

ORIGINAL ARTICLE

Biomechanical effects of the inclusion of holes to facilitate the integration in monofilament polypropylene meshes: An experimental study^{☆,☆☆}

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Abstract

Objective: To evaluate the biomechanical properties of a type of monofilament polypropylene mesh used to repair vaginal prolapse, as well as the effects of the inclusion of standard size orifices, called "helper orifices," on the interface resistance in the receiving area.

Material and methods: Forty, 3 month-old, female Wistar rats received an implant of monofilament polypropylene mesh, measuring 24 mm × 11 mm with no orifices, on the left side of the abdominal wall (block 1). On the right side, a similar mesh with two circular orifices (6 mm diameter) was implanted (block 2). The rats were euthanized 90 days later and their abdominal walls were removed and divided into two blocks. The biomechanical study used a precision tensiometer in which the mesh was uniaxially tensioned until it was loosened from the tissue interface. In order to determine the tissue adherence and elasticity in each group, the following variables were analyzed: maximum load; deflection at maximum load; work to maximum load; stiffness as well as load, deflection and work at detachment of the mesh.

Results: With the exception of stiffness, all the other variables showed statistical differences between the groups, considering that they were increased in meshes with orifices ($p < 0.001$). The inclusion of standard size orifices reduced 30% of the mesh weight.

Conclusion: Besides reducing the weight and amount of material, the inclusion of standard size orifices in the monofilament macroporous polypropylene mesh improved the elasticity and adherence to the tissues when implanted in the interface of the abdominal wall in adult female rats.

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PALABRAS CLAVE

Mallas;
 Polipropileno;
 Propiedades
 biomecánicas;
 Orificios facilitadores
 de la integración

Efectos biomecánicos de la inclusión de orificios facilitadores de la integración en mallas de polipropileno monofilamento: estudio experimental

Resumen

Objetivo: Evaluar las propiedades biomecánicas de un tipo de malla de polipropileno monofilamento utilizada para la reparación de prolapso vaginales y los efectos de la inclusión de orificios de tamaño estandarizado, que llamamos orificios facilitadores de la integración, sobre la resistencia en la interfaz con el lecho receptor.

Material y métodos: En 40 ratas Wistar, de 3 meses de edad (adultas), se implantó en la pared abdominal del lado izquierdo una malla de polipropileno monofilamento que medía 24 x 11 mm sin orificios (bloque 1) y del lado derecho una malla similar con dos orificios circulares de 6 mm de diámetro (bloque 2). Después de 90 días las ratas se sacrificaron y se les retiró la pared abdominal, dividiéndola en dos bloques. El estudio biomecánico se realizó con un tensiómetro de precisión con el cual se traccionó la malla en sentido uniaxial hasta que se desprendiera de la interfaz tisular. Para cuantificar en cada grupo la adherencia y elasticidad tisular se analizaron las siguientes variables: carga máxima, deflexión hasta la carga máxima, trabajo hasta la carga máxima y consistencia del material, además de carga, deflexión y trabajo en el desprendimiento de la malla.

Resultados: Exceptuando la variable consistencia del material, para el resto de las variables hubo diferencia estadísticamente significativa entre ambos grupos, siendo superior en las mallas con orificios ($p < 0,001$). La inclusión de orificios de tamaño estandarizado redujo en un 30% el peso de la malla.

Conclusión: La inclusión de orificios de tamaño estandarizado en mallas de polipropileno macroporosas monofilamento, además de reducir su peso y la cantidad de material, aumentó la elasticidad y la adherencia a los tejidos al implantarse en la interfaz de la pared abdominal de ratas adultas.

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Introduction

The vaginal wall prolapses are highly prevalent. It is estimated that 10% of North-American women have accentuated prolapses.¹ For their treatment, techniques based on sutures, site-specific corrections or, more recently, meshes and prostheses are used.^{2,3} Considering the high rate of recurrence with conventional techniques based on the repair of the pubocervical fascia with sutures, the meshes came to represent a potential option for the treatment of selected cases of urogenital prolapses.^{4,5} Then, it is justified to question the real need for meshes and the type of material to be used.^{6,7} In this sense, we have used, among others, biological grafts (porcine dermis, porcine intestinal submucosa, cadaveric fascia lata) and synthetic implants.^{8,9} There is the concept that the best results can be achieved using monofilament polypropylene meshes.^{6,10} This is the most widely used synthetic material, with cure rates of up to 90% in the treatment of vaginal prolapses.^{11,12} Considering biocompatibility, the advantages of the polypropylene meshes over other synthetic materials have already been established in animal and human studies.¹³⁻¹⁵ However, constant innovations are presented in order to obtain better anatomical and functional results, and minimize complications such as extrusion and dyspareunia.¹⁶⁻¹⁸ With the aim of reducing the amount of implanted material and, consequently, the weight of the mesh, as well as promoting greater adherence of the product to tissues, the inclusion of 6-mm diameter standard-sized holes in macroporous monofilament polypropylene meshes called "helper orifices of integration" was designed.

In this original study, which was approved by the Ethics Committee for Animal Experimentation of the State University of Campinas, we experimentally assessed the biomechanical properties of a type of macroporous monofilament polypropylene meshes, and the effects of the inclusion of these holes on the resistance at the tissue interface of the abdominal wall of adult rats.

Materials and methods

We used macroporous monofilament polypropylene meshes with original grammage of 84 g/m² called as follows:

Mesh 1: 24 mm × 11 mm flat mesh, without holes, with an average weight of 0.030 g (previously measured on a precision scale-GEHAKA BG440).

Mesh 2: mesh of equal size and material that contains two holes of 6 mm in diameter and weighs 0.021 g on average, thus, presenting a weight reduction of 30% compared with the control mesh.

We used a homogeneous group of 40 Wistar rats, aged 3 months on average, regarded as adults, weighing between 200 and 250 g. The animals were anesthetized with intravenous sodium pentobarbital at 6%, and positioned in horizontal dorsal decubitus after performing abdominal trichotomy and asepsis with povidone iodine solution. Then, there was a 2-cm transverse incision in the lower abdomen. After division of the subcutaneous tissue, mesh 1 was implanted at the interface, between the hypodermis and the left hemiabdomen muscle fascia. Similarly, mesh 2 was implanted on the right side of the abdomen (Fig. 1). No form

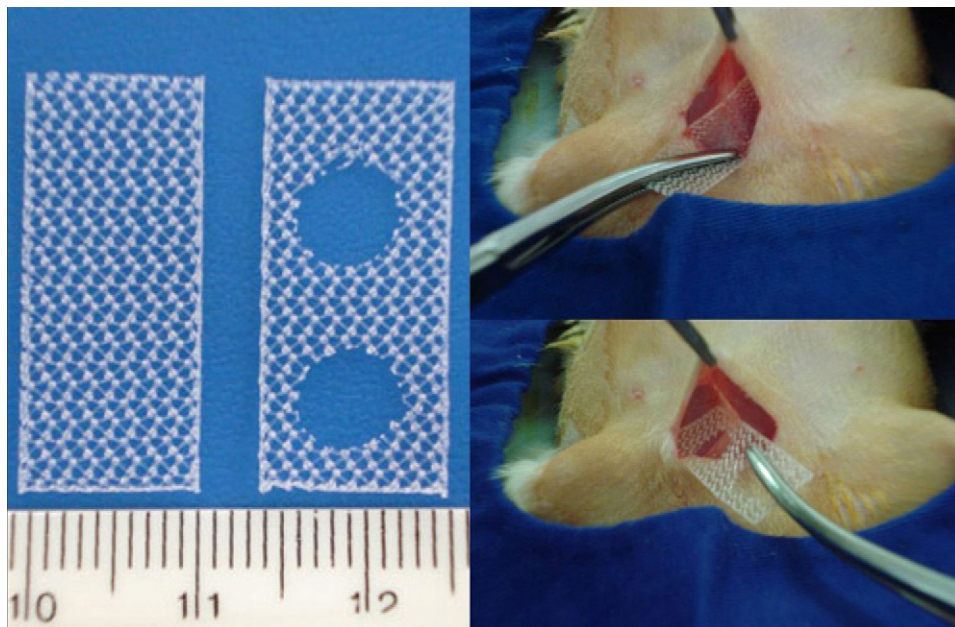


Figure 1 Macroporous monofilament polypropylene meshes without and with holes to facilitate integration. Next to them, surgical technique.

of fixation of the meshes was used. After 90 days, the rats were sacrificed by anesthetic depth and the abdominal wall was extracted, dividing it symmetrically into two blocks for biomechanical study.

Block 1: left side of the abdominal wall containing skin, subcutaneous cellular tissue, mesh 1, anterior fascia with abdominal muscles and peritoneum.

Block 2: right side of the abdominal wall containing the same structures with mesh 2.

The blocks were prepared exposing 2 mm of the proximal end of the meshes for fixation in the upper loop of

the tensiometer (Universal Testing Machine – Nexygen 3.0 – LLOYD Instruments) specially designed for load testing in soft tissues.¹⁹ The study was conducted 2 h after obtaining the material in all cases. The distal portion of the mesh-free abdominal wall (barely containing muscle and skin) was fixed to the lower loop of the tensiometer to perform the biomechanical study. Then, the tensiometer was activated and the loops were dislocated in the opposite direction, applying an increasing force (N) at constant speed (2 mm/s) until the mesh became detached from the tissue interface (Fig. 2). Each test resulted in a graph (Fig. 3) of which the

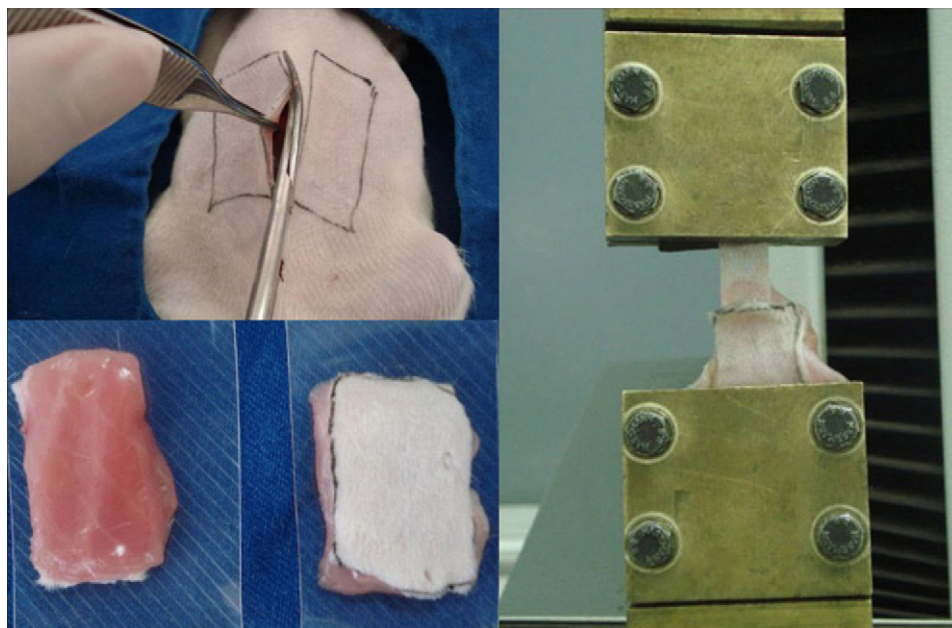


Figure 2 Block extraction and biomechanical tests.

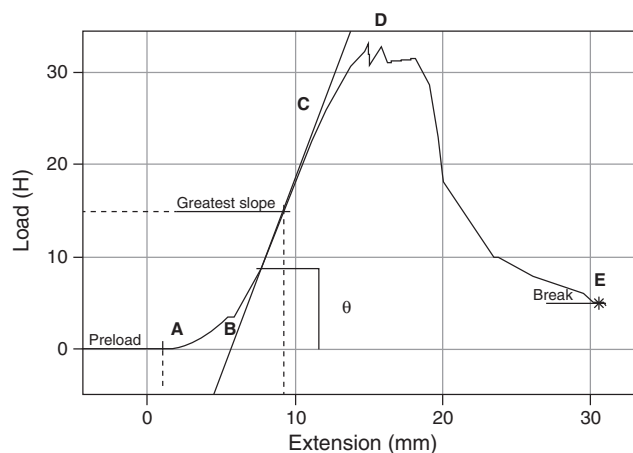


Figure 3 Characteristic curve (load \times displacement) of each test: (A–B) region of settlement; (B–C) linear increase of load; (C–D) strain hardening region (non-linear increase of load. Point D: peak load (maximum load). A–D extension on the x-axis: deflection to maximum load. Area under the curve A–D: work to maximum load. Point E: rupture (detachment of the mesh of the tissue interface). Area under the curve A–E: work to the detachment of the mesh (total work). Point E on the y-axis: load at breaking. Tangent of the θ angle: consistency of the material (modulus of elasticity).

following variables were automatically extracted for the paired comparative study: maximum load (N), deflection to maximum load (N/mm), work to maximum load (J), consistency of the material (N/m), load during shedding of the mesh (N), deflection to the detachment of the mesh (mm), and work up to the detachment of the mesh (J). Thus, the variables load, deflection, and work were assessed both during the test and at the break, i.e. the time when the mesh was completely detached from the tissue interface.

The horizontal region of the graph (A–B), in which the specimen did not fully respond to the load, was called 'region of settlement'. When the tested body generates a tensile strength, its stretching begins causing an almost

linear region (B–C) with increased applied load. The consistency of the material (or modulus of elasticity) was determined by calculating the tangent of the θ angle of the originated inclination of this linear region. Subsequently, we observed the transition from linear to non-linear behavior (C–D) called 'strain hardening region', which represents the alteration of the standard strength of the material, resulting from the 'fracture' of its components after deformed to cold. Finally, there is the peak load (D), which is the point where significant and irreversible material damage occurred. The displacement (stretching) from point A to point D represents the extension (or deflection) to the peak load, however, its resistance decreased with the damage suffered. The detachment of the mesh of the tissue interface with complete separation was called point E. The work, or energy released to the maximum load, was calculated by the area under the curve A–D. The work to the detachment of the mesh of the tissue interface, or total work, is represented by the area under the curve A–E.

For statistical analysis, we used the Wilcoxon test for related samples (*Signed rank test*) considering a p value <0.05 significant.

Results

Two rats died in the postoperative period, the remaining 38 being analyzed.

The results are shown in [Table 1](#).

As it can be seen in [Table 1](#), the measurable variables in the tests directly show the degree of adherence of the meshes to the tissues. This way, we observe that in the meshes with holes, the measured load values (N) are statistically higher than the values found for the meshes without holes. The measured values for the variable deflection (mm), which represents the elasticity or deformation suffered by the material during testing and is directly proportional to the adhesion, were also statistically higher in the meshes with holes. On the other hand, we note that, in

Table 1 Experimental biomechanical study of meshes with and without holes implanted in the subcutaneous cellular tissue of adult rats.

Variable	Maximum	Minimum	Mean	Median	Standard deviation	p value
Maximum load (N) ^a	27.02	5.57	15.21	15.37	4.47	
Maximum load (N) ^b	37.24	10.26	21.82	21.06	6.23	$p < 0.001$
Deflection to maximum load (mm) ^a	38.97	8.21	16.51	13.89	8.21	
Deflection to maximum load (mm) ^b	41.63	7.54	21.08	19.22	7.54	$p < 0.001$
Work to maximum load (J) ^a	0.40	0.06	0.11	0.10	0.06	
Work to maximum load (J) ^b	0.46	0.09	0.20	0.18	0.09	$p < 0.001$
Consistency (N/m) ^a	6960.4	1010.6	2513.3	2341.1	1190.7	
Consistency (N/m) ^b	6507.0	1227.9	2525.7	2266.8	1062.3	$p = 0.87$
Load at detachment (N) ^a	4.05	0.84	2.27	2.24	0.67	
Load at detachment (N) ^b	5.59	1.54	3.27	3.16	0.93	$p < 0.001$
Deflection to detachment (mm) ^a	67.83	8.41	27.30	24.03	12.54	
Deflection to detachment (mm) ^b	94.04	20.32	43.95	42.14	15.60	$p < 0.001$
Work to detachment (J) ^a	0.49	0.03	0.18	0.16	0.10	
Work to detachment (J) ^b	1.05	0.16	0.43	0.40	0.17	$p < 0.001$

1: meshes without holes; 2: meshes with holes.

the meshes with holes, the measured work values (J), which represent the energy released for a certain task and directly show the degree of adhesion, are statistically higher. The variable consistency of the material (N/m) showed no statistically significant difference between the two groups. According to Table 1, we observe that the load, deflection, and work values to rupture are significantly higher in the group of meshes with holes.

Discussion

The tissue reactions to the various types of synthetic materials used for the correction of the pelvic floor defects are already established, and they were not covered by this study.^{20–23} It is known that, apart from the mechanical properties of the meshes, local factors such as tissue tropism, infections, and surgical technique are directly related to the rates of extrusion.^{24,25} In surgery for stress incontinence, the extrusion rates of monofilament polypropylene meshes range from 3 to 12%.^{16,17,26}

The tissue integration is related to the weight, structure, and porosity of the meshes.^{22,23,27–29} The most flexible meshes seem to adhere and adjust to the underlying tissues more appropriately than more rigid ones.³⁰ The weft of the different polypropylene meshes and the thickness of their fibers can cause differences in flexibility. The mechanical properties of the different types of polypropylene meshes used in the correction of pelvic floor defects are usually stated on the packaging by manufacturers, but the behavior of the same in the receiving area still remains unknown. Recently, some studies aimed to analyze the properties of certain types of meshes after implantation in animals,^{22,23,27–29,31} although in most of these works, isolated meshes were analyzed, and the study of the biomechanical properties of these in the tissue interface has been little explored. Kubricht et al. used a fixed-arm tensiometer connected to a digital meter pulled by a crank.³¹ Yildirim et al., in order to measure the adhesion of different types of meshes to the surrounding tissues after implantation in the abdominal wall of rabbits, used increasing weights under the action of gravity to study the necessary strength for detachment of the mesh.²² The minimum weight necessary to achieve this separation reflected the mesh-tissue adhesion. Alfonso et al., using a sensitive tensiometer (Universal Testing Machine) similar to that used in our study, analyzed *in vitro* the biomechanical properties (tensile and flexural consistency) of 5 different types of meshes used in the treatment of urinary stress incontinence, and concluded that there are significant differences in mechanical properties between the urogynecological meshes studied by them.³⁰ Recently, Bazi et al. conducted a comparative study with different types of commercial polypropylene meshes used in mid-urethral slings. After implantation in the abdominal wall of rats, they analyzed the biomechanical behavior of mice, using the same tensiometer.²³ They concluded that this material exhibits different biomechanical properties once the implant is performed, particularly in relation to the consistency of the different types of meshes. However, they did not analyze the properties of these implants in the tissue interface, and their study was limited to just three

biomechanical variables (maximum load, deflection to maximum load, and initial consistency of the material).

The present study shows the biomechanical properties of a type of polypropylene meshes (macroporous monofilament) in the tissue interface of the abdomen of adult rats, and the effects of the inclusion of holes to facilitate integration in them. The inclusion of these holes in the meshes studied increased tensile strength and adhesion to surrounding tissues, as demonstrated in the analysis of the values found for the maximum load, work to maximum load, load at detachment of the mesh, and work at detachment of the mesh. The holes also conferred greater elasticity, as demonstrated in the analysis of the deflection values to maximum load and deflection to the detachment of the mesh. This way, we sought to deduct the biomechanical behavior in the human vagina, since the implant was performed similarly, between epithelial tissue and muscle fascia. Better integration of macroporous monofilament polypropylene mesh with holes that help integration could infer that the use of these would have clinical applicability.

Conclusion

The results found in the conditions of this study make it possible to conclude that the inclusion of holes to help integration in macroporous monofilament polypropylene meshes, as well as increasing their elasticity and reduce their weight, increases adhesion to tissues when implanted in the interface of the abdominal wall of adult rats. Such evidence could have a positive impact on clinical practice.

Conflict of interest

The authors declare that they have no conflict of interest.

Acknowledgement

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