Experimental study comparing the tensile strength of different surgical meshes following aponeurotic-muscle deformity synthesis on Wistar rats[1]

Estudo experimental comparando a resistência tênsil de diferentes tipos de telas cirúrgicas após síntese de defeito músculo-aponeurótico em ratos Wistar

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ABSTRACT

Purpose: To assess the tensile strength of polypropylene and polypropylene associated with polyglactin meshes (Vypro II® - Ethicon®, Somerville, NJ, USA) in a situation of partial separation of abdominal muscle aponeurosis on rats. **Methods**: Thirty rats were used of the Wistar strain, which were randomized into two groups of 15 specimens each. In both groups an aponeurotic-muscle deformity was created on the abdominal wall measuring 3.0 x 1.0 cm, which was closed with polypropylene mesh (polypropylene group) or Vypro® mesh (vypro group). After 28 days the rats underwent euthanasia and an area was removed from the abdominal wall with which a strip was made measuring 2.0 cm in length and 6.0 cm in width comprising the abdominal muscles with the implanted mesh. This sample was placed in a mechanical test machine in which a constant force was applied contrary to the tissue strips. Maximum force expressed in Newton was considered until full rupture of the sample occurred. The non-parametric Kruskal – Wallis test was used for statistical analysis admitting $p<0.05$. **Results**: Out of the thirty animals, there were two deaths in the vypro group and one unit in the polypropylene group was lost. One animal in the polypropylene group developed hernia during the study and another one developed granuloma of the abdominal wall. All animals in both groups developed epiplon adherence to the mesh. The average force was 48.08 N for the polypropylene group and 45.32 for the vypro® group. **Conclusion**: In these experimental conditions it could be observed that there is no statistically significant difference in the rupture force of the polypropylene and Vypro® meshes ($p=0.54$).
Key words: Surgery. Surgical Mesh. Tensile Strength. Wistar, Rats.

RESUMO

Objetivo: Avaliar a resistência tênsil das telas de polipropileno e polipropileno associado à poliglactina (Vypro II® - Ethicon®, Somerville, NJ, USA) em situação de afastamento parcial da aponeurose dos músculos abdominais em ratos. **Métodos**: Foram utilizados trinta ratos da linhagem Wistar randomizados em dois grupos de quinze exemplares cada um. Em ambos os grupos criou-se um defeito músculo-aponeurótico na parede abdominal medindo 3,0 x 1,0 cm que foi fechado com tela de polipropileno (grupo polipropileno) ou Vypro® (grupo vypro). Após 28 dias, foi feita a eutanásia e retirou-se uma área da parede abdominal com a qual fez-se uma tira medindo 2,0 cm de comprimento por 6,0 cm de largura englobando os músculos abdominais com a tela implantada. Essa amostra foi presa em máquina de ensaios mecânicos na qual se aplicou força constante contrária às tiras de tecido. Foi considerada a força máxima expressa em Newton até ocorrer a ruptura total da amostra. Para a análise estatística, utilizou-se teste não paramétrico de Kruskal - Wallis admitindo-se $p<0,05$. **Resultados**: Ocorreram dois óbitos do grupo vypro e uma unidade do grupo polipropileno foi perdida no teste mecânico. Um animal do grupo polipropileno desenvolveu hérnia durante o período do estudo e outro desenvolveu um granuloma de parede abdominal. Todos os animais de ambos os grupos desenvolveram aderência de epíplon à tela. A média das forças foi de 48.08 N para o grupo polipropileno e 45.32 N para o grupo vypro®. **Conclusão:** A tela de polipropileno apresentou uma força média de resistência à tração maior quando comparada com a de Vypro® nessas condições experimentais.
Descritores: Cirurgia. Telas Cirúrgicas. Resistência à Tração. Ratos Wistar.

Introduction

Incisional hernia (IH) is a problematic condition for the general surgeon[1,2,3,4], since its incidence varies from 1 to 11% and increases quite a lot if the closing of the cavity is done under stress[3] , reaching up to 33.8% if there is concurrent infection.[5] The incidence of IH is similar both in short and long-term follow-ups, since the literature points at the appearance of hernia years after the base surgery. This serves as evidence that IH continues to appear even years after the primary intervention.[4,6] Large incisional hernias result from the loss of abdominal domicile, which takes place when the abdominal content is no longer in the abdominal cavity, that is, when there is a disproportion between the continent (which has become smaller) and the content. In the event of a large abdominal deformity several techniques have been proposed, many of which with the utilization of grafts and prosthesis. As to grafts literature makes reference to fascia lata, dura mater, skin from the herniary sac itself according to the technique proposed by Alcino Lázaro da Silva. Another type of surgical technique is that which uses synthetic prostheses which are available in several varieties. Basically synthetic prosthesis may be made of nylon, polypropylene, polytetrafluorethylene, polyvinyl, acrylonytril, pulp acetate, polyglactin 910,[7] polypropylene bound to synthetic polyglactin.[8] Early studies done by Usher and Wallace[9] showed the validity of polyethylene(Marlex 50®) for the production of surgical meshes of optimal physical properties, being biologically inert and adequate to the surgical treatment of incisional hernias.[10] It is also regarded as useful in the management of recurring incisional hernia.[3] Falci[11] introduced the polypropylene mesh repair in Brazil. He confirmed the undeniable biological properties of the mesh and considered it a highly qualified adjuvant element in the treatment of incisional hernias. The present study is intended to assess the mechanical strength of two types of surgical meshes currently available in the medical-surgical field. A comparison will be made between the polypropylene mesh, which has qualities so well described in the literature, and a new mesh made of equal parts of unabsorbable (polypropylene) and absorbable (polyglactin) material (Vypro II® - Ethicon®, Somerville, NJ, USA).

Methods

This paper is in compliance with all the criteria, technical standards and international animal research rights recommended by the Brazilian College on Animal Experimentation (COBEA) and are in accordance with the Federal Law no. 6,638 of the Federative Republic of Brazil. The Ethical Committee on Research of the Santa Catarina South University – UNISUL has approved this study (protocol 05.282.4.01-III). The animals were kept throughout the experiment in the Operative Technique and Experimental Surgery Laboratory at UNISUL in ambient temperature, continuous air flow, free of noise and stress and obeying natural day and night cycles. They remained in individual cages on shelves in the same distance from the light source with feed and water *ad libitum*. Thirty rats were used of the Wistar strain (*Rattus norvegicus albinus*), males, weighing between 200 and 300 grams, apparently healthy, with an approximate age of 90 days, all coming from the UNISUL Central Biotery. The rats were randomized into two groups of 15 specimens each, identified by an individual number on the cages and distributed as follows:

Polypropylene group (n=15): a polypropylene mesh was used (Figure 1) measuring 4.0 cm in length and 2.0 cm in width (8 cm^2) to close the deformity caused on the abdominal wall.

Polypropylene associated with synthetic polyglactin group - Vypro® (n=15): same procedures adopted in the polypropylene group utilizing Vypro® mesh (Figure 1) for the synthesis of the deformity caused on the abdominal wall.

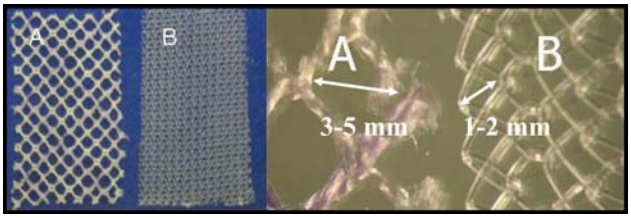

FIGURE 1 - Macroscopic (left) and microscopic comparison with 16x enlargement (right) of the Vypro® (A) and polypropylene (B) meshes.

The anesthetic induction was done with ether inhalation followed by an injection of ketamine hydrochloride and xilazine hydrochloride at 2% in the dilution 1:1 intramuscular (0.2ml/100g) on the inside of the right leg. The animals remained under spontaneous breathing throughout the operating time and at no time during the test were antibiotics used. Then, they were placed on their backs with adhesive tape securing them to a hard board. Manual depilation and antisepsis was done with polyvinylpyrrolidone iodine on the anterior abdominal wall. Median laparotomy was conducted with 4.0 cm and exposure of the anterior abdominal wall for resection of an area measuring 3.0 cm in length by 1.0 cm in width over the alba line, reaching aponeurotic-muscle layer and peritoneum (Figure 2). The deformity was closed by the meshes under study fixed in a bridge shape on the incision with their edges in contact with the muscular plane. In both cases polypropylene wire 6-0 was used for synthesis, mounted on cylindrical needles using simple separate stitches, on a single plane, intercalated with 1.0 cm spaces, 0.5 cm distance from the mesh, 1.0 cm from the incision edge and tied with 5 semi-knots (Figures 3 and 4). The meshes were lodged in a subcutaneous position and in direct contact with the viscera. The skin was closed with 3-0 nylon monofilament wire with greek-type suture (Figure 5). After 28 days the animals underwent euthanasia through massive ether inhalation, manual depilation was done and inverted "U" shaped incision with resection of an area of approximately 20 cm^2 of the anterior abdominal wall with interest on the skin, subcutaneous cellular tissue and muscle aponeurosis with the mesh implanted *in situ*. With this sample a strip was made measuring 2.0 cm in length and 6.0 cm in width, transversal to the surgical scar area of the abdominal wall which served for the mechanical analyses.

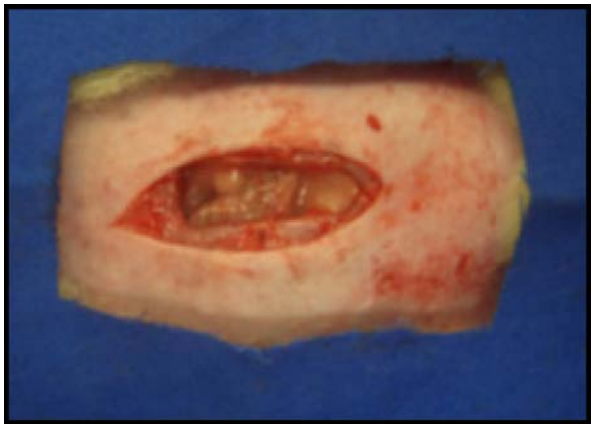

FIGURE 2 - Abdominal wall after muscle resection and production of deformity to be corrected later by one of the meshes.

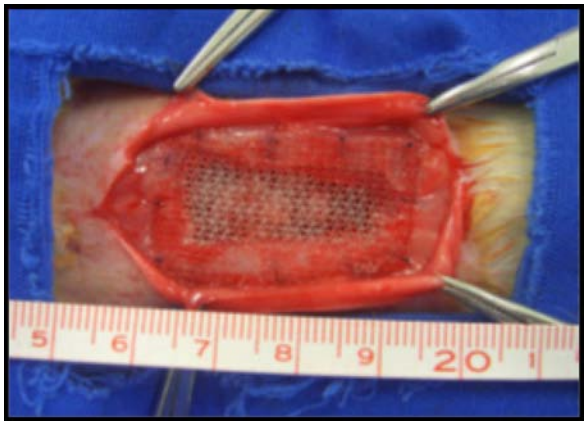

FIGURE 3 - Closing of the deformity with polypropylene mesh.

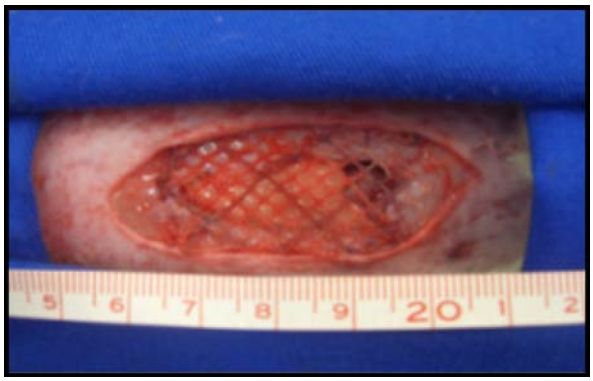

FIGURE 4 - Closing of the deformity with Vypro® mesh.

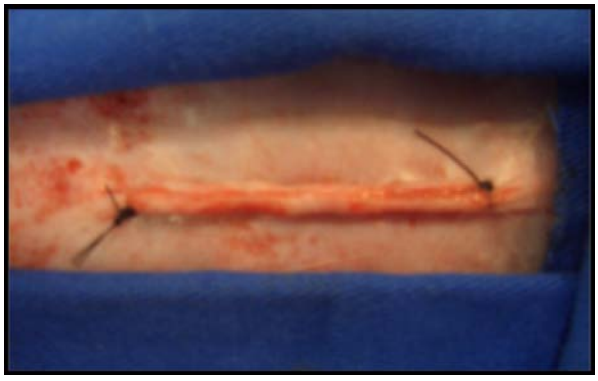

FIGURE 5 - Skin synthesis with greek- type suture.

The strip ends were fixed on clamps of a universal mechanical test machine EMIC® model DL – 2000 (Equipment and Testing Systems Ltda Curitiba, PR, Brazil) distant 1.0 cm from each side of the flap edge, leaving a free area of 2.0 cm contiguous to the spot where the mesh had been implanted (Figure 7). Constant traction was applied contrary to the tissue strip and maximum force, expressed in Newton, was considered and applied until rupture of the sample occurred (Figure 8). Statistical analysis was done using Kruskal -Wallis non-parametric test. Statistical significance level with a value of $p<0.05$ was admitted.

FIGURE 6 - Wall fragment removed for mechanical analysis in traction machine. Abdominal aponeurosis(A), implanted mesh(B).

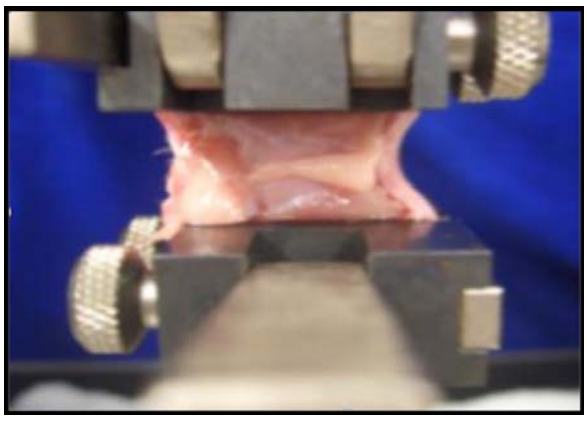

FIGURE 7 - Fixation of tissue fragment in traction machine.

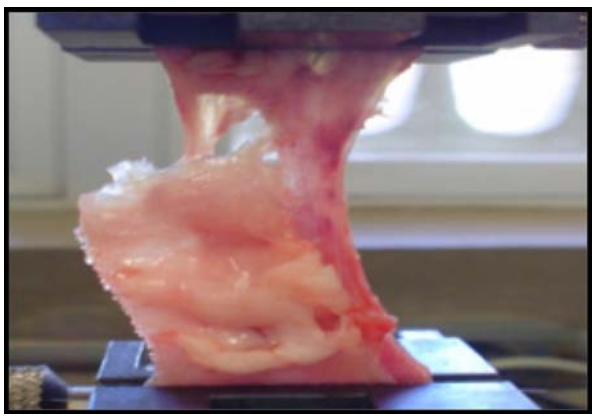

FIGURE 8 - Rupture, under stress, of the sample studied. Polypropylene group.

Results

Out of the thirty animals studied, two from the vypro group died on the first post-operatory day and a sample from the polypropylene group was lost during the mechanical assessment due to a clamp misfixation. One animal in the polypropylene group developed hernia during the period of the study, probably due to rupture of the suture wire and another one developed a foreign-body type granuloma (Figure 9 and Table 1). All animals in both groups presented intra-abdominal adherence to the meshes. (Figure 10 and Table 2). The forces expressed in Newton ($1N = 10^5$ d = 1 kgf = 9.806 65 N) obtained on the traction test are demonstrated on Table 1, Figures 9 and 10. All rats in both groups developed a rupture between the mesh and the muscle. An average force was found in favor of the polypropylene group, nevertheless the difference did not attain statistical significance at a confidence level of 95%. (p=0.54)

TABLE 1 - Result of traction test of polypropylene and vypro® groups. Force values expressed in Newton.

ANIMAL Nº	POLYPROPYLENE GROUP	VYPRO® GROUP
1	42.74	41.39
2	47.96	46.27
3	41.56	41.73
4	60.91	37.69
5	35.17	61.42
6	50.82	46.78
7	37.02	61.92
8	56.87	53.68
9	42.07	62.09
10	56.20	39.54
11	46.95	45.26
12	43.24	25.07
13	65.96	26.42
14	45.26	**
15	*	**
Average	48.05 N	45.32 N
Standard Bias	9.05	16.83

* sample lost in mechanical test

** death in post-operatory

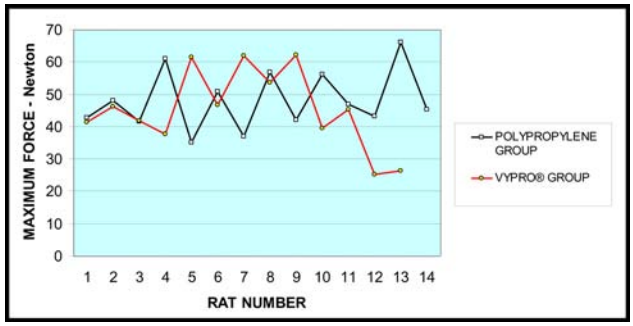

FIGURE 9 - Result of traction test comparing the tensile strength of the polypropylene and vypro® groups.

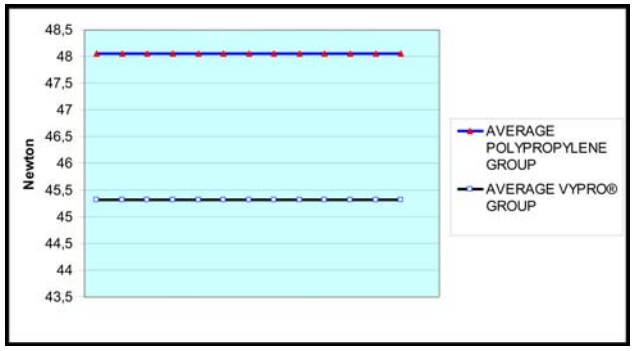

FIGURE 10 - Average values of tensile strength for polypropylene and vypro® groups.

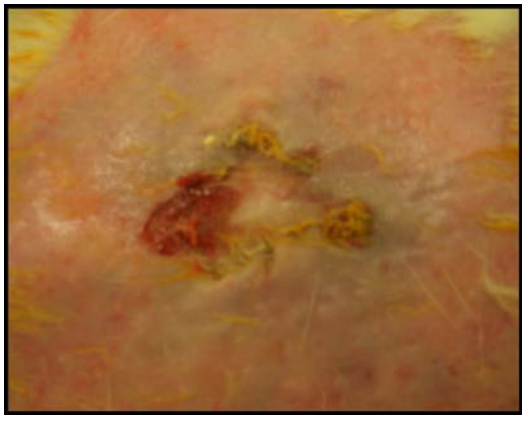

FIGURE 11 - Foreign body granuloma caused by the polypropylene mesh on the abdominal wall.

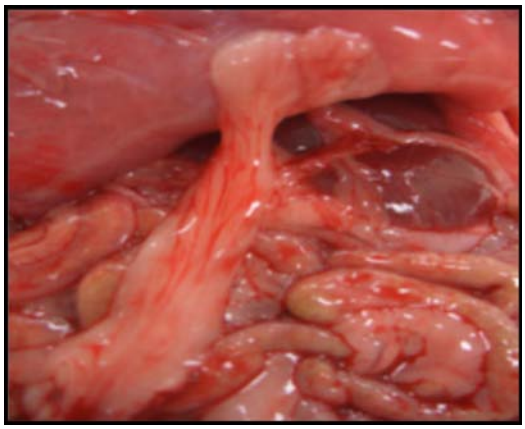

FIGURE 12 - Epiplon adherence to the mesh. Polypropylene group.

TABLE 2 - Comparison of the presence of macroscopic reaction to the polypropylene and vypro® mesh implant.

TYPE	POLYPROPYLENE GROUP	VYPRO® GROUP
Foreign body type reaction	1/14 (7.14%)	0/13 (0%)

TABLE 3 - Comparison of macroscopic adherences visualized after 28 days in the polypropylene and vypro® groups.

TYPO OF ADHERENCE	POLYPROPYLENE GROUP	VYPRO® GROUP
Epiplon	14/14 (100%)	13/13 (100%)
Small bowels	1/14 (7.14%)	0/13 (0%)

Discussion

Abdominal wall synthesis in situations in which there is not enough autogen tissue available for optimal primary closing is not always an easy task[12] and the occurrence of IH is an important cause of morbidity in these patients [13] because it interferes both in their quality of living and in their cosmetic appearance.[14] The attempt to solve this problem, the absence or impossibility of utilization of local tissue for the synthesis of the abdominal wall following a laparotomy led surgeons to opt for the utilization of prostheses, within a strategy to make the wall viable after the illness has been cured. In order to simulate a condition in which one cannot achieve good apposition of the incision edges, a deformity of the anterior abdominal wall was artificially created on these animals. This allowed the use of the meshes under study, since no experimental surgery data was found to provide an eminently mechanical comparative analysis between these two types of surgical meshes. The traditional polypropylene mesh was used, described by Usher and Gannon[15], who demonstrated that no fragmentation or decrease in the tensile strength took place six weeks after its implantation on dogs, being a useful material in the repair of tissue losses in human beings. Undoubtedly the polypropylene mesh is one of the great breakthroughs in medical-surgical technology, repairing deformities which in the past could not be sutured, allowing better integration, quick fixation and low risk of infection, enabling the infiltration of fibroblasts, collagen and macrophages to take place in the synthetic mesh.[7] It is formed by intertwined polypropylene and is currently patented as Marlex® (CR Bard, Branston, RI, USA), Prolene® (Ethicon, Somerville, NJ, USA) and Atrium® (Atrium Medical, Hudson, NH, USA). The use of a mesh preserves the elasticity of the abdominal wall as it allows proper tissue integration maintaining the necessary strength. Polypropylene meshes have good mechanical stability, reasonable elasticity and no tendency to degrade. The pores on this type of mesh, being rated as small (1-2 mm) produce a greater and longer-lasting foreign body inflammatory reaction. Such reaction depends exclusively on the amount of material and on the structure of the texture present on the mesh. Studies demonstrate that meshes have an excessive amount of material, contributing to the rigidity and restriction of the abdominal wall, as well as a greater foreign body reaction.[16] The polypropylene mesh was compared, in this study, with a Vypro® mesh which incorporates unabsorbable (polypropylene) and absorbable (polyglactin) material. The development of this type of mesh allowed a reduction of 70% in the polypropylene material used in other meshes, being characterized as a low-weight mesh as compared to meshes which present only polypropylene in their construction. The large pores on this mesh (3-5 mm) preserve elasticity when it is being incorporated and the extension of the inflammation caused by the prosthesis is significantly reduced. The material allows proper tissue integration with the formation of a network instead of a hard scar structure, thus helping prevent complications resulting from the use of the mesh. It offers excellent results in the treatment of incisional hernias.[16] When comparing two meshes of materials such as polypropylene and polyester it becomes evident that the polypropylene mesh provides high tensile strength, which has to do with the size of the pores. The rigidity of this mesh may be related to adhesions and erosions into the viscera, accumulation of seroma, mesh distortion and wrinkling.[17] The Prolene® mesh is also braided with polypropylene, but presents pores which are twice as big as those on the Marlex® mesh, being more flexible. This leads some surgeons to believe that the former presents lower erosion rates into the viscera, even in the lack of scientific data to prove it. Mesh flexibility and rigidity are directly related to pore size.[18] The mesh implant was demonstrated as being a simple model, of easy execution, viable and not requiring major resources. Likewise, the rupture force analysis on a mechanical test machine proved to be an appropriate technique that provides precise and quick results. Tensile strength studies are an important experimental tool, reflecting the effect of multiple and complex variables which may be imposed by one or several experimental conditions.[19] The tensile strength force analysis between the polypropylene and Vypro® groups was not statistically significant and we believe this is due to the intrinsic characteristics of the meshes studied, since the Vypro® mesh has a proportion of polypropylene in its composition. A previous study comparing the tensile strength of polypropylene and polyglactin 910 meshes did not present statistical significance, the strength being the same. [20] The intra-abdominal adherences observed in this study have been demonstrated in a paper which compared the polypropylene and Vypro® meshes implanted in the peritoneal cavity of rabbits.[20] Other studies have clearly demonstrated the occurrence of

adherences when the polypropylene mesh is used.[22] The occurrence of adherences is confirmed when the polypropylene mesh is used in peritoneostomies, incorporating itself to the neighbor tissues and making it impossible to be removed without damaging the intestinal loops.[23] The polypropylene mesh was shown to have higher strength and we believe its usage should be supported by the broadly spread knowledge about its characteristics, as well as by its lower cost when compared to that of the Vypro® mesh.

Conclusion

The polypropylene mesh presented a greater average tensile strength when compared to the Vypro® mesh under experimental conditions.

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