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Original Article

Does Collagen-Coated Polyester Mesh Decrease the Rate of Intraperitoneal Adhesions in Incisional Hernia Repair?

A tela de Poliéster recoberta por colágeno diminui a taxa de aderências intraperitoneais no reparo da hérnia incisional?

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ABSTRACT

Objective: The aim of this study is to evaluate the formation of adhesions after polypropylene (PP) and collagen-coated polyester (PC) mesh intraperitoneal placement. **Materials and methods**: Twenty six female Wistar rats were randomly assigned to three groups. In the Sham group there was no prosthesis placement, in the PP group the prosthesis was placed at the peritoneal surface, and in the PC group the collagen-coated polyester mesh was placed at the peritoneal surface. The rats were killed on postoperative day 21 to evaluate adhesions regarding their grade, percentage of the mesh surface involved, bowel involvement, and force needed to cause rupture of the adhesion. **Results**: There was no difference in weight between the groups. The sham group did not develop any adhesions. The PP and PC groups developed prosthetic mesh surface adhesions, mostly in the omentum. There was no difference in adhesion grade and percentage of surface involved between PP and PC groups. The collagen-coated polyester mesh did not develop adhesions. Adhesions occurred at the free edge of the mesh, in contact with the polyester. The PP group presented 80% of the surface involved with adhesions, while the PC group presented 10% ($p<0.005$). **Conclusion:** There was no difference between adhesion, grade of adhesion and strength needed to cause rupture. However, the PP mesh presented significantly higher surface of adhesion when compared to the PC mesh.

Key words: Adhesions. Ventral hernia. Polyester. Collagen. Polypropylene. Mesh.

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INTRODUCTION

More than two million abdominal surgeries are performed annually in the United States. Incisional hernia is the most common complication, occurring in 11% of the patients who undergo abdominal surgery and in 23% of those who develop post-operative wound infections. About 100,000 incisional hernia repair surgeries are performed each year.[1,2]

Nearly half of incisional hernias develop within two years of abdominal surgery, and 74% occur within three years of surgery.[3-5] The ideal mesh should have good tensile strength, be inert, non-carcinogenic, stable in the setting of infection and any accompanying inflammatory response, and must not provoke tissue rejection.[7] An ideal mesh for use inside the peritoneal cavity – in contact with the bowel – needs to have one side with high reactivity to promote tissue growth at the abdominal wall, while the another side should have the capacity to minimize adhesions.[8]

Among meshes used in open incisional hernias repairs, the polypropylene (PP) mesh, introduced by Usher in 1963,[9] is the most commonly used due to its flexibility, ability to stimulate cellular growth, satisfactory inflammatory response, easy manipulation, and low price. However, when in contact with the intra-abdominal contents PP mesh induces the formation of adhesions.[10-12] An experimental study with rats showed that the inflammatory process in the PP mesh may become chronic and delay the proliferative stage of healing. Collagen production

increases, reaching a maximum level on postoperative day 21, with a predominance of type III collagen in the early process and type I collagen after that.[13] This demonstrates the need to protect the bowel-facing surface of the mesh for longer than that. The Parietex Composite® mesh achieved satisfactory results in extra-peritoneal hernias because of low adhesion formation, appropriate tissue growth, absence of enterocutaneous fistulas, and low recurrence rates.[14-15]

Comparisons between bilaminar mesh and other components that include one sheet for temporary tissue separation were conducted in only a few *in* vivo studies.[16] The recurrence rate after surgical repair was as high as 49%.[17-18] The main postoperative complications are related to adhesions, and include bowel obstruction and fistulas. Up to 44% of these complications require surgical intervention, which demonstrates the importance of avoiding adhesion formation.[19]

OBJECTIVE

The aim of this study is to evaluate the formation of adhesions after intraperitoneal placement of polypropylene (PP) or collagen-coated polyester (PC/CCP) mesh.

MATERIALS AND METHODS

This study was performed at the Lutheran University of Brazil (ULBRA) bioterium according to institutional experimental animal model protocols. 26 Wistar female rats (*Rattus Norvengicus*) were used. They were kept at room temperature, fed standard laboratory chow, and were allowed tap water *ad libitum*. The choice to use exclusively female rats was due to their smaller size (weight around 200g), that allowed better use of the available meshes. The meshes were provided by venders at no cost. To calculate the sample size, we used *Sample Size determination in health studies* software.[20] We calculated the sample size considering a statistical power of 80% and a p value < 0.05, parameters used by other published studies.

The rats were randomized into three groups:

Group 0 (Sham group): consisted of six animals. A midline laparotomy was performed, with primary closure of the abdominal wall, without prosthetic implant.

Group 1 or PP: consisted of 10 rats. A midline laparotomy was performed and the defect was repaired with a 2 x 2 cm intraperitoneal PP (Marlex®) mesh.

Group 2 or PC: consisted of 10 rats. A midline laparotomy was performed and the defect was repaired with 2 x 2 cm intraperitoneal collagen-coated polyester (Parietex Composite®) mesh which was previously hydrated in normal saline during one minute.

Operative technique

The rats received intramuscular injection of 5 mg/kg xilazine (0.1 ml of solution at 2% diluted in 0.2ml of 0.9% normal saline) followed by 50 mg/kg intramuscular ketamine (0.35 ml of solution 50mg/ml). Abdominal trichotomy and antisepsis with 2% alcoholic chlorhexidine were performed.

In Group 0 a 3 x 4 cm midline incision was made with dissection of the subcutaneous tissue; the peritoneal cavity was opened through the linea alba. The abdominal wall was closed using 3-0 polypropylene sutures without mesh implantation.

In Group 1 a 3 x 4 cm midline incision was made with dissection of the subcutaneous tissue; the peritoneal cavity was opened through the linea alba. A 2 x 2 cm PP mesh was implanted using 4-0 polypropylene sutures at the four quadrants. After that, the skin was closed using 3-0 polypropylene sutures (Figure 1).

In Group 2 the same procedure as the group 1 was performed, except a 2 x 2 cm collagen-coated polyester mesh was implanted after it was hydrated in normal saline for one minute. 4-0 polypropylene sutures were made at the four corners of the polyester portion without damaging the collagen layer. The abdominal wall was closed with 3-0 polypropylene sutures (Figure 2).

After the procedure, the rats received 0.5 ml of subcutaneous 0.9% normal saline and recovered in a heated place. After recovery they were transferred to their cages with food and water ad libitum. Dipirone (90 mg/ml) diluted in water was offered for three days.

The variables evaluated were: presence or absence of adhesions (Table 1); structures adhered: liver (including round ligament), omentum, intestinal loop; retraction size; percentage of the prosthetic surface involved (less than 50%, or 50% or more); and the location of adhesion (periphery or central area

of the mesh). Tensile strength was measured using a millimeter ruler with a 5N dynamometer; it was pulled and the force needed to rupture the adhesion was measured. The assessment was performed by a surgeon and a pathologist, both blinded to type of mesh. Due to the lack of histologic analysis the force needed to cause rupture was used as a proxy for the amount of collagen.

Statistical analysis

Statistical analyses were performed using version 17 of the Statistical Package for Social Sciences (SPSS). The average, standard deviation, and minimum and maximum values were determined for the continuous variables. The Wilcoxon test verified if there was any difference between the average weight before and after the surgery with each of the meshes. Frequency distributions (number and percentage) were determined for the categorical variables. The Fisher's exact test was used to verify the associations between the categorical variables.

Ethical aspects

The study was approved by the Ethics and Research Committee of the Lutheran University of Brazil (Protocol number 2009-005A).

All of the animals were initially kept inside cages in groups of 4 or 5. There were 12 hour day and night shifts. The rats were kept at room temperature with appropriate sanitation. All of them received anesthesic induction before the surgical procedure and before being sacrificed.

RESULTS

There was one death in the sham group during the anesthesia, before surgery was begun. None of the other five animals in Group 0 had adhesions at the abdominal wall. One rat had the omentum sutured to the abdominal wall an unintended consequence of the surgical procedure.

The weight of the animals was measured before the surgical procedure and after their death. Statistical analysis using the Wilcoxon test,

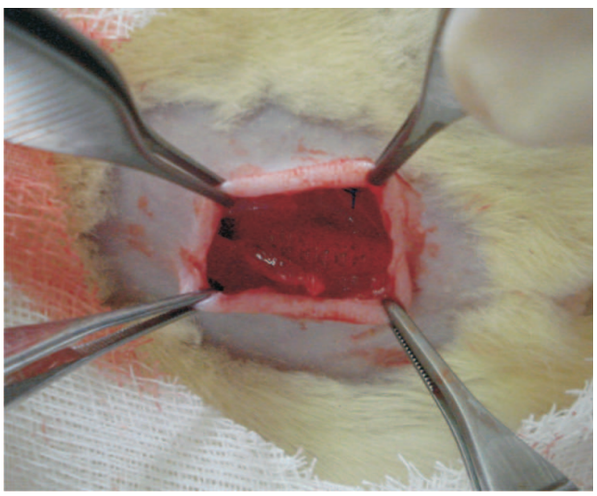

Figure 1 *- Intraperitoneal placement of polypropylene mesh.*

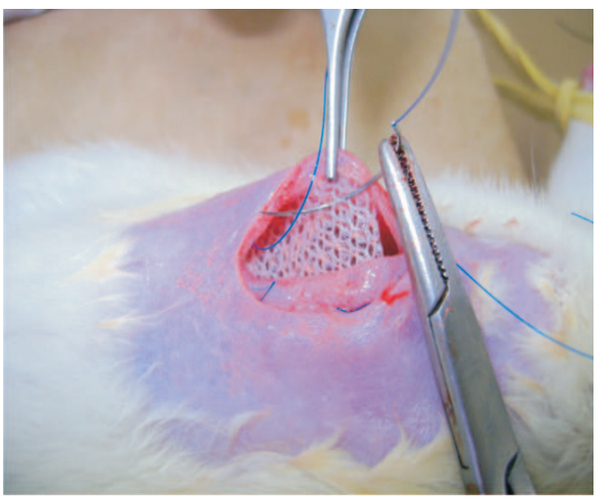

Figure 2 *- Intraperitoneal placement Parietex Composite® mesh.*

Table 1 - *Definition of Grades of adhesion.*

Adhesion Grade		Definition
0	None	Absence of adhesions.
1	Mild	Thin adhesions that are easily released.
2	Moderate	Adhesions that need blunt dissection to be released.
3	Severe	Firm adhesions which require significant force to release, partially or totally injuring the involved gut.

Table 2 - *Comparison between initial and final weight according to mesh type.*

Mesh type	Variable	n	Average	Standard deviation	Median	Minimum	Maximum	P*
Sham group	Initial weight	6	198.2					
	Final weight	6	220.2	15.55	209.2	182	248.1	0.005
Polypropylene	Initial weight	10	190.4	13.9	192.0	165.0	210.0	0.005
	Final weight	10	218.7	13.8	220.5	193.0	238.0	
Parietex Composite®	Initial weight	10	212.6	22.0	217.0	175.0	250.0	0.005
	Final weight	10	229.7	18.0	230.0	205.0	265.0	

** Wilcoxon test, p value.*

demonstrated a statistically significant difference between the initial and final weight for both the PP and PC groups, with the weight gain independent of the mesh type (p=0.005). (Table 2).

Evaluation of the incidence of adhesion according to type of mesh demonstrated that 100% of the rats that received the PP mesh developed adhesions. These adhesions involved the omentum in 100% of the rats, the liver in 30%, the small intestine in 30%, and the round ligament of the liver in 60% (Figure 3). 100% of the rats that received the PC mesh also had adhesions, involving the omentum in 100% of the rats, and involving the small intestine in 10%. There were no adhesions involving the liver or the round ligament (Figure 4). The only statistically significant difference between the two types of mesh was for round ligament adhesions. (Table 3)

The average force needed to cause rupture of the bowel adhesion for each of the two types of mesh can be seen in table 4; a statistically significant difference was found using the Mann-Whitney test.

There was no significant difference on mesh retraction between PP and PC. Regarding adhesion grade, 60% of the rats that received the PP mesh had grade 1 or 2 adhesions while 40% had level 3 adhesions. 90% of the rats that received the PC mesh presented developed level 1 or 2 adhesions and 10% had grade 3 adhesions. There was a predominance

Figure 3 - *Marlex® mesh adhesions.*

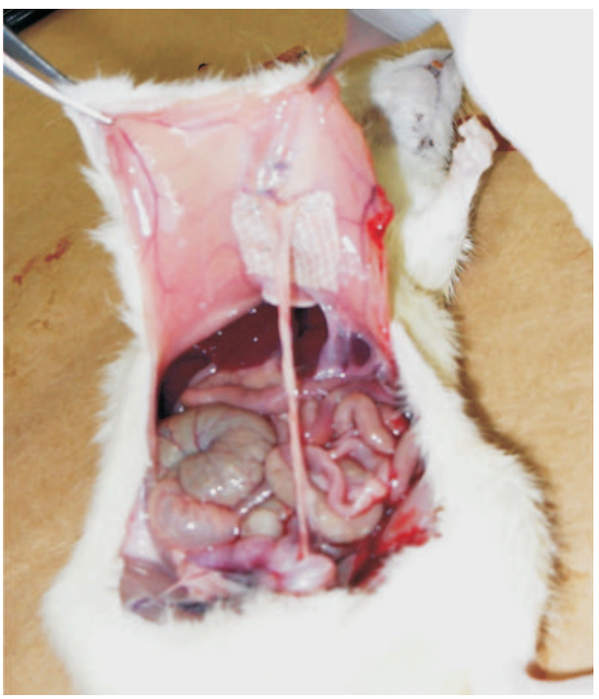

Figure 4 - *Parietex Composite® adhesions.*

Table 3 - *Frequency of adhesions according to type of mesh.*

	Adhesions						
	Sham Group (no mesh)		Polypropylene		Parietex Composite®		P*
Omentum	0	(0%)	10	(100%)	10	(100%)	-
Liver	0	(0%)	3	(30%)	0	(0%)	0.211
Small intestine	0	(0%)	3	(30%)	1	(10%)	0.582
Round ligament	0	(0%)	6	(60%)	0	(0%)	0.011

Data presented as n (%).
**P value for Fisher´s exact test.*

Table 4 - *Comparison between the two types of mesh of the force needed to cause rupture.*

Mesh	Adhesion strength (force needed to cause rupture)	
	Average	Standard deviation
Marlex polypropylene (n=10)	0.96	0.39
Parietex Composite (n=10)	0.37	0.18
p-value (*)	<0.001 (**)	

** Mann-Whitney test.*

of mild adhesions on the Parietex Composite® mesh (90%) in comparison to the polypropylene mesh (60%) according to Fisher´s exact test (p=0.303). Table 5.

The surface area of the mesh with adhesions was classified into two groups: one with adhesions involving less than 50% of the surface area and the other group with adhesions involving 50% or more of the surface. Eight PP meshes had adhesions involving 50% or more of the surface and two meshes had adhesions involving less than 50% of the surface.

90% of the PC meshes had adhesions involving less than 50% of the surface. The Fischer's exact test showed variation between the type of mesh and surface involvement (p=0.005). Table 6.

Regarding the location of the adhesions, they were found only along the edges of the PC mesh,

Table 5 - *Adhesion grades according to type of mesh.*

Type of mesh	Grade			
	1 or 2		3	
Polypropylene	6	60%	4	40%
Parietex Composite®	9	90%	1	10%

Data presented as n (%).
** p value=0.303 for Fisher's exact test.*

Table 6 - *Adhesion percentage according to type of mesh.*

Type of mesh	Percentage of mesh involvement			
	Less than 50%		50% or more	
Polypropylene (PP)	2	(20%)	8	(80%)
Collagen-coated polyester (PC)	9	(90%)	1	(10%)

Data presented as n (%).
** p value=0.005 for Fisher´s exact test.*

where the polyester layer was exposed . There were no adhesions in the center of the mesh, where the collagen coating was continguous. In the PP mesh 100% of the adhesions developed in the center. No statistical analysis was performed due to the fact that the adhesions developed in different locations on the two types of mesh.

DISCUSSION

The sham group should be viewed as the control group. The study found by postoperative day 21 the animals had gained weight.

There was no difference between the types of adhesions. Adhesions developed in the omentum and small intestine with both types of mesh. Adhesions developed in the liver and round ligament of the liver only with the PP mesh, a statistically significant difference (p=0.011). There was a statistically significant difference in the surface area of the mesh involved with adhesions between the two types of mesh (p=0.005) with greater involvement of the intraperitoneal PP mesh.

An analysis of the collagen-coated polyester mesh showed adhesions only at the edges of the prosthesis. The mesh designed for humans had been cut to use in the experiment with rats. Thus, the polyester component was exposed at the edges. Cutting the mesh is contraindicated by the manufacturer. There were no adhesions in the center of the mesh, as described in the literature.[21-22] Adhesions developed in the center of 100% of the implanted PP meshes. This is a limitation of this experimental model that can be solved with upcoming studies.

When the PP and PC meshes were compared the collagen layer appears to have a protective effect on adhesion formations, as there was a statistically significant difference in the surface area with adhesions (p=0.005).

CONCLUSION

There was no significant difference between PP and PC meshes when adhesion, adhesion grade, and force needed to cause rupture of the adhesion were evaluated. However, the PP mesh has significantly larger surface area with adhesions. Based on these data, the authors recommend collagen-coated polyester mesh for incisional hernia repair.

RESUMO

OBJETIVO: Comparar as aderências formadas após a colocação intraperitoneal da tela de polipropileno (PP) ou poliéster recoberta com colágeno (PC) em um modelo experimental. MATERIAIS E MÉTODO: Foram utilizadas 26 ratas fêmeas da raça Wistar, randomizadas em 3 grupos. No Grupo Sham não houve colocação de prótese, apenas laparotomia. No grupo (PP) houve implantação intraperitoneal da prótese de polipropileno e no grupo (PC) implantação da prótese composta por poliéster coberta por colágeno. Todos os animais foram mortos 21 dias após o procedimento e avaliados quanto às vísceras envolvidas nas aderências, o grau das aderências, o percentual de acometimento da tela pelo processo aderencial, bem como a força necessária para a sua ruptura. RESULTADOS: Não houve difeença entre os pesos dos grupos. O grupo Sham não apresentou aderências. Os grupos PP e PC apresentaram aderências na superfície da prótese, sendo que o orgão mais acometido foi o Omento. Não houve diferença entre os grupos quanto ao grau de aderências tela nos grupos PP e PC. O grupo PC nao desenvolveu aderências na região central da tela. As aderencias se formaram na área exposta das bordas da tela do poliester. O grupo PP apresentou 80% da superfície envolvida por aderências, enquanto que o grupo PC apresentou apenas, 10% (p<0,005). Conclusão: Não houve diferença entre o grau de aderências, tipo de aderências e de força necessária para causar ruptura. No entanto, a superfície da tela PP apresentou significativamente maior área de aderencias em comparação com a tela de PC.

Descritores: Hérnia ventral. Poliéster. Colágeno. Polipropileno. Aderências. Telas.

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