
Breast prosthesis implantation for reconstructive and cosmetic surgery: a rapid review

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Record Status

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Authors' objectives

This rapid review assessed the long-term safety and effectiveness of breast implantation for primary and revision breast reconstruction and augmentation, using a rapid systematic review of the literature. Articles published from 2005 and with five or more years follow-up were eligible for inclusion in this rapid review. Where authors listed the manufacturer of the implants a subgroup analyses was conducted in breast reconstruction and augmentation indications; as well as prior treatment with radiotherapy or chemotherapy in patients undergoing implantation for breast reconstruction.

Authors' conclusions

Due to the quality, characteristics and disparity of the literature available with duration of follow-up of five years or more, it was difficult to observe trends in the data. In addition, 17 of the 28 included studies were retrospective in design and therefore outcome assessment was dependent on the extent and accuracy of historical record keeping. This in addition to the poor methods of assessing rupture and determining patient satisfaction presented a challenge for this rapid review. The majority of the results reported for the safety and effectiveness of breast implantation across all indications was reported as Kaplan-Meier estimates calculated based on the incidence of safety and effectiveness outcomes in a subset of study participants. Validated tools and structured assessment tools tailored to the outcomes of breast implantation, such as the Breast Q tool (Pusic et al 2009) were not used to assess patient satisfaction in the included studies. Where reported, patient satisfaction predominantly comprised patient self-assessment using surveys of varying length and content. As rupture results for all indications were predominantly reported as Kaplan-Meier estimates it is difficult to determine from the literature the long-term incidence of rupture. Kaplan-Meier estimates and incidence data of capsular contracture increased over time, particularly between five and 10 and up to 15 year follow-up for all indications and implant types. Silicone gelfilled implants reported the lowest estimate of capsular contracture and, wrinkling and rippling in primary reconstruction patients compared to saline-filled and permanent expander implants. In addition, the Kaplan-Meier estimates of adverse events for primary augmentation with silicone gelfilled implants were similar to primary reconstruction patients. Permanent expanders, used for primary and revision breast reconstruction in three studies, resulted in a higher incidence of adverse events compared to Kaplan-Meier estimates for silicone gel-filled implants for the same indications, and saline-filled implants for primary breast reconstruction. In addition, at 12.5-year follow-up all permanent expanders had been removed in the two studies reporting re-operation; and complaints included capsular contracture, poor aesthetics and deterioration in patient satisfaction. The ability to determine the in vivo lifespan of breast implants across primary and revision breast reconstruction and augmentation was limited as the data was primarily comprised of Kaplan-Meier estimates. However, where reported incidence data compared to Kaplan-Meier estimates agreed with the trend in outcomes over time; namely, that capsular contracture, the likelihood of rupture and patient dissatisfaction all increase over time following implantation with any type of breast prostheses. The available data suggests re-operation is typically performed within five to 10 years following implantation due to a variety of reasons ranging from dissatisfaction with the style or size of implant, or the occurrence of capsular contracture or implant rupture. Consequently, developments in the available evidence-base for the assessment of the long-term safety and effectiveness of breast implantation should comprise prospectively designed comparative studies where data is stratified according to surgical technique and the characteristics of the implants used.

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