

Nonsurgical treatment of capsular contracture: Review of clinical studies

Journal of International Medical Research

48(6) 1–9

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DOI: 10.1177/0300060520927873

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Abstract

Capsular contracture is one of the most distressing complications of breast implant use in both aesthetic and reconstructive plastic surgery procedures. This systematic review was performed to assess the effectiveness of all nonsurgical treatments for established capsular contracture.

Keywords

Capsular contracture, breast implants, treatment, nonsurgical treatment, capsulotomy, medical treatment, breast augmentation

Date received: 26 November 2019; accepted: 29 April 2020

Introduction

Breast implants have been used for both breast augmentation and reconstruction for more than 40 years. One of the most distressing complications for both patients and surgeons is capsular contracture, the incidence of which reportedly ranges from 0.5% to 30% depending on the coating and type of implant, the plane of insertion, and the surgical protocol.¹ Insertion of the

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implant is followed by a foreign body reaction, and the host tissues then encapsulate the prosthesis. The foreign body reaction may be exaggerated by extrinsic factors such as the biophysical properties of the implant, infection, or hematoma formation. Thus, collagen production causes excessive fibrosis, resulting in the pathological condition we refer to as capsular contracture.^{2,3} The reaction may result in excessively firm and painful breasts in grade IV capsular contracture. In less severe reactions, the breasts may look and feel normal (grade I), they may be firm but with no distortion or change in shape (grade II), or there may be a change in shape (grade III).⁴ One factor on which the prevalence of capsular contracture depends is the indication for surgery (augmentation or reconstruction).⁵ The only effective treatment method is capsulotomy or capsulectomy with implant removal or a change in the plane of insertion.⁶ The gold standard is the combination of capsulectomy, site change, and implant exchange. Capsular contracture is one of the most common reasons for reoperation after breast augmentation (33.3%).⁷

However, no patient or surgeon would be keen to proceed to another surgical procedure to correct capsular contracture if a conservative treatment were available. In the present study, we reviewed all nonsurgical treatments for established capsular contracture. This is the first systematic review of all nonsurgical treatments for established capsular contracture.

Materials and methods

The population of interest comprised women with capsular contracture following aesthetic breast augmentation or breast reconstruction. The interventions considered were nonsurgical methods to treat capsular contracture, including closed capsulotomy, injection of steroids, medical treatment, and ultrasound treatment.

The outcome of interest was improvement of capsular contracture. We performed a PubMed search for articles focusing on capsular contracture and breast implants published from 1975 to 2019. The resulting articles were reviewed using the following criteria.

Inclusion criteria:

- English language
- Observational studies and controlled trials
- Subjects comprising women receiving nonsurgical treatment for established capsular contracture following aesthetic breast augmentation or implant-based breast reconstruction

Exclusion criteria:

- Studies evaluating surgical techniques (e.g., capsulectomy)
- Review articles, case reports, or communication letters
- Language other than English

This study is registered in PROSPERO (CRD42019135252: Non-surgical treatments for breast capsular contracture: a systematic review of clinical studies; registered 6 April 2020). Ethics committee approval was not needed because this was a systematic review of previously published studies.

Results

The computerized search was performed in September 2019. The primary search included the keywords “capsular contracture” and “breast implants” and “treatment” and covered the publication dates of 1 January 1975 to 1 September 2019, resulting in 869 articles. When filtered for observational studies, controlled trials, patient population, and English language, 713 papers were retrieved. After elimination of articles by title review using *a priori* criteria, 10 papers

resulted. Further review of the articles and addition of papers after manual reference checks yielded a final total of 19 articles that met the inclusion criteria (Figure 1).

Description of studies

In total, 931 patients in 19 studies underwent nonsurgical treatment of capsular contracture. All 19 papers were observational studies. No controlled trials met the inclusion criteria. Ten studies referred to medical treatment (diclofenac epolamine topical patch [Flector Tissugel Patch; Pfizer, New York, NY, USA], pirfenidone, intracapsular triamcinolone injection, and

zafirlukast), and nine studies referred to other types of nonsurgical interventions (closed capsulotomy, pulsed electromagnetic field therapy [Diapulse; Diapulse Corporation America, Great Neck, NY, USA] and closed capsulotomy, ultrasound treatment, and laser treatment).

Study analysis

The study designs and treatment methods used were highly variable among the articles. The data retrieved were heterogeneous and could not be combined numerically. Therefore, a narrative review was performed.

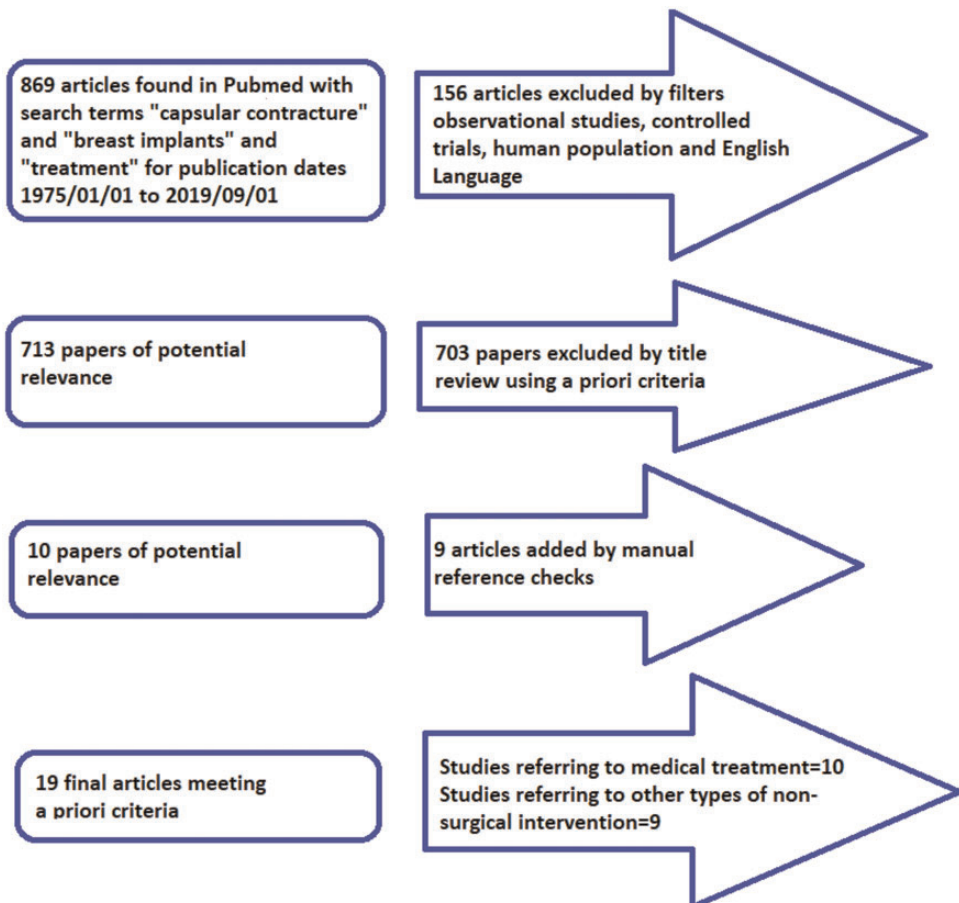


Figure 1. Article selection process

Data summary

Five studies involved closed capsulotomy,^{4,8-11} one involved Diapulse therapy and closed capsulotomy,¹² one involved the Flector Tissugel patch,¹³ one involved pirfenidone prolonged-release tablets,¹⁴ two involved intracapsular injection of triamcinolone,^{15,16} five involved zafirlukast,^{2,17-20} one involved montelukast,²¹ two involved ultrasound,^{22,23} and one involved low-level laser emission.²⁴ Among all studies, one showed no improvement²⁴ while all the others showed improvement. Only three studies had a control group.^{2,14,24} The studies are summarized in Table 1.

Discussion

Few studies have focused on nonsurgical treatment of capsular contracture, and most were inconclusive. Closed capsulotomy was developed in the mid-1970s in an effort to avoid additional costs and psychological burdens for patients.²⁵ Implant rupture, distortion of the breast shape, recurrence of contracture, and the inability to rupture the capsule are all possible complications of closed capsulotomy and are probably the reasons the relevant reports describing this technique became scarce after the mid-1990s.^{4,8-12,15,25} The only paper on Diapulse therapy was by Silver¹² in 1982. The author reported spectacular results with complete elimination of capsular contracture in 41 patients after treatment with a combination of Diapulse therapy, massage, and closed capsulotomy. The Diapulse system involves administration of non-thermal pulsed high peak power electromagnetic energy, and it is currently used for the treatment of ulcers.²⁶ However, no other studies have confirmed the effectiveness of Diapulse therapy for capsular contracture.

Ultrasound treatment was used by Planas et al.^{22,23} in two studies. In 1997,

they reported a series of 24 patients who underwent closed capsulotomy and ultrasound therapy, and all patients presented improvement at the 1-year follow-up.²² In 2001, they reported a series of 52 patients who were treated solely with ultrasonic applications, and 82.6% presented improvement at the 1-year follow-up.²³ Again, according to our review of the literature, no other reports have described ultrasonic treatment of capsular contracture.

Finally, the last study of a nonmedical and nonsurgical intervention was performed by Azimi et al.²⁴ in 2018. During the 6-week study period, 20 patients who received weekly treatments with either an active or inactive low-level laser handpiece were compared with 22 patients who received placebo. Laser treatment provided no improvement.

Medications have been used in the form of tablets, injections, or patches to treat capsular contracture. Le Louarn et al.¹³ treated capsular contracture using a patch that percutaneously released the nonsteroidal anti-inflammatory drug (NSAID) diclofenac epolamine, which suppresses cyclooxygenase-2. The patch was placed on the breasts of 19 women presenting with either unilateral or bilateral grade II to IV capsular contractures and was applied once or twice during a 24-hour period according to the severity of the contracture. Sixty-eight percent of patients presented improvement of capsular contracture. Veras-Castillo et al.¹⁴ used 600 mg of pirfenidone prolonged-release tablets three times daily for 6 months in 17 patients with capsular contracture. The control group comprised 13 patients who underwent capsulectomy. The authors found no evidence of capsular contracture at the end of pirfenidone administration.

Another mechanism of action of NSAIDs is lipoxigenase inhibition (antileukotrienes). Leukotrienes are implicated in the inflammatory cascade and are

Table 1. Studies on nonsurgical treatment of capsular contracture.

Authors and year	No. of patients	Treatment	Control	Follow-up	Result
Vinnik 1976	35 patients	Closed capsulotomy			Initial release in all cases followed by 9 recurrences
Frank and Robson 1978	20 patients	Closed capsulotomy with use of a pneumatic tourniquet		14 months	No recurrence of contracture
Tolhurst 1978	73 patients	"Nutcracker" technique		3 months	Recurrence of capsule formation in all cases
Little and Baker 1980	243 patients Baker II to IV	Closed capsulotomy		1 year	65% of patients developed recurrence within 6 months, 30% of patients developed recurrence from 6 to 12 months 44 patients presented improvement
Gruber and Jones 1981	75 patients	Closed capsulotomy			
Silver 1982	41 patients	Diapulse therapy and closed capsulotomy		3 months to 2 1/2 years	Elimination of capsular contracture
Caffee 1994	20 patients, 32 breasts, Baker III to IV	Intracapsular injection of triamcinolone at 5 mg/mL; closed capsulotomy 3 to 6 weeks later		6 months	12 patients had a successful outcome, 8 patients experienced treatment failure
Planas et al. 1997	24 patients (34 contractured breast implants; 1 patient with Baker II, 22 patients with Baker III, 11 patients with Baker IV)	Closed capsulotomy and ultrasound therapy		1 year	All contracted breasts had improved at the 1-year follow-up
Planas et al. 2001	52 patients with capsular contracture of grade II to IV; 48% of patients had bilateral capsular contracture	Ultrasonic applications (2 to 16 sessions)		1 year	82.6% improvement rate, with almost half of the contractures reaching grade I
Schlesinger et al. 2002	5 patients (2 with grade III, 3 with grade IV; 1 of the patients with grade IV had bilateral capsular contracture)	Zafirlukast (Accolate) at 20 mg by mouth twice a day for 3 months		1 to 5 months	2 patients with grade III reached grade I, 2 patients with grade IV reached grade I, and 1 patient with bilateral grade IV reached grade III in 1 breast and II in the other

(continued)

Table 1. Continued.

Authors and year	No. of patients	Treatment	Control	Follow-up	Result
Reid et al. 2005	23 patients positively screened for early capsular contracture	Zafirlukast at 20 mg orally twice a day for 6 months		6.3 months	75.7% complete or partial resolution of capsular contracture
Scuderi et al. 2006	20 women (36 prostheses)	Zafirlukast at 20 mg orally twice a day for 6 months		6 months	All treated breasts responded either completely or partially
Scuderi et al. 2007	120 women with mild to severe capsular contracture in at least one breast	Patients in Group A (n = 108) received zafirlukast (Accolate) at 20 mg orally twice a day for 6 months	Patients in Group B (n = 108) received vitamin E at 400 IU orally twice a day for 6 months		Significant decrease in the values of breast compliance after 6 months in Group A but not in Group B
Le Louarn et al. 2008	19 patients, 26 breasts with capsular contracture, Baker II to IV	Placement of Flector Tissuegel patch			68% of patients exhibited improvement of capsular contracture
Huang and Handel 2010	17 patients with capsular contracture, 4 bilateral (21 breasts in total, Baker grade \geq II)	10 mg of montelukast (Singulair) for 90 days and instructed to massage their breasts twice daily		5 to 36 months	11% of patients showed worsened contracture, 16% showed no change, 26% improved, and 37% achieved complete resolution
Schonfienza et al. 2011	25 patients with grade IV capsular contracture (1 breast in each patient, 25 breasts in total)	Injection of 1 mL of triamcinolone acetonide diluted in 10 mL of saline solution was injected under ultrasound guidance		1 and 6 months	All patients exhibited improvement (reduction) of maximum capsular thickness and reduction of pain on a visual analog scale
Mazzocchi et al. 2012	60 women with mild to severe capsular contracture in at least 1 breast	Patients received 20 mg of zafirlukast (Accolate) orally twice a day for 6 months		1 year	5.47% reduction in mammary compliance 1 year after drug withdrawal

(continued)

Table 1. Continued.

Authors and year	No. of patients	Treatment	Control	Follow-up	Result
Veras-Castillo et al. 2013	17 patients (14 patients unilateral contracture, 3 patients bilateral contracture; total of 20 breasts), Baker grade III, IV	600 mg of pirfenidone prolonged-released tablets 3 times daily for 6 months	13 patients underwent capsulectomy	6 months	70% of pirfenidone-treated group had no evidence of contracture at the end of pirfenidone administration
Azimi et al. 2018	42 patients with capsular contracture who had undergone implant-based breast reconstruction 6 months previously	20 patients received weekly treatments over 6 weeks with either an active or inactive low-level laser handpiece	22 patients received placebo	6 months	No improvement

hypothesized to be involved in the formation of capsular contracture. The leukotriene antagonists zafirlukast and montelukast are prescribed for the treatment of asthma. Studies have shown that they cause improvement in the appearance of scars as a beneficial side effect, and by lateral thinking, physicians began using these medications for improvement of capsular contracture.^{13,20} In 2005, Reid et al.¹⁷ used zafirlukast at 20 mg orally twice a day for 6 months in 23 patients with capsular contracture and found that 75.7% of them presented complete or partial resolution of capsular contracture. Zafirlukast was also used in three studies at Sapienza University of Rome.^{2,18,19} In 2006, Scuderi et al.¹⁸ used zafirlukast at 20 mg orally twice a day for 6 months in 20 women and reported that all treated breasts responded either completely or partially. In 2007, Scuderi et al.² again performed a comparative study between a group of 108 patients who were treated with zafirlukast at 20 mg orally twice a day for 6 months and a group of 108 patients who received vitamin E at 400 orally twice daily for 6 months. The authors noticed a significant decrease in the values of breast compliance after 6 months in the zafirlukast group but not in the vitamin E group. In another study by the same team, reduction of mammary compliance was greater during drug intake (22.5% after 6 months) and then gradually decreased after drug discontinuation up to 5.47% at the 1-year follow-up.¹⁹ The use of zafirlukast must be monitored carefully because normal doses have been reported to cause liver failure manifesting as anorexia, right upper quadrant pain, pruritus, or jaundice. The onset of hepatocellular dysfunction is 2 to 18 months after the start of zafirlukast therapy.¹⁹ In 2010, Huang and Handel²¹ used montelukast at 10 mg for 90 days in a series of 17 patients and noticed improvement in 26% and complete resolution in 37%. The authors

were unable to find a correlation between the duration of therapy and response to treatment.

Steroids are also known for their anti-inflammatory effect.²¹ Caffee¹⁵ used intra-capsular injection of triamcinolone at 5 mg/mL in 16 patients who could not be treated with closed capsulotomy and in 4 patients who had undergone three or more capsulotomies. The authors observed resolution of breast capsular contracture in 8 of 16 patients and 4 of 4 patients, respectively. They reported four major complications: one implant puncture and three major atrophies and several minor complications (mainly thinning of the skin).¹⁵ In 2011, Schonfienza et al.¹⁶ reported injection of triamcinolone under ultrasound guidance in a series of 25 patients with grade IV capsular contracture. They claimed that the technique was more controlled than that performed by Caffee¹⁵ because of the use of ultrasound guidance. All patients presented reduction of the maximum capsular thickness and reduction of pain at the 1- and 6-month follow-ups. However, none of these treatments are supported by extensive bibliographies, generating skepticism regarding their effectiveness. The only effective treatment for capsular contracture is currently capsulotomy or capsulectomy with implant removal or a change in the plane of insertion.⁶ Nonsurgical treatment, perhaps in the form of NSAID administration, can be applied for 6 months as the initial measure in patients who are reluctant to undergo surgery, provided that there are no comorbidities that prevent the use of such drugs.

The main limitation of this study is that few clinical studies on conservative treatment of capsular contracture were available for review. A systematic review of experimental studies on conservative treatment of capsular contracture might be more fruitful.


Declaration of conflicting interest

The authors declare that there is no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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