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Intra-operative techniques to reduce the risk of capsular contracture in patients undergoing aesthetic breast augmentation – A review

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ABSTRACT

Background: Capsular contracture is a significant complication following aesthetic breast augmentation. Efforts to reduce this incidence have focused on the surgical approach, implant selection and IV antibiotics. Intra-operative methods to reduce the risk have had less investigation. This review focuses on these interventions and will document evidence to support pocket irrigation, nipple shields, drains and the use of an implant insertion funnel.
Methods: A comprehensive review of Pubmed, Scopus and Embase was performed to identify relevant papers published since 2000. These were reviewed and pertinent papers selected. Data regarding the intervention and its impact were recorded and compared.
Results: Ten relevant studies were identified. A total of 11,772 patients were included in the studies, with a pooled capsular contracture rate of 2.54%. Six papers reported the use of antibiotic irrigation, two papers reported the use of drains, two the use of an insertion funnel, two the use of povidone-iodine and one the use of nipple shields. Antibiotic irrigation was shown to reduce capsular contracture 10 fold in two papers, have no effect in one and increase it in a further paper. However these changes did not persist after multivariate analysis.
Conclusions: There was limited evidence to support intra-operative techniques to reduce capsular contracture rate. Where available the literature tends to support the use of antibiotic and povidone-iodine irrigation, the use of insertion funnels and nipple shields and the avoidance of drains. However due to the poor quality of the evidence these findings should be treated cautiously.

Introduction

It is estimated that, globally, more than 4 million women have breast implants as part of either aesthetic or reconstructive breast surgery. Capsular contracture remains the most reported complication following breast augmentation.[1] The incidence reported varies from 0 to 75% although this variation likely relates to the variety of techniques and indications

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for the use of breast implants. Two of the most carefully controlled series of breast augmentations using silicone implants are those produced by Mentor and Allergan in their pre-approval trials.[2–4] In these series the capsular contracture rates for those undergoing primary augmentation were reported as 2.4% (Mentor) and 6.1% (Allergan) at six and seven years of follow up respectively. Within these cohorts the follow-up rates were 75% in the Allergen trial at seven years and 69% at six years in the Mentor trial. The incidence of capsular contracture appeared to be fairly uniform at approximately 1% per year after implantation in the Allergan cohort. Capsular contracture may present as a distortion in the shape or volume of the breast implant. In severe cases this is also associated with pain and discomfort.[5] It is most often classified according to the scale attributed to Baker into one of four groups.[6] Baker 1 describes a soft non visible implant. Baker 2 represents an implant that is solid and palpable but not visible. Baker 3 refers to implant that are hard, palpable and visible, whilst a Baker 4 capsular contracture includes those that are not only hard and deformed but painful.

Despite over 25 years of research the precise aetiology of capsular contracture formation is not known. Significant risk factors include the formation of a biofilm around the implant, infection at the time of surgery, haematoma formation, radiotherapy, gel bleeds and a propensity for hypertrophic scarring.[1,5,7,8] Clear evidence of the risks of both radiotherapy and infection on the formation of capsular contracture have been shown.[9] The role of infection has been particularly highlighted with evidence that bacteria were present on 76% of contracted implants at explantation and that 86% of implants removed from patients with capsular contracture in a separate series were culture positive.[10,11] However the reported rates of infection post implant surgery range from 1% to 6%, with lower rates of less than 2.5% in those associated purely with aesthetic breast surgery.[9,12,13] It is suggested that subacute infection and the formation of a biofilm must have a role that accounts for the discrepancy in the incidence of post operative infection and capsular contracture.[8] A biofilm is a cluster of bacterial cells of multiple types that are embedded in matrix and which are more tolerant to antimicrobials and host cells than individual floating bacterial cells.[8] The significance of this in patients with breast implants is that the very presence of an implant can reduce the number of bacteria needed to initiate a significant response by a million fold.[14] The source of the these bacteria may be either the patients skin or their nipple as it is thought that the breast ductal system is colonised with a number of bacteria including *staph. epidermis*, *bacillus subtypes* and *diptheroids*. Manipulation of the nipple during surgery may result in these being expressed onto the skin and result in contamination of the implant. It has recently been postulated that biofilm may also play a role in the development of breast implant associated anaplastic large cell lymphoma (BIA-ALCL). The precise mechanisms of this relationship are not fully understood but may involve a combination of the textured surface of the implant, the proliferation of T lymphocytes in response to the bacterial load, and the transformation of T helper (T_H) cells to this form of T cell lymphoma.[15,16] Whilst further work is required in this area it emphasises the need to keep bacterial contamination to a minimum to reduce the formation of biofilm and any subsequent long term complications.

A number of methods have previously been reported as successful in reducing the rate of capsular contracture. Many of these reports are based around the implant being used or the surgical approach employed. Evidence supports the use of an infra-mammary incision,[1] the positioning of the implant in the sub-muscular plane,[7] the use of textured rather than smooth implants,[7] and the administration of IV antibiotics pre-operatively.[12] Intraoperatively many surgeons use a variety of techniques to further reduce the risk of contamination and thus capsular contracture. In an era of evidence based medicine an understanding of the evidence that supports these techniques is vital, not only to guide best practice, but also to help facilitate their adoption especially when they may have a cost implication.

This review will interrogate the evidence to support intra-operative techniques to reduce capsular contracture. It will focus on patients undergoing breast augmentation as a cosmetic procedure. Intra-operative interventions to reduce the risk of capsular contracture will be identified and the outcomes reported compared to those achieved without the intervention. The review will focus on the rate of capsular contracture, however, where this is not documented the secondary outcome of post operative local infection will be recorded.

Methods

The web based Medline, Embase and Scopus databases were searched using the following keywords "breast" or "mammary" and "augmentation" or "implant" or "prosthesis" and "capsular contracture" or "infection" or "contamination" or "capsule". The inclusion criteria were that the study was a clinically orientated human study, published in English between 2000 and 2016 (studies published prior to 2000 were excluded to try and ensure that the implants used in the studies reviewed were as contemporaneous as possible) included only patients undergoing cosmetic augmentation and reported the effect of an intra-operative intervention on capsular contracture rate or post operative infection. Papers were excluded if they reported data pertaining to breast reconstruction as part of cancer treatment (to avoid the possible confounding effects of radiotherapy and other adjuvant treatments). Due to incomplete information, abstracts and conference reports were also excluded.

Results

All citations initially identified were reviewed (n = 1458) by the study team and the full papers for those identified as relevant to this study were sourced (n = 40). Any disagreement on inclusion was resolved by the senior author. Each of these 40 papers were then read and a further 32 were rejected as they, either didn't focus on intra-operative methods of reducing capsular contracture (n = 12), were review papers (n = 6, two of which included breast cancer patients, two were not systematic reviews, one focused on the treatment of capsular

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