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REVIEW

Capsular contracture in breast reconstruction: A systematic review and meta-analysis

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Summary *Background:* Capsular contracture after implant-based breast reconstruction is not an uncommon problem and affects reconstruction outcomes. It can be influenced by various factors, such as the plane of implant placement, implant surface and implant type. This systematic review and meta-analysis aimed to evaluate how the abovementioned risk factors can affect capsular contracture rates.
Methods: A systematic review and meta-analysis was performed. PubMed MEDLINE, EMBASE (OvidSP) and Cochrane Library were searched. Comparison groups included subpectoral versus prepectoral implant placement, smooth versus textured implants and saline versus silicone implants. Odds ratios (ORs) were calculated for capsular contracture for each group. The level of evidence was evaluated using the Oxford Centre for Evidence-Based Medicine.
Results: Twenty-three studies met the inclusion criteria. Sixteen studies compared subpectoral versus prepectoral implant placement, with no statistically significant differences in capsular contracture rates [OR, 1.21; 95% confidence interval (95% CI), 0.75–1.95; P = 0.44]. Five studies compared smooth versus textured implants, with no statistically significant differences in

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capsular contracture rates (OR, 0.99; 95% CI, 0.50-1.93; P = 0.97). Two studies compared saline versus silicone implants for capsular contracture. Patients receiving saline implants had significantly lower capsular contracture rates than silicone implants (OR, 0.19; 95% CI, 0.08-0.43; P < 0.0001). *Conclusions:* Implant-based breast reconstruction using saline implants demonstrated reduced capsular contracture rates compared to silicone implants. However, no significant differences were observed in capsular contracture rates between subpectoral versus prepectoral implant placement and smooth versus textured implants.

Contents

Breast cancer is one of the leading causes of death among women in the United States.[1] Mastectomy can be an important and definitive treatment option, and implant-based breast reconstruction is the most commonly used procedure to restore the breast after mastectomy.[2] Implant-based reconstruction is associated with faster recovery and fewer scars than autologous reconstruction.[3] It enhances the quality of life by improving the sense of body image, sexuality and self-esteem.[4]

Breast reconstruction, while offering a transformative solution, comes with a fair share of complications, such as infections, seromas, sensory changes of the breast and nipple-areolar complex and notable capsular contracture.[5] Capsular contracture is not an uncommon complication after breast reconstruction, with a prevalence rate of 18.4%.[6] It is typically graded using the Baker classification, with class III or IV usually requiring intervention.[7] Several factors have been advocated to contribute to the development of capsular contracture. These include implant texture, plane of implant placement (subpectoral vs. prepectoral) and implant type (saline vs. silicone).[8]

Textured implants were initially designed to provide implant stability by promoting angiogenesis, disrupting fibrosis and stimulating tissue ingrowth.[9] They were later shown to reduce capsular contracture rates.[10] However, subsequent studies have highlighted that textured implants often exhibit more pronounced rippling than their smooth counterparts and have been implicated in anaplastic large-cell lymphoma, prompting surgeons to cautiously evaluate their use in breast reconstruction.[11,12] Polyurethane foam coating has been suggested to reduce capsular contracture risk.[13] Nevertheless, this implant has been discontinued in some countries, including the United States, due to the potential toxicity of polyurethane.[13] The plane of implant placement has also been suggested to affect the incidence of capsular contracture. Historically, the most common technique of breast reconstruction was to place the implant into the subpectoral pocket as it was felt to decrease implant visibility, palpability and rippling.[14] However, subpectoral implant placement carries its own risks, including

morbidity due to muscle manipulation and breast animation deformity.[15] Conversely, prepectoral implant placement is gaining attention for being less invasive, requiring reduced postoperative analgesia and providing a more natural breast shape.[2,4,16] However, this method poses its own challenges, including potential complications such as skin flap necrosis, implant extrusion and capsular contracture.[14] Finally, the relationship between implant filler material and capsular contracture risk has been a topic of ongoing debate in the literature, with some studies showing higher capsular contracture rates associated with silicone implants compared to saline[17,18] and some others finding similar rates.[19,20]

This meta-analysis reviewed the available data related to capsular contracture for implant-based breast reconstruction comparing subpectoral versus prepectoral implant placement, smooth versus textured implants and saline versus silicone implants.

Materials and methods

Search strategy

A systematic review of the literature and meta-analysis was performed in accordance with the guidelines from the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement.[21] The Prospero Registration Number of this meta-analysis is CRD42024497129. A comprehensive literature search was performed from inception to 25th of December 2023, using PubMed MEDLINE, EMBASE (OvidSP) and Cochrane Library. A detailed search strategy is provided in Table Supplemental Digital Content 1. The reference lists of review articles were also searched.

Selection criteria

Studies were included if capsular contracture was clearly defined as grade III or IV; comparison of saline versus silicone breast implants, subpectoral versus prepectoral and smooth versus textured; breast reconstruction with implants; human subjects; and published as a full-text article. Studies were excluded from the analysis if capsular contracture was not clearly defined; breast augmentation with implants; animal models; and studies were case reports, letters, comments, reviews, conference abstracts or not in the English language.

Data extraction

Two reviewers (N.C. and M.S.) independently considered the study eligibility of all retrieved studies by screening the titles and abstracts, and the full-text was obtained for studies that were identified for potential inclusion. Any disputes regarding study inclusion and exclusion were resolved through discussion with the senior authors (G.K., R.D.M., J.W., J.W.Y., D.W.M., and C.K.). The following data were extracted from the included studies: first author, year of publication, number of cases (breasts/patients), patient demographics (age, comorbidities), follow-up, capsular contracture case numbers, use of acellular dermal matrix (ADM), implant surface, implant filler material and plane of implant placement.

Included studies were assessed for risk of bias using the Scottish Intercollegiate Guidelines Network Checklist.[22] The following risk domains were used: selection bias, attrition bias, detection bias and confounding. The overall assessment of the study was graded as high quality (++), acceptable (+) or low quality(0); high quality indicated that most criteria were met; acceptable indicated that most criteria were met; and low quality indicated that most criteria were not met or there were significant flaws relating to the key aspects of the study design. Retrospective studies could not receive a rating higher than '+ '. The level of evidence for the included studies was evaluated using the Oxford Centre for Evidence-Based Medicine (OCEBM).[23]

Statistical analysis

The included studies were heterogeneous; thus, the Mantel-Haenszel statistical method was applied for capsular contracture (dichotomous data). Odds ratios (ORs) were calculated at 95% confidence intervals (95% CIs). τ^2 and I^2 tests were used to assess the dispersion of observed and true effects among studies. I^2 values were interpreted according to the Cochrane Handbook for Systematic Reviews of Interventions version 6.3.[24] All statistical analyses were performed by Review Manager 5.4.1.

Results

Eligible studies

A total of 2261 studies were identified through PubMed MEDLINE, EMBASE (OvidSP) and Cochrane Library. Twenty-three studies met the inclusion criteria for qualitative and quantitative syntheses of this meta-analysis. All included studies were retrospective, except three prospective and non-randomised studies[16,25,26] and three prospective and randomised studies.[18,27,28] All cases featured primary implant-based breast reconstruction. There were 6 level 1b and 17 level 2b studies based on OCEBM grading. Figure 1 shows the study flow diagram. The demographics are summarised in Table Supplemental Digital Content 2. The risk of bias in the included studies is described in Table Supplemental Digital Content 3. The overall assessment of the included studies was acceptable in most included studies, except three[25,27,29] that were graded as high quality.

Subpectoral versus prepectoral implant placement

Sixteen studies (3499 cases) compared subpectoral versus prepectoral implant placement for capsular contracture.[16,25,30-43] The implant characteristics of these studies are summarised in Table 1. ADM was used in all cases of both groups in eight studies,[25,33,36,38,40-43] in more subpectoral cases compared to prepectoral in three studies,[31,32,39] in more cases in the prepectoral group compared to subpectoral in one study[35] and unspecified/no information if statistically significant in four studies.[16,30,34,37] Most included studies did not specify implant surface or filler material.[16,25,31-33,37-39,43] Three studies used only silicone implants,[30,34,42] two included silicone and saline with no

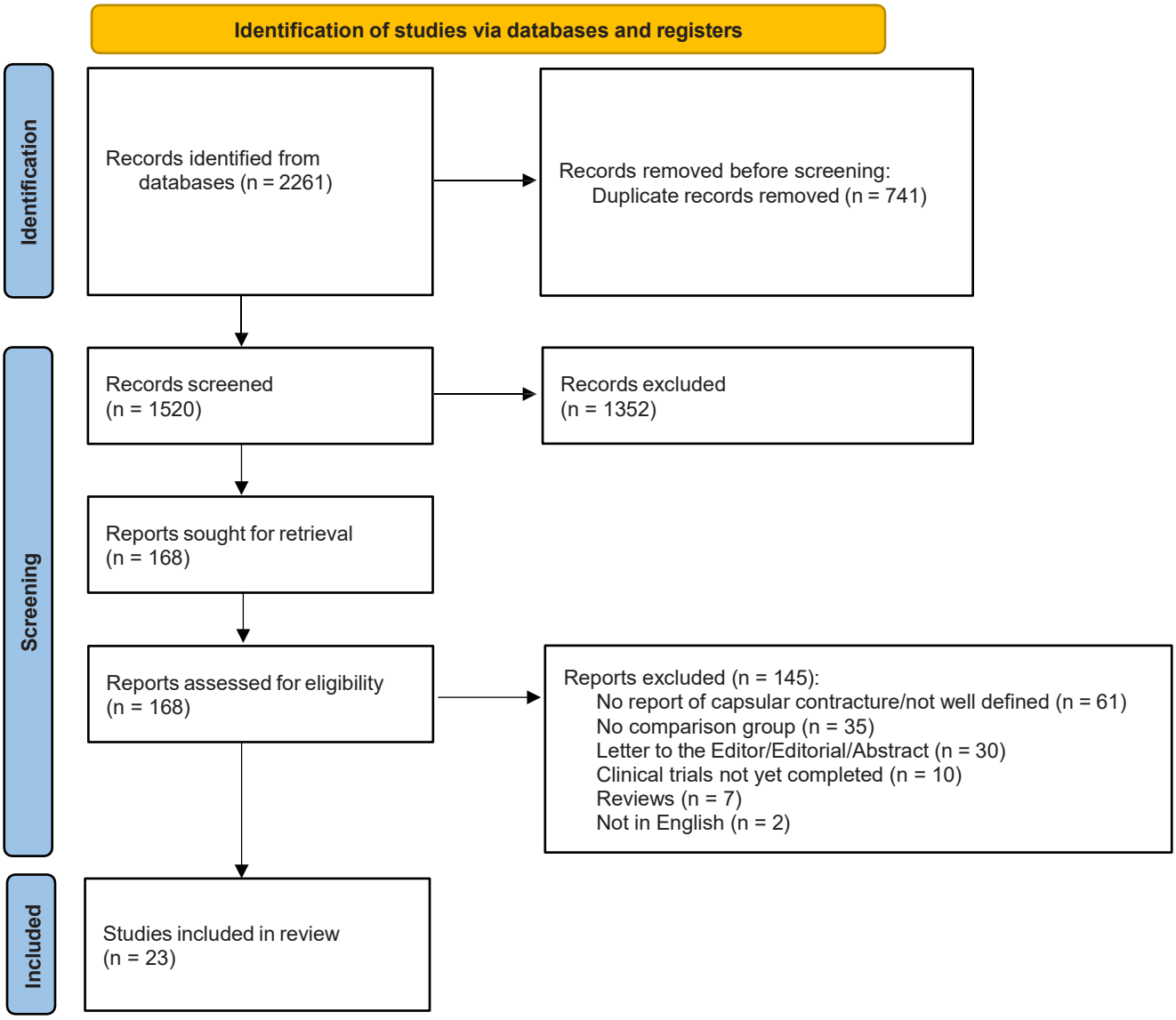

Figure 1 PRISMA flow diagram. PRISMA 2020 flow diagram for new systematic reviews that included searches of databases and registers only. From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi:10.1136/bmj.n71.

statistical significance between the two types,[35,36] and one did not specify any statistical significance.[41] Two studies included only smooth implants,[30,41] and one included only textured implants.[34] Interestingly, King et al.[35] used textured implants in more patients of the prepectoral group, whereas Scheflan et al.[40] used textured implants in more patients of the subpectoral group. Manrique et al.[36] included smooth and textured implants, with no statistical significance between the subpectoral and prepectoral groups. Mastectomy type was not significantly different between the two groups in six of the included studies.[29,31,32,36,38,40] Five studies[25,30,34,35,37] included patients who have undergone only nipple-sparing mastectomies, whereas Maruccia et al.[43] included non-skin-sparing mastectomy patients. Total mastectomy was done for all prepectoral patients, whereas nipple- and skin-sparing mastectomy was done for all subpectoral patients in one of the included studies.[42] The remaining studies did not include any information on mastectomy type. Five studies[16,33,34,36,38] included direct-to-implant (DTI) patients only, two[25,30] included two-stage (tissue expander followed by implant) patients and one[43] included permanent tissue expander patients only. The rest of the studies included a mixture of DTI and two-stage patients.

Pooling of all 16 studies showed no statistically significant difference between the subpectoral and prepectoral groups in capsular contracture incidence (Figure 2; OR, 1.21; 95% CI, 0.75-1.95; $P = 0.44$). Throughout these studies, dispersion was low for this analysis ($I^2 = 26\%$). Subgroup statistical analysis was done based on the description of ADM use. There was no statistically significant difference in capsular contracture incidence in any of the subgroup analyses, unspecified ADM use (OR, 1.61; 95% CI, 0.20-13.12; $P = 0.65$), ADM use and no significant difference (OR, 1.12; 95% CI, 0.65-1.92; $P = 0.69$), ADM use more in subpectoral (OR, 0.88; 95% CI, 0.34-2.29; $P = 0.80$), and ADM use more in prepectoral (OR, 2.28; 95% CI, 0.81-6.40; $P = 0.12$).

Table 1 Implant characteristics of prepectoral versus subpectoral implants.

Study, year	No. patients/breasts		Mean/median follow-up, months		ADM use	Implant surface	Implant filler material
	SP	PP	SP	PP			
Alcon, 2023	114	38	7.0	7.0	NA	Smooth	Silicone
Asaad, 2023a	100	184	17.9	15.6	**More often used in SP**	NA	NA
Asaad, 2023b	121	573	26.0	16.0	**More often used in SP**	NA	NA
Bernini, 2015	34	35	26.0	25.0	NA	NA	NA
Chandarana, 2018	83	71	19.6	9.8	Both groups (no statistical significance)	NA	NA
Cogliandro, 2023	52	29	≥ 24.0		NA	Textured	Silicone
King, 2021	202	203	31.2	20.4	**More often used in PP**	**More textured in PP**	No statistical significance between silicone and saline
Manrique, 2019	69	55	21.0	20.3	All cases of both groups	No statistical significance between smooth and textured	No statistical significance between silicone and saline
Maruccia, 2016	54	38	12.0		All cases of both groups	NA	NA
Moriarty, 2022	216	119	NA		Both groups (unspecified statistical significance)	NA	NA
Patel, 2022	86	48	23.3	8.7	All cases of both groups	NA	NA
Plachinski, 2021	103	83	21.4	15.6	**More often used in SP**	NA	NA
Sbitany, 2017	17	7	NA		All cases of both groups	NA	NA
Scheflan, 2020	105	71	21.3	18.6	All cases of both groups	**More textured in SP**	NA
Sinnott, 2018	140	370	30.8	18.7	All cases of both groups	Smooth	Silicone and saline (unspecified statistical significance)
Yang, 2019	47	32	13.0	11.1	All cases of both groups	NA	Silicone

NA, not available; SP, subpectoral; PP, prepectoral. Statistically significant differences are highlighted in bold.

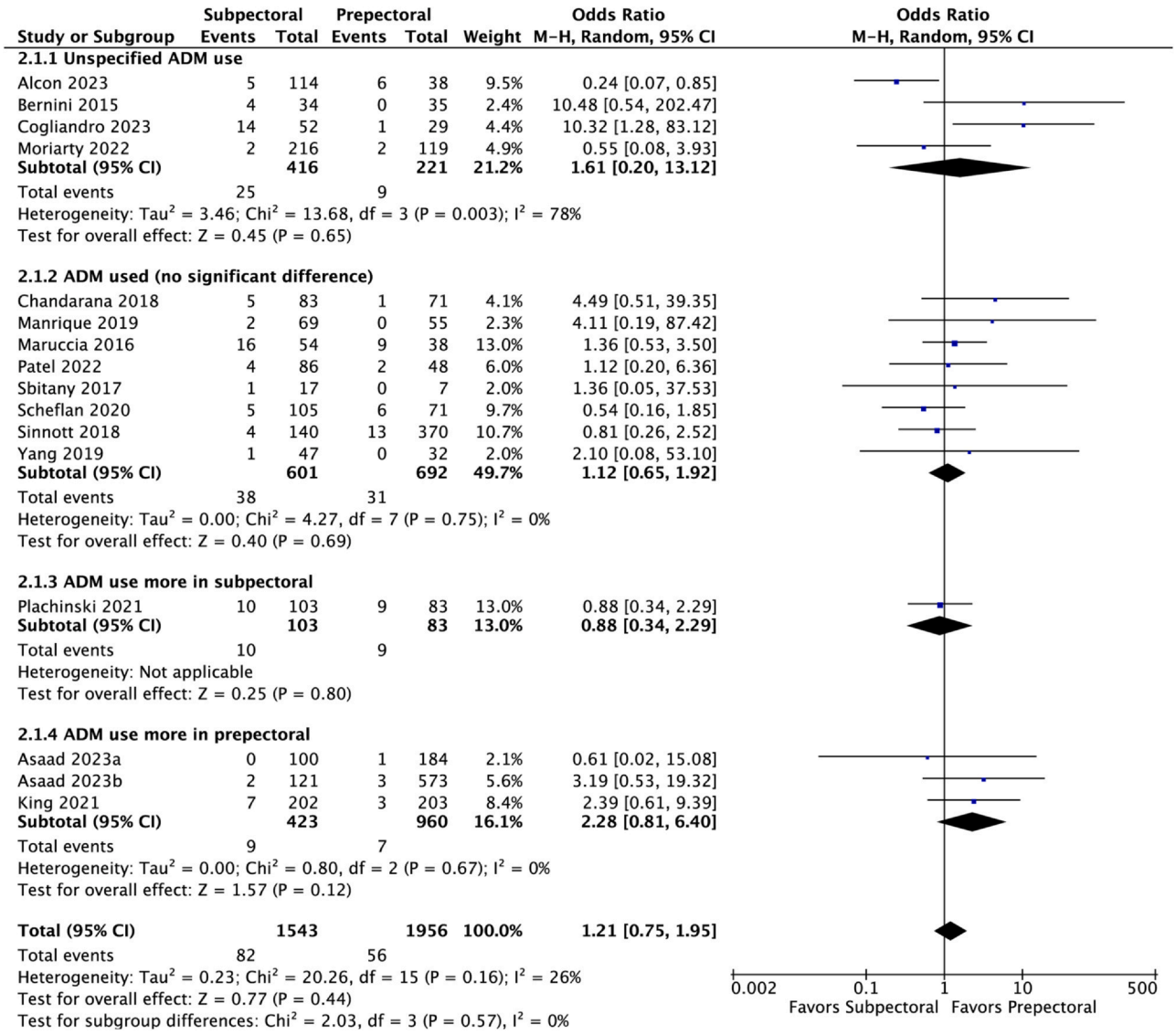

Figure 2 Forest plot for subpectoral versus prepectoral implant placement.

Smooth versus textured implants

Five studies (1974 cases) compared smooth versus textured implants for capsular contracture.[26,27,44-46] The implant characteristics of these studies are summarised in Table 2. Two of the included studies utilised ADM in all cases,[44,45] whereas the remaining three did not specify if ADM was used.[26,27,46] Silicone implants were used in four studies,[26,27,45,46] whereas the fifth one did not specify implant filler material.[44] The plane of implant placement was not specified in two studies.[26,46] Interestingly, in Jeon et al.,[45] the prepectoral plane was used more frequently in smooth implants, whereas no statistical difference in implant plane was observed by Bellaire et al.[44] Thuesen et al.[27] utilised only the subpectoral placement during breast reconstruction. Mastectomy type was only described in two of the included studies. Hammerstad et al.[26] included patients with modified or radical mastectomies, whereas Jeon et al.[45] included patients with no statistically significant differences between the types. Two studies[27,46] included two-stage patients and the remaining three included DTI patients only. There was no statistically significant difference in smooth versus textured implants in capsular contracture incidence [Figure 3; OR, 0.99; (95% CI, 0.50-1.93; P = 0.97)]. Dispersion among these studies was substantial (I^2 = 56%).

Saline versus silicone implants

Two studies (132 cases) compared saline versus silicone implants for capsular contracture.[17,18] Both studies used the subpectoral method of reconstruction and included DTI patients only. None of them specified implant surface type or whether ADM was used. Both studies included modified radical and simple mastectomies. Patients receiving saline implants had a significantly lower capsular contracture rate than silicone implants (Figure 4; OR, 0.19; 95% CI, 0.08-0.43; P < 0.0001). Dispersion among these studies was very low (I^2 = 0%).

Table 2 Implant characteristics of smooth versus textured implants.

Study, year	No. patients/breasts		Mean/median follow-up, months		ADM use	Plane of insertion	Implant filler material
	SM	TEX	SM	TEX			
Bellaire, 2021	296	148	28.6	22.2	All cases from both groups had ADM	No statistical difference between SP and PP	NA
Hammerstad, 1996	46	47	32		NA	NA	Silicone
Jeon, 2023	137	203	15.1	28.6	All cases from both groups had ADM	**PP used more frequently in smooth implants**	Silicone
Thuesen, 1995	9	11	36.0		NA	Subpectoral	Silicone
Vorstenbosch, 2021	785	292	60.0	90.2	NA	NA	Silicone

SM, smooth; TEX, textured. Statistically significant differences are highlighted in bold.

Discussion

Implant-based breast reconstruction involves using various prostheses and surgical techniques, factors that could affect capsular contracture rates. This meta-analysis analysed clinical studies comparing the effects of implant plane (prepectoral vs. subpectoral), surface texture (smooth vs. textured) and implant type (saline vs. silicone) on capsular contracture rates after implant-based breast reconstruction. The universally accepted Baker grade was used across all included studies to define capsular contracture, with Baker grades III and IV considered clinically significant.[7]

Subpectoral versus prepectoral implant placement

This meta-analysis found no statistically significant difference in capsular contracture rates between the prepectoral and subpectoral positions of the implant (OR, 1.21; 95% CI, 0.75–1.95). ADM has been reported to reduce capsular contracture rates.[47] ADM use varied within the included studies of this meta-analysis; therefore, a subgroup analysis was done. However, there were no statistically significant differences in the subgroups.

These findings were consistent with two previous meta-analyses[48,49] but differed from the three other meta-analyses,[50-52] which found that prepectoral placement was associated with significantly lower capsular contracture rates than subpectoral placement. However, these latter three meta-analyses[50-52] did not clearly state which Baker grades of capsular contracture were included. This meta-analysis included 16 studies reporting data on 3499 cases; from the previous ones, the highest number of studies included was 13[48] and the highest number of cases was 2437.[52] Only one previous meta-analysis did a statistical analysis considering ADM use.[49]

Several theories have been proposed to explain how the prepectoral placement of breast implants can reduce capsular contracture rates compared to the subpectoral plane. Interference by the overlying pectoralis muscle may contribute to capsular contracture in the subpectoral pocket.[53] Creating the subpectoral pocket requires additional surgical steps that could increase the risk of contamination and seroma formation.[53] Moreover, prepectoral placement may result in a thinner capsule wall with less vascularity and less mechanical stress on the implant.[16] In the subpectoral pocket, the implant is placed deeper anatomically, where the blood supply is richer and more prone to damage from the contraction of the overlying muscle, resulting in inflammation and potentially capsular contracture.[49] Chen et al.[54] postulated that the prepectoral plane mimics natural anatomy, decreasing inflammation and myofibroblast proliferation around the implant.

In contrast, massaging the implant by placement in the subpectoral plane can reduce the capsular contracture rate and provide a protective barrier from bacteria-laden breast tissue.[55] Previous studies showed a strong correlation between culture positivity (particularly with *Staphylococcus epidermidis*) of implant capsules and clinically significant capsules.[56] It was previously speculated that the biofilm on the outer surface of the implant could serve as a source of infection and chronic inflammation, accelerating capsular contracture. Implant placement in the subpectoral pocket

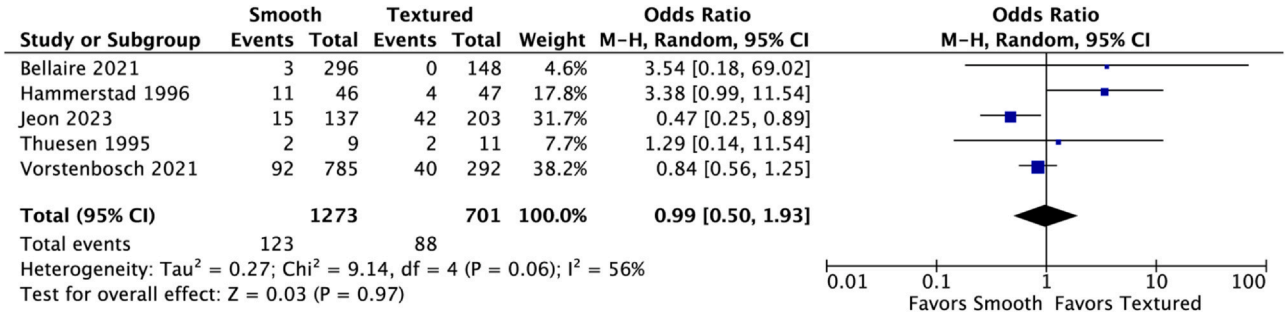

Figure 3 Forest plot for smooth versus textured implants.

decreases contact with the glandular tissue; thus, exposure to the breast flora is minimised.[57] The net sum of both enhancers and suppressors of subpectoral and prepectoral placement could explain the results of our meta-analysis of no technique being superior to the other.

Smooth versus textured implants

This meta-analysis found no statistically significant difference between smooth versus textured implants in capsular contracture rates (OR, 0.99; 95% CI, 0.50–1.93). No previous meta-analysis compared capsular contracture rates between smooth versus textured implants in breast reconstruction. These findings can be explained using the two main hypotheses of the mechanism for capsular contracture: scar proliferation and infection.[58]

Previous studies indicated that myofibroblasts play a role in capsular contracture by generating a contractile force on connective fibres when arranged parallel to each other along the implant surface.[59] Electron microscopy studies showed that textured implants exhibit changes in the fibre direction in each layer, generating mechanically ineffective forces for capsular contracture to occur.[60] It was also suggested that the wrinkling of textured implants may prevent capsule formation.[61]

In contrast, Burkhardt et al.[62] provided strong evidence supporting the hypothesis that subclinical infection, including pathogens such as *S. epidermidis*, significantly contributes to capsule formation. This is supported by clinical data and basic science studies.[63,64] The substantially increased surface area of textured implants makes them more vulnerable to contamination and capsule formation. If both hypotheses were correct, then the texturing of the implant counteracted its increased surface area, making it more prone to infection, with no overall effect on capsular contracture rates.

ISO 14607:2018 classifies breast implants based on surface roughness, with smooth implants having a roughness of $< 10\,\mu m$, microtexture having a roughness of 10 to $50\,\mu m$ and macrotexture having a roughness of $> 50\,\mu m$.[65] This classification system is undergoing changes in 2024, with a new draft under development. However, this continues not to consider the host inflammatory response, which is likely a relevant contributor to capsular contracture.[66] Newer-generation smooth implants behave differently from older-generation ones.[67] Only two of the included studies[26,27] clearly stated the generation of breast implants used; hence, a subgroup analysis was not possible.

Saline versus silicone implants

This analysis showed that saline implants were associated with lower capsular contracture rates than silicone implants (OR, 0.19; 95% CI, 0.08–0.43). This was consistent with a previous meta-analysis,[68] which investigated this comparison after breast augmentation. This previous meta-analysis also included Baker grade II capsular contractures that were not clinically significant. Although deflation rates for silicone implants were lower than saline ones,[69] the cohesion between the silicone molecules could still fail to prevent implant leakage.[70] In the event of a leak, saline is completely absorbed, which is not the case with silicone.[69] This exacerbates local inflammation, a known precursor to capsular fibrosis and subsequent contracture.[71] These silicone molecules provide an optimum environment for bacterial growth, leading to subclinical infections and capsular contracture.[29] Furthermore, a prospective study by Danino et al.[72] analysed 35 periprosthetic capsules from saline and silicone implants. They found silicone particles surrounded by macrophages and giant cells in all capsule layers from silicone gel implants. In contrast, no silicone particles were observed from saline breast implants. These findings suggested that particle bleeding originates from the inner silicone gel and not from the outer silicone surface of the implant. Although this meta-analysis suggested that saline implants are associated with lower capsular contracture rates, this type of implant is associated with higher rates of other complications, such as implant rupture and rippling.[73]

Limitations

This meta-analysis has some potential limitations that must be considered when interpreting the results. First, patient populations were diverse, with some studies not providing information on the plane of implant insertion, ADM use, implant filler material, implant surface and mastectomy type. Some studies included DTI patients only, whereas others included two-stage breast reconstruction patients or a mixture of both techniques. Lipofilling, which can potentially affect capsular contracture rates,[74] was significantly more common in the subpectoral group in one of the included studies.[41] Maruccia et al.[43] excluded patients who received lipofilling; the remaining ones did not mention this factor. Although capsular contracture usually occurs within the first year of implantation,[75] research has also shown that contracture is a progressive phenomenon with accumulating risks over time from surgery.[76] Therefore, more long-term studies would be required to increase the validity of comparing the different

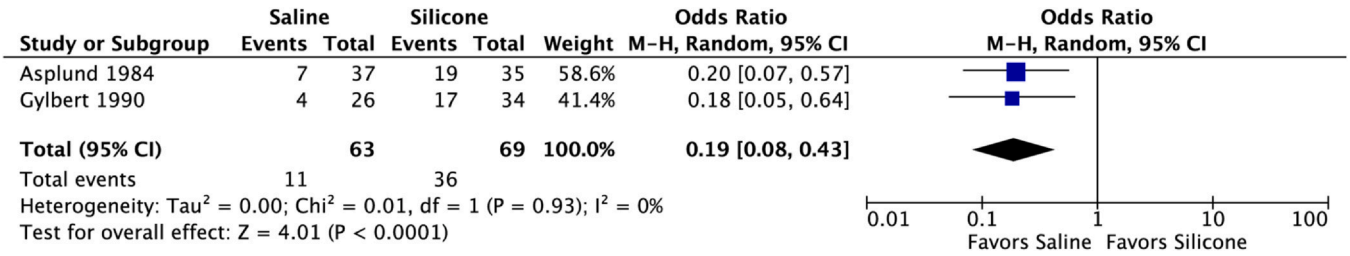

Figure 4 Forest plot for saline versus silicone implants.

implant materials and surgical techniques. There was no minimum follow-up time in the inclusion criteria of the studies, with three of them not specifying this variable[18,25,37] and four of them having < 12 months follow-up for one or two of the groups.[30,38,42,77] Follow-up times between the two groups in some of the included studies varied.[33,35,39,41,45,46] Further research with comparable follow-up times is needed to validate these findings. Radiation therapy has been associated with an increased risk of capsular contracture.[78] Variability in terms of radiation exposure was observed in the included studies. Most of them included irradiated and non-irradiated breasts,[16-18,30-40,42,44,46] with no separate data of the two subgroups available for statistical analysis to be made, four of them excluded irradiated patients[26,27,41,43,45] and one of them included only irradiated patients.[25] Antibiotic irrigation of the implant pocket, which has been associated with reduced capsular contracture rates,[79] was only implemented in four of the included studies,[33,39,40,44] with the remaining ones not describing such protocol.[16-18,25-27,30-32,34-38,41-43,45,46] Although the Baker classification is the most commonly used tool for capsular contracture grading, it is subjective and inherently limited by possible operator differences in attributing severity.[80] Measurement of capsular contracture should consider more than one modality with objective methodologies such as elastography.[81]

Conclusion

This meta-analysis demonstrated statistically significant differences in capsular contracture rates in favour of saline versus silicone implants. There were no statistically significant differences in capsular contracture rates between subpectoral versus prepectoral implant placement and smooth versus textured implants. Subgroup analysis for subpectoral versus prepectoral implant placement in terms of ADM use showed no statistical significance. Nevertheless, additional studies must be completed to determine if ADM or any other meshes are beneficial in reducing capsular contracture. Saline implants are associated with an increased risk of rupture and rippling. Therefore, silicone implants have their advantages as well. Given the popularity of implant-based breast reconstruction and the implications of its complications, more quality research in this area is necessary.

Ethical approval

Not required.

Conflict of interest statement

All authors have no related financial interests or conflicts of interest to declare.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.bjps.2024.08.057.

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