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REVIEW

Systematic review of the effectiveness of polyurethane-coated compared with textured silicone implants in breast surgery

Paula J. Duxbury [a,b], **James R. Harvey** [a,b,*]

[a] *University of Manchester, Manchester Academic Health Science Centre, 46 Grafton Street, Manchester M13 9NT, UK*
[b] *Nightingale Centre, University Hospital of South Manchester, Wythenshawe Hospital, Southmoor Road, Manchester M23 9LT, UK*

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Review

Summary *Background:* Silicone gel implants are used worldwide for breast augmentation and breast reconstruction. Textured silicone implants are the most commonly placed implant, but polyurethane-coated implants are increasingly being used in an attempt to ameliorate the long-term complications associated with implant insertion.
Methods: This systematic review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines. Electronic searches of MEDLINE, EMBASE, the Cochrane Library and www.ClinicalTrials.gov were undertaken in March 2014 using keywords.
Results: Following data extraction, 18 studies were included in the review, including four core studies of textured silicone implants and five studies reporting outcomes for polyurethane-coated silicone implants. There are no clear data reporting revision rates in patients treated with polyurethane implants. In the primary reconstructive setting, capsular contracture rates with silicone implants are 10—15% at 6 years, whilst studies of polyurethane implants report rates of 1.8—3.4%. In the primary augmentation setting, core studies show a capsular contracture rate of 2—15% at 6 years compared with 0.4—1% in polyurethane-coated implants; however, the polyurethane studies are limited by their design and poor follow-up.
Conclusions: The use of polyurethane implants should be considered a safe alternative to textured silicone implants. It is likely that an implant surface does influence short- and long-term outcomes; however, the extent of any benefit cannot be determined from the available evidence base. Future implant studies should target the short- and long-term benefits of implant surfacing by

* Corresponding author. Nightingale Centre, University Hospital of South Manchester, Wythenshawe Hospital, Southmoor Road, Manchester M23 9LT, UK. Tel.: +44 (0)161 2914436; fax: +44 (0)161 2914435.
E-mail address: James.Harvey@uhsm.nhs.uk (J.R. Harvey).

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procedure with defined outcome measures; a head-to-head comparison would help clarify outcomes.

Contents

Introduction

Worldwide, silicone gel- and saline-filled implants are offered for breast augmentation and post-mastectomy breast reconstruction.[1,2] Silicone implants have been used in this setting since 1962; however, their use declined worldwide due to safety concerns in the 1990s.[3] As a direct result of safety concerns, in 1988, the US Food and Drug Administration (FDA) set up a process by which all manufacturers were required to demonstrate safety and effectiveness in a premarket approval application. Silicone implants were therefore designed to meet performance and safety benchmarks before being assessed and approved by the FDA. This process has led to good-quality, long-term data being available on large cohorts of patients with silicone implants. All breast implants are associated with complications; the most frequently reported are capsular contracture, reoperation and removal. Additional complications include implant rupture, infection, asymmetry, wrinkling, scarring and pain.[4]

Polyurethane foam coatings were developed to cover silicone implants and were first used in the 1970s. Studies have indicated that polyurethane-coated silicone implants may reduce capsular contracture.[5,6] After formation of the capsule around the implant, the polyurethane coating breaks down to become part of the capsule, and it is hypothesised that the tightening observed with traditional silicone implants does not occur.[7] This may be due to the polyurethane coating preventing the organised alignment of myofibroblasts, thereby interrupting the strength required for capsular contracture to occur.[8] Following their introduction, the use of polyurethane implants spread worldwide (to >35 countries, including Europe, Australia and Asia, as well as the USA and UK).[9]

However, in 1991, a specific association was reported between polyurethane and the carcinogen 2,4-toluenediamine (TDA).[10] This led to a complete prohibition of polyurethane-coated silicone implants in the USA by the FDA, which has never been lifted. In the UK, in 1992, polyurethane-coated implants were likewise prohibited although surgical use of silicone gel implants was sustained. Measures were taken in the UK to monitor the safety and effectiveness of breast implant procedures, and investigation into the carcinogenic risk of polyurethane found it to be 'small, unquantifiable'.[11] The CE Mark was introduced in Europe in 1996 for approval of all medical devices. For certification of breast implants, manufacturers were required to provide evidence of standards of materials, manufacturing and quality assurance. By default, this conferred approval of polyurethane-coated implants for clinical use in the UK was upheld by the Medicines and Healthcare products Regulatory Agency (MHRA) in 2005.[12]

Despite this controversy, surgical use of polyurethane-coated implants continued in other countries. As the key