing the bowel loops as protection against adhesions; it is reabsorbable within 1 month. Its structure (three-dimensional multifilament fiber) speeds up the process of cellular integration and revascularization and also provides the mesh with elasticity.

- **Composix® (Bard):**

  Composed of a layer of polypropylene and a layer of ePTFE, tied together with a monofilament of ePTFE. The superficial layer stimulates tissue growth, while ePTFE protects the bowel from adhesions formation. It assures a high resistance to rupture and traction.

- **Proceed® (Ethicon):**

  Laminar prosthesis, thin and flexible, multilayer, made of oxidized regenerated cellulose, of a light non-absorbable mesh.

- **Hi-Tex® (Textile, Celbio):**

  Composite prosthesis made of a polytetrafluoroethylene (PET), covered on one side by polyurethane.

- **Dual Mesh Goretex® (Gore):**

  Biomaterial combines proven reliability, proven performance and unique material. The biomaterial offers two distinct surfaces and is designed for intraperitoneal hernia repair where adhesions to the bowel or bowel erosion are a concern.

Fixing devices:

Biological sealants have been used are; Tissucol® (Baxter) and Quixil® (Ethicon) and synthetic; Glubran ® (Gem); and metallic staples are EMS® (Ethicon) and Protack® (Covidien).

Tissucol®:

Tissucol fibrin glue is produced by combining human-derived fibrinogen and human-derived thrombin activated by calcium chloride, leading to the formation of a matrix of polymerized fibrin fibres. Tissucol is an adjuvant to haemostasis, and it has also been shown to have adhesive properties, promote wound healing and enhance fibroblast proliferation. In abdominal wall reparation, Tissucol is diluted with distilled water to retard the polymerization process to 3 minutes, permitting then a uniform distribution on the entire surface of the Prosthesis.

The standard dilution for a 2-ml package (50 IU of 1:10 thrombin and 25 IU of 1:20 thrombin) of thrombin using distilled water was as follows:

1. Remove the black 2-ml syringe containing the thrombin solution from the Duploject.
2. Discard 1.8 ml of thrombin and leave 0.2 ml in the syringe.
3. Draw 1.8 ml of distilled water into the syringe containing the 0.2 ml of thrombin.

Quixil®:

A biological surgical sealant for human use, made of two components: a biological active component and thrombin, mixed at the moment of use. It is an adjuvant to haemostasis, and it has also been shown to have adhesive properties, promote wound healing and enhance fibroblast proliferation.

Glubran 2®:

A synthetic surgical sealant made of cyanoacrilate. GLUBRAN 2 is synthetic cyan acrylic surgical glue modified by addition of a monomer synthesized by the manufacturer. GLUBRAN 2surgical glue has outstanding haemostatic and adhesive properties, and once set, the glue produces an effective antiseptic barrier against infectious or pathogenic agents commonly found in surgical operations. On contact with living tissue in a moist environment, it polymerizes rapidly to create a thin elastic film of high tensile resistance which guarantees firm adherence of tissues. The film conforms naturally to tissue anatomy where it has been applied, is impermeable and is not impaired by blood or organic fluids. The polymerization time depends on the type of tissue with which the glue comes into contact, the amount and nature of the fluids present and the amount of product applied. When applied properly, the glue starts to set after 1-2 seconds, completing its setting reaction after about 60-90 seconds.

EMS®:

Particular titanium 10 mm staples with a wide depth of 3.8 mm and a width of 8 mm which fixes firmly. The particular shape of these staples reduces the risk of nerve entrapment.

Protack®:

These are titanium staples, helical in shape. The diameter of these fasteners measures approximately 4 mm and the length is approximately 3.8 mm with this particular shape that gives a firm fixation of the prosthesis.

Surgical technique: The pig is placed in the supine position with a slight anti-Trendelenburg tilt. A pneumoperiteoneum is induced by means of a Veress needle inserted above the umbilical scar so that the scope is as far as possible from the operative site. After a pressure of 12 mmHg is obtained, a 12-mm trocar is inserted in place of the Veress needle. A 30° scope is inserted which allows a better view than that obtained with a flat scope. The other two 5-mm trocars are inserted under direct view on the xyphopubic line; the trocars should form a triangle converging toward the defect.

After the mesh is introduced through the 12-mm trocar (rolling it up as a cigarette with the collagen film on the inside), it is unrolled and carefully spread so that the non-adhesive side comes into contact with the bowel loops. After positioning them on the abdominal wall we fix the meshes with the different methods that we want to study.

A special device (Duplotip®; Baxter International) is used to apply the Tissucol through the 5- mm trocar in concentric circles, beginning from the outer margin of the mesh.

Fixation of Quixil is the same as that of Tissucol, using its own dispenser, able to mix the two components at the moment of the application on the prosthesis. Glubran is applied directly on the prosthesis by percutaneous way, with straight needles passing from the outside of the abdominal wall. To position EMS® and Protack®, we place a first round of staples to 1 cm to the margin of the prosthesis, and a second one 2 cm.

Before desufflation, we check for haemostasis then, extraction of the trocars under direct vision.

RESULTS

We did not observe intraoperative and postoperative complications on the pigs. Our results are based on micro and macroscopic evaluations and in textile strength.

Microscopic evidences:

We gave a laparoscopic second look, after 15 and 30 days, pulling on the meshes to test adhesion and taking samples of mesh for histology. A veterinary pathologist performed the histological analysis on all specimens.

Results of second look at 15 days: (Tables I, II)

Tissucol + Hi-Tex (Fig. 1) – The prosthetic material is visible in the form of small clusters surrounded by a thin connective capsule that can be identified by giant cell foreign body, inflammatory cells (lymphocytes, macrophages), and small capillaries. Connective tissue interposed between the individual clusters of prosthetic material is a fabric very period of mesenchymal-like appearance. Not visible on the peritoneum.

Tissucol + Parietex – The prosthetic material is visible in the form of large aggregates on average surrounded by a thin connective capsule that can be identified by numerous giant cells, foreign body, inflammatory cells (lymphocytes, macrophages), and small capillaries. Within the cluster, the net prosthesis is apparently very cohesive, and among them are sometimes visible glue residues. Connective tissue interposed between the individual clusters of prosthetic material is a fabric very period, in part to mesenchymal-like appearance. The peritoneum appears well structured.

Tissucol + Proceed – The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective matrix, surrounded by a connective capsule rather thin and uneven, full of giant cells. Connective tissue interposed between the individual clusters of prosthetic material is a fabric very period, in part to mesenchymal-like appearance. The peritoneum has a distorted structure, oedematous and hyperaemic.

Tissucol + Composix – The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective matrix, surrounded by a capsule consisting of connective, in which giant cells are present in low numbers and vice versa are very abundant phenomena of neo-vascularization. Connective tissue interposed between the individual clusters of prosthetic material is a fabric very period, in part to mesenchymal-like appearance. The peritoneum is showing a highly disepithelizedhaemorrhagic phenomenon.

Goretex + Tissucol not accessible for intraoperative detachment of the prosthesis

Quixil + Hi-Tex (Fig. 2) – The prosthetic material is visible in the form of small clusters surrounded by a capsule consisting of connective where they are identifiable in large quantities from giant cell foreign body, inflammatory cells (lymphocytes, macrophages), and numerous capillaries. Among the net formed by the prosthetic material are sometimes visible glue residue. Connective tissue interposed between the individual clusters of prosthetic material is a fabric very period, in part to mesenchymal-like appearance. The peritoneum is highly disepithelized and sub-serous tunic hypertrophic.

Quixil + Parietex – The prosthetic material is visible in the form of large aggregates on average surrounded by a thin connective capsule that can be identified by numerous giant cells, foreign body, inflammatory cells (lymphocytes, macrophages), and small capillaries. Within the cluster, the net prosthesis is apparently very cohesive, and among them is sometimes visible glue residue. Connective tissue interposed between the individual clusters of prosthetic material is a fabric very period, in part to mesenchymal-like appearance. The peritoneum appears well-structured.

Quixil + Proceed – The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective matrix, surrounded by a capsule of connective granulomatous and non-homogeneous, which are abundant haemorrhagic phenomena. Connective tissue interposed between clusters of prosthetic material has an appearance in the "mature". The peritoneum appears well-structured, but is frequently haemorrhagic phenomena.

Quixil + Composix – The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective matrix, surrounded by a connective capsule in which the giant cells are present in low numbers and vice versa are very abundant haemorrhagic phenomena and neo-vascularization, but sometimes even identifiable fibrin accumulation. The peritoneum appears in principle well-structured, but is frequently hyperaemic.

Quixil + Goretex, not accessible for intraoperative detachment of the prosthesis

Glubran +Hi-Tex – The prosthetic material is visible in the form of small clusters surrounded by an irregular granulation tissue with major haemorrhagic events and with a small number of giant cells. The intervening connective tissue is quite oedematous. The peritoneum is highly disepithelized and haemorrhagic phenomena.

Glubran + Parietex – The prosthetic material is visible in the form of large aggregates on average, surrounded by an irregular connective capsule which can be identified by numerous giant cells, foreign body, abundant inflammatory cells (lymphocytes, macrophages), and haemorrhagic phenomena and neo-vascularization. The connective tissue was interposed aspects variables. The peritoneum shows a significant haemorrhagic phenomena and hyperaemia.

Glubran + Proceed – The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective matrix, surrounded by a connective matrix in which is quite abundant haemorrhagic phenomena and neo-vascularization. Connective tissue interposed between clusters of prosthetic material is not very responsive. The peritoneum has a strongly altered, and is mostly devoid of epithelium.

Glubran + Composix – The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective matrix surrounded by an irregular connective capsule in which the giant cells are present in low numbers. Connective tissue interposed between clusters of prosthetic material is not very responsive. Not visible on the peritoneum.

Glubran + Goretex, not accessible for detachment of the prosthesis.

EMS + Hi-Tex – The prosthetic material is visible in the form of small clusters surrounded by a capsule consisting of connective where identifiable cells in large quantities from foreign giants, and many inflammatory cells (lymphocytes, macrophages). Immersed in the connective capsule surrounding individual aggregates of prosthetic material, is quite frequent outbreaks inflammation, host of phenomena sometimes necrosis. The intervening connective tissue has a variable appearance. The peritoneum has a strongly altered, and is mostly devoid of epithelium.

EMS + Parietex – The prosthetic material is visible in the form of small clusters surrounded by a capsule consisting of connective where identifiable cells in large quantities from foreign giants, and many inflammatory cells (lymphocytes, macrophages). Immersed in the connective capsule surrounding individual aggregates of prosthetic material, is quite frequent outbreaks inflammation, host of phenomena sometimes necrosis. The intervening connective tissue has a variable appearance. The peritoneum has a strongly altered, and is mostly devoid of epithelium.

EMS + Proceed – The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective matrix, surrounded by groups of giant cells and intense haemorrhagic phenomena. The intervening connective tissue has a variable appearance. The peritoneum appears in principle well-structured, but is frequent aspects hyperaemic.

EMS + Composix–The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective matrix, surrounded by groups of giant cells. In the connective between the individual clusters of prosthetic material are common inflammatory small outbreaks.

In addition, the connective between the individual clusters of prosthetic material has a mesenchymal-like appearance, but is surrounded by a connective tissue to look "mature." The peritoneum has a strongly altered, and is scarcely visible.

Protack: Similar histological examinations

Comments on second look at 15 days:

The material Tissucol and Quixil seems to go to a good reminder of inflammatory cells and induction of neo-vascularization, and appear with Hi-Tex and Parietex, stress appears to be changing the appearance of connective tissue. Proceed and Composix seem to be accompanied by hyperaemic and haemorrhagic phenomena. Again, as with Tissucol, the paired Quixil + Parietex seems to ensure optimal integration and peritonealisation prosthesis. The material Glubran seems to be linked to a deficiency of training of connective capsule surrounding the prosthetic material, when paired to Hi-Tex and Parietex, and a lack of formation of connective capsule around the mesh if paired to proceed and Composix. It is also evident that a tendency to induction of haemorrhagic phenomena and neo-vascularization. The peritoneum appears generally altered. The material EMS and Protack seems to go more or less extensive outbreaks of inflammatory findings; Composix and proceed even appear in this, as in previous cases, be accompanied by a higher propensity, compared to Hi-Tex and Parietex, to the formation of a connective that appears structurally not very responsive.

Results of second look at 30 days: (Tables III, IV)

Tissucol + Hi-Tex – The prosthetic material is visible in the form of small clusters surrounded by a connective tissue capsule which is thicker than that of 15 days, small cells from giant foreign body can be seen around the prosthetic mesh material. In the connective tissue interposed between the individual clusters of prosthetic material, appearance, albeit in part, still reactive, can be identified a few small outbreaks inflammatory. The peritoneum appears oedematous and hypertrophic heavily in sub-serous tunic.

Tissucol + Parietex (Fig. 3) – The prosthetic material is visible in the form of large aggregates on average surrounded by a connective tissue capsule which is thicker than that of 15 days, small cells from giant foreign body can be seen around the prosthetic mesh material. Within the cluster, the net prosthesis is apparently very cohesive, and among them is sometimes visible glue residue. In the connective tissue interposed between the individual clusters of prosthetic material, appearance, albeit in part, still reactive, is sometimes identified several small outbreaks inflammatory. The peritoneum appears well structured, although hypertrophic appearance at the sub-serous component.

Tissucol + Proceed –The prosthetic material is still visible in voluminous and rounded solutions continuous connective tissue matrix, surrounded by inflammatory cells and giant cells. The connective tissue was interposed appearance yet, even in part, reactive. The peritoneum appears with altered structure, hypertrophic and hyperaemic.

Tissucol + Composix– The prosthetic material is poorly visible in voluminous and rounded solutions continuous connective tissue matrix, surrounded by giant cells in low numbers. The connective tissue was interposed appearance yet, even in part, reactive. The peritoneum shows altered structure, and hypertrophic in the sub-serous component.

Quixil + Hi-Tex– The prosthetic material is visible in the form of small clusters surrounded by a capsule consisting of connective tissue. Among the net formed by the prosthetic material can be seen numerous giant cells, small. In the connective tissue interposed between the individual clusters of prosthetic material, appearance, albeit in part, still reactive, can be identified a few small outbreaks inflammation, and numerous small vessels. The peritoneum is not visible.

Quixil + Parietex (Fig. 4) –The prosthetic material is visible in the form of large aggregates on average surrounded by a connective tissue capsule fairly. Among the net formed by the prosthetic material can be seen numerous giant cells. In the connective tissue interposed between the individual clusters of prosthetic material, appearance, even if in part, still reactive, is identified numerous small vessels. The peritoneum appears broadly correct structure, but with hyperaemic and haemorrhagic phenomena.

Quixil + Proceed – The prosthetic material is sometimes still visible surrounded scarce giant cells and massive haemorrhagic phenomena. Connective tissue interposed between clusters of prosthetic material has a variable appearance. The peritoneum is not visible.

Quixil + Composix – The prosthetic material is hardly visible within bulky solutions continuous connective tissue matrix, surrounded by an important and extensive inflammation with numerous outbreaks and confluent inflammation, blood extravasation and accumulation of fibrin. The peritoneum is not visible.

Glubran + Hi-Tex– The prosthetic material is sometimes still visible, surrounded by oedematous connective tissue, sometimes showing accumulations of esinophils& granulocytes. Peripherally, however, the connective tissue has a "mature". The peritoneum is not visible.

Glubran + Parietex – The prosthetic material is still visible in the form of large aggregates on average, surrounded by an irregular connective tissue capsule which is very important and haemorrhagic inflammation. Peripherally, however, the connective tissue has a "mature". The peritoneum has a distorted and presents important haemorrhagic phenomena.

Glubran + Proceed – The prosthetic material is still visible in some cases, bulky solutions within the continuous matrix of connective tissue, surrounded by a matrix of connective aspect rather "mature", though with considerable haemorrhagic processes, and the connective tissue is said in some cases clearly is about to gain the solutions continuously. The peritoneum appears broadly correct structure, even if representative connective hypertrophy.

Glubran + Composix – The prosthetic material is poorly visible in voluminous and rounded solutions connective continuous matrix, which appears to look "mature", said the connective tissue is evident in some cases that is about to gain the solutions continuously. The peritoneum has altered the structure, with strong presence of oedematous phenomena.

EMS + Hi-Tex – The prosthetic material is still visible in the form of small clusters surrounded by an irregular connective capsule. Connective tissue interposed between clusters is immature in appearance and is strongly affected by an extensive inflammatory process. The peritoneum has a distorted structure, which is strongly affected by oedema.

EMS + Parietex – The prosthetic material is visible in the form of large aggregates on average, surrounded by an irregular connective tissue capsule which can be identified by numerous giant cells, foreign body, and inflammatory cells (lymphocytes, macrophages). In the connective between the individual clusters of prosthetic material are common inflammatory small outbreaks. In addition, the connective between the individual clusters of prosthetic material has a mesenchymal-like appearance and is particularly rich in small vessels, but is surrounded by a connective tissue to look "mature." The peritoneum has a distorted structure, but you notice areas of regeneration and structural reorganization.

EMS + Proceed – The prosthetic material is sometimes still visible in voluminous and rounded solutions

continuous connective matrix, surrounded by groups of giant cells. Connective tissue interposed between clusters of prosthetic material has a "mature". The peritoneum has a distorted structure, but you notice areas of regeneration and structural reorganization.

EMS + Composix – The prosthetic material is sometimes still visible in voluminous and rounded solutions. Continuous connective tissue matrix, appears still mesenchymal-like, but surrounded by a peripheral connective tissue "mature." The peritoneum is strongly altered, and is scarcely visible.

Goretex + EMS and Protack - The prosthetic material is partly covered with connective tissue in the absence of macrophages, PMN, lymphocytes and tissue neovascularization. We can also see a good reperitonalization without prosthesis integration in the abdominal wall.

Comments on second look at 30 days:

At 30 days, the material seems Quixil accompanied by a persistent inflammation seen in the form of giant cells in relation to the prosthetic mesh material, and persistence, even in part, an aspect not fully structured (in development) of connective tissue, and these issues are common to Tissucol. On the other hand, seems Quixil also, responsible to a greater extent than Tissucol persistent induction of vascularization. Again, as in 15 days, the paired Tissucol + Parietex and Quixil + Parietex seem to have connective capsule around the mesh if paired to proceed and Composix. Proceed + Composix pair also includes a clear process, even if gradual, of filling up with neo-peritoneum spaces of prosthetic material uncovered. The observation of the peritoneum makes us consider the Glubran and proceed as the best pair. EMS and Protack seem to be associated to the persistence of inflammatory foci, if paired with Hi-Tex and Parietex, and to the formation, especially peripherally, of a "mature" connective when paired to proceed and Composix. The observation of the peritoneum, makes us to consider that EMS and Proceed as the best pair.

Macroscopical evidences:

Also for the macroscopic evidences, at 15 and 30 days, the best prosthesis resulted to be Parietex Composite and Hi-Tex. We evaluated them by pulling on the meshes to test their adhesion to the abdominal wall, and looking at the new peritoneum, adhesion formation and shrinking phenomenon. The Parietex and Hi-Tex meshes showed no adhesion formation, good tissue integration, good reperitonalization, no shrinking and no migration of the meshes. The Gore-Tex prosthesis does not show integration and presents a serous sac and its fixation depends exclusively on Protack.

Regarding the fixing devices, Glubran seem to be related to hemorrhagic phenomenon and no peritoneum formation. EMS and Protack are ensuring a good stability and tensile strength of the prosthesis but they are responsible for a less tissue integration which is on the contrary, well stimulated by the human sealants (Tissucol and Quixil). Protack also is a cause for more adhesion formation and one case of intestinal migration / perforation.

Tab I. Macroscopical and microscopical evidences after 15 days.

	Parietex Composite	Proceed	Composix	Hi-Tex
Adhesions	/	++	+	/
Reperitonealization	++	+	+	++
Tensile strength	++	+	++	++
Shrinking	/	+	/	/
Tissue integration	+++	++	++	+++
Inflammatory reaction	+++	++	++	+++

(+) is a semiquantitative scale for exemple: (/) means nothing, (+) means poor, (++) means good, (+++) means a lot.

Tab II. Macroscopical and microscopic of fixing devices evidences after 15 days.

	Tissucol	Quixil	Glubran	EMS	Protack
Adhesions	/	/	+++	/	++
Reperitonealization	++	++	/	++	+
Granuloma	/	/	++	+	++
Fibroblastic ingrowth	++	++	/	/	/
Inflammatory reaction	++	++	+++	++	++
Stability	+++	+++	+++	+++	+++
Intestinal migration / perforation	/	/	/	/	/

(+) is a semiquantitative scale for exemple: (/) means nothing, (+) means poor, (++) means good, (+++) means a lot.

Tab III. Macroscopical and microscopical evidences after 30 days.

	Parietex Composite	Proceed	Composix	Hi-Tex
Adhesions	/	++	+	/
Reperitonealization	+++	++	++	+++
Tensile strength	+++	++	+	+++
Shrinking	/	+	/	/
Tissue integration	+++	++	++	+++
Inflammatory reaction	++	+++	++	++

(+) is a semiquantitative scale for exemple: (/) means nothing, (+) means poor, (++) means good, (+++) means a lot.

Tab IV. Macroscopical and microscopic of fixing devices evidences after 30 days.

	Tissucol	Quixil	Glubran	EMS	Protack
Adhesions	/	/	+++	/	++
Reperitonealization	+++	+++	/	++	+
Granuloma	/	/	++	+	++
Fibroblastic ingrowth	+++	+++	/	/	/
Inflammatory reaction	+	+	++	++	++
Stability	+++	+++	+++	+++	+++
Intestinal migration/perforation	/	/	/	/	++

(+) is a semiquantitative scale for exemple: (/) means nothing, (+) means poor, (++) means good, (+++) means a lot.

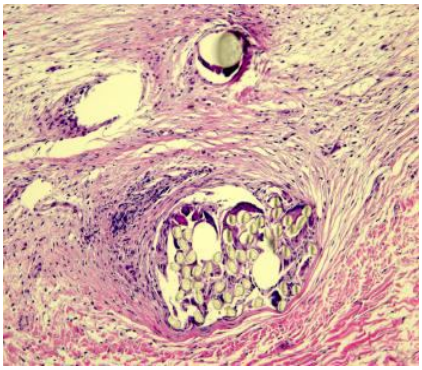

Fig 1.Tissucol + Hi-Tex.

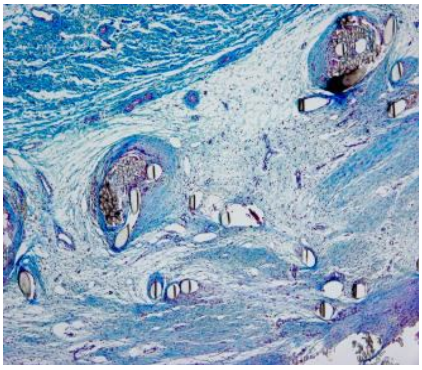

Fig 3.Tissucol + Parietex.

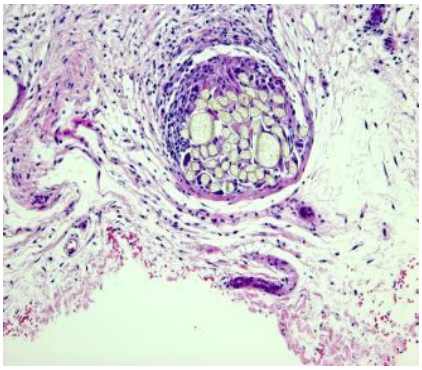

Fig2. Quixil + Hi-Tex.

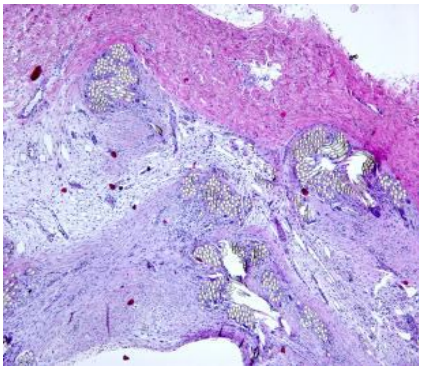

Fig 4.Quixil + Parietex.

DISCUSSION

The last decade has brought new technical developments to incisional hernia repair. Agreement has been achieved that tension-free hernia repair using prostheses reducing recurrence rates significantly.[19,23-24] Currently, discussion focuses on surgical approach (laparoscopic /intraperitonealonlay mesh = IPOM versus open/sublay), and on the questions as to which mesh should be used and which fixation method is more appropriate. There are many meshes available in the market for IPOM repair, and new meshes are introduced regularly. The 'ideal' mesh should lead to scar formation and provide adequate strength to the repair and, at the same time, should avoid formation of visceral adhesion.[30,31-34] Consequently the question concerning the best approach and the best mesh can't be answered sufficiently yet. Having regard to this statement, our experimental study was designed trying to help in answering these questions. Intraperitoneal positioning of the mesh, with consequent exposition of abdominal organs to direct contact with the mesh itself. This fact may cause the problem of visceral adhesion formation, which, consequently may lead to various complications like bowel obstruction, visceral erosion and formation of enterocutaneous fistula. These are typical complications of polypropylene prosthesis (Composix), as demonstrated by Burger et al,[25] which on one side they grant excellent tissue regeneration, but on the other side they increase recurrence rate.

In our study, this fact is confirmed by the creation of adhesions of laminar prosthesis (Composix) with poor peritoneum formation. In their experimental study on rabbits, Kiudelis et al[11] demonstrated the effective reduction of adhesion using a polypropylene prosthesis (Composix). Heninford et al[19] confirmed the effective lack of adhesion in pure ePTFE prosthesis, but they show the shrinking phenomenon. Schug-Pass et al[26] showed no significant differences were seen in the chronic inflammatory reaction between Proceed and Parietene Composite. We found better results came with the study of composite prosthesis, which combine the good qualities of laminar and reticular prosthesis in one. We evaluated prosthesis after 15 and 30 days from their implantation and the reason is that these two times represent different phases of adhesion formation and integration of the mesh. After 15 days the inflammatory response I ended, and it starts the proliferative phase. According to Baptista et al,[27]all adhesions at this point had to be formed. After 30 days, proliferative phase is ended and it starts the remodeling phase. We have to attend that the neoperitoneum is formed and it covers the mesh. As for the consideration set of prosthetic materials and materials for fastening, it can be concluded that: The best materials resulted to be Parietex Composite and Hi Tex, with formation of more organized granulation tissue, rich in fibroblast populations and a good neovascularization. They were also the only two meshes entirely covered.

The other two prosthesis; Proceed and Composix seem to stimulate less inflammatory process, and consequently the process of tissue integration. They were partially covered with peritoneum, and they showed more hemorrhagic processes.

The ideal mesh fixation should significantly reduce postoperative complication rate, particularly with regard to (chronic) pain. Unfortunately, experimental and clinical documentation for safety and efficacy are often not available for the clinician and the quality of the few available studies is poor. The most diffused technique is the fixation of the mesh with staples and permanent transabdominal sutures.[19] Some Authors tried to reduce operative time and the postoperative pain avoiding or reducing the use of transabdominal sutures and using only metallic staples.[19-31]

Considering the fixing device, both the fibrin glue materials; Quixil and Tissucol are the best material, providing greater stability and stimulating tissue integration together with higher fibroblast populations.[35]Glubran, EMS and Protack reported worse results, with a higher rate of haemorrhages and no peritoneum formation. Stability of the prosthesis and the efficacy of the treatment depend also on the fixing device used to fix the prosthesis to the abdominal wall. This represents one of the critical points of the laparoscopic technique, which may affect the recurrence rate.[22]

Regardless of the adhesive material used (Tissucol, Quixil), which is a 15 to 30 days and Hi-Tex and Parietex seem to induce and maintain the formation of more or less developed capsule formation around the aggregates of prosthetic material, and to the integration of implants with the abdominal wall. Also this was shown by Olmi et all.[22]

In conclusion the results we reported demonstrate the safety and efficacy of the meshes Parietex Composite and Hi-Tex fixed with fibrin glue (Tissucol and Quixil). Both the prosthesis show good tissue integration, good reperitonalization and do not cause adhesions. Their fixation with Tissucol and Quixil guarantees excellent strength and resistance to traction. It also stimulates tissue integration and reperitonalization more than the other devices we studied. In this sense, further studies investigating these open questions concerning the best approach and the best mesh and the best fixation method are very important.

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