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Long-term outcomes with the McGhan Style 153 dual-lumen breast implant: Implications for future implant design☆

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Summary *Background:* A variety of saline and silicone implants have been introduced over the years to optimize the shape, aesthetic result and safety profile for use in breast surgery. The McGhan Style 153 dual-lumen silicone implant represented an early generation of anatomically shaped implants later removed from the market due to a high rate of rupture. This study reports long term outcomes and complications, including a revised rupture rate, and discusses potential mechanisms of implant failure and their implications for future implant design.
Methods: A retrospective review was performed on 79 patients (134 implants). Demographics, operative details, outcomes, and complications were recorded. Rupture rate and location of rupture were included.
Results: The revised implant rupture rate was 36.6% of implants. At least one rupture occurred in 49.4% of patients. Clinical exam was the most common method of detection (55.1% of ruptures). The most common location of rupture was the superior pole (30.6%), followed by a posterior location (24.5%). The capsular contracture rate (Baker grade III/IV) was 51.5%. The total implant removal rate (for rupture, contracture, size change, or asymmetry) was 77.6%. The average time to implant removal was 91.8 months, or 7.5 years (±47.3 months). Average follow up was 120.7 months or 10 years (±49.9 months).
Discussion: The experiences with this anatomic gel implant highlight the importance of shell stability over time, suitable gel cohesiveness to support the asymmetric anatomic shape, avoidance of fold flaws due to wrinkling, and the prevention of distinct stress points on the shell that can result from dual lumen or multi-compartment designs.
Level of evidence: Level III, retrospective cohort, therapeutic study.

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Introduction

The design of silicone and saline implants for both reconstructive and cosmetic breast surgery has advanced significantly since their introduction in the early 1960s. Many modifications in implant design have been directed towards manufacturing a long lasting durable and safe device, while providing a natural contour and consistency. Over the past several decades, the evolution of implant design has produced a wide range of devices that vary in shape, size, projection, and surface texture to optimize the aesthetic result while reducing operative complications.

Tracking these complications is crucial to ensuring high-quality care, patient safety, and informed decision making. The Mentor and Allergan Core studies on silicone implants are the largest cohort prospective studies which have investigated the rates of these complications over a 10-year period in both primary and secondary augmentation and reconstruction.[1–3] These studies currently represent the most rigorous and validated data available for complication rates following implant placement.

Introduced into the market in 1996, the textured dual-lumen implant represented an early generation of anatomically shaped silicone gel devices (Style 153®, McGhan™, Santa Barbara, CA, USA). In 2005, the 3-year data of the Core study showed a significantly higher rupture rate for this dual-lumen implant compared to other silicone devices and the device was voluntarily removed from the market. The higher rupture rate was attributed to a design flaw at the posterior surface where the inner lumen was attached to the outside silicone shell.[4] In 2011, Hammond et al. reported an average rupture rate of 19.1% at 82 months.[5] The purpose of this study was to report longer term follow-up data, including a revised rupture rate, and discuss potential mechanisms of implant failure and implications for future implant design.

Materials and methods

The study design was approved by the Institutional Review Board at Spectrum Health Butterworth Hospital (Grand Rapids, MI, USA, August 2015, IRB # 2015-166) and adhered to all ethical standards outline in the World Medical Association Declaration of Helsinki (June 1964) and subsequent revisions. No research grants were obtained. No animals were included in this study.

Written informed consent was obtained from a consecutive series of patients presenting to the senior author's local practice (Grand Rapids, MI, USA) who underwent implant placement with the dual-lumen anatomic textured implants from 6/1998 to 7/2002 (Style 153®, McGhan™, Santa Barbara, CA, USA). Both reconstructive and aesthetic cases were included. Patients either deceased or lost to follow-up at the time of data collection were excluded from the study.

Age, demographics, surgical history, previous radiation, indications for implantation, and length of follow-up were recorded. Operative details included type of surgery at time of implant placement, drain duration, and implant size. Complications including hematoma, seroma, infection, tissue necrosis, capsular contracture, wrinkling, rupture rate, method of rupture detection, as well as degree and location of rupture, were calculated. A selected cohort of patients underwent magnetic resonance imaging. Total implant removal rate and time to removal were also included in the study.

Summary statistics were calculated for the data. Nominal variables were expressed as a percentage and quantitative data as a mean (±standard deviation).

Results

The initial review published in 2011 included 157 implants in 97 patients.[5] At the time of this review, eleven of these patients (15 implants) were deceased and 7 patients (8 implants) were lost to follow-up. After excluding these cases, the study cohort included 134 implants in 79 patients with a mean age of 49.6 years-old. Average follow up was 120.7 ± 49.9 months (Table 1).

Previous breast surgical history included previous implant placement (43 breasts), tissue expansion (45 breasts), latissimus flap + tissue expansion (50 breasts), TRAM reconstruction (4 breasts) or reduction mammaplasty (2 breasts). Six breasts had a history of radiation (Table 2).

The dual-lumen implant was placed at the time tissue expander removal (78 implants), immediate implant

Table 1 Patient demographics.

Characteristic	
Number of patients	79
Number of implants	134
Mean age at time of implant (yrs)	49.6
Mean follow-up (mos)	120.7 ± 49.9
Lost to follow-up (patients)	7
Lost to follow-up (implants)	8
Deceased (patients)	11
Deceased (implants)	15

Table 2 Surgical history.

Surgery prior to 153 placement	# Breasts
Implant placement	43
Tissue expander reconstruction	45
Latissimus dorsi flap + tissue expander	50
Pedicled TRAM reconstruction	3
Free TRAM reconstruction	1
Reduction mammaplasty	2
Radiation	6
Surgery at time of 153 placement	**# Implants**
Reconstruction	
Exchange of tissue expander	78
Immediate implant placement	7
Aesthetic	
Primary augmentation	9
Augmentation-mastopexy	1
Revision of reconstruction/aesthetic	
Replacement of previous implant	39