

Histopathological Evaluation of Inflammatory Response and Capsular Formation Induced by Smooth, Textured, and Polyurethane Implants in Rats

Avaliação histopatológica da resposta inflamatória e formação capsular com implantes lisos, texturizados e de poliuretano em ratos

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Abstract

Introduction Silicone breast prostheses, designed in the 1960s, have undergone several modifications to minimize the inflammatory response and capsular contracture. Biomaterial research enhances the understanding of the interaction between implants and tissues, providing insights into innovation, repair, regeneration, and capsular contracture.

Objective To evaluate the biological response to smooth, textured, and polyurethane-coated implants, to identify associated complications, and to compare postoperative capsular formation in animals receiving these implants.

Materials and Methods Ten female Wistar rats, approximately 3 months old and weighing from 200 to 250 grams, were divided into 2 groups. Each rat received three implants, one of each type. A pathologist blinded to the origin of the samples performed the histopathological analysis. There was no statistically significant difference ($p > 0.05$) in acute inflammation between the implants. For chronic inflammation, textured and polyurethane implants differed significantly ($p < 0.05$) from smooth ones. Foreign body reactions were more common in polyurethane implants compared with smooth and textured implants ($p < 0.05$). There was no statistical difference regarding granulation tissue and fibrosis ($p > 0.05$).

Conclusion Compared with smooth and textured implants, polyurethane-coated implants increased the occurrence of foreign body reactions, led to more intense chronic inflammation, and resulted in a greater amount of granulation tissue.

Keywords

- biocompatible materials
- breast implantation
- clinical trials as topic
- implant capsular contracture
- inflammation

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Resumo

Palavras-chave

- contratura capsular em implantes
- ensaio clínico
- implante mamário
- inflamação
- materiais biocompatíveis

Introdução As próteses mamárias de silicone, idealizadas na década de 1960, passaram por diversas modificações para minimizar a resposta inflamatória e a contratura capsular. Pesquisas em biomateriais possibilitam melhor compreensão da interação entre o implante e o tecido, especificada por inovação, reparo, regeneração e contratura capsular.

Objetivo Avaliar a resposta biológica de diferentes implantes: liso, texturizado e revestido de poliuretano, identificar complicações associadas e comparar a formação capsular pós-operatória em animais submetidos aos implantes.

Materiais e Métodos Foram utilizados 10 ratos Wistar, fêmeas, com aproximadamente 3 meses e peso entre 200 e 250 gramas, divididos em 2 grupos. Cada rato recebeu três implantes, um de cada tipo. Foram realizadas análise histopatológica, por um patologista cego à origem das amostras. Não houve diferença estatística relevante ($p > 0,05$) na inflamação aguda entre os implantes. Para inflamação crônica, os implantes texturizados e poliuretano diferiram significativamente ($p < 0,05$) dos lisos. A ocorrência de corpo estranho foi maior em implantes de poliuretano em comparação com lisos e texturizados ($p < 0,05$). Não houve diferença estatística para tecido de granulação e fibrose ($p > 0,05$).

Conclusão Em comparação com os implantes lisos e texturizados, os implantes revestidos por poliuretano causaram maior ocorrência de corpo estranho, maior inflamação crônica, com maior presença de tecido de granulação.

Introduction

Silicone breast implants, developed by Cronin and Gerow in the 1960s, have undergone numerous modifications to minimize adverse effects and improve outcomes.¹ Capsular contracture is the most common side effect of breast implants, and the complication most avoided by plastic surgeons.² It is a foreign body reaction with scar tissue formation around the breast implant. Histologically, capsular contracture consists of a multilayered structure composed of fibroblasts, fibrocytes, myofibroblasts, and histiocytes surrounded by acellular tissue rich in collagen fibers.²

The materials and textures used in implants are strongly related to the inflammatory response and the degree of capsular contracture. In the Baker classification (1981), contracture grades range from I to IV depending on symptoms and findings at the physical examination of the breasts.³

Studies on capsular contracture indicated different inflammatory responses to smooth and textured implants. However, analyses on polyurethane-coated implants remain scarce.⁴

An attempt to reduce capsular contracture led to the development of textured surface prostheses; however, the intensity of the inflammatory reaction around the prosthesis did not change significantly.⁴ Implants covered with polyurethane foam, introduced in the 1970s, emerged as an alternative to minimize inflammation and contracture induced by smooth and textured implants.⁵

The Scales' criteria (1953) define an ideal implant as inert, not causing adverse reactions or carcinogenesis, withstanding mechanical forces, and maintaining tissue integrity.⁵

It is essential to understand the histopathological interaction between the tissue and the implant coating to assess the risk of chronic inflammation or immunological events, which can directly influence the safety and durability of the material. The selection of the coating type is a key factor in the body's biological response, potentially impacting the formation of the fibrous capsule around the implant and the occurrence of complications, such as capsular contracture.⁶

Ongoing studies are crucial in understanding the histopathological interaction between the tissue and the implant coating, to assess the risk of chronic inflammation or reaction, and to identify materials and surfaces that minimize capsular contractures and inflammatory conditions.⁷

Objective

Main objective: To perform a histological assessment of the inflammatory response and capsular contracture induced by smooth, textured, and polyurethane-coated implants in the backs of Wistar rats.

Specific objectives

- a) To identify the complications resulting from the procedure according to each implant used;
- b) To compare the postoperative capsular formation in animals undergoing implantation.

Materials and Methods

Experimental animals: Ten female Wistar rats, approximately 3 months old and weighing between 200 and 250 g.

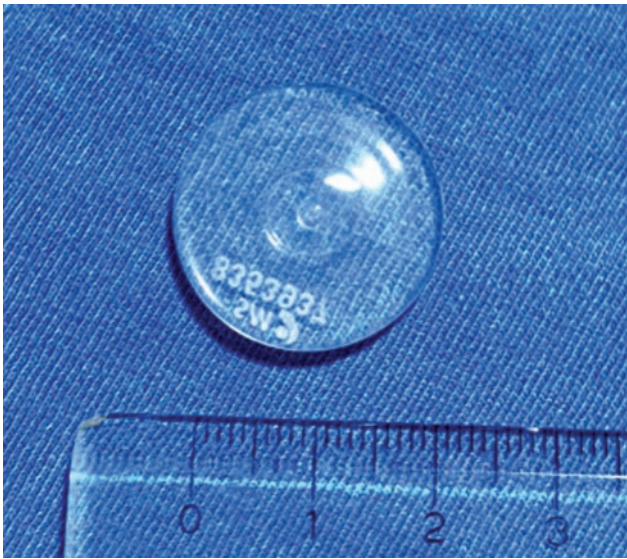


Fig. 1 Smooth implant.

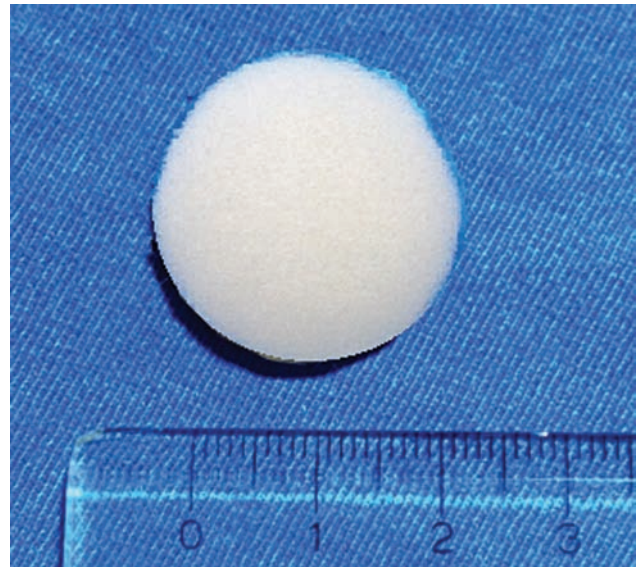


Fig. 3 Polyurethane-coated implant.

Study design: The study compared the inflammatory response and capsular formation of three types of silicone implants, namely, smooth (A), textured (B), and polyurethane-coated (C). We divided the animals into 2 groups ($n=5$), and each one received one implant of each type. Histopathological analysis occurred after four months.

Experimentation material: We used the following disc-shaped silicone implants supplied by Silimed (Silimed Indústria de Implantes Ltda):

Smooth implant: 2.3 cm diameter x 0.4 cm thickness, 3.18 cm³ (► **Fig. 1**).

Textured implant: 2.4 cm diameter x 0.7 cm thickness, 3.61 cm³ (► **Fig. 2**).

Polyurethane-coated implant: 2.5 cm diameter x 0.9 cm thickness, 4.0 cm³ (► **Fig. 3**).

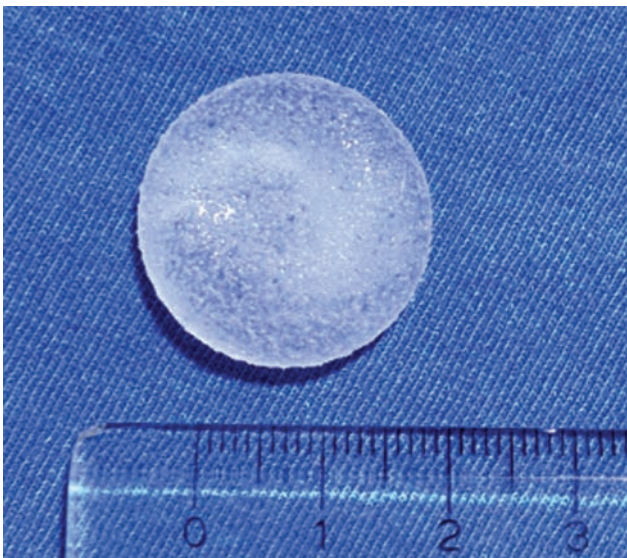


Fig. 2 Textured implant.

All implants underwent sterilization with ethylene oxide.

Surgical procedure

Anesthesia: Anesthesia consisted of 10% ketamine (40 mg/kg) and 2% xylazine (5 mg/kg) via the intramuscular route. The duration of anesthesia was approximately 3 hours. After anesthesia, we proceeded to the trichotomy of the dorsal region of each rat (► **Fig. 4**).

Implant insertion: We made a 3-cm transverse incision in the back of each rat, creating three subcutaneous pockets for smooth, textured, and polyurethane-coated implants (► **Figs. 5–6**).

After implant insertion, we performed a simple suture between the subcutaneous pockets to prevent the implants from overlapping (► **Fig. 7**).

Lastly, we performed skin closure with simple 4-0 nylon sutures (► **Fig. 8**).

Implant removal: After 4 months, the animals underwent another surgery with the same anesthetic protocol and euthanasia with a lethal dose of ketamine and xylazine.

Transverse and horizontal incisions on the back allowed implant visualization (► **Fig. 9**). The implants remained in their respective subcutaneous pockets. We dissected each implant separately to obtain the capsule surrounding it. The surgical margins of the histological specimens constitute the ridges of the implants, and resection occurred from the dermis to the muscle plane (► **Fig. 10**).

Histopathological analysis

We removed the membranes covering the implants (► **Figs. 11–13**) and fixed them in 10% formalin for future histopathological analysis. Each sample received a code corresponding to the rat number and the type of implant (e.g., 1A: first rat, smooth implant; 1B: first rat, textured implant; 1C: first rat, polyurethane-coated implant).

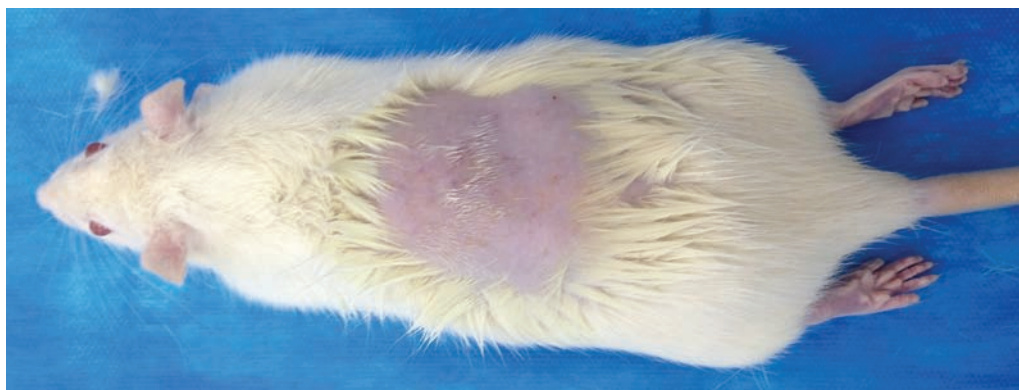


Fig. 4 Trichotomy in the dorsal region.



Fig. 5 Lodge displacement for implant positioning.

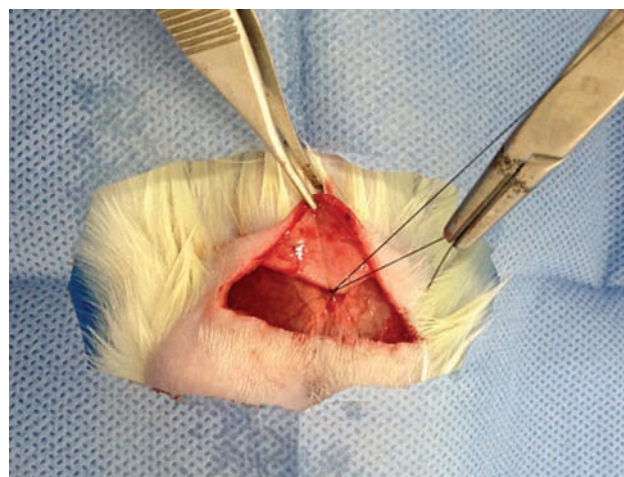


Fig. 7 Suture between the subcutaneous lodges.



Fig. 6 Implant positioning in the subcutaneous lodge.

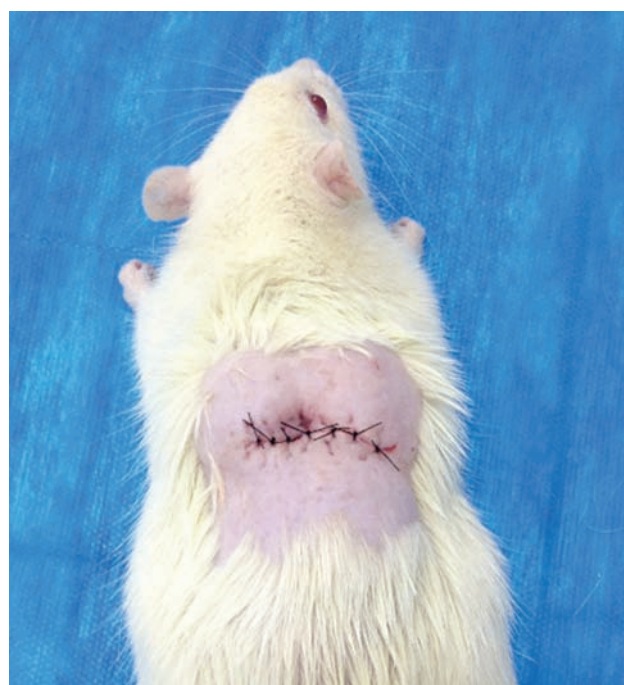


Fig. 8 Postimplant appearance and skin suture.

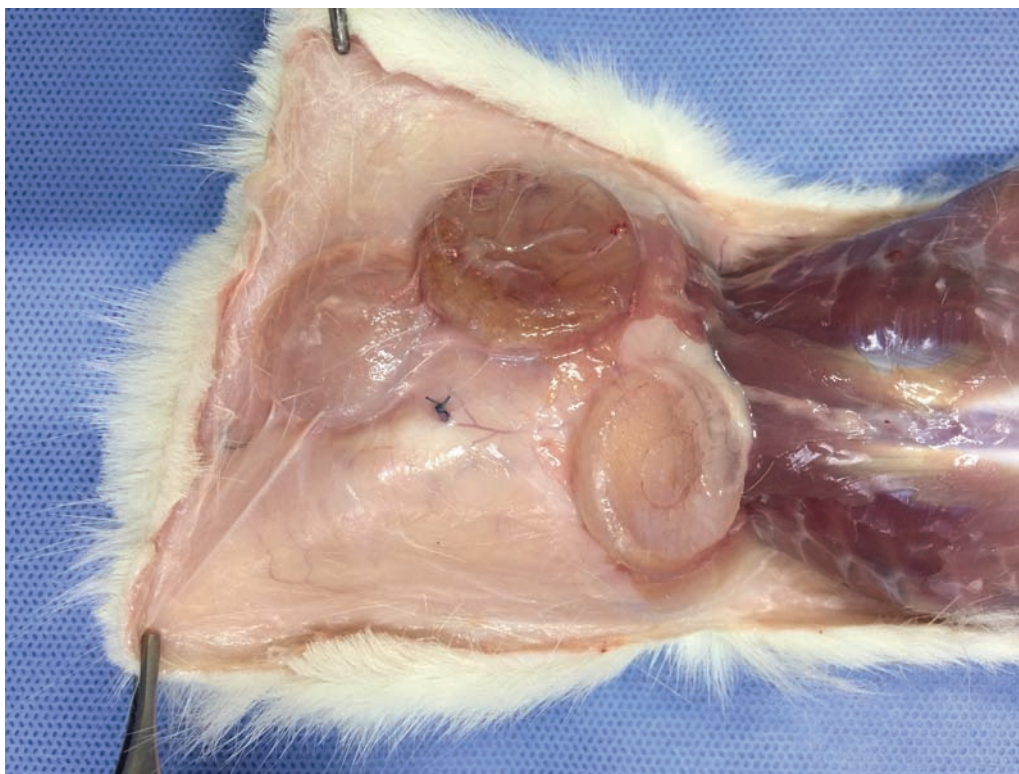


Fig. 9 Subcutaneous tissue resection showing the implants.

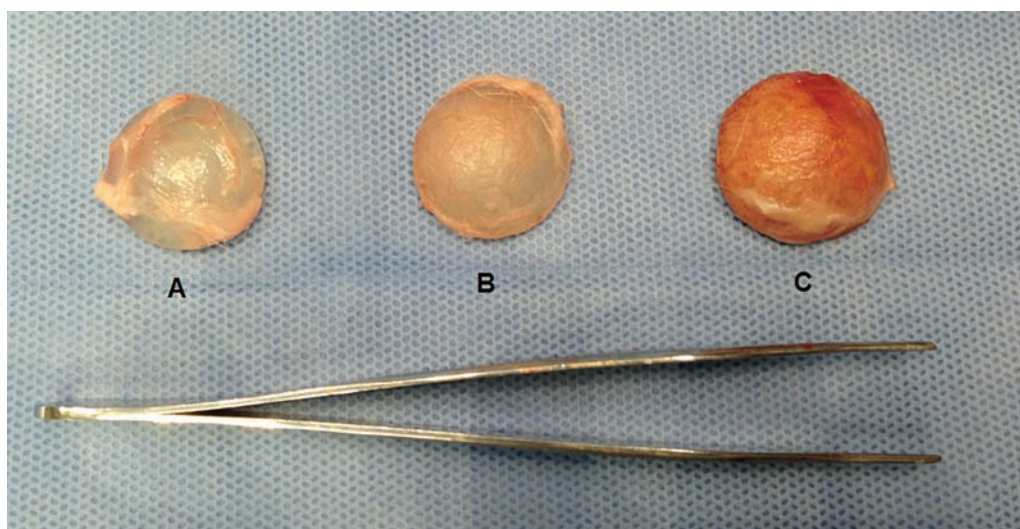


Fig. 10 Explanted implants; (A) smooth implant; (B) textured implant; and (C) polyurethane-coated implant.

Complications: Two animals exhibited an intense reaction and extruded both the smooth and textured implants; as such, we excluded them from the study. The polyurethane-coated implants remained, allowing for analysis of the remaining membrane.

Results

We converted the histopathological assessment results into numerical values for statistical analysis of the variables (► **Table 1**).

We compared each type of implant (smooth, textured, and polyurethane-coated) with each variable (refractive material, lymphocytes, neutrophils, macrophages, giant cells, granulation tissue, and fibrosis). The variables refractile material, lymphocytes, macrophages, and giant cells showed a significant difference ($p < 0.05$) in comparison with each implant type (smooth, textured, and polyurethane-coated). However, there were no statistically significant differences ($p > 0.05$) between the variables neutrophils, granulation tissue, and fibrosis regarding each implant.

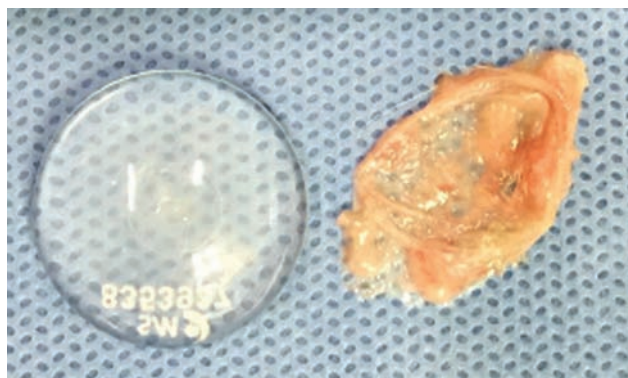


Fig. 11 Membrane removed from the smooth implant.

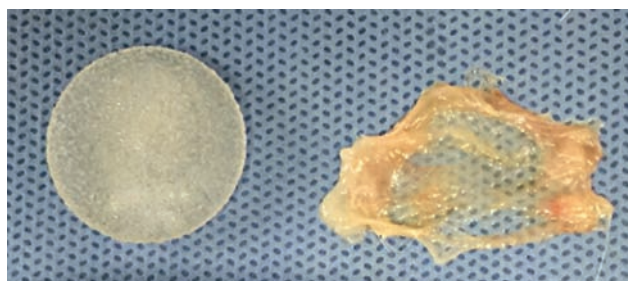


Fig. 12 Membrane removed from the textured implant.

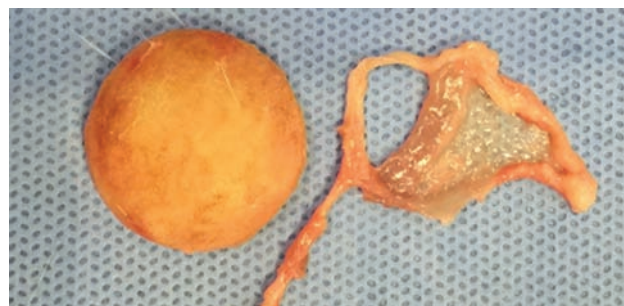


Fig. 13 Membrane removed from the polyurethane-coated implant.

We determined the development of acute inflammation according to the presence of neutrophils. The histopathological analysis revealed acute inflammation in 37.5% of the rats with smooth implants, 12.5% with textured implants, and 40% with polyurethane-coated implants.

► **Table 2** reveals no statistically significant difference ($p > 0.05$) between implant types.

We defined chronic inflammation as the presence of lymphocytes and macrophages (► **Fig. 14**). Cell quantification was performed using crosses (+), according to which zero (0) indicated the absence of cells and 2 crosses (++) designated a moderate presence. No implant type exhibited an intense cell presence (+++).

Table 1 Description of the scores assigned to the evaluated parameters according to groups and results of comparative tests for the different types of implants

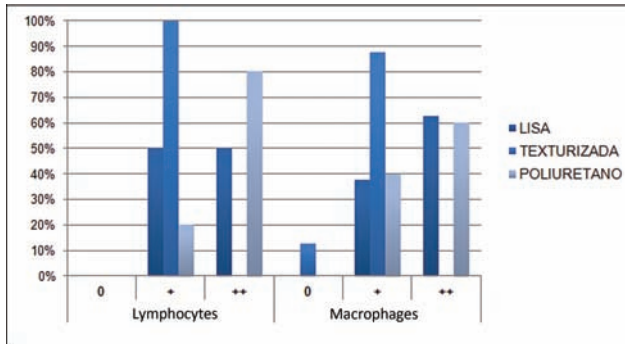
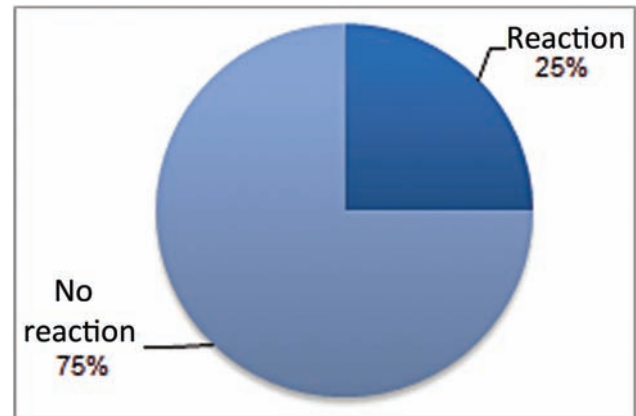
Variable	Comparison	Mean difference	Standard error	p	95%CI	
					Lower	Upper
Refractile material	Polyurethane-coated x smooth	0.600	0.207	0.022	0.081	1.119
	Textured x smooth	0.000	0.219	1.000	-0.547	0.547
	Textured x polyurethane-coated	-0.600	0.207	0.022	-1.119	-0.081
Lymphocytes	Polyurethane-coated x smooth	0.300	0.188	0.266	-0.170	0.770
	Textured x smooth	-0.500	0.198	0.048	-0.995	-0.005
	Textured x polyurethane-coated	-0.800	0.188	0.001	1.270	-0.330
Neutrophils	Polyurethane-coated x smooth	-0.350	0.325	0.537	-1.163	0.463
	Textured x smooth	-0.625	0.342	0.183	-1.482	0.232
	Textured x polyurethane-coated	-0.275	0.325	0.678	-1.088	0.538
Macrophages	Polyurethane-coated x smooth	-0.025	0.224	0.993	-0.587	0.537
	Textured x smooth	-0.750	0.237	0.011	-1.342	-0.158
	Textured x polyurethane-coated	-0.725	0.224	0.010	-1.287	-0.163
Giant cells	Polyurethane-coated x smooth	1.250	0.305	0.001	0.487	2.013
	Textured x smooth	0.000	0.321	1.000	-0.804	0.804
	Textured x polyurethane-coated	-1.250	0.305	0.001	-2.013	-0.487
Granulation tissue	Polyurethane-coated x smooth	-0.125	0.293	0.905	-0.857	0.607
	Textured x smooth	-0.750	0.308	0.058	-1.522	0.022
	Textured x polyurethane-coated	-0.625	0.293	0.105	-1.357	0.107
Fibrosis	Polyurethane-coated x smooth	0.125	0.131	0.612	-0.203	0.453
	Textured x smooth	0.250	0.138	0.188	-0.095	0.595
	Textured x polyurethane-coated	0.125	0.131	0.612	-0.203	0.453

Note: Values of p in bold indicate statistical significance.

Table 2 Comparison of acute inflammation between implant types

Variable	Comparison	Mean difference	Standard error	p	95%CI	
					Lower	Upper
Neutrophils	Polyurethane-coated x smooth	−0.350	0.325	0.537	−1.163	0.463
	Textured x smooth	−0.625	0.342	0.183	−1.482	0.232
	Textured x polyurethane-coated	−0.275	0.325	0.678	−1.088	0.538

Note: Values of *p* in bold indicate statistical significance.

**Fig. 14** Chronic inflammation.**Fig. 15** Smooth implant.

► **Table 3** shows that there was no statistically significant difference ($p > 0.05$) between smooth and polyurethane implants. However, there was a statistically significant difference ($p < 0.05$) when comparing textured with smooth and polyurethane-coated implants.

Foreign body reactions were defined by the presence of giant cells. Only 25.0% of rats with smooth implants showed a foreign body reaction (► **Fig. 15**). The same occurred with textured implants, as 25.0% of rats presented a foreign body reaction (► **Fig. 16**). Regarding polyurethane-coated implants, foreign body reactions were absent at 10.0% of rats, mild in 40.0%, moderate in 40.0%, and intense in 10.0% (► **Fig. 17**).

► **Table 4** reveals that there was no statistically significant difference ($p > 0.05$) when comparing smooth and textured implants. The comparison between smooth versus polyurethane-coated implants and textured versus

polyurethane-coated implants found no statistically significant difference ($p < 0.05$).

Fibrosis was categorized as mild, moderate, or intense. Smooth implants predominantly presented with moderate fibrosis (87.5%), while textured implants showed 87.5% moderate fibrosis and 12.5% intense fibrosis. Polyurethane-coated implants demonstrated 100% moderate fibrosis. Granulation tissue underwent the same categorization. In smooth implants, moderate and intense forms predominated (37.5% each). In textured implants, most forms were mild (62.5%).

► **Table 5** indicates no statistically significant differences ($p > 0.05$) when analyzing the presence of granulation tissue and fibrosis in the three implants studied.

Table 3 Comparison of chronic inflammation according to the presence of lymphocytes and macrophages between implant types

Variable	Comparison	Mean difference	Standard error	p	95%CI	
					Lower	Upper
Lymphocytes	Polyurethane-coated x smooth	0.300	0.188	0.266	−0.170	0.770
	Textured x Smooth	−0.500	0.198	0.048	−0.995	−0.005
	Textured x polyurethane-coated	−0.800	0.188	0.001	1.270	−0.330
Macrophages	Polyurethane-coated x smooth	−0.025	0.224	0.993	−0.587	0.537
	Textured x smooth	−0.750	0.237	0.011	−1.342	−0.158
	Textured x polyurethane-coated	−0.725	0.224	0.010	−1.287	−0.163

Note: Values of *p* in bold indicate statistical significance.

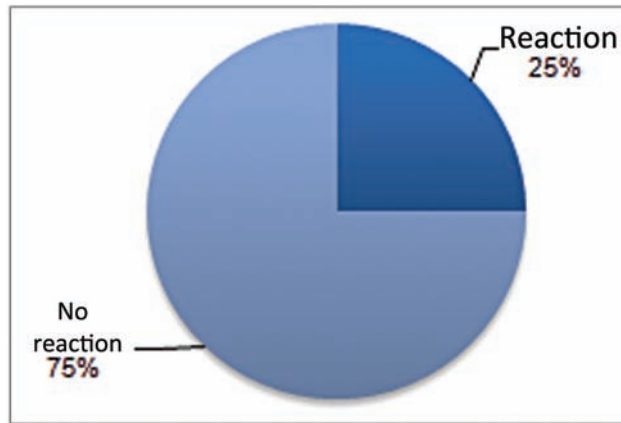


Fig. 16 Textured implant.

The refractile material corresponded to the presence of implant residue. Histopathological analysis concluded that only the samples from the polyurethane-coated implants presented implant residue, corresponding to 50% of the

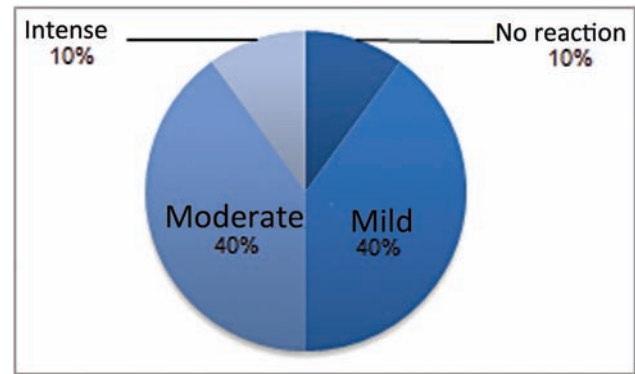


Fig. 17 Polyurethane-coated implant.

samples in group C. This finding demonstrates that the polyurethane coating triggers an intense inflammatory response, which leads to capsule formation around the implant to integrate with the coating.

► **Table 6** shows that there was no statistically significant difference ($p > 0.05$) when comparing smooth and textured implants. Comparison of smooth versus polyurethane-coat-

Table 4 Comparison of foreign body reactions between implant types

Variable	Comparison	Mean difference	Standard error	<i>p</i>	95%CI	
					Lower	Upper
Foreign body reaction	Polyurethane-coated x smooth	1.250	0.305	0.001	0.487	2.013
	Textured x smooth	0.000	0.321	1.000	-0.804	0.804
	Textured x polyurethane-coated	-1.250	0.305	0.001	-2.013	-0.487

Note: Values of *p* in bold indicate statistical significance.

Table 5 Comparison of granulation tissue formation and fibrosis between implant types

Variable	Comparison	Mean difference	Standard error	<i>p</i>	95%CI	
					Lower	Upper
Granulation tissue	Polyurethane-coated x smooth	-0.125	0.293	0.905	-0.857	0.607
	Textured x smooth	-0.750	0.308	0.058	-1.522	0.022
	Textured x polyurethane-coated	-0.625	0.293	0.105	-1.357	0.107
Fibrosis	Polyurethane-coated x smooth	0.125	0.131	0.612	-0.203	0.453
	Textured x smooth	0.250	0.138	0.188	-0.095	0.595
	Textured x polyurethane-coated	0.125	0.131	0.612	-0.203	0.453

Note: Values of *p* in bold indicate statistical significance.

Table 6 Comparison of the presence of refractile material between implant types

Variable	Comparison	Mean difference	Standard error	<i>p</i>	95%CI	
					Lower	Upper
Refractile material	Polyurethane-coated x smooth	0.600	0.207	0.022	0.081	1.119
	Textured x smooth	0.000	0.219	1.000	-0.547	0.547
	Textured x polyurethane-coated	-0.600	0.207	0.022	-1.119	-0.081

Note: Values of *p* in bold indicate statistical significance.

ed implants and textured versus polyurethane-coated implants revealed a statistically significant difference ($p < 0.05$).

Discussion

The choice of the experimental animal, the Wistar rat, was based on its ease of acquisition and handling, adaptation to the artificial environment, and the possibility of placing three implants in the same animal. Its dimensions do not interfere with the analysis of macroscopic and microscopic characteristics.⁸

Several researchers have used rodents in experiments with silicone implants.⁹ A recent study reported that the tissue reaction caused by silicone breast implants leads to the formation of a periprosthetic capsule, which is similar in experimental animals and in humans.¹⁰

In this study, polyurethane-coated implants exhibited an intense acute inflammatory reaction. A large number of giant cells partially engulfed the implant material, indicating a foreign body inflammatory process characteristic of this material, consistent with several similar studies.⁹ This acute inflammatory reaction was observed late, characterizing a chronic inflammation with the presence of lymphocytes and macrophages.

The presence of refractile material (implant residue) only in samples from polyurethane-coated implants indicates a greater inflammatory response compared with other implants (i.e., smooth and textured), which did not present refractile material in the histopathological analysis. It is worth noting that the polyurethane coating integrates with the membrane surrounding the implant, resulting in a more intense inflammatory response.^{11,12}

Therefore, compared with smooth and textured implants, the polyurethane-coated implant induced greater foreign body reactions, acute and chronic inflammation, and granulation tissue formation.

Conclusion

In the present study, after comparing the inflammatory reaction caused by the three types of implants (smooth, textured, and polyurethane-coated), it was concluded that:

- The polyurethane-coated implant caused more acute inflammation when compared with smooth and textured implants;
- Chronic inflammation was greater in polyurethane-coated implants and lower in textured implants.
- Polyurethane-coated implants elicited a foreign body reaction in 90% of the rats, while smooth and textured implants did it in only 25% of the rats.
- The fibrosis caused by smooth, textured, and polyurethane-coated implants was virtually the same in all cases. Granulation tissue around the polyurethane-coated implants was in moderate quantity in 80% of rats, indicating a greater inflammatory reaction.

- The polyurethane-coated implants were the only ones that presented difficulty in removing the membrane that surrounded them. This fact was proven by histopathological analysis as they were the only samples with refractile material, that is, remnants of the polyurethane coating.

Data Availability

Data will be available upon request to the corresponding author.

Authors' Contributions

CES: conceptualization, study conception and design, investigation, methodology, performance of surgeries and/or experiments, writing – original draft preparation, writing – review & editing; **DLP:** project management, supervision; **HAG:** Supervision; **LC:** writing – original draft preparation, writing – review & editing.

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Clinical Trials

None.

Conflict of Interests

The authors have no conflict of interests to declare.

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