

Evaluation of Intraperitoneal Adhesions Associated with the Double Layer Mesh PTFEe/Polypropylene in the Ventral Hernia Repair – An Experimental Study in Rats

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ABSTRACT

OBJECTIVE: To compare adhesion formation in two groups of albino rats that underwent intraperitoneal placement of polypropylene or expanded polytetrafluoroethylene (ePTFE). **MATERIALS AND METHODS:** Twenty-six female Wistar rats were randomized into three groups. All animals were anesthetized before surgical procedure and were submitted to opening of abdominal cavity for placement of a prosthesis. In group 0 there was no placement of any mesh, in group 1, it was placed polypropylene mesh and in group 2, it was placed ePTFE/polypropylene mesh. All animals were killed 21 days after the procedure and evaluated through organs involved in adhesions, degree of adhesion, percentage of mesh compromised by adhesion and strength needed to rupture these adhesions. **RESULTS:** Group 1 and 2 had 100% adhesion on prosthesis surface. Group 1 presented 60% adhesion type 1 or 2 and 40% type 3, and group 2 presented 90% type 1 or 2 and 10% adhesion type 3. Both meshes presented the same percentage of surface covered with adhesions, 60% of each type of mesh had surface compromised in less than or 50% and 40% of each kind compromised over than 50% surface of the mesh. Only ePTFE presented 30% adhesion when excluding border adhesion and polypropylene had 100% adhesion. **CONCLUSION:** Both meshes presented similar behavior regarding the evaluated parameters. However, in an isolated analysis ePTFE has showed to be better than polypropylene as it depicts lower adhesions rates.

Key words: Ventral hernia, ePTFE, Polypropylene, Mesh, Adhesion, Marlex®, Composix®.

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INTRODUCTION

More than 2 million abdominal surgeries are performed annually in the United States³. Incisional hernia is the most common complication observed in 11% of the patients submitted to this surgery and in 23% of the patients who develop postoperative wound infection^{2,5}. Repairing incisional hernia corresponds to a hundred thousand new surgeries every year^{2,5}.

Incidence of incisional hernias after surgical procedures varies from 3% to 40%¹. In cases where primary incisional hernia repair occurs recurrence rates vary from 25% to 52%^{1,2,3}. Complications such as intestinal obstruction and enterocutaneous fistula depict the necessity to avoid adhesion formation which causes the procedure to be safe, as 41% to 44% of the intestinal obstruction due to adhesion need surgical

repair and overall mortality rate reported in the literature is of 11.4%⁴.

Due to this elevated rate it is necessary to search high quality synthetic material in order to improve long-term results of surgical intervention. The objective of the current study is to compare adhesion formation between two groups of albino rats submitted to ventral herniorrhaphy with intraperitoneal polypropylene or expanded polytetrafluoroethylene/mesh.

MATERIALS AND METHODS

This current study is an experimental study developed in the Bioterium of the Lutheran University of Brazil (Universidade Luterana do Brasil-ULBRA) approved by the Research and Ethics Committee of the Lutheran University of Brazil

under the protocol number 2008-004 of this committee.

This research involves 26 female Wistar albino rats which were initially maintained in a cage with 4 or 5 animals and they were feeding according to the rules of the research that was being developed. The size of the sample was calculated according to literature data^{21,22,23,24,25,26}.

The animals were anesthetized with intramuscular xylazine(0,1ml of 2% solution diluted in 0,2ml of 0,9% saline solution) at a dose of 5mg/kg and intramuscular ketamine (0,35ml solution at 50mg/ml) at a dose of 50mg/kg. After an adequate anesthetic induction was obtained, it was performed an abdominal tricotomy at the operative field and antisepsis with 2% alcoholic solution of chlorhexidine in the same region.

The animals were randomized in three groups. In six animals of the group 0, it was performed a 3 to 4 cm median incision with dissection of the subcutaneous tissue and the peritoneal cavity was opened through the Alba line. In this group mesh was not implanted, the abdominal wall was closed and skin was suture using 3-0 Prolene®.

In ten animals of the group 1, it was performed a 3 to 4 cm median incision with dissection of the subcutaneous tissue and the peritoneal cavity was opened through the Alba line. After the cavity was exposed a 2 x 2 cm polypropylene mesh was implanted (Figure 1). To fix the mesh to the abdominal wall a transfixing suture in the four quadrants of the mesh was performed with 4-0 Prolene (Figure 1/2). After this, the abdominal wall was closed and the skin was suture with 3-0 Prolene®.

In 10 animals of the group 2, it was performed a 3 to 4 cm median incision with displacement of the subcutaneous tissue and the peritoneal cavity was opened through the Alba line. After the cavity was exposed a 2x2cm ePTFE/polypropylene mesh was implanted. To fix the mesh to the abdominal wall a transfixing suture in the four quadrants of the mesh was performed with 4-0 Prolene. After this, the abdominal wall was closed and the skin was suture with 3-0 Prolene® (Figures 3 e 4).

When the procedure finished, all animals were with subcutaneous administration of 0,5ml of 0,9% saline solution and they were placed separately in a warm room to recover. When the animals were completely awaked they were transferred to their ori-

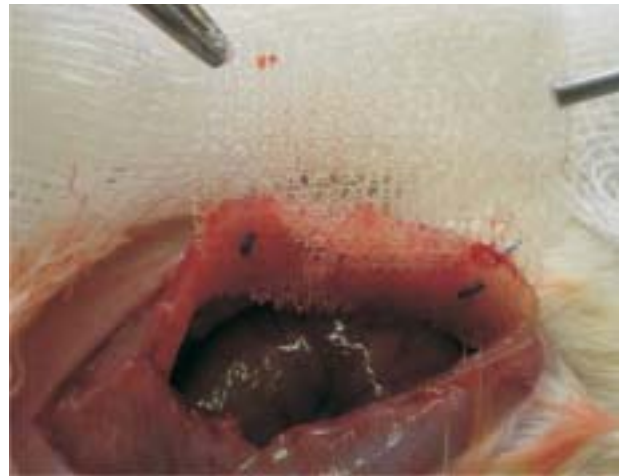


Figure 1 - Propylene mesh fixation.

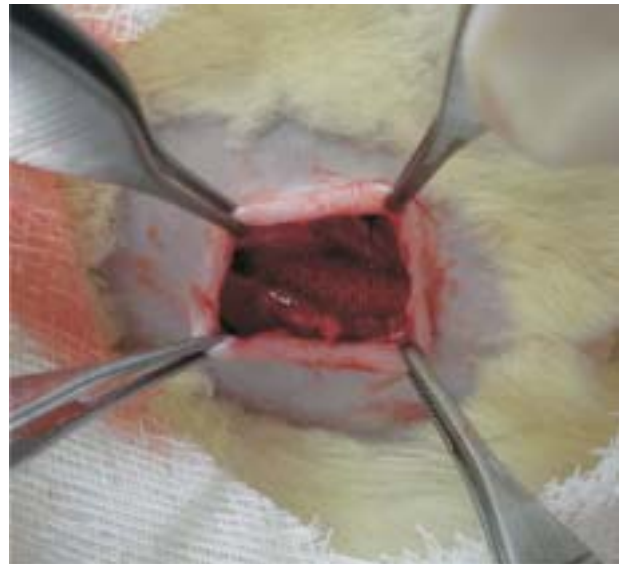


Figure 2 - Intraperitoneal placement of the polypropylene mesh.

ginal cages where food and water were served to all animals (Figure 5).

After the procedure and complete postoperative recovery the animals were daily monitored to evaluate complications to the procedure.

All animals were euthanized in a closed chamber with carbon dioxide on the 21st postoperative day. Abdominal tricotomy was performed once again, as well as an "U" incision along the abdominal wall. The imperfection of the abdominal wall was repaired in both sides and the abdominal wall was elevated to evaluate the rate of adhesion, viscera involved in the adhesion, percentage of the mesh covered with the



Figure 3 - ePTFE mesh fixation.

adhesion and its rupture strength. The classification of the adhesion occurred according to table 1.

The evaluation of tension traction was performed using a milimetric ruler with a 5N dynamometer. A repair was placed in the viscus involved and the dynamometer was carefully pulled, when the adhesion burst it was evaluated the necessary strength for its rupture.

The dead animals were wrapped and kept under refrigeration according to the rules of the Biotherium of the Lutheran University of Brazil.

All the data collected were registered in Excel to posterior statistical analysis.

Statistical analysis was performed by Mann-Whitney nonparametric test for the quantitative variables; Wilcoxon nonparametric test will be used for comparison (cross frequency and graphics of columns) of categorical variables (presence or not of adhesion) analyzed for each type of structure (Epiplon,



Figure 4 - Intraperitoneal placement of the ePTFE/polypropylene mesh.

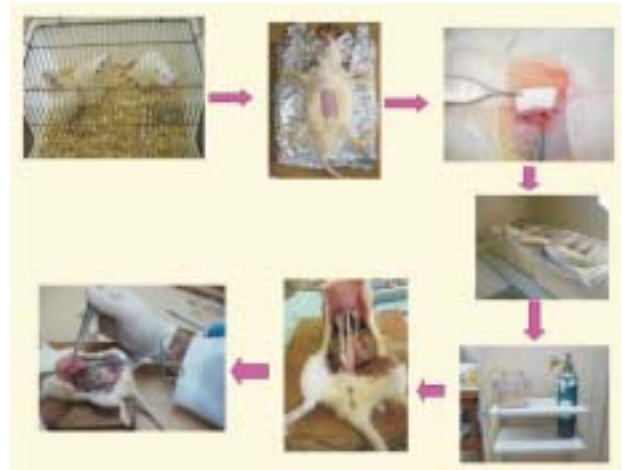


Figure 5 - Organogram of the procedure performed.

Liver, Small Intestine and Round Ligament) and for comparison of initial and final weight. The tests presented results of $p < 0.05$ (5% significance) for the magnitude of the differences they were considered statistically significant. SPSS (Statistical Package for Social Science) version 14.0 was used to analyze data.

Table 1 – Description of the type of adhesion.

Type of adhesion	Definition
0	- absence of adhesions.
1	- thin and easily removable adhesions.
2	- adhesions that need blunt dissection to be removed.
3	- firm adhesions in which the lysis of adhesion can only be applied with enough strength occurring partial or total injury of the viscus involved.

RESULTS

In group 0, one animal died due to anesthesia. None of the animals depicted abdominal adhesion in this group (Figure 6). Only one animal presented the great omentum suture at the abdominal wall and it was considered a consequence to the surgical procedure.

All animals were weighed before the surgical procedure and after their death. The analysis evaluating the animals weight before and after surgery was performed through the Wilcoxon test with 5% significance and we could observe that there is a significant difference between the mean of the initial and final weight for both types of mesh (polypropylene and ePTFE/polypropylene), a significant gain of weight occurred for both type of mesh ($p = 0,005$). Table 2. This show us that the procedure did not compromise the animals.



Figure 6 - Animal of the Grupo 0 without adhesion.

In the evaluation of the incidence of adhesion by the type of mesh we observed that polypropylene mesh presented 100% of adhesion (Figure 7) in which 100% involved the epiploon (Figure 10), 30% the liver, 30% the small intestine and 60% the round ligament of the liver. The ePTFE/polypropylene mesh equally presented 100% of adhesion (Figures 8), in which 90% involved the epiploon, 20% the liver, 30% the small intestine (Figure 9) and 50% the round ligament of the liver. There was no significant statistic difference for these variables as it is observed in table 3.

It was performed analysis of the maximum strength of rupture of each viscus that constitute the adhesion process in the meshes. The mean strength of rupture of each viscus may be observed in table 4. Through the Mann-Whitney nonparametric test using significance of 5%, we can conclude that there is no significant difference between the mean of the maximum strength of rupture of the viscera that were adhered to the polypropylene and ePTFE/polypropylene meshes.

When the degree of adhesion with meshes were evaluated, it was observed that the polypropylene mesh presented 60% of adhesions of first and second degree and 40% of adhesions of third degree. The ePTFE/polypropylene mesh presented 90% of first and second degree adhesions and 10% of third degree adhesions. Through the Fisher exact test ($p=0,303$) at 5% significance level there was no association between type of mesh and degree of adhesion. Table 5.

We evaluate the percentage of the area of the mesh affected by the adherence process. This variable was categorized in two groups (\leq or equal to 50% of the surface affected by adhesion in the mesh or $>$ 50% affected by adhesion). It was observed that 60% of the polypropylene mesh depicted adhesion that affected less than or equal to 50% of the surface of the mesh and 40% depicted adhesion that affected more than 50% of the surface of the mesh. In the

Table 2 - Comparison between initial and final weight by type of mesh.

Type of mesh	Variable	n	Minimum	Maximum	Mean	Standard deviation	p
Polypropylene	InitialWeight	10	165,0	210,0	190,4	13,9	0,005
	Final Weight	10	193,0	238,0	218,7	13,8	
ePTFE/polypropylene	InitialWeight	10	166,0	230,0	201,5	19,9	0,005
	Final Weight	10	186,0	248,0	225,4	19,3	



Figure 7 - Marlex® mesh adhesion.



Figure 8 - Composix® mesh adhesion.



Figures 9 and 10 - Adhesion of the bowel loops to the ePTFE mesh.

ePTFE/polypropylene mesh group, it was also observed that in 60% of the meshes, the adhesions affected a surface less than or equal to 50% and that 40% depicted adhesion that affected more than 50% of the mesh surface. Through the Fisher exact test ($p=1,000$) at 5% significance level, there was no association between the type of mesh and the percentage of mesh affected by adhesions. Table 6.

We analyzed the ePTFE/polypropylene mesh regarding adhesion at the edges, at the part exposed to polypropylene and at the center of the mesh, containing ePTFE. The expanded polytetrafluoroethylene obtained 30% of adhesion, in which 20% in the epiploon and 10% in the small intestine. The polypropylene showed 100% of adhesion, in which 50% were in the epiploon, 27,8% in the round ligament, 11,1% in the small intestine and 11,1% in the liver. Table 7. Through the Wilcoxon test, at 5% significance level, we can report that there is significant difference between the adhesions found in the surface of the mesh containing ePTFE and the ones found at the edge of the mesh, where the polypropylene is exposed. In this mesh, the adhesion were predominantly in the part with polypropylene ($p=0,005$).

Finally, we compared the adhesion found in the center of the ePTFE mesh (excluding from this analysis the adhesion at the edges) with the ones found in the polypropylene mesh. The first presented 30% of adhesion (IC: 0,06 -0,065) while the second presented 100%. As the polypropylene mesh has depicted this rate it was not possible to calculate the upper limit of the confidence interval; however, its lower limit was 0,69. These values are not found in

Table 3 - Crossing Presence/ Absence of adhesion by the type of mesh.

Type of mesh	Local	Presence			
		yes		no	
		n	%	n	%
Polypropylene	Epiplon	10	100,0	0	0,0
	Liver	3	30,0	7	70,0
	Small Intestine	3	30,0	7	70,0
	Round Ligament	6	60,0	4	40,0
ePTFE/polypropylene	Epiplon	9	90,0	1	10,0
	Liver	2	20,0	8	80,0
	Small Intestine	3	30,0	7	70,0
	Round Ligament	5	50,0	5	50,0

the interval calculate to the ePTFE/polypropylene mesh, proving that this difference is statistically significant to a 95% confidence interval.

DISCUSSION

Approximately 50% of all incisional hernias develop in the first two years after the procedure and 74% within three years postsurgery^{6,7,8,9}. It is hypothesized that its formation start from acute subclinical fascial separations that early occur in the postoperative setting^{6,7}. During the first 30 days after surgery, the tensile strength of the suture decreases resulting in a heavy dependence upon its integrity to avoid early separation of the tissues⁶. Among the symptoms caused by these hernias, we observed mild abdominal discomfort and pain, as well as strangulation, incarceration and bowel obstruction¹⁰.

The rate of incisional hernia formation ranges from 3% to 20% after open surgery repair²⁷. Its recurrence after surgical repair is described in the literature in the range of 31 to 54% due to extensive dissection of the tissues for the placement of the mesh and its large incision²⁷. Polypropylene mesh is the most commonly used mesh in this situation and the technique is the placement of a pre-peritoneal prosthesis retromuscular. The introduction of this type of mesh in the sixties have represented a significant decrease in hernia recurrences.

Currently, it is known that hernias formations is due to a biological failure that provokes instability in the healing process. Therefore the use of prosthesis is the method of choice in the surgical repair of hernias.

In spite of presenting good tissue integration and little degradation after fixation the polypropylene mesh presents some disadvantages that limit its use,

Table 4 - Descriptive statistics for the variables of maximum strength of rupture (of each site evaluated) stratified analysis by each type of mesh.

Type of Mesh	Measument	n	Minimum	Maximum	Mean	Standard-Deviation
Polypropylene	Epíplon Strength	10	1,0	4,5	1,9	1,2
	Liver Strength	10	0,0	2,5	0,6	1,0
	Small Intestine Strength	10	0,0	2,5	0,6	1,0
	Round Ligament Strength	10	0,0	4,0	1,6	1,5
ePTFE/PP	Epíplon Strength	10	1,0	3,0	2,1	0,7
	Liver Strength	10	0,0	3,0	0,6	1,3
	Small Intestine Strength	10	0,0	0,5	0,2	0,2
	Round Ligament Strength	10	0,0	3,5	1,1	1,3

Analysis through Mann-Whitney nonparametric test, at 5% significance.

Table 5 - Comparison between the degree of adhesions and the meshes.

Type of mesh	Degree			
	1 ou 2		3	
	n	%	n	%
Polypropylene	6	60,0	4	40,0
ePTFE/polypropylene	9	90,0	1	10,0

Table 6 - Crossing the type of mesh by the percentage of the surface affected by adhesion.

Mesh	Percentage of the mesh affected			
	less than or equal to 50%		more than 50%	
	n	%	n	%
Polypropylene	6	60,0	4	40,0
ePTFE/polypropylene	6	60,0	4	40,0

such as the association with adhesion and fistula formation when in direct contact with the abdominal cavity. *Franklin et al.*, who have performed laparoscopic ventral hernia repair with a polypropylene prosthesis and reported strong adhesions in at least one-third of the patients who underwent re-laparoscopy²⁸.

Because of this, there is a necessity of development of a prosthesis that could be used laparoscopically with satisfactory tissue integration biologically inert and that could not produce intraperitoneal adhesions.

Currently laparoscopic repair of these hernias have been evidenced as the best surgical treatment as it presents shorter hospital day, early return to daily activities and word, less postoperative pain and mainly less complications due to the procedure. After an extensive literature review *Cassar e Munro* described recurrence rates to repair incisional hernia through suture, open repair with prosthesis collocation and laparoscopic repair of 49%, 10% and until 9%,

respectively.²⁹ *Carbajo et al*, in 1999 evaluated hernias recurrence in laparoscopy or laparotomy with prosthesis collocation. The first group did not depicted recurrence and the second depicted 7% after 27 months²⁹.

Although several studies confirm this superiority, the collocation of prosthesis in the peritoneal cavity is not yet a standard procedure in surgery. This is due to the high tendency of these materials to develop intraperitoneal adhesion, bowel obstruction and enterocutaneous fistulas³⁰.

We found in the literature several manuscripts describing the use of polypropylene and ePTFE/polypropylene prosthesis^{28,30}. *Zigren et al* compared the intraperitoneal adhesion between Prolene and Vypro in pigs and they did not found differences in the adhesions degree or in its incidence.

BardComposix® mesh is composed of nonabsorbable, hydrophobic, microporous fluoropolymer of ePTFE bonded to macroporous polypropylene. Theoretically, it reduces adhesion

Table 7 - Comparison of the adhesions of the ePTFE/Polypropylene.

	n	Mean	Standard deviation	P
ePTFE	10	0,30	0,48	0,008
Polypropylene	10	1,00	0,00	

Analysis through the Wilcoxon test ($p < 0,005$).

formation at the visceral side of the prosthesis and increases the percentage of mesothelialization.

It was not observed in the present study difference between the types of adhesions involved. Both meshes presented epiploon, round ligament of the liver, small intestine and liver as a consequence of the adherence process. The incidence of these adhesions were also similar in both groups, as well as the maximum strength of rupture of each viscus, the percentage of the surface of the mesh affected by the adhesion and the degree of adhesions.

When the exclusive analysis of the mesh composed of ePTFE and polypropylene was performed we could observe that the adhesions were predominantly at the edge of the prosthesis, presenting a percentage of 30% to the ePTFE and 100% to the polypropylene of this same mesh, as it has been already described in the literature³⁰.

We presumed that the reason for these findings should be because of the direct contact of the part composed of polypropylene with the abdominal cavity. This is due to the fact that in order to use the prosthesis in the surgical procedure, it should be cut so it is exposed. It is worthy to emphasize that these findings do not reflect long-term consequences of intraperitoneal placement of the prosthesis and long-term studies should be performed.

CONCLUSION

The two groups were statistically indifferent to all the parameters evaluated. When the ePTFE is analyzed separately, the Compositix mesh depicts as a suitable option to repair laparoscopically incisional hernias, due to its potential ability to incorporate the subjacent tissue provided by the polypropylene layer and its anti-adherence potential supplied by the ePTFE.

Further studies are necessary to evaluate the long-term consequences of intraperitoneal contact and to define its real use in the surgical field.

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