Comparative study of Polypropylene versus Parietex composite®, Vicryl® and Ultrapro® meshes, regarding the formation of intraperitoneal adhesions[1]

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Abstract

Purpose: To compare the polypropylene mesh (Marlex®) to Vicryl®, Parietex composite® and Ultrapro® meshes to assess the occurrence of adhesions in the intraperitoneal implantation.
Methods: Sixty Wistar rats were allocated into three groups: PP+V, in which all the animals received a polypropylene and a Vicryl® mesh; PP+PC, with the implantation of polypropylene and Parietex composite® meshes and PP+UP, in which there was implantation of polypropylene and Ultrapro®. Macroscopic analysis was performed 28 days later to assess the percentage of mesh area affected by adhesion.
Results: in the PP+ V group, the Vicryl® mesh showed lower adhesion formation (p=0.013). In the PP+PC, there were no differences between polypropylene and Parietex composite® (p=0.765). In the PP+UP group, Ultrapro® and polypropylene meshes were equivalent (p=0.198).
Conclusion: All the four meshes led to adhesions, with the Vicryl® mesh showing the least potential for its formation.
Key words: Hernia, ventral. Surgical Mesh. Abdominal Wall. Tissue Adhesions. Peritoneum. Rats.

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■ Introduction

Incisional hernia, ventral hernia or eventration correspond to the protrusion of viscera through areas of the abdominal wall weakened by trauma or surgery and its incidence is around 10% to 20%[1]. In the United States, incisional hernia is the most common surgical complication[2,3].

Treatment options are fascial repair with tissue reapproximation and suture, or repair with the use of surgical mesh, implemented by Usher in 1958[4,5]. Burger *et al.*[6] reported that after 10 years of postoperative follow-up, 63% of patients with fascial repair had hernia recurrence, while with the use of meshes, 32% of patients had the same problem. Hence, the use of surgical meshes for correction of abdominal hernias was strengthened due to its lower recurrence rates[6-14].

With the advent of laparoscopic surgery and the placement of intraperitoneal meshes, major adhesion formation was highlighted[2,7,14-19]. The composite meshes – which have the surface facing the viscera made of absorbable and microporous material and the surface facing the muscles made of synthetic macroporous material – are the ones with the best results[20,21]. This composition would be ideal since the biological component of the inner surface would avoid contact between the macroporous part and the abdominal viscera, reducing rates of complications such as adhesions[12]. The macroporous side (>75μm) can also lower the risk of infection since it allows more infiltration of macrophages and neutrophils within the pores, which does not happen in microporous meshes and therefore allows bacterial growth[5].

The ideal characteristics were described at the beginning of the 1950s by Cumberland and Scales, and updated by Hamer-Hodges and Scott in 1985. Among these characteristics are chemical stability, good resistance to mechanical strain, lack of carcinogenic substances, easy sterilization, limited foreign-body reaction, resistance to infection, pliability, being non-allergenic, and presenting similar properties to native tissue[22,23]. The search for the ideal composition became necessary with the introduction and development of laparoscopic repair of abdominal hernias, which required intraperitoneal mesh fixation[4,22].

Among the surgical meshes available on the market, the polypropylene ones are the most commonly used nowadays[4,16,18]. Polypropylene is a carbon-based material – which can be monofilament or multifilament – of easy handling, low cost, and non-biodegradable. However, when used intraperitoneally, it can present high adhesion formation rates[5,22].

The Vicryl® mesh is a completely absorbable surgical mesh made of polyglactin 910 – a copolymer made from polyglycolic acid and lactic acid, capable of lending temporary support to wounds or organs, with malleability and resistance. Since this type of surgical mesh is absorbable, it tends to induce lesser foreign body reaction and consequently, less adhesion formation[9].

The Ultrapro® mesh is a macroporous partially absorbable surgical mesh, composed of a monofilament layer of polypropylene and poliglecaprone, which yields higher tensile strength, besides biocompatibility[24].

The Parietex composite® mesh is comprised of a double-layer mesh. The layer on the muscle side is a polyester barrier, and the surface in contact with the interior of the cavity is a layer of absorbable collagen, polyethylene glycol, and glycerol[2, 6].

The present study aims at evaluating the Vicryl®, Parietex composite® and Ultrapro® surgical meshes, regarding adhesion formation when they are applied intraperitoneally, and comparing them to polypropylene.

■ Methods

The present study was based on data obtained from studies from a line of research,

submitted to the Animal Research Ethics Committee (CEUA) of the Universidade Federal do Paraná, Department of Biological Sciences.

The projects followed the Federal Law #11.794, from October 8, 2008, and obeyed the recommendations of the Brazilian Guidelines on Care and Use of Animals for Scientific and Didactical Purposes and of the Brazilian Society of Laboratory Animal Science.

The studies were performed as part of the subject Surgical Technique and Experimental Surgery, UFPR, and registered through the following processes:

- Vicryl® *vs* polypropylene ("Comparative study between polypropylene and polyglactin 910 meshes regarding intraperitoneal adhesion formation"): process #792, approved under the number 23075.016467/2014-15 on May 22, 2014.

- Ultrapro® *vs* polypropylene ("Comparative study between polypropylene and poliglecaprone mesh (Ultrapro®) and polypropylene mesh regarding intraperitoneal adhesion formation"); process #769, approved under the number 23075.006274/2014-48 on March 20, 2014.

- Parietex composite® *vs* polypropylene ("Polypropylene mesh and polyester mesh with collagen coating and the formation of intraperitoneal adhesions"): process #768, approved under the number 23075.055576/2013-69 on March 20, 2014.

There were four surgical meshes in this study: 1. Polypropylene (Marlex®); 2. Vicryl®, which is made of polyglactin 910 and completely absorbable; 3. Parietex composite®, made of multifilament polyester covered with an absorbable collagen film; 4. Ultrapro®, a partially absorbable mesh composed of monofilament polypropylene and poliglecaprone.

Sixty male rats of the Wistar strain, 100 to 120 days old, were used. The animals were kept in a *vivarium*, under appropriate temperature, light-dark cycle, and humidity conditions, and had unrestricted access to commercial feed and water.

The animals were randomly allocated in three groups. In the PP+V group (n=20), each animal received two intraperitoneal meshes, Vicryl® in one side, and polypropylene in the other. Moreover, in half of these animals (n=10), Vicryl® meshes were implanted in the left side and polypropylene in the right side, while the other half received the meshes in opposite sides, to avoid bias due to the weight of viscera, such as the liver, in the results. In the PP+PC group (n=20), two meshes were implanted in each animal, Parietex composite® in one side of the abdominal cavity, and polypropylene in the other. In the PP+UP group (n=20), each animal had an Ultrapro® mesh implanted in one side, and a polypropylene one in the other. The same methodology was followed for all the groups.

Anesthesia was performed by a veterinarian with a 3:1 ketamine hydrochloride (50 mg/mL) and xylazine hydrochloride (2%) solution respectively. Each animal received 0.5 mL of the solution, and anesthesia was maintained with inhaled isoflurane. The abdominal wall was shaved and antisepsis was performed with povidone-iodine.

Midline xiphoid pubic laparotomy and intraperitoneal mesh placement in the ventrolateral wall were performed, with mesh dimensions of 10 mm width by 20 mm length, in each animal. Meshes were secured with transfixing sutures on the corners of the mesh with Prolene® 5-0, and the knots were placed extraperitoneally. Peritoneal and skin closure were performed with nonlocking continuous suture using nylon 4-0.

After 28 days, the animals were euthanized following the protocol described by resolution #1000/2012 of the Federal Council of Veterinary Medicine. A U-shaped incision was made and the abdominal wall flap was elevated for macroscopic analysis of adhesions. Adhesions to the sutures that secured the mesh or to the laparotomy incision line were not considered, because at these sites the adhesions could have been caused by ischemic sutures and by foreign body reaction to the suture, regardless of the type of mesh[19].

Macroscopic analysis of adhesions included its presence or absence, and the area of the mesh covered by adhesions. Adhesion areas were transferred to millimeter paper with the same dimensions of the mesh (20 mm x 10 mm). Larger adhesions or adhesions to viscera were sectioned and removed for analysis of the previously hidden surface of the mesh, for more accurate results. Millimeter paper transfers were analyzed to obtain the percentage of the mesh covered by adhesions.

The results of the area covered by

adhesions were analyzed by the nonparametric Wilcoxon test, comparing polypropylene with Vicryl®; polypropylene with Ultrapro®; and polypropylene with Parietex composite®. For analysis of the total sample of polypropylene meshes (n=60) and acknowledgement of their behavior in the three groups, the Kruskal-Wallis test was used. Graphs were obtained by the Statistica version 8.0 software (StatSoft Inc. 2008, data analysis software system). We established p≤0.05 as the rejection region for the null hypothesis.

■ Results

There was one death in the PP+V group due to an anesthetic accident. All meshes gave rise to adhesion (Table 1).

Table 1 - Percentage of mesh area covered by adhesions in the PP+V, PP+UP and PP+PC groups, mean and standard deviation.

	PP+V			PP+UP			PP+PC	
	Rat	Polyp.	Vicryl®	Rat	Polyp.	Ultrapro®	Rat	Polyp.	Parietex composite®
	1	100	31	1	18.5	100	1	10	30
	2	18	48.5	2	37.5	53.5	2	28.5	17.5
	3	39.5	2.5	3	49	80	3	22.5	15
	4	22	49	4	17.4	44	4	17	16
	5	20	30	5	10.5	68.5	5	16	100
	6	31.5	20.5	6	25	13	6	22	45
	7	80	50	7	12	43	7	25	20
	8	19.5	15,5	8	19	30	8	28	48
	9	32	5	9	49	42	9	10.5	62
	10	loss		10	19	20.5	10	16	57
	11	54	2.5	11	20	100	11	23.7	9.5
	12	83.5	3	12	56.5	44	12	24	32
	13	31.5	37.5	13	18	8.5	13	24	20.5
	14	42	28.5	14	17	10	14	15	19
	15	18	12.5	15	76	9	15	92.5	7.5
	16	100	57	16	62.5	80	16	52.5	25
	17	100	58	17	26.5	10	17	92.5	45
	18	10	5	18	100	100	18	54.5	35.5
	19	8.5	8.5	19	33	13	19	65	18.5
	20	100	50	20	15	25	20	19	8.5
Mean		47.8947	27.0789		34.07	44.7		32.91	31.575
SD		34.255	20.3772		24.2172	32.8587		25.0527	22.7644
% SD		71.51	75.25		71.09	73.51		72.12	72.09

Polyp. = Polypropylene.
SD = Standard deviation.
Nonparametric Wilcoxon test:
Polypropylene x Vicryl® p=0.013
Polypropylene x Ultrapro® p=0.198
Polypropylene x Parietex composite® p=0.765

For analysis of the behavior of polypropylene meshes in the three groups, the nonparametric Kruskal-Wallis test was used (Figure 1). It was proved that there was no difference in the behavior of the polypropylene meshes among the groups (p=0.289). Hence we could compare the three groups.

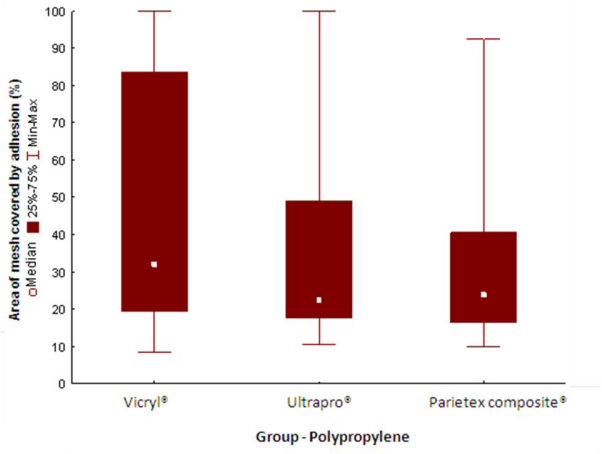

Figure 1 - Comparison of area covered by adhesions in the polypropylene meshes in the PP+V, PP+UP, PP+PC groups (p=0.289).

It was observed that the minimum and the maximum percentages of the surface covered by adhesions were smaller for the Vicryl® meshes than for the other ones (Figure 2). When compared to the performance of polypropylene within its own group (PP+V), Vicryl® showed lower rates of mesh compromise by adhesion (p=0.013). There was no difference either between polypropylene and Ultrapro® (p=0.198), or between polypropylene and Parietex composite® (p=0.765).

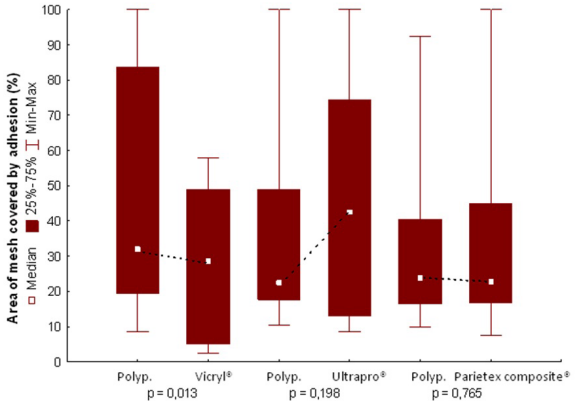

Figure 2 - Paired comparison of median, minimum-maximum and 25%-75% values of groups PP+V, PP+UP and PP+PC.

The differences between polypropylene and each of the other meshes used in this study were evaluated. Values were obtained through the following equation: Difference = polypropylene – other treatment. Vicryl® had an entirely positive 25%-75% interval while the same interval for Ultrapro® and Parietex composite® contained zero, backing up the previously obtained data – Vicryl® has a smaller area of mesh affected by adhesions than polypropylene, but Ultrapro® and Parietex composite® do not (Figure 3).

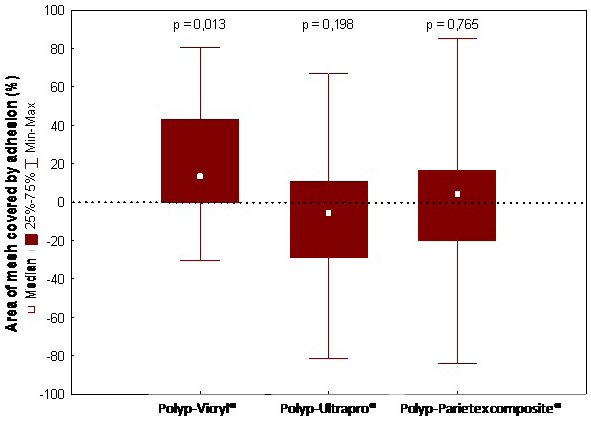

Figure 3 - Difference between polypropylene and other treatment among the PP+V, PP+UP and PP+PC groups.

Regarding the abdominal viscera affected by adhesions, the most affected were the omentum, spermatic cord, liver, and small intestine.

In the PP+V group, the abdominal viscera affected by adhesions were the omentum (100%) and the spermatic cord (90%). The liver was involved in 5% of cases, and the small intestine in 2% of cases.

In the PP+UP group, for both meshes, there was adhesion formation to the omentum (98.5%) and to the spermatic cord (80%). The liver was affected by adhesions in 20% of the meshes – being 5% with polypropylene

meshes and 15% with polypropylene with poliglecaprone (Ultrapro®) ones – and the small intestine in 2.5% of the meshes.

In the PP+PC group, both meshes were affected by adhesion to the omentum (100%) and to the spermatic cord (70%). The liver was affected in 25% of the animal models, being 35% with polypropylene meshes and 15% with Parietex composite® meshes. Finally, the small intestine was affected with 10% of the polypropylene meshes and with 5% of the Parietex composite® meshes.

■ Discussion

The use of surgical meshes for closure of the abdominal cavity has improved hernia recurrence rates because the mesh provides higher tensile strength to the abdominal wall and decreases the recurrence of postoperative hernia[6,9,10-14,21]. However, surgical meshes have brought with them several complications, such as fistulas and adhesions, especially with intraperitoneal use[2,7,14,16-19].

Postoperative adhesions to the surgical meshes may bring complications such as bowel obstruction, female infertility, postoperative abdominal pain, and repair difficulties in future surgeries[25].

Adhesion formation is a complex and dynamic process[26]. After the implant, there is interaction with the blood, forming a provisional matrix for deposition of blood proteins on the material, giving support to the following processes. There is cytokine release, which attracts phagocytes. The initial inflammatory response usually lasts less than a week[27]. Duron describes neutrophils as the first cells to appear, followed by monocytes – which differentiate into phagocytes – and then mesothelial cells appear by the seventh day[25]. In chronic inflammatory response, however, monocytes, lymphocytes, and foreign body giant cells appear. The inflammatory response, both initial and chronic, needs to be resolved in up to two weeks, when biomaterial implants are used[27]. Non-absorbable materials tend to cause more foreign body reaction[9]. The implant coating is capable of altering the actions of monocytes, macrophages, and foreign body giant cells[27].

According to Duron[25], in adhesion formation, there is pathological healing with failure of the fibrinolytic system. During the tissue repair process, a fibrin gel is formed, connecting the peritoneal edges. Although the next step would be plasminogen and fibrinolytic systems activation, this activation is reduced and the fibrin layer formed will form fibrous connective tissue.

Gaertner *et al.*[12], in a study comparing synthetic bioabsorbable-film-coated meshes to biologic meshes in rats, observed that synthetic polypropylene meshes led to more extensive adhesion formation, whereas biologic or synthetic meshes with a bioabsorbable layer had similar covered areas, and significantly smaller.

In the present study, all the meshes caused adhesion formation. The Vicryl® mesh was the only one to show reduction of mesh percentage affected by adhesion (p=0.013). This result is in agreement with the results obtained by Gaertner and Dasika[12,17].

In the current study, there was no difference between Parietex composite® and polypropylene in the formation of adhesions (p=0.765). This result differs from other results reported in literature. Ditzel *et al.*[28] compared, in rats, Parietex composite® and polypropylene meshes, among others, and observed a smaller adhesion formation area with Parietex composite®, 30 days after mesh implantation. The same result was observed in the studies by Burger *et al.*[4], van't Riet *et al.*[6], Schreinemacher *et al.*[14] and Lamber *et al.*[19], with the analysis in the last one being performed 21 days after implantation. Ditzel *et al.*[6] and Burger *et al.*[28] also noted that Parietex composite® showed better incorporation to the abdominal wall.

Rodríguez *et al.*[16], as well as Bellón *et al.*[29], compared adhesion formation between

Parietex composite® and polypropylene meshes after a 14-day period in rabbits, and observed that the Parietex composite® mesh showed lower incidence of adhesions.

Judge *et al.*[30] used Parietex composite® and polypropylene in rabbits, assessed them after 30 days and then after five months, and observed less adhesion formation and greater incorporation to the abdominal wall with the Parietex composite® mesh. However, this mesh showed a higher degree of retraction.

Handling difficulties with Parietex composite® were noted in the present study, since the collagen biofilm underwent contraction when in contact with fluids.

In the current study, there was no difference in percentage of mesh covered by adhesions between Ultrapro® and polypropylene (p=0.198).

Burger *et al.*[6], in a study with rats comparing eight meshes, including polypropylene and Ultrapro®, did not observe any significant difference in adhesion formation, tissue incorporation, retraction, and tensile strength between the two meshes, 30 days after the implant.

Schreinemacher *et al.*[19], in an experiment using rats, did not find any difference between the polypropylene and Ultrapro® meshes regarding adhesion formation rates and tissue incorporation, not only in the analysis seven days later, but also 30 days after the surgical procedure. Nevertheless, Ultrapro® presented more visceral adhesions than polypropelene.

Aramayo *et al.*[1] compared high-density polypropylene to Ultrapro® in rabbits and noted that, after 30 days, the Ultrapro® was superior regarding the area and vascularization of adhesions, mesh contraction, and the acute and chronic inflammatory process.

Bellón *et al.*[16] suggested that, three and fourteen days after implantation, there was no difference in adhesion formation, when using polypropylene or Ultrapro® in rabbits.

Utiyama *et al.*[3] concluded that Ultrapro® and polypropylene have similar results concerning the inflammatory response, adhesion formation, mesh contraction, and complications in rats, with extraperitoneal use.

In the present study, no significant difference was found in the percentage of the mesh covered by adhesions, when comparing polypropylene to Parietex composite® or to Ultrapro®. However, there was significant difference regarding adhesion formation between polypropylene and Vicryl®. Data obtained with Vicryl® and Ultrapro® are in agreement with current literature, while data obtained with Parietex composite® are not.

In this study, one of the animals had 100% of the mesh covered, being discrepant with the other animals, which caused the mean and standard deviation of the group to be altered. Perhaps, with a larger number of animals, the analysis of the extent of meshes affected by adhesion would be more precise, even with the presence of discrepancies.

Standard deviation was high, with its percentage being above 70% in all groups, reflecting the individual reaction to mesh placement, showing that not all animals behave the same, and they do not follow a pattern.

There are still difficulties in confronting data with literature, as there is no universal or standardized score for evaluation of adhesions. Moreover, the animal models can be different, and purely subjective data may be used in the analysis. Gaertner *et al.*[12] reported the same difficulty in analyzing results from other studies, since criteria such as resistance, difficulty in breaking adhesions, and severity, are subjective. There is still a lack of standardization in the experiment, which allows more analytical flexibility, although it generates interpretation differences among the obtained results. An example of this lack of standardization would be including adhesions to the sutures or not. Some authors deem adhesions to suture material to be a part of the adhesion process caused by the use of meshes, while other professionals exclude these adhesions, considering them not to be caused exclusively by the presence of the mesh,

but also by ischemia, and the inflammatory reaction caused by the presence of the stitches. Luijendijk *et al.*[7] reported that 25% of patients presented adhesion to the sutures, which can make it difficult to differentiate them from adhesions formed due to the mesh, and therefore interfere with the results.

The current study aimed at comparing the propensity for adhesion formation of four surgical meshes available on the market, polypropylene (Marlex®), polyglactin 910 (Vicryl®), polypropylene with poliglecaprone (Ultrapro®) and polyester with a collagen layer (Parietex composite®). None of the four meshes analyzed was shown to be free from adhesion induction, although the polyglactin 910 mesh (Vicryl®) has shown lower rates of adhesion formation. This provides further evidence to the hypothesis that there is still no safe indication for the intraperitoneal use of surgical meshes and that all meshes are, to a higher or lower extent, subject to complications.

Thus, it is necessary to seek new materials and combinations that decrease complications, but still provide proper reinforcement for the correction of hernias.

■ Conclusion

The meshes evaluated, placed in intraperitoneal position, led to adhesion formation, although the polyglactin 910 mesh (Vicryl®) has shown lower potential.

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