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Incidence of breast implant rupture in a 12-year retrospective cohort: Evidence of quality discrepancy depending on the range☆

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Summary *Background & objective:* The majority of studies assessing the rupture rate of breast implants were performed by the breast implant manufacturing industry with questionable independence. After repetitive removals of ruptured implants from the same model, our team decided to assess the rupture rate and the estimated risk thereof for most of the silicone gel–filled implants we have used since they regained market approval in France in 2001.
Methods: Our study is a retrospective cohort of 809 patients operated in our University Hospital from 2001 to 2013 for cosmetic or reconstructive goals. We could track 1561 implants, 90% of them from the same manufacturer, Allergan (Irvine, CA, USA). For each of those, we gathered their exact reference, date of implantation, surgical approach, status, last follow-up visit or the eventual date, and cause of removal.
Results: Of 225 explanted devices, only 27 were ruptured, all from the Allergan brand. Risks of removal for rupture were estimated: 0.5% at 1000 days, 6% at 2000 days, and 14% at 3000 days. Risks were significantly different between the models from this same manufacturer. One of the range of macro-textured round implants showed risks of removal for rupture of 33% at 3000 days compared to 6% for the anatomically shaped range.

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Conclusions: These results suggest a qualitative discrepancy among the different ranges of breast implants of a single manufacturer within the same timeframe of implantation. To determine the in vivo lifespan of the implants that we use more precisely and sooner, we suggest that each removed implant should be analyzed for wear and tear, independently from the industry.

Background

Prosthetic breast augmentation is one of the most frequently performed cosmetic surgery procedures each year, and implant-based breast reconstruction is the most used technique for breast reconstruction.[1] Even though breast implants have been used for the last five decades, the lifespan of the implants has always been difficult to predict for the physician, and has been a focus of fear for patients. With multiple controversies throughout the history of breast implants, and with the most recent Poly Implant Prothèses affair,[2] patients and physicians have never been more concerned about the quality and lifespan of the implants.

Most of the survival studies have been led by the industry for their need of market approval.[3–8] Even though these cohort studies followed high methodological standards, one could not be sure about their independence from the manufacturers that planned and funded them. The ANSM (French National Agency for Medicines and Health Products Safety) published a report in 2014 detailing the breast implant device vigilance from 2010 to 2013 in France.[9] The data are only observational, and therefore probably incomplete, which is underlined by the authors who regret the insufficient declaration of events.

In our practice, we report each adverse event we encounter with breast implants, especially where rupture after clinical or radiological suspicion made us perform a removal. In the last few years, we have been reporting repetitive ruptures of the same range from our main manufacturer, and this made us wonder if those ruptures were due to (1) the implant range itself, (2) its specifications, or (3) the surgical approach through which it was implanted.

We led this retrospective study with the objective of assessing the outcome of most of the silicone gel—filled implants used in our department since they regained market approval in 2001, and to eventually isolate factors (surgical approach, volume, shape, projection, or range) that could be associated with a higher rupture rate.

Methods

Our study is designed as a retrospective cohort of patients operated in our University Hospital from 2001 to 2013 for cosmetic or reconstructive goals using a silicone gel—filled breast implant. We used data from the coding database and the operating room registry to identify patients and implants. For all the patients, we reviewed their medical records and gathered their exact reference, date of implantation, surgical approach, status, last follow-up visit or the eventual date and cause of removal. All files with incomplete data were excluded. Our local ethical committee approved this protocol.

Risks of removal for rupture were calculated globally and according to the range, shape (anatomical or round), projection (low or high), and surgical approach. For anatomically shaped Style 410 and round Inspira implants, low and medium projections were considered "low", whereas full or extra-full were considered "high".

Discrete variables are expressed as counts (percentage) and continuous variables as means (range). Estimation of the cumulative incidence functions and Gray's test across groups were performed from competing risks.[10,11] $p < 0.05$ was considered significant. All analysis was performed using R 3.0.2 software and the survival and cmprsk (competing risk estimates) packages.

Results

We could track a total of 809 patients and 1561 implants. Half of these implants (n = 782) were used for reconstructive cases, whereas the other half (n = 779) were for cosmetic purposes. The main surgical approach was the mastectomy scar in 40% of cases (n = 626), followed by the areolar approach in 32% (n = 497), infra-mammary in 24% (n = 369), vertical breast-lift in 3% (n = 42), and other incisions accounting for less than 1% (n = 27). Mean follow-up was 546 days (0—3800).

The manufacturer of 90% (n = 1405) of these implants was Allergan (Irvine, CA, USA). Other brands used were Cereplas (Sailly Lez Cambrai, France) for 9% of the implants (n = 141), and Mentor (Santa Barbara, CA, USA) for 1% (n = 15). Of the 1405 Allergan implants, 63% (n = 886) were anatomically shaped Style 410 implants, 15% (n = 216) were round CUI implants, 12% (n = 163) were round low-profile Style 110 implants, 8% (n = 112) were round Inspira implants, and the remaining 3% were round high-profile Style 120 implants. Details of Allergan implants by range, projection, and surgical approach are reported in Table 1. Implants by Cereplas and Mentor were round. Mean volume was 287 cm^3 (90—640 cm^3). All implants were either macro-textured or micro-textured. No smooth implants were used.

Removal was performed in 14% (n = 225) of all implants. The main reason was size change for 56% of cases (n = 125), followed by rupture for 12% (n = 27). Two

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