Breast Surgery

Eight-Year Safety Data for Round and Anatomical Silicone Gel Breast Implants

Aesthetic Surgery Journal
2018, Vol 38(2) 151–161

DOI: 10.1093/asj/sjx117
www.aestheticsurgeryjournal.com
OXFORD UNIVERSITY PRESS

Franck Duteille, MD; Pierre Perrot, MD;
Marie-Hélène Bacheley, MSc; and Sharon Stewart, PhD

Abstract

Background: The safety and efficacy of all medical devices, including breast implants, is important and consistent performance is best shown by undertaking long-term clinical and vigilance studies. Local complications such as capsular contracture and rupture are risks often associated with breast implant surgery.

Objectives: The authors investigate and evaluate the safety and performance of Eurosilicone's (Eurosilicone S.A.S, Apt Cedex, France) Cristalline Paragel breast implants at 8 years postimplantation.

Methods: In this prospective clinical study, 995 Eurosilicone textured cohesive Cristalline Paragel mammary implants were implanted in 526 women undergoing augmentation and reconstructive surgery at 17 centers across France. Complications were recorded at 3 months and annually thereafter for 8 years. Descriptive statistics were used and key complications were analysed using the Kaplan-Meier method.

Results: Capsular contracture was reported in 8.5% of implants across all cohorts through 8 years. The Kaplan-Meier risk of capsular contracture (Baker Grade III/IV) per implant was 8.4% in the primary augmentation cohort and 18.0% in the primary reconstruction cohort. Eight implant ruptures were identified by surgeon examination during this follow-up period. The Kaplan-Meier risk of rupture occurring within 8 years postimplantation, across all cohorts, was 1.4% per patient and 0.9% per implant. Actual implant removal rate (explantation/exchange) was 6.0% and 13.8% for primary augmentation and primary reconstruction, respectively. Actual rates of local complications including infection and seroma were low with risk rates of 0.6% and 0.2% by subject.

Conclusions: This multicenter clinical study involving Eurosilicone's silicone gel breast implants in both round and shaped profiles demonstrates an excellent safety and efficacy profile through 8 years.

Level of Evidence: 3

Editorial Decision date: May 26, 2017; online publish-ahead-of-print June 24, 2017.

Breast implant surgery is one of the leading cosmetic surgery procedures undertaken by women and this number has been shown to be increasing.[1,2] Despite the introduction of techniques such as lipomodelling,[3] breast implants continue to be the standard for breast augmentation.[2] It is over 50 years since the introduction of the first generation of breast implants and since that time they have evolved and developed. The breast implants currently used in breast augmentation and reconstruction are fifth and sixth generation. This generation of implants demonstrate the most advanced silicone technologies and implant texturing which, combined with advancements in surgical techniques, has contributed to the popularity of breast augmentation amongst women.[2]

Dr Duteille is the Principal Investigator and Dr Perrot is a Clinical Investigator, Centre des Brûlés, Immeuble Jean Monnet, Centre Hospitalier Universitaire, Nantes, France. Ms Bacheley is a Clinical Trial Monitor, Eurosilicone, Apt Cedex, France. Dr Stewart is a Clinical Project Manager, GC Aesthetics, Glasgow, UK.

Corresponding Author:
Dr Sharon Stewart, Clinical Project Manager, GC Aesthetics, 129 Deerdykes View, Westfield Industrial Estate, Cumbernauld, Glasgow, G68 9HN, United Kingdom.
E-mail: sharonstewart@gcaesthetics.com

Table 1. Initial Indication for Implantation

Augmentation		Reconstruction		Other		Total	
Primary	Revision	Primary	Revision	Primary	Revision	Primary	Revision
360 (68.4%)	73 (13.9%)	49 (9.3%)	25 (4.8%)	13 (2.5%)	4 (0.8%)	422 (80.2%)	102 (19.4%)

* Data for 2 patients (0.4%) is missing.

Despite the many advancements in breast implant technology and surgery, the complications observed following breast implant surgery remain the same with the most prevalent being capsular contracture and implant rupture. Capsular contracture continues to be the most common complication and, although its aetiology is not fully understood, its development has been shown by various studies to be a multifactorial process.[4,5] Implant rupture is another significant complication and its occurrence has been linked to the age of an implant. As such it requires continuous monitoring to ensure long-term safety of patients following implantation.[6] Advances in silicone gel stability and a focus on surgical technique have reduced the occurrence of rupture but the risks remains a significant consideration for women undergoing breast implant surgery.[6]

In recent years the breast implant industry has had attention focused on it because of the very public PIP scandal (Poly Implant Prothèse, La Seyne-sur-Mer, France) whereby the safety of women was jeopardised due to the fraudulent use of "low grade" silicone gel by the PIP implant manufacturer. This finding had far reaching consequences globally and investigations saw an increased rate of rupture of PIP implants when compared to the rupture rate of "medical grade" silicone gel breast implants. Consequently, there continues to be a need for surgeons and manufacturers to provide the highest quality implants for their patients and a requirement for the long-term performance of implants to be monitored closely.

This study was developed by Eurosilicone S.A.S, a leading European manufacturer of breast implants, and was designed to demonstrate the high safety and performance of the Cristalline Paragel range of mammary implants. The results at 8 years postimplantation are presented as an update to the previously published 5 year results and as part of the continuing 10 year postmarket surveillance study.[7]

METHODS

This study complies with the Declaration of Helsinki and ISO 14155 (2003). [The study was introduced before the version in 2011 (ISO 14155 (2011)). Eurosilicone is in compliance with all other aspects of the MDD 93/42/EEC as amended (2007). The database is not registered. This clinical study was audited by Eurosilicone's notified body SNCH during an ISO 13485 certificate renewal in 2012.]. This prospective postmarket clinical study was initiated in 2003 at both university and private hospitals in 17 centers across France. Eurosilicone's Cristalline Paragel range of round and anatomical textured silicone gel-filled mammary implant designs received their CE mark (European Conformity) in 1997 and are used exclusively in this study. Five hundred and thirty four consecutive patients were screened and enrolled between January 2003 and July 2006 against inclusion and exclusion criteria, as outlined in the clinical study protocol. Of this, 526 women (995 implants) were evaluable for this 8 year analysis with 332 women attending their 8 year follow up (study date range, January 2003-July 2014). Patients were followed up ±6 months either side of their date of surgery so the data reported here refer to a study duration of 8 years ± 6 months (102 months). Once patients were enrolled they were designated into cohorts based on their indication for surgery; this can be seen in further detail in Table 1. Patients were designated as either primary augmentation, primary reconstruction, revision augmentation, or revision reconstruction. The revision cohorts included patients who were changing their implants to increase the size or to correct a complication from a previous surgery (19%). The majority of patients had no prior operation (>80%) at the site of implantation and were either in the primary augmentation or primary reconstruction cohorts.

Patients were implanted with the study device(s) after they provided written informed consent and agreed to cooperate with all postoperative follow up procedures. Patients enrolled in this study did not receive any form of payment or incentive for their participation. Following the PIP scandal in France it has been observed that patients will readily return for regular follow-up appointments and that patient retention has improved following the recent press surrounding breast implants. To minimize the loss to follow up, patients were not removed from the study if they missed an appointment. They were kept in the study and encouraged to return for examination the following year. As these devices are CE marked, patients were implanted in accordance with the instructions for use and the study was conducted in accordance with good clinical practice. Intravenous antibiotics were given to all patients prior to surgery, as per French national recommendation. No information was routinely requested regarding the washing of pockets and this parameter was not reviewed or analyzed

in detail in this study. Physicians carried out follow-up assessments at 3 months, 1 year, and annually thereafter to 8 years. The majority of patients (84.6%) were examined by the performing surgeon, however, some women completed their assessment via the telephone (15.4%) due to their distance from the relevant hospital. All patients will be examined by the physician at the 10 year follow-up assessment.

The study included patients with both round and anatomical-shaped textured breast implants filled with a soft or high cohesive silicone gel. The textured surface of the breast implant was chosen by the surgeons involved rather than it being imposed as a constraint of the study. Patients discussed and agreed the most appropriate shape and size of implant with their surgeon and the decision to enrol into the clinical study was made in collaboration between both parties once all inclusion/exclusion criteria had been assessed.

The round device is a seamless device and is available in 4 profiles: Low, Medium, High, and Extra High. The anatomical device is available in 3 profiles: Low, Moderate and High. All devices were textured with Eurosilicone's latest texturing technology, intended to favor tissue adherence and reduce the incidence of capsular contracture. For the purpose of this study all sizes of these devices were available and included.

Clinical data were collected using study case report forms and entered onto a clinical database which underwent data validation checks. This data were used to assess the safety and performance of Eurosilicone's implants including the number of reoperations involving implant removal (explantation/exchange), capsular contracture, rupture, and other local complications. The cumulative risk of reoperations and other complications was calculated per patient and per implant using the Kaplan-Meier method together with the corresponding 95% confidence interval. The time period used for this calculation was from the date of surgery to the first date the complication was reported within 8 years ± 6 months (102 months) from the annual scheduled visit date. Kaplan-Meier risk rates and descriptive statistics were generated using IBM (IBM Corp., Armonk, NY) SPSS Statistics 22 software.

RESULTS

Patients and Surgical Characteristics

The median age at implantation for the women was 36 years (range, 15-67 years). Parental consent was required for patients below 18 years of age. Two patients were enrolled over the age of 65. Age distribution at enrolment is presented in Figure 1.

Table 2. Summary of Operative Details

Characteristic	All cohorts
Number of patients	526 (100%)
Device distribution (%)	
•Textured round	481 (91.5%)
•Textured anatomical	45 (8.5%)
Device placement (%)	
•Submuscular	268 (50.9%)
•Subglandular	257 (48.9%)
•Unknown	1 (0.2%)
Incision location (%)	
•Periarerolar	219 (41.6%)
•Inframammary	184 (35.0%)
•Transaxillary	91 (17.3%)
•Not disclosed	32 (6.1%)

Implants included in this study were both round and anatomical designs. Of the 995 implants, the majority comprised a volume between 200 and 280 cm^3 (mean volume, 262 cm^3; range, 60-500 cm^3). Round implants were used in more than 90% of cases. Regarding implant location, there was an almost 50:50 split between implants placed in the subglandular and submuscular positions. The most popular incision site was periareolar followed by inframammary. A summary of the operative details is given in Table 2.

The primary variables for review were the number of reinterventions (explantation or exchange) disregarding the reason. The rate of capsular contracture, rupture, and secondary local complications were also analyzed at 8 years postimplantation (follow-up range: 86-108 months; mean follow-up time: 95.8 months) and these are discussed in turn.

Implant Removals (Explantation/Exchange)

Of the 526 patients, there were 57 reoperations which resulted in an explantation or exchange of implants across all cohorts through 8 years. Most of the devices that were removed were associated with patients in the reconstructive cohorts (actual rate 16.4% in the primary revision cohort). Of the 360 primary augmentation patients, 6.9% had their implants removed over the 8-year period. The Kaplan-Meier risk rate of removal was 8.2% and 20.4% per patient for the primary augmentation and primary revision cohorts, respectively. The reason for explantation or exchange across all cohorts is given in the Figure 2.

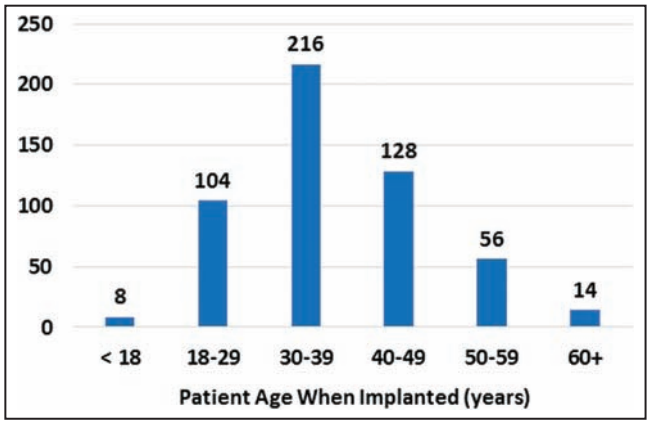

Figure 1. Age distribution at enrollment.

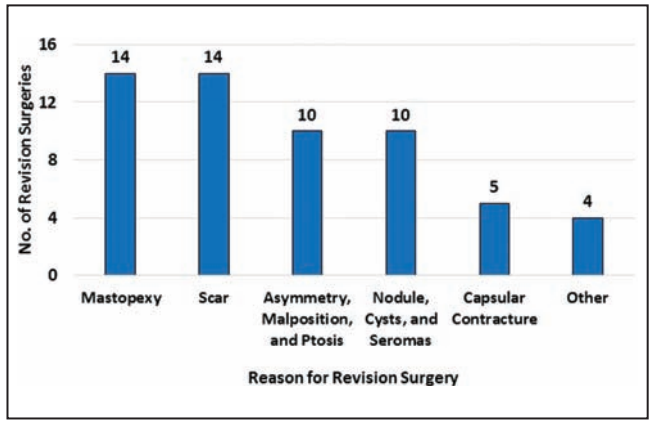

Figure 2. Reasons for removal (explantation or exchange).

Rupture

Of the 995 implants, only 8 ruptures were identified by surgical examination within the first 8 years of implantation. Patients were examined by their breast surgeon during follow-up appointments and those presenting with suspected ruptures were analyzed further. Two patients were diagnosed with ruptures following an ultrasound and a further two patients diagnosed with ruptured implants following an MRI examination. The remaining four patients had their rupture confirmed upon surgical intervention. The Kaplan-Meier risk of a rupture occurring within this period was 1.4% per patient and 0.9% per implant. The first implant rupture occurred due to mechanical trauma during implantation. There were no further reported ruptures until one case at 5 years. It is known that ruptures increase with time and this was observed with 2 further ruptures reported at 6 years, 2 more at 7 years, and 2 reported at 8 years postimplantation. In addition to the rupture on implantation, one case was reported as a result of a road traffic accident and another perforated during implant intervention. The five remaining cases were reported as spontaneous rupture with no known cause associated with them. Each of the patients presenting with rupture were in the primary augmentation cohort.

Capsular Contracture (Baker III/IV)

Of the 526 patients implanted, 65 capsular contractures occurred within the first 8 years postimplantation (Kaplan-Meier risk = 15.7%). This was further broken down into women presenting with capsular contracture Baker Grade III and those presenting with Baker Grade IV. A total of 63 women presented with Baker Grade III capsular contracture which gave a Kaplan-Meier risk of 15.3% and a total of 14 women presented with Baker Grade IV capsular contracture which gave a Kaplan-Meier risk of 3.8%. A breakdown of Kaplan-Meier risk rates for capsular contracture across each cohort is shown in Table 3.

Local Complications and Other Safety and Efficacy Outcomes

The secondary objectives set out in the protocol relate to local complications, which may occur as a result of surgery itself rather than due to the presence of the implants.

Hematoma is a complication often associated with surgery and is often reported following breast implantation. Of the 526 patients, 18 women (25 implants) experienced hematoma. The Kaplan-Meir risk rate of developing hematoma was 3.8% per patient and 2.7% per implant.

Wrinkling was assessed as part of the protocol. Sixty-two women in total experienced wrinkling giving a Kaplan-Meier risk rate of 14.7% across all cohorts.

Asymmetry was observed and reported in 68 cases. The Kaplan-Meier risk rate was shown to be 16.1% and there was no statistical difference in the occurrence of asymmetry between augmentation and reconstruction cohorts, primary, or revision surgery or between individual groups (P = not significant).

Pain was reported at individual visits and was reported 107 times, however, pain was found to diminish considerably over time (57 of these reports were reported within 12 months). As pain is often thought to be associated with either incision location or final implant position, secondary analyses were carried to compare the rate of occurrence of pain.

Other local complications were extremely low. One woman (one implant) experienced seroma within 8 years postimplantation. The Kaplan-Meier risk of developing seroma was 0.2% per patient and 0.1% per implant. The incidence of infection was reported in 3 women (5 implants). Kaplan-Meier risk rates were 0.6% per patient and 0.5% per implant.

Within 8 years postimplantation, breast cancer was reported in 11 women (12 implants) where almost half of these cases involved reconstruction patients (5 women).

Table 3. Kaplan-Meier Risk Rate of Capsular Contracture Per Cohort

	Primary augmentation	Revision augmentation	Primary reconstruction	Revision reconstruction
Capsular contracture (III)	11.9	25.7	26.1	23.5
Capsular contracture (IV)	3.9	6.7	0.0	4.3
Capsular contracture (III and IV)	12.5	25.7	26.1	21.6

Table 4. Summary of All Complications by Patient Cohort

	Primary augmentation	Revision augmentation	Primary reconstruction	Revision reconstruction	Other
Capsular contracture (Grade III)	11.9%	25.7%	26.1%	23.5%	—
Capsular contracture (Grade IV)	3.9%	6.7%	—	4.3%	—
Capsular contracture (III or IV)	12.5%	25.7%	26.1%	21.6%	—
Rupture	1.9%	—	—	—	—
Pain	21.0%	17.2%	33.1%	16.3%	59.2%
Reintervention	8.2%	20.4%	24.1%	25.9%	8.3%
Unsatisfactory cosmetic result	17.7%	32.3%	25.8%	38.2%	27.9%
Asymmetry	13.2%	23.3%	20.8%	31.9%	28.1%
Wrinkling	16.0%	17.4%	2.7%	16.5%	—
Periprosthetic effusion	1.2%	1.5%	4.8%	—	—
Infection	0.3%	1.4%	2.6%	—	—
Haematoma	3.8%	5.7%	2.6%	—	5.6%
Seroma	0.3%	—	—	—	—
Irritation/inflammation	0.3%	1.5%	2.0%	7.7%	—
Cancer (breast)	1.2%	4.9%	5.1%	11.4%	5.6%
Cancer (other)	0.6%	—	—	—	—
Pregnancy complication	0.6%	4.6%	—	—	—
Breastfeeding complication	0.7%	—	—	—	—
Nipple complications	5.0%	4.4%	—	—	—
Extrusion	0.3%	1.8%	—	—	—
Malposition	4.0%	8.2%	10.6%	—	6.3%
Palpability/visibility	1.5%	2.4%	—	—	—
Ptosis	8.5%	19.7%	12.8%	—	7.1%

The Kaplan-Meier risk for developing breast cancer in all cohorts is 2.6% per patient and 1.5% per implant. Two cases of cervical cancer were reported for women in the aesthetic cohort. All women diagnosed with primary cancers in the aesthetic cohort were confirmed as "alive" in April 2015. The Kaplan-Meier risk for developing cervical cancer in all cohorts is 0.5% both per patient and per implant.

It is important to note that no cases of anaplastic large cell lymphoma presented in this study. This rare but significant complication was not routinely analyzed as per the study protocol but there were no recorded incidents of this complication at 8 years.

A summary of all the complications reported per patient and per implant is presented Table 4.

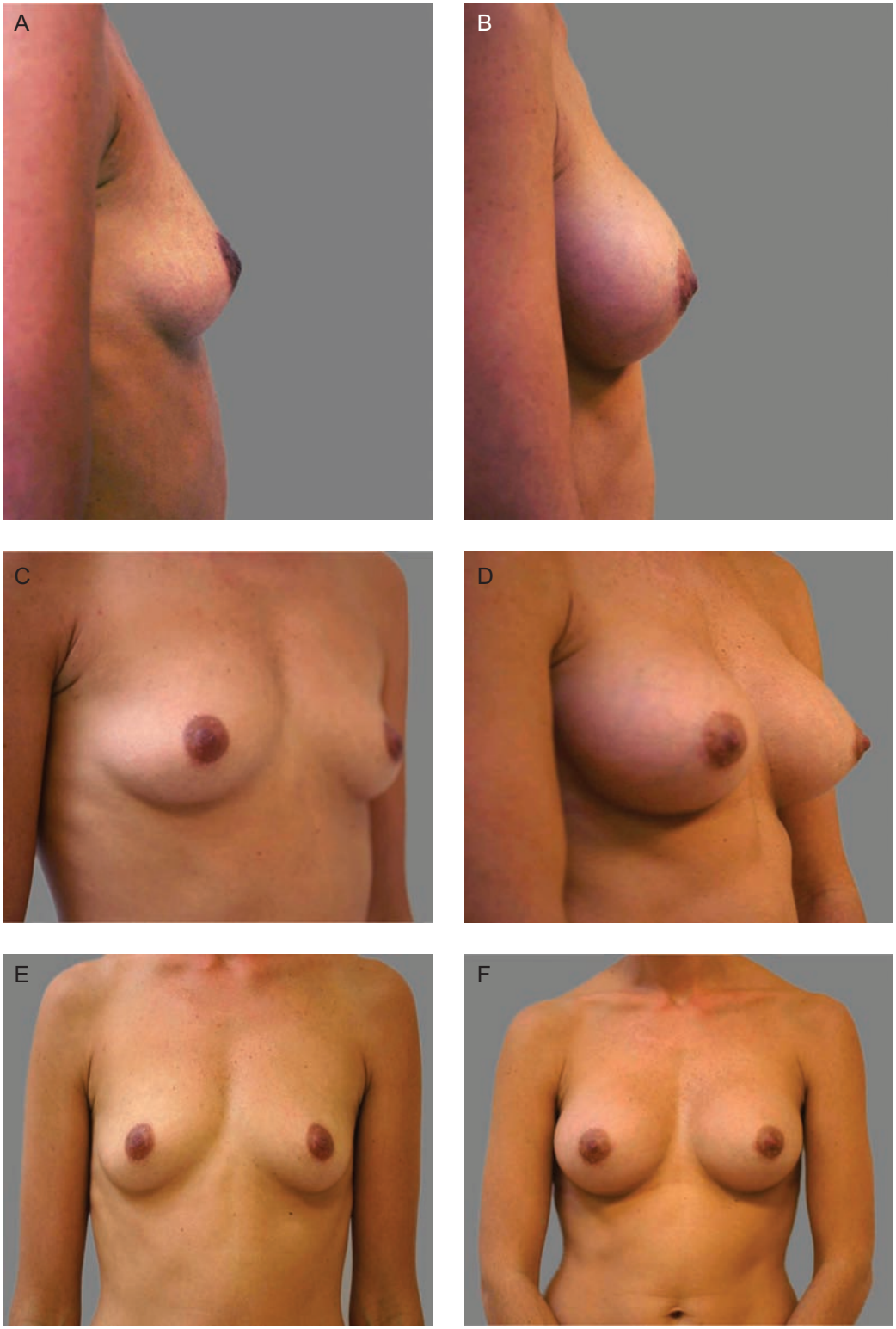

Figure 3. (A, C, E) This 33-year-old woman presented for breast augmentation. She received round implants (260 cm^3 volume) in the submuscular plane via a hemiareolar incision. (B, D, F) Photographs taken 7 years postoperatively.

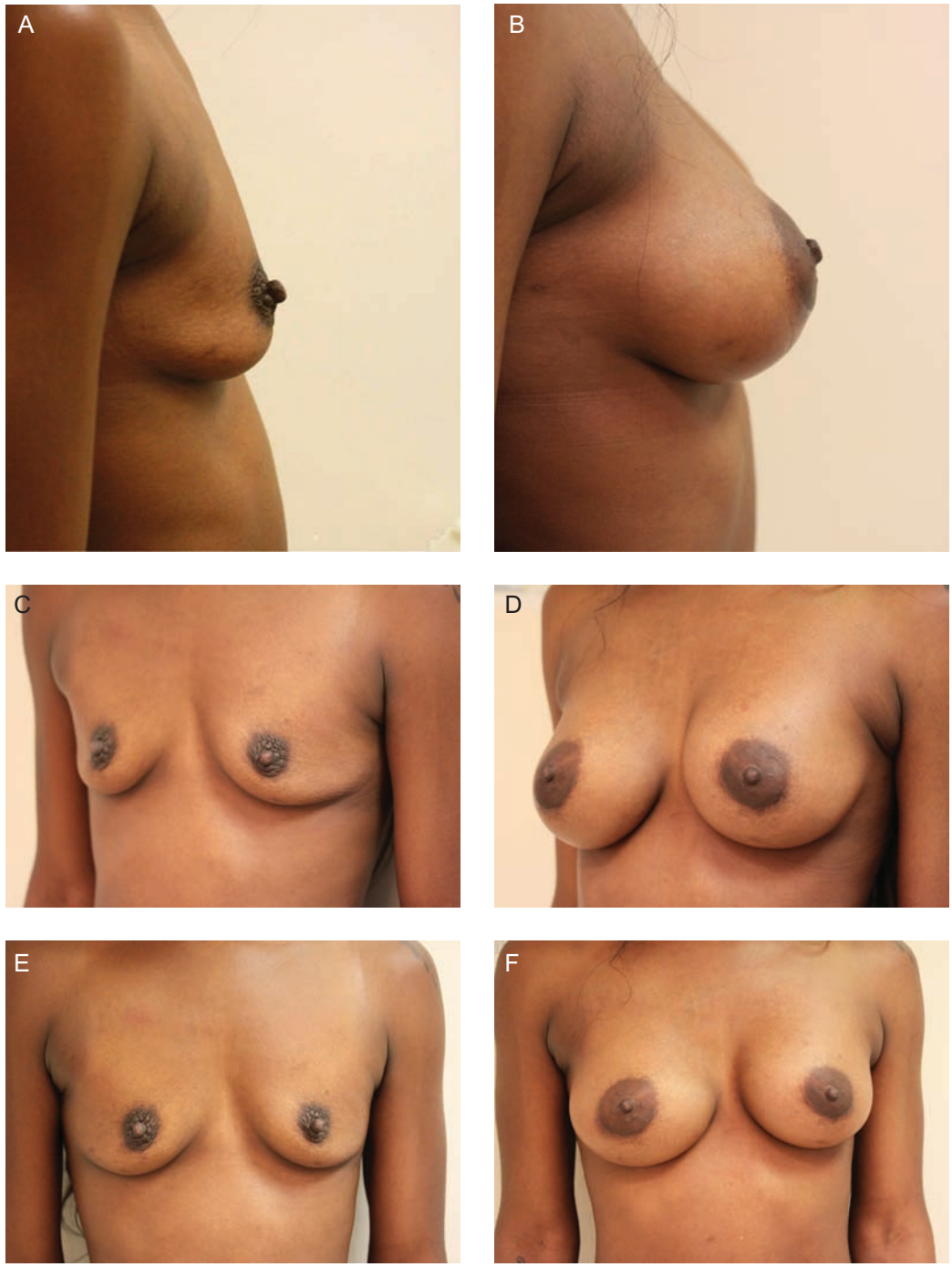

Figure 4. (A, C, E) This 26-year-old woman presented for breast augmentation. She received anatomical shaped implants (350 cm^3 volume) with dual plane positioning via a periareolar incision. (B, D, F) Photographs taken 5 years postoperatively and this woman remains complication free.

DISCUSSION

The results presented here in the ongoing Eurosilicone postmarket clinical study illustrate the low level of complications and the high degree of performance associated with long-term implantation of Eurosilicone Cristalline Paragel breast implants. High resolution photographs taken pre- and postoperatively are illustrated in Figures 3 and 4 and provide examples of results observed for both round and anatomical breast implants. Both women were in the augmentation cohort and remain free of complications at 8 years. However, there are risks associated with

breast implant surgery which are common to many types of surgery and include hematoma, seroma, infection, pain, and unfavorable scarring and have no relationship with the implant. The key complications observed specifically in breast surgery include capsular contracture, implant rupture, and the need for subsequent reoperations. This study examines 995 of Eurosilicone's textured cohesive silicone gel-filled mammary implants through 8 years of follow up and demonstrates low complication rates consistent with those reported in the literature.

The primary objective of this study was to demonstrate the safety and efficacy of Eurosilicone breast implants for both cosmetic and reconstructive indications specifically though the observation of the Kaplan-Meier risk for implant removal (explantation/exchange). The Kaplan-Meier estimator is a survival analysis method used to calculate survival probabilities over a time period where patient dropouts occur throughout the analysis. The number of people at risk is defined as any individual who has not experienced the event or has not been censored. Censoring in survival analysis occurs when a patient's last known status is healthy but there is no further information from additional follow-up visits. Patients who are censored are therefore considered as at risk up until their last known status and then ignored in calculations for subsequent time points. In this way, event probabilities can be calculated which account for patient dropouts without making any assumptions about the status of patients who have dropped out. The analysis presented in the following sections show cumulative probabilities.

Differences in study design and patient profiles mean that it is very difficult to make direct comparisons with these numbers and other long-term clinical studies. Specifically in this case, one of the main objectives was to maximize patient follow-up numbers through 10 years and to reach that objective a small number of patients (51) were followed up via the telephone to ensure that excessive travel did not preclude them from being assessed within their stated follow-up window. This remote assessment is a limitation to the overall study, however, the values reported for implant removal rates resulting in explantation and exchange were consistently lower than those reported in the literature. Eurosilicone's 8-year Kaplan-Meier results for implant removal/exchange in the primary augmentation cohort was observed at 8.2% which is significantly lower than the 9-year rates reported for Sientra (Sientra, Inc., Santa Barbara, CA) (13.9%) and the 10 year results reported for Allergan (Allergan Inc., Irvine, CA) (18.6% implant replacement and 2.8% implant removal).[8,9] Patients in the primary reconstruction cohort who had undergone reconstruction following cancer diagnosis also showed lower complication rates when compared with competitor designs (20.4% vs 36.4% and 48% for Sientra and Allergan, respectively). Patients in the reconstructive cohort typically experience higher implant removal rates than their cosmetic counterparts having undergone significant trauma following mastectomy and adjuvant therapies that could interfere with the healing process (radiotherapy).

Reoperations in the primary augmentation cohort took place mainly for aesthetic reasons (mastopexy, scar, and asymmetry). Cysts and seromas were also provided as reasons for having implants removed and/or exchanged. Fifty-seven reoperations (10.8%) were recorded at 8 years postimplantation and the reasons for removal explantation/exchange are represented in Figure 2 across all cohorts. This clearly shows that the majority of all removals (>65%) were due to an unsatisfactory result (malposition, scar, volume change, wrinkling, and mastopexy) as reported by the patient and not as a consequence of poor performance by the breast implant. In contrast, the number of reoperations performed due to performance of the implants alone was much lower and reported in only 19 patients. Therefore, the reoperation rate due to complications deriving from the product was 3.6% at 8 years postimplantation, thus demonstrating an excellent safety and efficacy profile for Eurosilicone breast implants. The Kaplan-Meier risk rates for each complication following reoperation across different cohorts is given in Table 5.

The rupture rate in Eurosilicone's ongoing study remains significantly low at 8 years post-implantation with a Kaplan-Meier risk of 1.9% for the primary augmentation cohort. Other manufacturer rupture rates at similar time points are consistently higher than the results presented here. Mentor's (Mentor Worldwide LLC, Irvine, CA) Kaplan-Meier rupture rate at 8 years is 10.3% (MRI cohort), Allergan reports a rupture rate of 9.3% at 10 years (MRI cohort) and Sientra report rupture rates of 9.0% at 10 years. It is important to recognize that a limitation of this study design is that there was no MRI analysis routinely performed in this clinical study and that rupture may be under reported as a result. Diagnosis was made by surgeon examination only and is therefore, a subjective diagnosis. However, there are many studies reported in the literature whereby a small cohort of patients are screened to investigate the silent rupture of implants. Typically, only a small cohort of the total population is examined this way and not everyone benefits from this screening. It remains that in the majority of studies, rupture is diagnosed by surgeon examination alone and we expect this exceptionally low rupture rate to continue throughout the remainder of this clinical study through to ten years.

Capsular contracture remains one of the most important complications to follow up post-breast implant surgery. The risk of this complication increases over time[10-12] as evidenced by the increase in capsular contracture reported previously in the Eurosilicone 5-year results.[7] At 5 year postimplantation the Kaplan-Meier risk rate for

Table 5. Kaplan-Meier Complication Rates Following Surgical Reintervention Across All Cohorts

	Primary augmentation	Revision augmentation	Primary reconstruction	Revision reconstruction	Other
Abscess	0.4	—	—	—	—
Asymmetry	—	2.9	4.9	5.0	—
Breast cancer	1.3	1.8	3.7	—	—
Capsular contracture	2.2	5.1	15.4	16.9	—
Extrusion	0.3	—	—	4.5	—
Infection	0.3	—	—	—	—
Malposition	0.3	—	—	4.3	12.5
Other	0.4	—	2.2	14.3	—
Pain	0.3	—	—	—	—
Ptosis	0.3	—	—	—	—
Rupture	3.8	2.3	—	—	—
Unsatisfactory cosmetic result	4.6	11.4	8.4	—	8.3
Wrinkling	—	1.7	5.9	—	—

capsular contracture for the primary augmentation cohort was 10.7%. At 8 years post-implantation the Kaplan-Meier rate has increased slightly to 12.5% for the primary augmentation cohort but remains comparable to Kaplan-Meier rates for capsular contracture reported by other manufacturers for their primary augmentation cohorts, namely, Mentor (11.3%) and Sientra (12.0%) at 9 years and Allergan (18.9%) at 10 years postimplantation. Capsular contracture rates in the reconstruction cohorts, although higher than cosmetic cohorts, were within the expected range for this group of patients. For patients in the primary reconstruction cohort the Kaplan-Meier risk rate was 21.6% with patients presenting with Baker Grade III capsular contracture only. The risk rate for the revision reconstruction cohort was slightly less at 21.6% and this consisted of patients presenting with both Baker Grade III and Baker Grade IV capsular contracture. The figures for this complication are summarized in Table 3.

Several studies have highlighted that subglandular placement is associated with a higher rate of capsular contracture and need for revision surgery.[13,14] Despite an even split between submuscular and subglandular positions, more capsular contractures were observed in women with implants in the subglandular position in the Eurosilicone series (Logrank (Mantel-Cox); $P = 0.05$). The reason for this observation is not known but one consideration is that diagnosis of capsular contracture in the submuscular location may be misdiagnosed due to the thickness of the muscle. Upon further analysis, capsular contracture (Baker Grades III and IV) was demonstrated to be independent of incision location ($P > 0.05$). An investigation into the split between women presenting with capsular contracture Baker Grade III and Baker Grade IV revealed a total of 63 women presented with Baker Grade III capsular contracture and a total of 14 women presented with Baker Grade IV capsular contracture. This gave an overall Kaplan-Meier risk rate of 15.3% for Baker Grade III capsular contracture and 3.8% for Grade IV capsular contracture. Capsular contracture remains a multifactorial process that has yet to be clearly defined. There are a number of factors that can influence the occurrence of capsular contracture but the authors remain satisfied that while keeping abreast of these factors, such as surface texture, implant type, incision location, infection, inflammation, and biofilm formation, the results here are in line with those expected at 8 years postimplantation and are similar to those published in the literature citing similar long-term postmarket clinical studies.

Breast implant surgery can be associated with local complications often as a result of surgery and those associated with breast implant placement. The Kaplan-Meier risk rates for wrinkling were higher than expected across all cohorts. It is not clear why this was observed and the way in which wrinkling was assessed and recorded was limited in this study as the severity of this complication was not measured across each cohort. However, it is well documented in the literature that wrinkling is observed in thin skinned patients and implants placed in the subglandular position possible due to thin tissue coverage.[15-18] It was found that wrinkling was reported more frequently by women in the subglandular cohort in this series and this is consistent with the findings in other long-term studies.[18,19]

However, the rate of reoperation for wrinkling remains low (Kaplan-Meier = 1.7%, revision augmentation cohort and 5.9% primary reconstruction cohort) and concurs with the view that a submuscular implant placement is the preferred solution to minimise this complication across all implant designs.

Pain was reported throughout the duration of this study and was found to decrease with time, as expected. However, limitations of the study design derive mainly from the lack of a precise method to assess the level and location of this complication. Pain was reported more often in women who had received a transaxillary incision. Transaxillary incisions are not widely used due to perceived limitations in pocket access, visualization, control, and subsequent risk of postoperative complications.[20] Hence the correlation of pain with transaxillary incisions in this study may reflect difficulties in the placement and maintenance of implants rather than the route of incision itself.[21,22] However, it is important to note that few patients were reoperated for pain (0.3%, primary augmentation; all other cohorts, 0%).

CONCLUSIONS

The results presented at 8 years post-implantation from the ongoing Eurosilicone 10 year prospective postmarket clinical study continue to demonstrate the high degree of safety and performance for the range of Eurosilicone Cristalline Paragel gel-filled mammary implants when used in breast augmentation or reconstructive surgery. The data which have been presented in this article serve to provide further information to patients and surgeons considering the use of Eurosilicone breast implants. Reoperation rates resulting in implant removal (explantation/exchange) were low and superior to those reported for other manufacturers implant designs. Rupture rates are exceptionally low in this series in comparison with those reported in the literature in similar long-term safety studies for gel-filled mammary implants. Capsular contracture rates are similar to those reported in the literature and reported lower incidences of this complication when looking specifically at women with implants placed in a submuscular position. Other local complications were low and in line with other manufacturers implant designs. This study will continue to evaluate the complication profile of Eurosilicone gel filled mammary implants for 10 years postimplantation and would expect to demonstrate an excellent long-term safety and efficacy profile based on these 8-year interim results.

Disclosures

Dr Duteille is the Principal Investigator for Eurosilicone's ongoing clinical study involving their Cristalline Paragel range of mammary implants and has lectured in several course and symposia organised by GC Aesthetics (Dublin, Ireland), the parent company of Eurosilicone, and has received lecturer fees. He has no stocks and holds no appointed position with any medical firm. Dr Perrot declared no potential conflicts of interest with respect to the research, authorship, and publication of this article. Ms Bacheley is an employee of Eurosilicone. Dr Stewart is an employee of GC Aesthetics.

Funding

Eurosilicone provided funding to cover the cost of surgical examination at each follow-up time point and for medical reporting assistance.

REFERENCES

1. Cosmetic surgery national data bank statistics. *Aesthet Surg J*. 2016;36(Suppl 1):1-29.
2. British Association of Aesthetic Plastic Surgeons (BAAPS). https://baaps.org.uk/media/press_releases/38/super_cuts_daddy_makeovers_and_celeb_confessions_cosmetic_surgery_procedures_soar_in_britain. Accessed May 9, 2016.
3. Joint Guidelines from the Association of Breast Surgery, the British Association of Plastic, Reconstructive and Aesthetic Surgeons and the British Association of Aesthetic Plastic Surgeons. http://associationofbreastsurgery.org.uk/events/previous-meetings/2012/abs-conference-2012/. Accessed May 9, 2016.
4. Headon H, Kasem A, Mokbel K. Capsular contracture after breast augmentation: An Update for Clinical Practice. *Arch Plast Surg*. 2015;42(5):532-543.
5. Adams WP Jr. Capsular contracture: what is it? What causes it? How can it be prevented and managed? *Clin Plast Surg*. 2009;36(1):119-126, vii.
6. Shah AT, Jankharia BB. Imaging of common breast implants and implant-related complications: A pictorial essay. *Indian J Radiol Imaging*. 2016;26(2):216-225.
7. Duteille F, Rouif M, Laurent S, Cannon M. Five-year safety data for eurosilicone's round and anatomical silicone gel breast implants. *Plast Reconstr Surg Glob Open*. 2014;2(4):e138.
8. Stevens WG, Calobrace MB, Harrington J, Alizadeh K, Zeidler KR, d'Incelli RC. Nine-year core study data for Sientra's FDA-approved round and shaped implants with high-strength cohesive silicone gel. *Aesthet Surg J*. 2016;36(4):404-416.
9. Spear SL, Murphy DK; Allergan Silicone Breast Implant U.S. Core Clinical Study Group. Natrelle round silicone breast implants: Core Study results at 10 years. *Plast Reconstr Surg*. 2014;133(6):1354-1361.
10. Handel N, Cordray T, Gutierrez J, Jensen JA. A long-term study of outcomes, complications, and patient satisfaction with breast implants. *Plast Reconstr Surg*. 2006;117(3):757-767; discussion 768.
11. Cunningham B. The mentor core study on silicone memorygel breast implants. *Plast Reconstr Surg*. 2007;120(7 Suppl 1):19S-29S; discussion 30S.

12. Cunningham B, McCue J. Safety and effectiveness of Mentor's MemoryGel implants at 6 years. *Aesthetic Plast Surg*. 2009;33(3):440-444.
13. Kulmala I, McLaughlin JK, Pakkanen M, et al. Local complications after cosmetic breast implant surgery in Finland. *Ann Plast Surg*. 2004;53(5):413-419.
14. Stevens WG, Pacella SJ, Gear AJ, et al. Clinical experience with a fourth-generation textured silicone gel breast implant: a review of 1012 Mentor MemoryGel breast implants. *Aesthet Surg J*. 2008;28(6):642-647.
15. Hendricks H. Complete submuscular breast augmentation: 650 cases managed using an alternative surgical technique. *Aesthetic Plast Surg*. 2007;31(2):147-153.
16. Panettiere P, Marchetti L, Accorsi D. Soft cohesive silicone gel breast prostheses: a comparative prospective study of aesthetic results versus lower cohesivity silicone gel prostheses. *J Plast Reconstr Aesthet Surg*. 2007;60(5):482-489.
17. Khan UD. Breast augmentation, antibiotic prophylaxis, and infection: comparative analysis of 1628 primary augmentation mammoplasties assessing the role and efficacy of antibiotics prophylaxis duration. *Aesthetic Plast Surg*. 2010;34(1):42-47.
18. Sientra, Inc. Summary of safety and effectiveness data (SSED). http://www.accessdata.fda.gov/cdrh_docs/pdf7/p070004b.pdf. Accessed October 12, 2016.
19. Mentor Corporation. Summary of safety and effectiveness data (SSED). https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030053b.pdf. Accessed October 12, 2016.
20. Huang GJ, Wichmann JL, Mills DC. Transaxillary subpectoral augmentation mammaplasty: a single surgeon's 20-year experience. *Aesthet Surg J*. 2011;31(7):781-801.
21. Price CI, Eaves FF 3rd, Nahai F, Jones G, Bostwick J 3rd. Endoscopic transaxillary subpectoral breast augmentation. *Plast Reconstr Surg*. 1994;94(5):612-619.
22. Niechajev I. Improvements in transaxillary breast augmentation. *Aesthetic Plast Surg*. 2010;34(3):322-329.