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Five-year Safety Data for Eurosilicone's Round and Anatomical Silicone Gel Breast Implants

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Background: Multicenter prospective studies assessing the safety and efficacy of silicone gel breast implants are relatively rare. Eurosilicone S.A.S. present their safety and efficacy data herein for the largest European silicone gel breast implant study published to date.
Methods: One thousand and ten of Eurosilicone's textured cohesive Cristalline Paragel range of mammary implants was implanted in women undergoing augmentation and reconstructive surgery at 17 centers throughout France. Physical examinations and complications were recorded by physicians at 3 months and annually thereafter until 10 years postimplantation. Descriptive statistics were used and key complications were analyzed using the Kaplan-Meier analysis method.
Results: Two ruptures were observed within 5 years postimplantation, one of which was subject to mechanical trauma during reoperation and the other was identified during routine screening. Capsular contracture, one of the most common complications associated with breast implants, was reported in 6.6% implants across all indications through 5 years. The Kaplan-Meier risk of capsular contracture (Baker III/IV) was 10.7% (95% confidence interval, 7.2–14.2%) and 17.2% (95% confidence interval, 5.4–29%) in the primary augmentation and primary reconstruction patient cohorts, respectively. Implant removal (explantation/exchange) was 8.5% and 16.5% for primary augmentation and primary reconstruction cohorts, respectively. Rates of local complications including infection and seroma were low with risk rates of 0.6% and 0.2% by subject.
Conclusions: Eurosilicone S.A.S. prospective study involving 1010 Eurosilicone silicone gel breast implants in both round and shaped profiles demonstrated a low rupture rate and an excellent safety profile through 5 years. *(Plast Reconstr Surg Glob Open 2014;2:e138; doi: 10.1097/GOX.0000000000000082; Published online 28 April 2014.)*

Breast implant surgery continues to be one of the leading surgical procedures undertaken by women.[1,2] Despite the introduction of techniques such as lipomodeling,[3] breast implants continue to be the standard for breast augmentation.[2] Eurosilicone S.A.S., a leading European manufacturer of breast implants, undertook a prospective large-scale implant study for both aesthetic and reconstructive indications, the first of its kind to be published on European women.

Recent events have highlighted the need for surgeons to provide high-quality implants for their patients. Eurosilicone's Conformité Européene (CE)-marked silicone breast implants are subject to the highest level of examination and quality. Each

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Eurosilicone breast implant is manufactured using long-term implantable medical-grade silicone from NuSil Technologies, an ISO 9001-certified supplier with more than 25 years' experience manufacturing biocompatible silicone-based materials for healthcare. These class III devices meet the requirements of European Medical Device Directive (93/42/EEC as amended 2007) and other international government agencies including Therapeutic Goods Administration and Agência Nacional de Vigilância Sanitária.

Eurosilicone S.A.S., a GC Aesthetics company, offers a host of aesthetic and reconstructive solutions for the modern-day plastic surgeon. Eurosilicone is an independent manufacturer, producing more than 200,000 implants per year at its facility in Apt, Vaucluse, France. Eurosilicone's breast implant designs are provided in a wide range of profiles and sizes in either round or anatomical shapes with smooth or textured surface to meet patient needs. All Eurosilicone breast implants are manufactured using their 360° Paragel barrier encompassing the entire implant while their textured shells also incorporate Eurosilicone's Cristalline technology.

Currently, Eurosilicone is conducting an ongoing clinical study in France on their Cristalline Paragel range of mammary implants and presents their 5-year data herein. Eurosilicone's Cristalline Paragel range of round and anatomical textured silicone gel–filled mammary implant designs received their CE mark in 1997 and are used exclusively in this study.

SUBJECTS AND METHODS

This study complies with the Declaration of Helsinki and ISO: 14155 (2003). [The study was introduced before the last revision in 2011 (ISO 14155: 2011). Eurosilicone is in compliance with all other aspects of the MDD 93/42/EEC as amended (2007). Database is not registered.] This prospective postmarket clinical study was initiated in 2003 (it took 3.5 years to recruit patients) at both university and private hospitals in 17 centers across France. Five hundred and fifty-five patients were screened for this study of which 534 were implanted and evaluable for this 5-year analysis. [This report assesses complication rates for women implanted for at least 5 years + 6 months (≤66 months).] The majority of patients had no prior operation at the site of implantation involving primary augmentation and primary reconstruction cohorts. Revision augmentation subjects enrolled in Eurosilicone's study as they wished to exchange their implants (silicone/saline designs) for Eurosilicone's Cristalline Paragel range for a variety of reasons (size change, malposition, capsular contracture, rupture, and asymmetry). A breakdown of the initial reason for surgery is presented in Table 1. Physicians carried out follow-up assessments at 3 months, 1 year, and annually thereafter.

Women were implanted with the study device(s) if they had given a written informed consent and were willing to return to the hospital/clinic and cooperate with all postoperative follow-up procedures. As these devices are CE marked, patients were implanted in accordance with the instructions for use.

Data Collection and Statistical Analysis

Clinical data were collected on study case report forms and underwent data entry into a validated clinical database. These data were used to assess the safety and efficacy of Eurosilicone implants including the number of reoperations involving implant removal (explantation/exchange), capsular contractures and ruptures, and other local complications. The cumulative risk of reoperations and other complications was calculated on a per patient basis using the Kaplan-Meier risk method (1 – the complication-free survival rate) together with the corresponding 95% confidence intervals (CIs) from the date of surgery to the first date that the complication was reported within 5 years ± 6 months from the annual scheduled visit date. Hence, 5-year Kaplan-Meier risk rates were calculated within 66 months postimplantation using SPSS PASW Statistics 18 (IBM Corporation, New York). Descriptive statistics were also used.

Demographic Data

The median age for all women was 37 years (range, 18–65 years). Implants included in this study were both round and anatomical designs and with a

Disclosure: *Dr. Duteille has no financial interest in Eurosilicone S.A.S. mentioned in this article. He is the principal investigator for Eurosilicone's ongoing clinical study involving their Cristalline Paragel range of mammary implants and has lectured in several courses and symposia organized by Eurosilicone S.A.S. and has received lecturer fees. He has no stocks and holds no appointed position with any medical firm. Dr. Rouif is a clinical investigator in Eurosilicone's ongoing clinical study on their Cristalline Paragel range of mammary implants. Ms. Laurent is the clinical trial monitor for Eurosilicone's ongoing clinical study on their Cristalline Paragel range of mammary implants and is an employee of Eurosilicone S.A.S., France. Dr. Cannon is an employee of GC Aesthetics, the parent company of Eurosilicone S.A.S., France. The Article Processing Charge was paid for by the authors.*

Table 1. Initial Indication for Implantation by Subject and by Cohort

Primary Augmentation	Revision Augmentation	Primary Reconstruction	Revision Reconstruction	Other
365 (68.4%)	74 (13.8%)	50 (9.4%)	25 (4.7%)	20 (3.7%)

median size of 300 cm^3 (range, 60–500 cm^3) (Fig. 1). 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 (Table 2).

Safety Data

Complications occurring in association with the breast implant surgery and/or breast implant are presented in Table 3, and these Kaplan-Meier risk rates are presented for individual cohorts.

Reasons for Reoperation

Of the 534 patients, 72 women (13.5% of subjects) underwent at least one reoperation across all cohorts within 5 years (66 months) of implantation. Reoperations that occurred for any reason including implant removal (with/without replacement) shall be described as any reoperation. Most of these were performed for cosmetic reasons (style/size change, asymmetry). In the primary augmentation cohort, the reoperation rates for capsular contracture using the Kaplan-Meier risk method was 1.9% while the most frequent reason for reoperation was mastopexy (10.7%) followed by scar (3.6%). (Unplanned mastopexy relates to operations that took place ≥24 months postimplantation.) Among the 13 reoperations in the revision augmentation cohort, the most common reasons are described in Table 4.

Nine subjects had a reoperation in the primary reconstruction cohort where capsular contracture was the main reason for additional surgery (Kaplan-Meier risk, 5.2%) followed by asymmetry (Kaplan-Meier, 4.5%). Table 5 describes the reasons for reoperation for the revision reconstruction cohorts.

Implant Removals (Explantation/Exchange)

Thirty-five reoperations resulted in an explantation or exchange of implants across all cohorts through 5 years. The primary reasons for implant removal are shown in Figure 2, whereas Figure 3 summarizes implant removal rates across all cohorts. Most of the devices that were removed were associated with patients in the reconstructive cohorts (12%, primary and revision reconstruction subjects). Of the 365 primary augmentation patients, 4.4% had their implants removed over the 5-year period (revision augmentation, 8%).

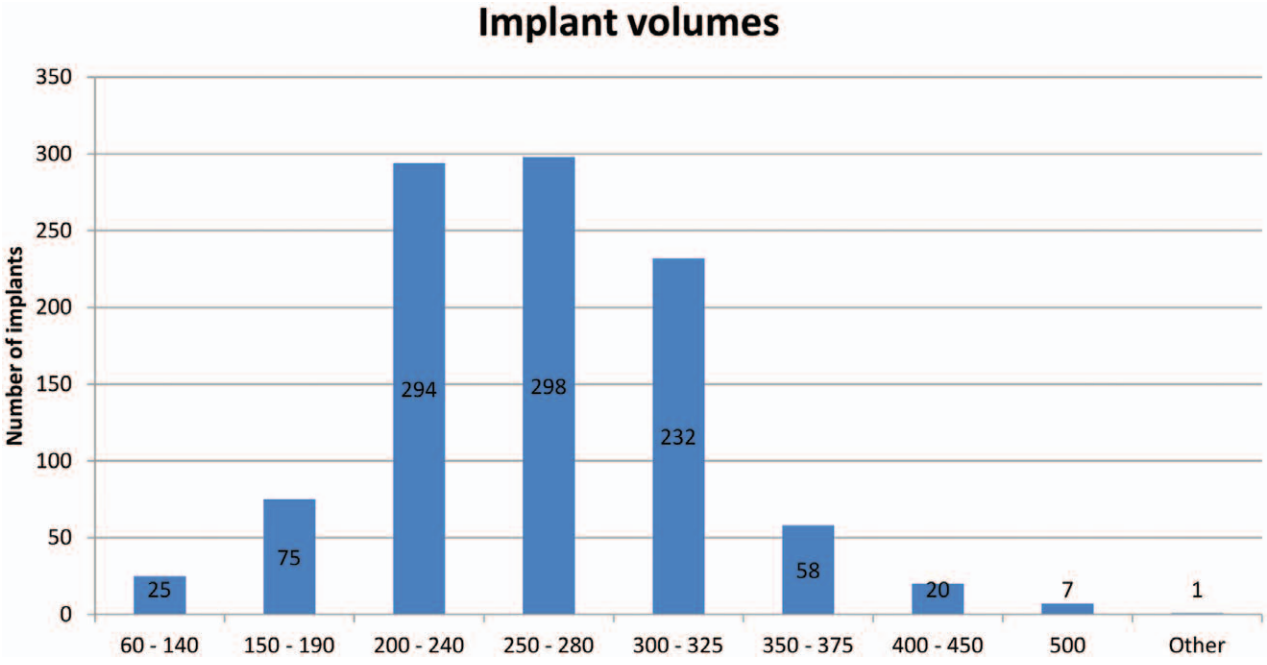

Fig. 1. Volume segmentation of Eurosilicone mammary prostheses implanted.

Table 2. Operative Details by Indication

Characteristic	Overall	Primary Augmentation	Revision Augmentation	Primary Reconstruction	Revision Reconstruction	Other
No. implants	1010	728	147	71	32	32
Device distribution (%)						
Textured round	91.4	73.5	15.5	5.6	2.2	3.3
Textured anatomical	8.6	57.5	4.6	21.8	13.8	2.3
Device placement (%)						
Submuscular	49.3	65.3	16.6	10.2	5.4	2.4
Subglandular	50	79.8	12.7	3.2	0.4	3.9
Other	0.7	0	0	42.9	42.9	14.3
Incision location (%)						
Transaxillary	17.9	85.1	8.8	1.1	1.1	3.9
Inframammary	34.9	68.2	12.8	11.9	5.4	1.7
Periareolar	42.7	75.9	18.5	1.9	0	3.7
Other	4.5	13.3	13.3	40	24.4	8.9

Of the subjects (26) who had their implants exchanged across all cohorts, only 12 of these implants were associated with the primary augmentation group. The primary reasons for exchange of implants in the primary augmentation cohort were size change (4 implants), malposition (2 implants), and rupture (2 implants) followed by capsular contracture, asymmetry, extrusion, and pain. Regarding the revision augmentation cohort, 11 implants were exchanged in total, 4 due to size change, 3 for asymmetry, and 2 for capsular contracture and wrinkling (2 implants). Implants were exchanged in the primary reconstruction cohort for another device due to capsular contracture, asymmetry, and shape involving 4, 3, and 2 implants, respectively. Problems identified in the revision reconstruction cohort involved pinched implants and asymmetry (3 implants).

The main reasons for implant removal without replacement were performed for women who developed breast cancer (6 implants) followed by size change (2 implants), ptosis (2 implants), infection (1 implant but bilateral explantation performed), and malposition (1 implant). Of the implants associated with subjects diagnosed with breast cancer, 1 of these patients had prior implant surgery (revision augmentation) and 2 of the remaining patients had their implants removed within less than a month after implantation due to diagnosis of the disease. The cumulative Kaplan-Meier risk for implant removal (definitive explantation) in each of the individual cohorts was 8.5% in primary augmentation, 14.7% in primary reconstruction, 22.9% in revision augmentation, and 15.2% in revision reconstruction groups.

Implant-related Complications

Rupture

Of the 1010 prostheses implanted, only 1 implant was found to be ruptured upon clinical examination. Another implant ruptured subject to mechanical trauma during explantation. Although implant

Table 3. Kaplan-Meier Adverse Event Risk Rates by Subject across Individual Cohorts*

Local Complication	Primary Augmentation (95% CI)	Revision Augmentation (95% CI)	Primary Reconstruction (95% CI)	Revision Reconstruction (95% CI)
Implant removal (with/without replacement)	8.8 (0.5–16.5)	22.9 (1.3–44.5)	14.7 (3.7–25.7)	15.2 (0–31.1)
Capsular contracture	10.7 (7.2–14.2)	21.4 (9.1–33.7)	17.2 (5.4–29)	19.8 (0–41)
Rupture	0.8 (0–2.0)	—	—	—
Wrinkling	22.6 (9.5–35.7)	14 (4.8–23.2)	3.1 (0–9.2)	—
Asymmetry	13.6 (6.7–20.5)	20.2 (0.4–40)	16.6 (5.2–28)	15.6 (0–32.1)
Cyst, nodule	7.7 (2.8–12.6)	3.7 (0–8.8)	11.7 (0.5–22.9)	—
Nipple complications	4.2 (1.8–6.6)	6.5 (0–14.3)	—	—
Hematoma	3.3 (1.5–5.1)	6.1 (0.2–12)	2 (0–5.9)	10.2 (0–23.7)
Malposition	3.1 (1.1–5.1)	5.1 (0–10.8)	5.7 (0–13.5)	—
Scar	2.4 (0.6–4.2)	3.5 (0–8.4)	2.2 (0–6.5)	5.9 (0–17.1)
Palpability/visibility	1.6 (0.2–3)	—	—	—
Irritation/inflammation	0.7 (0–1.7)	1.9 (0–5.6)	2.1 (0–6.2)	—
Seroma	0.3 (0.9)	—	—	—
Infection	—	1.4 (0–3.9)	3.1 (0–9.2)	—
Collagenosis	—	—	—	—

*Data are presented from a subject by Kaplan-Meier analysis. Safety data for patients included in the "other" cohort are not included due to diverse nature of this group involving 20 patients.

Table 4. Risk of Reoperation by Subject in the Augmentation Cohort*

Local Complication	Primary Augmentation (95% CI)	Revision Augmentation (95% CI)
Capsular contracture	1.9 (0–3.5)	15.8 (0–38.3)
Rupture	0.8 (0–1.9)	0
Mastopexy	10.7 (0–29.1)	3.7 (0–8.8)
Scar	3.6 (0.6–6.5)	12.5 (0–35.4)
Cyst, nodule	1.2 (0–2.6)	0
Patient request for size change	0.9 (0–1.9)	2 (0–5.7)
Ptosis	0.8 (0–1.9)	1.5 (0–4.4)
Adenofibroma	0.5 (0–1.5)	0
Seroma	0.3 (0–0.9)	0
Pain	0.3 (0–0.9)	0
Malposition	0.3 (0.8)	2.1 (0–6.2)
Extrusion	0.3 (0–0.8)	0
Hematoma	0.3 (0–0.9)	0
Wrinkling	0	12.5 (0–35.4)
Lymphorrhea	0	1.4 (0–4.2)
Implant shape/pinch	0	1.9 (0–5.6)
Other	0	1.8 (0–5.1)

*Data are presented from a subject by Kaplan-Meier analysis.

imaging was not a requirement of the protocol, just over 50% of patients had a least 1 form of imaging performed on a routine basis [32%, 19%, and 2% of patients had at least 1 mammography, ultrasound, and magnetic resonance imaging (MRI), respectively]. In fact, the above-mentioned ruptured implant was suspected following mammography and confirmed upon MRI examination/explantation. Additionally, no ruptures were discovered during 35 reoperations. The total Kaplan-Meier risk of rupture was 0.4% per patient.

Table 5. Risk of Reoperation by Subject in the Reconstruction Cohort (Kaplan-Meier)*

Local Complication	Primary Reconstruction (95% CI)	Revision Reconstruction (95% CI)
Capsular contracture	5.2 (0–12.5)	0
Rupture	0	0
Asymmetry	4.5 (0–10.6)	6.2 (0–18.2)
Implant shape/pinch	3.1 (0–9.2)	4.8 (0–13.8)
Mastopexy	2.6 (0–7.7)	0
Scar	2.4 (0–7.1)	6.7 (0–19.2)
Malposition	2.3 (0–6.8)	4.8 (0–13.8)
Ptosis	2.2 (0–6.5)	0
Patient request for size change	0	0
Adenofibroma	0	10 (0–28.6)
Other	0	5 (0–14.6)
Infection	0	0
Cyst, nodule (mass)	0	0
Seroma	0	0
Pain	0	0
Hematoma	0	0
Wrinkling	0	0
Lymphorrhea	0	0
Extrusion	0	0

*Data are presented from a subject by Kaplan-Meier analysis.

Capsular Contracture (Baker III/IV)

Of the 534 subjects, 52 women experienced capsular contracture through 5 years. The Kaplan-Meier risk of capsular contracture was 13% (95% CI, 9.5–16.5) on a per subject basis. There was no significant difference in the occurrence of capsular contracture between the individual cohorts analyzed or with incision location utilized.

A breakdown of the number of capsular contractures that were observed according to implant position and incision location is provided in Table 6.

Local Complications

The secondary objectives set out in the protocol related to local complications and may relate to complications occurring as a result of surgery itself rather than the presence of the implants themselves. The Kaplan-Meier risk of both implant and local complications that occurred are presented in Table 3.

Hematoma is a complication often associated with surgery and has been reported following breast implantation. Of the 534 subjects, 18 women presented with hematoma giving Kaplan-Meier risk rates of 3.5% per patient (95% CI, 1.9–5.1%). One woman experienced seroma within 5 years postimplantation while the incidence of infection was low (Table 3).

Wrinkling was observed in 45 women across all cohorts, and the majority of which were associated with the subglandular position (68%). Although the Kaplan-Meier risk associated with wrinkling was higher than expected across individual cohorts (Table 3), reoperation rates for wrinkling were low whereby no patient in the augmentation, primary, and revision reconstruction cohorts were reoperated to correct this complication (Table 4).

Asymmetry was observed and not surprisingly a significantly higher level of asymmetry was reported in both the "reconstruction" and "other" groups when compared with the augmentation group (log-rank Mantel-Cox $P < 0.05$). Twenty-three of the implants associated with asymmetry were reported to have been malpositioned while 1 implant extruded.

Pain was reported at individual visits and was reported 95 times (60 of which were reported within 12 months). Incidence of pain diminished with time, which is typical of this type of surgery. As pain is often thought to be associated with either incision location or final implant position, secondary analyses were carried out to compare the rate of occurrence of pain. Implantation position did not influence its development (P = not significant); however, the number of reports of pain in association with the transaxillary incision were significantly higher than that observed for the periareolar incision (log-rank Mantel-Cox $P < 0.05$).

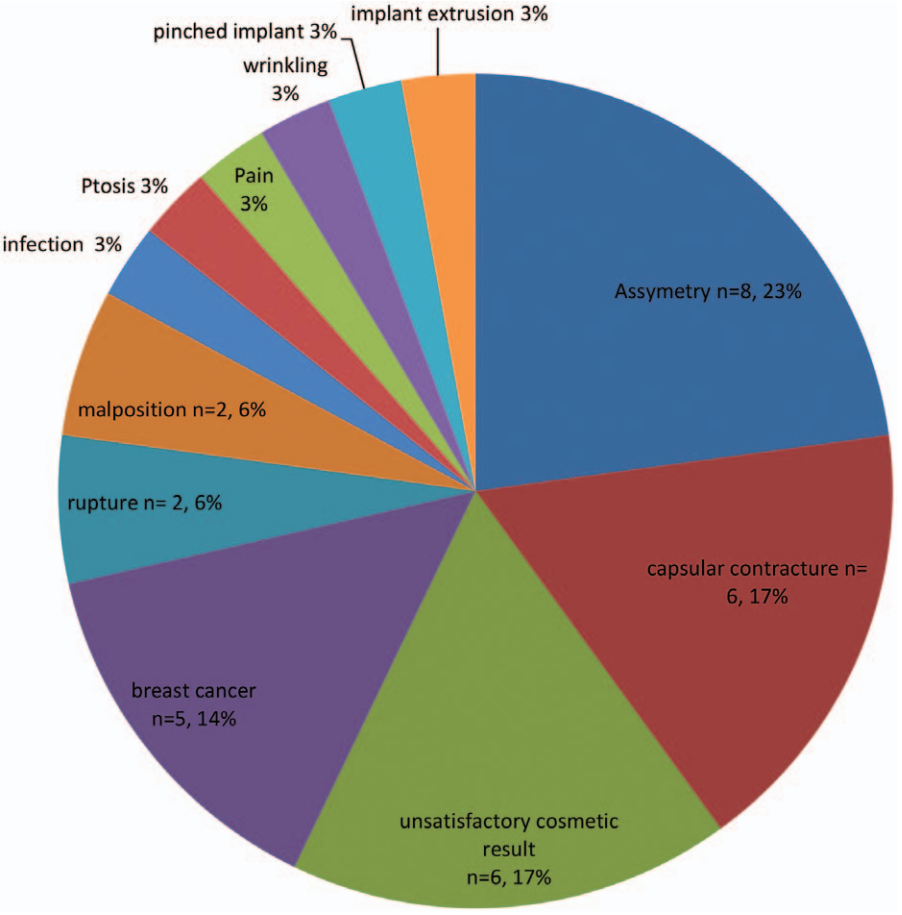

Fig. 2. Reasons for implant removal (with or without replacement) on a per subject basis.

A summary of clinical findings with regard to reproduction and breast feeding complications and autoimmune disease, cancer (new diagnosis and metastatic disease), and benign disease is presented herein.

Connective Tissue Disease, Benign Disease, and Cancer

There were no reports of connective tissue or autoimmune disease. Benign disease was assessed and included adenofibromas, a benign ovarian tumor, and one report of mastocytosis (16 patients within 5 years postimplantation with Kaplan-Meier risk rates of 3.9% per patient; 95% CI, 1.9–5.9%). Cysts and nodules of the breast were reported in 4.3% of all patient cohorts.

Breast cancer has been reported in 10 women where half of these cases involved reconstruction patients. For primary augmentation patients, 5 women were diagnosed with breast cancer (1.4%). Two cases of cervical cancer were reported for women implanted for aesthetic reasons at 4 and 5.5 years, respectively.

Reproduction Complications

Two women in the primary augmentation group reported some issues with breast feeding. One of these experienced the onset of lactogenesis having given birth even though she did not wish to breast feed and capsular contracture was detected in another patient having begun same. Sixteen women reported sensitivity, discomfort, or dysaesthesia in the nipple area (2.9%). No miscarriages were reported.

DISCUSSION

The risks associated with breast implant placement are common to many types of surgery and include hematoma, seroma, surgical site infection, pain, altered sensitivity, and unfavorable scarring while rupture and capsular contracture are generally considered as problems specific to breast implants.[4,5] This study examines 1010 of Eurosilicone's textured cohesive silicone gel–filled mammary implants through 5 years of follow-up and demonstrates low complication rates consistent with those reported in the literature.

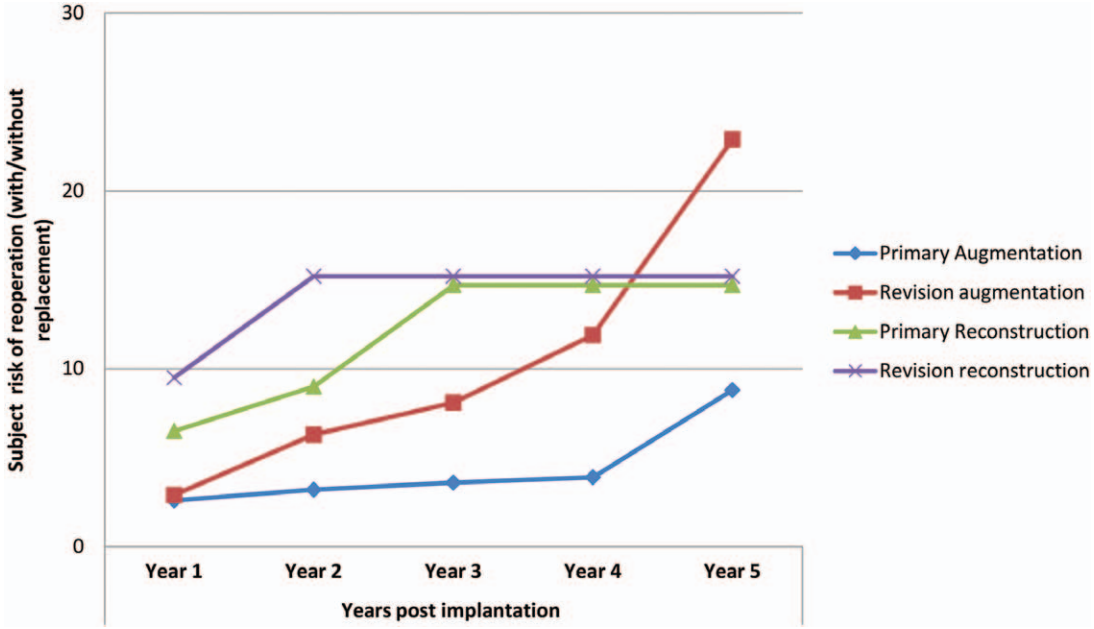

Fig. 3. Implant removal (with or without replacement). Cumulative incidence of reoperations. Kaplan-Meier 1 minus survival curve.

The primary objective of this study was to demonstrate the safety and efficacy of Eurosilicone S.A.S. breast implants for both cosmetic and reconstructive indications specifically through observation of the Kaplan-Meier risk for implant removal (explantation/exchange). Although direct comparisons cannot be made with other competitor studies due to differences in study design and patient profiles, implant removal rates resulting in explantation and exchange were consistently lower than those reported in the literature. Eurosilicone's 5-year results of removal for their primary augmentation cohorts (8.5%) were lower than the 5-year rates reported by Sientra[6] (8.7%) and 4-year results for Allergan (9.6%).[7,8] Patients in the primary reconstruction cohort who had undergone reconstruction following cancer diagnosis also showed lower rates when compared with competitor designs (14.7% vs 24.8% and 31% for Allergan and Sientra, respectively).[7,8] As such, patients in the reconstructive cohorts 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). By contrast, reoperations in the primary reconstruction group that had likely undergone significant tissue trauma were performed for capsular contracture (Kaplan-Meier risk, 5.2%).

Most implants were exchanged due to asymmetry followed by capsular contracture, while the main reason for a definitive explantation was breast cancer. Breast cancer rates were just lower than expected using probability estimated for their current age (5 cases of breast cancer were observed in the aesthetic cohort vs 6.3 expected).[9]

Despite the fact that more than 50% of patients in Eurosilicone's study has undergone routine imaging of their breasts (mammography, ultrasound), Eurosilicone have taken the prudent approach and compared their rupture rate to the non-MRI cohorts of competitor premarket approval studies that describe rupture rates varying from 0% to 10% in non-MRI cohorts within 4 years.[8,10] Hence, Eurosilicone's rupture rate of 0.4% is well within the range expected for current designs of mammary implants.

Table 6. Capsular Contracture Cases

Implantation Details	Total No. Implants	Kaplan-Meier Risk Rate by Implant Associated with Capsular Contracture (%)
Implant position		
Submuscular	498	2.4
Subglandular	505	4.1
Other	7	0.1
Incision location		
Periareolar	432	3.5
Inframammary	352	1.8
Transaxillary	181	1
Other	45	0.3

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 associated with wrinkling were higher than expected across all cohorts. The case report form that recorded the data was limited in some respect as it did not require that the severity of complications such as wrinkling or pain were described and are open to criticism. That said, only one patient in the revision augmentation cohort necessitated a reoperation for this complication. It is well documented in the literature that wrinkling is more prevalent in thin patients and implants placed in the subglandular position possibly due to limited tissue coverage.[11–14] Hence, it was not surprising, therefore, that wrinkling was reported more frequently in the subglandular rather than submuscular position (45 vs 21 implants), and this result was statistically significant ($P \leq 0.001$). Although other manufacturer data report lower Kaplan-Meier risk rates for wrinkling, these data are associated with implants placed mainly in the submuscular position (70% of implants).[6,10] Hence, subglandular implant placement may have contributed to the higher apparent wrinkling rates in Eurosilicone's study. Unfortunately, we cannot provide an insight into the influence of French anatomy or weight loss on the severity of wrinkling due to the data collection mechanism, but it is notable that only one patient required a reoperation for wrinkling and this patient was part of the revision reconstruction cohort. Perhaps, the severity of wrinkling was minimal based on the number of reoperation rates observed. In summary, submuscular placement may offer the most prudent solution for all silicone implant designs.

Pain was the most widely reported local complication in this study which reduced with time postimplantation. Most Eurosilicone implants were placed via a periareolar incision which has been correlated with pain in another study,[15] but pain was significantly associated with the transaxillary incision in this series (Log rank $P < 0.05$). Transaxillary incisions are not widely used due to perceived limitations in pocket access, visualization, control, and subsequent risk for postoperative complications.[16] Hence, the correlation of pain with transaxillary incisions in this study may reflect difficulties in the placement and maintenance of implants at the proper level rather than the route of incision itself.[17,18]

Limitations of the study design derive mainly from the lack of a precise method to assess the level and location of pain,[19,20] and it is noteworthy that few patients were reoperated for it (0.3%, primary augmentation; all other cohorts, 0%).

The Kaplan-Meier risk of capsular contracture for Eurosilicone's augmentation cohorts (primary and revision) was within the range of corresponding 5- to 6-year data presented for successful premarket approval applications of Sientra and Mentor (Sientra Primary revision 8.8%, 5 years; Mentor 15.4%, 6 years, 2003)[6,10] but was not influenced by implant position in this series.[21,22] Capsular contracture rates in the reconstruction cohorts although higher than cosmetic cohorts were still within the expected range for patients who have had a mastectomy.

Several studies have highlighted that subglandular placement is associated with a higher rate of capsular contracture and need for revision surgery.[23,24] Despite an even split between submuscular and subglandular positions, more capsular contractures were associated with the subglandular position in Eurosilicone's series (41 vs 25 cases) (not significant). Capsular contracture rates although within the range expected may have been slightly elevated due to its more extensive use in this study. Subglandular placement has been often associated with increased complication rates and its development may be more obvious for implants placed in this position.[24–27] Perhaps implant duration was fundamental to capsular contracture development in Eurosilicone's study as rates were significantly lower in the submuscular position at 4 but not at 5 years (Log rank $P < 0.05$). This phenomenon has also been observed in other long-term studies.[28,29]

Capsular contracture now considered a multifactorial process that could be influenced by any one or more of the following: surface texture, incision location, implant type, implant location, infection, inflammation, foreign material, hydrophobicity, and biofilm formation.[4,21,22,28,30–35] The weight of evidence surrounding the infectious theory is gathering momentum with studies discussing biofilm formation and those highlighting that breast ducts harbor bacteria.[33,36] Any correlation between capsular contracture and infection could not be assessed during this study such that capsules were not routinely cultured to assess for subclinical infections/biofilm formation. Literature emphasizing means to reduce inflammation and trauma and thereby capsular contracture through choice of the optimal implant plane, implant size, and shape may also have some merit.[21–23,27,36,37]

CONCLUSIONS

Although a long-term follow-up has not been performed, these 5-year interim results demonstrate the safety and efficacy of Eurosilicone gel–filled mammary implants for both augmentation and reconstruction indications. Reoperation rates resulting

in implant removal (explantation/exchange) were low and superior to that described for other implant designs. In agreement with other implant studies, subglandular implant placement was associated with higher complication rates. Concerning local complications, the Kaplan-Meier risk rates for seroma, scarring/hypertrophic scarring, and infection were lower than those reported by competitors.[6,8,10] Similarly, rates of implant/displacement extrusion were in line with other manufacturers.[6,8,10] This study will continue to evaluate the complication profile of Eurosilicone gel–filled mammary implants until 10 years postimplantation and would be expected to demonstrate an excellent long-term safety and efficacy profile based on these 5-year interim results.

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