

Review Article

What is the impact of capsulectomy on systemic symptoms attributed to silicone breast implants? Systematic literature review

Qual o impacto da capsulectomia nos sintomas sistêmicos atribuídos às próteses mamárias de silicone? Revisão sistemática da literatura

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■ ABSTRACT

Introduction: Several studies have analyzed the possible relationship between silicone breast implants and systemic symptoms. Removal of breast implants with capsulectomy has been indicated in an attempt to improve these symptoms. The surgeon must have data based on the literature to inform the patient whether there is a relationship between the removal of a breast prosthesis with capsulectomy and improvement in symptoms, what is the rate of improvement, and how long it lasts. Method: A search was carried out in the Cochrane Library and PubMed virtual databases from January 1990 to April 2023. The search was carried out using a combination of free terms ("breast implant illness", "breast capsulectomy," and "breast implant explantation") and by using Boolean operators for Mesh descriptors such as [autoimmune diseases (MeSH Terms)] and [breast implant (MeSH Terms)]. Results: 1,203 articles were obtained, 14 of which were selected for the study, consisting of 7 retrospective cohort articles, 3 prospective cohort articles, and 4 case-control articles. The improvement rate varied between 50 and 100% of cases, and the follow-up time varied between 2 months and 2.7years. Several types of capsulectomies were performed in the studies, with similar rates of improvement. Conclusion: There is evidence of improvement in systemic symptoms in patients with silicone breast implants who underwent breast implant removal with capsulectomy. The improvement in symptoms persisted during the period in which the patients were followed in the studies. More recent studies have demonstrated that the type of capsulectomy does not influence the improvement of systemic symptoms.

Keywords: Autoimmune diseases; Breast diseases; Mammaplasty; Breast implantation; Quality of life.

■ RESUMO

Introdução: Diversos estudos têm analisado a possível relação entre a prótese mamária de silicone e sintomas sistêmicos. A remoção das próteses de mama com capsulectomia tem sido indicada na tentativa de melhorar esses sintomas. É necessário que o cirurgião tenha dados embasados na literatura para informar ao paciente se há relação entre retirada de prótese de mama com capsulectomia e melhora dos sintomas, qual a taxa de melhora e por quanto tempo se mantém. Método: Foi realizada pesquisa nos bancos de dados virtuais Cochrane Library e PubMed de janeiro de 1990 até abril de 2023. A busca foi realizada pela combinação de termos livres ("breast implant illness", "breast capsulectomy" e "breast implant explantation") e pelo uso de operadores booleanos para descritores Mesh como [autoimmune diseases (MeSH Terms)] e [breast implant (MeSH Terms)]. Resultados: Foram obtidos 1.203 artigos, sendo 14 selecionados para o estudo, consistindo em 7 artigos de coorte retrospectivo, 3 de coorte prospectivo e 4 caso-controle. A taxa de melhora variou entre 50 e 100% dos casos e o tempo de acompanhamento variou entre 2 meses e 2,7 anos. Diversos

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tipos de capsulectomia foram realizados nos estudos, com taxas semelhantes de melhora. **Conclusão:** Há evidências de melhora dos sintomas sistêmicos em pacientes com prótese mamária de silicone submetidas a retirada de prótese de mama com capsulectomia. A melhora dos sintomas persistiu durante o período em que as pacientes foram acompanhadas nos estudos. Estudos mais recentes demonstraram que o tipo de capsulectomia não tem influência na melhora dos sintomas sistêmicos.

Descritores: Doenças autoimunes; Doenças mamárias; Mamoplastia; Implante mamário; Qualidade de vida.

INTRODUCTION

The breast prosthesis is one of the most studied medical devices regarding its safety¹. Much research has been done on the possible relationship between silicone breast implants and rheumatic and autoimmune diseases².

Several articles were unable to prove the relationship between silicone breast implants and connective tissue diseases, mainly due to confounding factors present in the studies^{3,4}. In a meta-analysis, few well-designed and controlled studies were found to confirm this relationship⁵.

Systematic review studies of articles found an association between breast implants and a small increase in the risk of having Sjögren's syndrome and rheumatoid arthritis⁶⁻⁸.

Within this review of articles, the largest study on the safety of prostheses was a 7-year retrospective follow-up of 100,000 patients undergoing breast prosthesis inclusion. In this study, it was concluded that Sjögren's syndrome, scleroderma, and rheumatoid arthritis have a higher incidence in the population with breast prostheses compared to those without prostheses⁹. Local complications in the breasts are better described in the literature¹⁰.

The set of systemic symptoms observed in patients with silicone breast implants has been reported as human adjuvant disease, silicone-induced adjuvant disease, adjuvant-induced autoimmune disease (ASIA syndrome), and silicone implant incompatibility syndrome. The term silicone disease has become popular in the media, which can encompass systemic symptoms of autoimmune and rheumatic diseases, as well as symptoms of local complications such as capsular contracture⁴.

The most common symptoms were fatigue, memory loss, arthralgia, hair loss, dysphagia, depression, skin erythema, and headache. Symptoms related to breast implants are very similar, even in patients from different social conditions, races, and cultures. It is possible that lawsuits against the

manufacturer of the breast prosthesis, psychosomatic illness, stress, somatization, or influence by the media cause these complaints^{6,11,12}.

Therefore, demand for the procedure of prosthesis removal and total intact capsulectomy, popularized by the media as en bloc breast prosthesis explantation, has increased. In this surgery, the prosthesis is removed together with its capsule without breaking it⁷. The terminology "en bloc" is not the most correct, as it uses the term from oncological surgery, since "en bloc" means "removing healthy tissue to have a safety margin", and in total intact capsulectomy, there is no safety margin, especially when the prosthesis is in the submuscular plane⁸.

Total intact capsulectomy has been indicated for patients with breast implants who present local or systemic symptoms in an attempt to improve these symptoms, and the justification for removing the capsule completely would be to avoid leaving silicone residues present in it¹³. Reconstruction options include breast fat grafting and mastopexy¹⁴.

To make decisions supported by Evidence-Based Medicine, it is necessary to have literature that indicates that total intact capsulectomy or some other variation of capsulectomy is beneficial for patients with breast implants and systemic symptoms. Otherwise, a simpler surgery could be offered, such as removing only the prosthesis without capsulectomy or using non-surgical treatments, such as herbal medicine, psychological support, and reassurance to the patient that the symptoms are not related to the implant ¹⁵.

The surgeon should have data to inform which patients may experience improvement, the percentage and duration of this improvement, and whether there is a risk of recurrence.

OBJECTIVE

To carry out a systematic review of the medical literature evaluating the relationship between breast prosthesis removal and capsulectomy on systemic symptoms in patients with silicone breast implants.

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METHOD

Search strategy for study identification

A search was carried out in the virtual databases Cochrane Library and PubMed, considering results between January 1990 and April 2023. This article was carried out by the author from January to April 2023 in the city of São Paulo-SP, and the Helsinki principles were followed.

The search was carried out by combining free terms ("breast implant illness", "breast capsulectomy," and "breast implant explantation") and using Boolean operators for Mesh descriptors such as [autoimmune disease (MeSH Terms)] and [breast implant (MeSH Terms)] (Figures 1 and 2). The Cochrane Sensitivity Maximizing Version strategy was used. There was no restriction on the language of the study.

Search	Actions	Details	Query	Results	Time
#8		>	Search: (((breast implant illness) OR (breast capsulectomy)) OR (breast implant explantation)) OR ((autoimmune disease[MeSH Terms]) AND (breast implant[MeSH Terms]))	1,188	09:04:0
#7		>	Search: (autoimmune disease[MeSH Terms]) AND (breast implant[MeSH Terms])	178	09:02:5
#6		>	Search: breast implant[MeSH Terms]	7,240	09:02:2
#5		>	Search: autoimmune disease[MeSH Terms]	538,217	09:01:45
#4		>	Search: ((breast implant illness) OR (breast capsulectomy)) OR (breast implant explantation)	1,036	09:00:5
#3		>	Search: breast implant explantation	604	08:56:5
#2		>	Search: breast capsulectomy	309	08:56:4
#1		>	Search: breast implant illness	223	08:56:2

Figure 1. Article search strategy in PubMed.

Advanced Search

Figure 2. Strategy for searching articles in the Cochrane Library.

Inclusion and exclusion criteria

Studies that evaluated the relationship between capsulectomy in patients with silicone breast implants and systemic symptoms were included.

Studies that evaluated patients with a personal history of autoimmune or rheumatic diseases review articles, case reports, and articles that only evaluated laboratory changes or local symptoms, such as capsular

contracture or rupture, were excluded. Studies that associated drug treatment with capsulectomy, patients who underwent only capsulotomy or who had been replaced by another prosthesis were also excluded.

Two independent researchers read the titles and abstracts, selecting articles according to the eligibility criteria. Disagreements between the inclusion of studies were resolved by consensus between the two researchers. The risks of bias in the studies were assessed using an instrument similar to that used by the Cochrane Collaboration.

RESULTS

One thousand one hundred eighty-eight studies were obtained from the PubMed database and 46 studies from the Cochrane Library following the search strategy described in Methods, for a total of 1,234 studies. Eliminating repeated studies in both databases, the total number of studies obtained was 1,203.

After reading the titles and/or summaries, 1,116 articles were excluded following the eligibility criteria. Eighty-seven articles were selected for full reading, and after the selection process, 14 articles were included in the study, 10 of which were cohort studies and 4 were control cases (Figure 3).

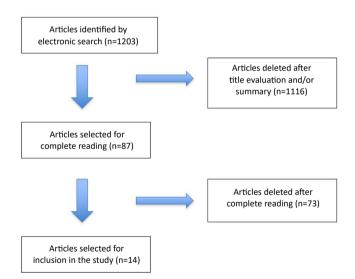


Figure 3. Article search strategy.

Of the 87 articles selected for full reading, 23 were excluded because they only evaluated local complications of breast prostheses, 17 because they evaluated patients undergoing breast reconstruction, 15 because they were review articles, 8 because they associated immunosuppressive medications in the treatment, 6 were editorial letters and 4 case reports.

According to Table 1, during the analysis, the following were observed: study design, case series, most frequent symptoms, and the percentage of improvement in symptoms after capsulectomy.

The percentage of improvement in symptoms was observed considering all studies and by type of study (Figure 4).

Figure 5 shows the percentage of studies according to follow-up time. Only prospective studies such as prospective cohort and case-control were considered.

Figure 6 demonstrates the percentage of study types included in the review.

DISCUSSION

The removal of breast prostheses and capsules has been an increasingly requested surgery in recent years. Part of this is influenced by the recall of a prosthesis brand, changes in patients' lifestyles, and the dissemination on social media of possible associations between breast prostheses and various symptoms.

In addition to systemic symptoms, patients removed their prostheses for fear of complications such as rupture, aesthetic reasons, and fear of needing additional surgeries at an older age. A study showed that the most satisfied patients were those who removed the breast implant due to fear of the long-term consequences of having a foreign body²⁸. It is important to remember that it is necessary to distinguish local

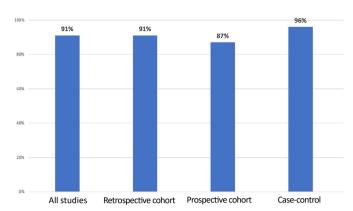


Figure 4. Percentage of symptom improvement after prosthesis removal and capsulectomy considering all studies and according to each type of study.

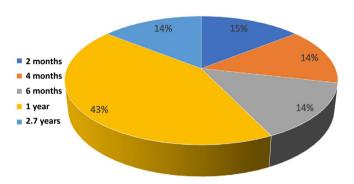


Figure 5. Percentage of follow-up time of prospective cohort and case-control studies

Table 1. Type of study, case series, symptoms, and results reported in the selected articles.

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Reference	Kind of study	N	Symptoms	Results
$Melmed^{11}$	Retrospective cohort	240	fatigue, arthralgia, depression, memory loss	Improvement in 74% of cases
Rohrich et al. ¹⁵	Retrospective cohort	50	fatigue, arthralgia, headache	Improvement in 50% of cases
Svahn et al. ¹⁶	Retrospective cohort	63	fatigue, arthralgia, memory loss	Improvement in 78% of cases
Vasey et al. ¹⁷	Retrospective cohort	33	fatigue, myalgia, arthralgia	Improvement in 73% of patients
Wee et al. ¹⁸	Retrospective cohort	750	fatigue, arthralgia, memory loss	Improvement in 100% of cases
Katsnelson et al. ¹⁹	Retrospective cohort	248	fatigue, myalgia, arthralgia	Improvement in 90% of cases
Metzinger et al. ²⁰	Retrospective cohort	200	fatigue, myalgia, breast pain	Improvement in 96% of cases
Peters et al. ²¹	Prospective cohort	75	arthralgia, myalgia, breast pain	Improvement in 74% of cases
Maijers et al. ²²	Prospective cohort	52	fatigue, arthralgia, myalgia, night sweats, injuries dermatological	Improvement in 69% of cases
Bird & Niessen ²³	Prospective cohort	140	fatigue, arthralgia, myalgia	Improvement in 100% of cases
Rohrich et al. ²⁴	Case-control	38 casos/ 38 controle	fatigue, myalgia, arthralgia	100% improvement in cases
Walden et al. ²⁵	Case-control	22 casos/ 20 controle	arthralgia, skin lesions	Improvement in 100% of cases
Glicksman et al. ²⁶	Case-control	50 casos/ 100 controle	fatigue, arthralgia, myalgia	Improvement in 94% of cases
Glicksman et al. ²⁷	Case-control	50 casos/ 100 controle	Fatigue, anxiety, memory loss	Improvement in 94% of cases

N = number of patients.

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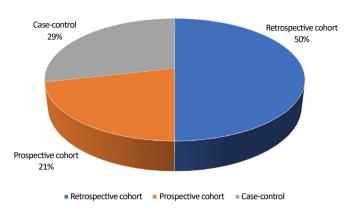


Figure 6. Percentage of types of studies included in the review.

complications of the prosthesis (rupture, seroma, contracture) from systemic symptoms⁴.

One of the reasons for performing a capsulectomy lies in the theory that the biofilm that surrounds the capsule and the prosthesis would be related to systemic symptoms and local complications such as contracture. Biofilm is a layer of bacteria adhered to the silicone surface. This theory is controversial since the capsule is not an absolute barrier to these bacteria, the most common being Propionibacterium – in addition to these bacteria being naturally found in other regions of the body²⁹⁻³¹.

Another reason is the reduction of seromas, palpability, and removal of traces of silicone present in the capsules³². There is also the theory that the increase in the inflammatory response associated with the breast implant and its capsule would be related to systemic symptoms, capsular contracture, BIA-ALCL, and as a trigger for the appearance of autoimmune diseases in predisposed patients^{18,19,33,34}. A case-control study found that 3 (IL-13, IL17A, and IL22) of the 12 cytokines studied were higher in the group of patients with breast prostheses and systemic symptoms when compared to control groups³¹.

Another argument for removing the capsules would be that they would contain a greater amount of heavy metal from breast implants, such as zinc, copper, nickel, and others. However, no statistically significant differences were found in heavy metals in the capsules of patients with silicone prostheses between the groups with systemic symptoms and the group without symptoms. Furthermore, no toxic levels of heavy metals were found in any patient in the study groups³⁵.

All included studies were consistent in demonstrating improvement in systemic symptoms in patients undergoing breast prosthesis removal and various types of capsulectomies. It is important to highlight that the capsulectomy can be total intact, total, or partial. In intact total capsulectomy, the capsule

is removed without tears or holes together with the prosthesis. In total capsulectomy, the prosthesis can be removed first and then the capsule removed in its entirety.

The follow-up time of patients in prospective cohort and case-control studies ranged from 2 months to 2.7 years. The improvement in symptoms was maintained throughout the postoperative follow-up period in studies without recurrences²¹⁻²⁷.

In the studies selected in this systematic review, the most frequent symptoms were arthralgia, myalgia, fatigue, and memory loss. The improvement in systemic symptoms with capsulectomy ranged from 50% to 100% in cohort studies and from 94% to 100% in case-control studies 36,37 .

There is a greater percentage of improvement in patients without a diagnosis of rheumatological or autoimmune disease when compared to patients with these diseases. The greater the number of symptoms preoperatively, the greater the number of symptoms that will improve postoperatively³³.

Patients who reported systemic symptoms related to the prostheses showed statistically significant improvement after removal of the prostheses and capsulectomy; these improvements persisted for 6 to 12 months^{23,26}. The improvement was observed regardless of the type of capsulectomy performed, whether total intact, total, or partial^{26,27,35}. One study evaluated laboratory changes and also did not identify any difference between the groups that underwent total intact, total, or partial capsulectomy³¹.

Most of the studies were cohort studies, 7 retrospective and 3 prospective, and 4 case-control studies.

Retrospective cohort study

Melmed11 performed prosthesis removal with capsulectomy in 240 patients. Capsular contracture was the main complaint, in addition to fatigue, arthralgia, and memory loss. Silicone was found in the pathological anatomy results in all the capsules removed. Improvement in systemic symptoms occurred in 74% of patients.

Rohrich et al.¹⁵ observed that no isolated or paired complaint was associated with predicting the outcome, making it difficult to correlate subjective preoperative complaints with improved quality of life after capsulectomy. Patients who reported five or fewer medical symptoms before explantation were more likely to notice an improvement in quality of life after surgery than patients who had nine or more complaints.

Svahn et al. 16 found that 81% of patients were satisfied with the result of prosthesis removal with

capsulectomy. There was an improvement in quality of life in 78% of cases. Surgery resulted in the worsening of the condition in 3% of cases and did not change the condition in 19%.

Vasey et al.¹⁷ observed that, in the group of 17 patients who chose not to remove the prosthesis, there was no change in symptoms. In the group of 33 patients who underwent capsulectomy, 24 of them had improvement in symptoms; in eight, the symptoms did not improve, and in one, the symptoms worsened.

Wee et al.¹⁸ retrospectively analyzed data from 750 patients undergoing capsulectomy, using data from questionnaires filled out by the patients themselves regarding the evolution of 11 symptoms most frequently reported before and after surgery. They found improvement in all 11 symptoms, which began before the first 30 days after surgery and continued after this period.

Katsnelson et al. 19 carried out a cohort study on 248 patients with systemic symptoms attributed to silicone disease who underwent prosthesis removal and capsulectomy, reporting improvement in symptoms in 90.4% of patients.

Metzinger et al. 20 carried out a retrospective cohort study between 2016 and 2020 with 200 patients with systemic symptoms who underwent prosthesis removal with capsulectomy and observed an improvement in symptoms in 96% of patients after the procedure.

Prospective cohort study

Peters et al.²¹ analyzed 100 patients undergoing capsulectomy, but only 75 patients responded to the questionnaire. An improvement in symptoms was observed in 56 of the patients after an average follow-up of 2.7 years.

Maijers et al.²² identified that 75% of patients reported pre-existing allergies to breast implants, suggesting a possible intolerance to silicone and other substances. In this case, removal of the prosthesis with capsulectomy improved symptoms in 69% of cases.

Bird & Niessen²³ carried out a prospective cohort study on 140 patients with systemic symptoms who underwent prosthesis removal and capsulectomy and identified improvements in symptoms in all patients in the study.

Case-control

Rohrich et al.²⁴ tried to determine if there was any preoperative parameter that could determine which patients could have their symptoms improved after capsulectomy. They found statistically significant evidence that intact total capsulectomy improves

subjective complaints, especially musculoskeletal complaints.

Walden et al.²⁵ compared three groups: patients undergoing capsulectomy, patients undergoing cholecystectomy, and patients not undergoing surgery (control group). When evaluating rates of depression and self-esteem in the groups, higher rates of anxiety and depression were observed in patients undergoing capsulectomy, in addition to lower rates of satisfaction with their breasts.

Glicksman et al.²⁶ carried out a case-control study on 150 patients divided equally into three groups: patients with systemic symptoms requesting prosthesis removal and capsulectomy, patients without symptoms requesting prosthesis removal and capsulectomy, and patients undergoing mastopexy who had never used a prosthesis. In the study, the group of women with systemic symptoms who underwent prosthesis removal and capsulectomy had improvement in symptoms regardless of the type of capsulectomy performed.

Glicksman et al. 27 carried out a case-control study with three groups of 50 patients, each followed for 1 year. In this study, it was observed that the improvement in symptoms was maintained for 1 year after surgery to remove the prosthesis with capsulectomy.

Criticisms of studies

The selected cohort studies did not present data with the population adjusted for age, comorbidity, and personal and family history. Many studies placed patients undergoing intact, total, and partial capsulectomies in the same group or did not identify the type of capsulectomy performed.

Most cohort studies were retrospective and had small populations with short follow-up times. The ideal would be prospective cohort studies, with a larger population, adjusted by parameters and followed over a long term²⁰.

Total intact capsulectomy involves risks, the main one being hematoma (1.6%), followed by infection (0.5%). The incidence of hematoma in capsulectomies is higher when compared to prosthesis removal without capsulectomy (2.8% vs. 1.9%) or implant exchange without capsulectomy $(1.6\% \text{ vs. } 0.9\%, \text{ respectively})^{38}$.

Due to the risks involved in capsulectomy, it is important to verify whether the improvements observed in the studies could not be obtained with minor surgeries, such as simply removing the prosthesis or capsulotomy.

In this review, the rate of symptom improvement was not compared between patients who only had a breast prosthesis removed and those who had a breast prosthesis removed with capsulectomy.

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Patients with symptoms who sought prosthesis removal with capsulectomy had higher levels of somatization, obsessive-compulsive disorder, depression, and anxiety³⁹. It should be assessed whether there is a group of patients predisposed to presenting systemic symptoms after the inclusion of a breast prosthesis.

The ideal would be to create a score to predict which patients are most at risk of developing systemic symptoms when undergoing a breast prosthesis. Along the same lines, it would be useful to have a score to identify which patients with breast prosthesis implants and systemic symptoms could show the highest rates of improvement after breast prosthesis removal and capsulectomy.

CONCLUSION

The medical literature presents evidence that there is consistent improvement in systemic symptoms in patients with silicone breast implants who undergo breast implant removal with capsulectomy. The improvement in symptoms persisted during the period in which the patients were followed in the studies.

More recent studies have demonstrated that the type of capsulectomy does not influence the improvement of systemic symptoms.

COLLABORATIONS

REM Analysis and/or data interpretation, Conception and design study, Conceptualization, Data Curation, Final manuscript approval, Formal Analysis, Methodology, Realization of operations and/or trials, Writing - Original Draft Preparation, Writing - Review & Editing.

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