Single Center and Surgeon's Long-Term (15-19 Years) Patient Satisfaction and Revision Rate of Round Textured Eurosilicone Breast Implants

Kooiman, Laurens; Torensma, Bart; Stevens, Hieronymus; van der Lei, Berend

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Laurens Kooiman, MD; Bart Torensma, MSc, PhD;
Hieronymus Stevens, MD, PhD; and Berend van der Lei, MD, PhD

Abstract

Background: Breast augmentation is one of the most commonly performed aesthetic plastic surgical procedures, with over 250,000 procedures in the United States in 2020 alone. However, the safety of breast implants should be closely researched and monitored, especially in the long term.

Objectives: This study was undertaken to evaluate the long-term results of round micro-textured Eurosilicone (Eurosilicone S.A.S, Apt Cedex, France) Cristalline Paragel breast implants from a single-center, single-surgeon experience regarding both patient-reported outcome measures and revisions.

Methods: A retrospective cohort study was undertaken of 84 patients who underwent primary breast augmentation with round micro-textured Eurosilicone Cristalline Paragel breast implants, either submuscular (dual-plane) or subglandular placed, between 2001 and 2004. All patients were contacted for informed consent, and after approval, the validated BREAST-Q questionnaire was sent and utilized to analyze patient satisfaction. In addition, objective data regarding revisions, including capsular contracture, rupture rate, pain, and/or aesthetic causes needing revision surgery, were analyzed.

Results: High BREAST-Q scores (67%-100% for 0-100 scale variables and 66.0%-77.3% of the patients scored "very satisfied" on categorical variables) were found without clinically significant differences between patients with dual-plane–placed implants and subglandular-placed implants. The overall revision rate was 29.8%, also with no significant differences between groups ($P = 0.317$).

Conclusions: This study showed high patient satisfaction and relatively low revision rates after 15 to 19 years of follow-up of round micro-textured Eurosilicone Cristalline Paragel breast implants. No clinically relevant significant differences were found between dual-plane and subglandular placement of the implants.

Level of Evidence: 4

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Dr Kooiman is a postgraduate house officer of plastic surgery, Department of Plastic Surgery, Haaglanden Medical Centre (HMC), The Hague, the Netherlands. Dr Torensma is a clinical epidemiologist, Department of Anesthesiology and Epidemiology, Leiden University Medical Centre (LUMC), Leiden, the Netherlands. Dr Stevens is a plastic surgeon, Department of Plastic Surgery, Velthuis Clinics, Rotterdam, the Netherlands. Dr van der Lei is a professor of aesthetics, University of Groningen and University Medical Centre Groningen (UMCG), Groningen, the Netherlands.

Corresponding Author:
Dr Laurens B. R. Kooiman, Postgraduate House Officer of Plastic Surgery, Haaglanden Medical Centre, Lijnbaan 32, 2512 VA, The Hague, the Netherlands.
E-mail: laurenskooiman@gmail.com

Ever since silicone breast implants were introduced in the early 1960s, their utilization and popularity has grown tremendously. Numbers of The Aesthetic Society national statistics 2020 suggest that over 250,000 breast augmentations were conducted that year, and it is the most performed aesthetic surgical procedure in people aged 17 to 35 years.[1]

A wide variety of breast implants is available for breast augmentation as well as different surgical techniques, implant shape (anatomical vs round), implant filling (saline vs silicone), implant surface (smooth vs [micro-]textured), location (subglandular vs [partially] subpectoral), and incision location (inframammary vs periareolar vs transaxillary). Thus far, many studies have been performed to analyze all the aforementioned differences in breast augmentation. However, most of these studies were multicentric, multi-surgeon studies focused on only 1 or 2 specific differences and had relatively short follow-up times until the maximum of 10 years.

Eurosilicone's (Eurosilicone S.A.S, Apt Cedex, France) micro-textured breast implants are one of the types of breast implants regularly utilized now and one of the preferred breast implants in our clinic. So far, only medium-term follow-up (5-10 years) results of these implants have been published, with an overall acceptable patient satisfaction and low revision rate. These studies have shown that over time, the cumulative risk of capsular contracture increases from 7% to 13% and that unsatisfactory aesthetic results occur in approximately 22% of the primary breast augmentations, a figure very similar to other textured silicone breast implants.[2,3] A significant longer-term evaluation study definitely would add important data to the literature: therefore, this long-term (15-19 years) follow-up study evaluation was set up. Fortunately, we had a significant series of patient data from a single-center, single-surgeon setting that has employed Eurosilicone's round micro-textured Cristalline Paragel breast implants for many years. All breast augmentations were performed through an inframammary incision and placed either submuscular (modified dual plane type 3) or subglandular. Objective data regarding patient satisfaction and revisions, including capsular contracture, rupture rate, pain, and/or aesthetic causes needing revision surgery, were analyzed. Patient satisfaction was evaluated by utilizing the BREAST-Q scale, a standardized, validated, patient-reported outcome measure.

The goal is to assess the long-term results regarding subjective patient satisfaction and objective revision rates for patients who underwent primary breast augmentation utilizing micro-textured Eurosilicone breast implants, placed either subglandular or dual-plane, through inframammary incision by a single surgeon in a single center with a minimum follow-up of 15 years. Quantitative data were collected employing the BREAST-Q for patient satisfaction and the Dutch Breast Implant Registry (DBIR) revision list for revision surgeries.

METHODS

Study Design

This retrospective cohort study compared the results of a long-term follow-up (average, 17.03 years; range, 15-19 years) of patients who underwent primary breast augmentation, utilizing round micro-textured Eurosilicone Cristalline Paragel breast implants, either placed subglandular or in dual-plane (modified type 3). All surgeries were performed in the period between January 2001 and December 2004 in a single center by a single plastic surgeon. Data were collected between May 2020 and December 2020, and subsequent analysis was performed until April 2021.

Patient Selection

Once the Ethical Review Committee of the University of Groningen approved the study after reviewing the protocol and gave positive feedback to the board of directors of the JKX Plastic Surgery Clinic in conducting this study, all patient information regarding our primary goal was extracted from the surgeon's database. This information included patient characteristics, dates, and specifications of primary surgery, and, if applicable, revision surgery and the corresponding reasons for revision surgery.

All patients were contacted by the investigator. To ensure the highest response rate, we were inspired by the Total Design Method by Dillman.[4] Written consent was provided by which the patients agreed to the utilization and analysis of their data. Patient e-mail addresses were collected and encrypted for privacy reasons. The BREAST-Q questionnaire was subsequently sent along with additional questions regarding patient characteristics. All patients in this study were consecutive patients from 2001 to 2004 who met the inclusion criteria.

Inclusion Criteria

Women, aged 18 years or older at time of surgery, who underwent primary breast augmentation surgery performed by a single surgeon between 2001 and 2004, utilizing solely Eurosilicone Cristalline Paragel round micro-textured breast implants placed through an inframammary incision, were eligible for this study.

Exclusion Criteria

Women who underwent additional breast surgery such as mastopexy or nipple translocation were excluded. Additionally, patients who could not be contacted because of obsolete phone numbers and/or e-mail addresses were excluded. Finally, patients who would not give informed

consent or decided not to participate in this study were excluded.

Satisfaction of Patients

The effectiveness of the augmentation surgery was scored with the validated BREAST-Q questionnaire. The BREAST-Q has different modules for different breast surgeries. In this study, the postoperative breast augmentation module was employed. It was shown in earlier studies that the BREAST-Q scales provide a valid and reliable patient reported outcome measure.[5] No studies were found describing the utilization of the BREAST-Q 15 to 19 years postsurgery.

The postoperative augmentation module consists of 10 scoring forms, comprising psychosocial well-being, sexual well-being, satisfaction with breasts, physical well-being, satisfaction with implants, satisfaction with outcome, satisfaction with information, satisfaction with surgeon, and satisfaction with medical team. These forms are mostly converted into 0-100 scores utilizing the BREAST-Q converter in the final analysis.

Reasons for Revision Surgery

If revision surgery was performed, classification was conducted according to the DBIR revision list, a standardized list for breast implant revision surgery, which is now being utilized in the Netherlands by almost all plastic surgeons.[6] The original DBIR revision list is attached in Appendices A and B (available online at www.aestheticsurgeryjournal.com). Antiquity of implants was added to the list in this research.

Statistical Analysis

All data were tested for normality employing the Kolmogorov-Smirnov test, the Levene's test, and Q-Q plot. Continuous, normally distributed variables were expressed by their mean and standard deviations, skewed variables by their median and interquartile range. Numbers and percentages described categorical variables.

Categorical variables were tested with the Pearson's chi-square test or Fisher's exact test, when appropriate. For normally distributed data, the independent samples *t* test was performed; in case of non-normally distributed data, a log transformation was performed to reduce skewness. If there was no positive effect, the non-normally distributed data were tested with the independent samples Mann-Whitney U-test.

Kaplan Meyer analysis was performed, and thereby the log-rank test was performed for testing differences between groups over time.

All BREAST-Q scales were scored separately as shown before. Most scores were transformed to a 0- to 100-point scale employing a conversion table provided along with the BREAST-Q itself. Significance level was set at $P < 0.05$. Statistical analysis was performed with SPSS Statistical software (version 26.0, SPSS Inc., Chicago, IL, USA).

Data Capture

The analysis was performed on a blinded data set after medical/scientific review was completed and all protocol violations were identified and the data set was declared complete. All data were collected in a data management system (Castor EDC, Amsterdam, the Netherlands; https://www.castoredc.com), handled according to Good Clinical Practice guidelines and Data Protection Directive certificate, and comply with Title 21 CFR Part 11. Furthermore, the datacenter where all the research data are stored is ISO27001, ISO9001 certified and Dutch NEN7510 certified.

RESULTS

This study enrolled a total of 209 patients. All patients were female. Because data from a long time ago (period 2001-2004) were utilized, not all information was up to date. For all patients, at least a phone number or an e-mail address was known, but when contacting them for informed consent and inclusion, 96 patients were excluded due to outdated contact information. Furthermore, 7 patients did not wish to participate in this study, and 2 patients, who did not have sufficient understanding of the Dutch language, could not fill in the online questionnaire.

This left 104 patients who were successfully reached, and the survey was sent to them. After numerous reminders, 20 patients did not complete the survey, so finally 84 patients completed the entire survey. The patient enrollment diagram is shown in Figure 1.

Baseline and Follow-up Characteristics

In this analysis, 84 patients were finally included: 44 patients had dual-plane–placed breast implants and 40 patients had subglandular-placed breast implants. At time of surgery, the mean age was 32.5 ± 7.4 years and BMI was 20.37 ± 1.72 kg/m^2 in the dual-plane group, and the mean age was 33.6 ± 8.5 years and BMI was 21.84 ± 2.02 kg/m^2 in the subglandular group. Mean implant size at primary surgery was 290.3 ± 39.2 cc for all dual-plane–placed implants and 306.3 ± 50.9 cc for all subglandular-placed implants. Of all dual-plane–placed implants, 41 (93.2%) had a low profile vs 37 (92.5%) of the subglandular-placed implants. In the dual-plane group, 10 (22.8%) of the patients smoked compared with 18 (45%) in the subglandular group.

At time of research, the mean age was 50.3 ± 7.5 years in the dual-plane group and 50.7 ± 8.3 years in the subglandular group. BMI was 21.66 ± 2.49 vs 23.56 ± 2.70 kg/m^2. Of all

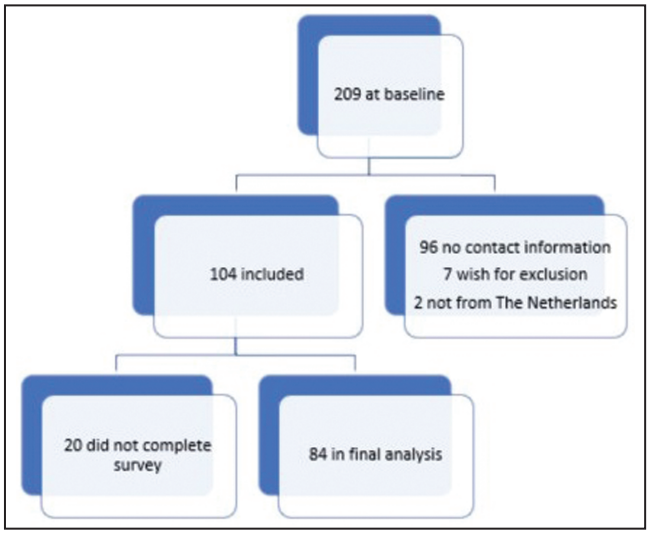

Figure 1. Patient enrollment diagram.

patients, 7 (15.9%) in the dual-plane group and 10 (25%) in the subglandular group smoked.

Between surgery and research, 28 (63.6%) of the patients in the dual-plane group reported no pregnancies, whereas 6 (13.6%) reported 1 pregnancy, 7 (15.9%) reported 2 pregnancies, and 3 (6.8%) reported 3 pregnancies. In the subglandular group, 31 (77.5%) reported no pregnancies, 3 (7.5%) reported 1 pregnancy, 4 (10%) reported 2 pregnancies, and 2 (5%) reported 3 pregnancies. Of all patients, breastfeeding occurred with 11 (25%) in the dual-plane group and 4 (10%) in the subglandular group.

Of all patients (European) cup and band sizes were listed preoperatively and at time of research. These are listed in Table 2. Before surgery, 42 (95.5%) of the patients in the dual-plane group and 30 (75%) of the patients in the subglandular group had cup sizes AA, A, or B.

None of the reported baseline and follow-up characteristics in Tables 1 and 2 were significantly different, except for BMI, which was higher in the subglandular group ($P = 0.001$).

Patient Satisfaction After 15 to 19 Years

Overall, relatively high satisfaction rates were found, with scores in the range of 67% to 100% for 0- to 100-scale variables and 66.0% to 77.3% of the patients scored "very satisfied" on categorical variables. Only a significant difference between dual-plane and subglandular groups was found in psychosocial well-being ($P = 0.031$), in favor of the dual plane group; however, this was not clinically relevant (75.5% for the dual-plane group compared with 71% for the subglandular group). No significant difference was found among the other BREAST-Q items. All possible factors regarding patient satisfaction in the post-augmentation module were scored, and the median scores with minimum-maximum are listed in Table 3.

Revision Surgery Data

In the dual-plane group, 33 patients (75%) still had their original implants, 7 patients (15.9%) had new implants, 1 patient (2.3%) had undergone an explantation, and 3 patients (6.8%) had revision surgery with reimplantation of the original implants. In the subglandular group, 26 patients (65%) still had their original implants, 13 patients (32.5%) had new implants, and 1 patient (2.5%) had undergone an explantation, whereas no revision surgery with reimplantation of same implants occurred.

Table 4 shows the indications for revision surgery. Twenty-five (29.8%) of 84 patients underwent revision surgery. There was no significant difference ($P = 0.317$) between the 2 groups (11 patients [25.0%] in the dual-plane group and 14 patients [31.8%] in the subglandular group). Revision surgery included explantation, replacement of implants, and revision of the pockets and capsule leaving the same implants in place (see Table 3).

In the dual-plane group, 2 patients had 2 revision surgeries shortly after their primary augmentation leaving the original implants in place. One patient had 1 revision surgery leaving the original implants in place. Seven patients had new implants and 1 patient an explantation. In the subglandular group, 1 patient had 11 revision surgery leaving the original implant in place, 13 patients had new implants, and 1 patient had explantation. One of the 13 patients with new implants was also the patient with previous revision surgery leaving the original implant in place. No significant difference regarding status of implants was found ($P = 0.142$).

The indications for (relatively short-term) revision surgery with reimplantation of same implants reported in our analysis were seroma/hematoma and capsular contracture. No significant difference in the number of patients with seroma/hematoma ($P = 0.614$) or capsular contracture ($P = 0.093$) was found.

The indications for revision surgery with new implants were capsular contracture, implant rupture, silicone extravasation, breast cancer, Autoimmune/Inflammatory Syndrome Induced by Adjuvants syndrome, dissatisfaction with implant volume, and antiquity of implants. No significant difference was shown between both groups regarding any of these indicators.

Stratification by Revision Surgery

An additional analysis was performed including only those patients who underwent revision surgery (29.8%). Within this selection of patients, significant differences were found between the dual-plane and subglandular groups.

Table 1. Patient Characteristics at Baseline and at Follow-Up

Characteristic	Dual-plane (n = 44)		Subglandular (n = 40)	
	Baseline	Follow-up	Baseline	Follow-up
Age, mean ± SD, y	32.5 ± 7.5	50.3 ± 7.5	33.6 ± 8.5	50.7 ± 8.3
Sex, F/M	44/0		40/0	
BMI, mean ± SD, kg/m^2	20.37 ± 1.72	21.66 ± 2.49	21.85 ± 2.02	23.56 ± 2.70
Implant size, mean ± SD, cc	290.3 ± 39.2		306.3 ± 50.9	
Patients with, no.[a]				
Low profile	41 (93.2)		37 (92.5)	
High profile	3 (6.8)		3 (7.5)	
Patients, no.				
Non-smoking	34 (77.3)	37 (84.1)	22 (55)	30 (75)
Smoking <10/d	5 (11.4)	5 (11.4)	6 (15)	4 (10)
Smoking >10/d	5 (11.4)	2 (4.5)	12 (30)	6 (15)
Patients, no.[a]				
Not pregnant between		28 (63.6)		31 (77.5)
1× Pregnant between		6 (13.6)		3 (7.5)
2× Pregnant between		7 (15.9)		4 (10)
3× Pregnant between		3 (6.8)		2 (5)
Patients, no.[a]				
Breastfeeding between		33 (75)		36 (90)
1× Breastfeeding between		7 (15.9)		2 (5)
2× Breastfeeding between		4 (9.1)		1 (2.5)
3× Breastfeeding between		0 (0)		1 (2.5)
Patients with, no.[a]				
Original implants		33 (75)		26 (65)
Revision with original implants		3 (6.8)		0 (0)
New implants		7 (15.9)		13 (32.5)
Explantation (uni-or bilateral)		1 (2.3)		1 (2.5)

SD, standard deviation. [a]Variables are described with no. (%).

Implant volume (271.8 cc in the dual-plane group compared with 320.5 cc in the subglandular group) was significantly larger in the subglandular group (P = 0.012) and BMI (21.49 kg/m^2 in the dual-plane group compared with 24.54 kg/m^2) was significantly higher in the subglandular group at baseline (P = 0.000). Significantly more people smoked at baseline in the dual-plane group (P = 0.015). No significant differences in all reasons for revision surgery or BREAST-Q scores were found.

Analyzing the baseline characteristics comparing revision vs non-revision, without stratification between subglandular and dual-plane, only BMI at baseline was significantly different (P = 0.041). Regarding patient satisfaction, a significant difference was seen in the BREAST-Q

Table 2. Cup and Band Size of Participants at Baseline and Follow-up[a]

Cup or band size	Dual-plane (n = 44)		Subglandular (n = 40)	
	Baseline	Follow-up	Baseline	Follow-up
Cup size				
Unknown	0 (0)	1 (2.3)	1 (2.5)	0 (0)
AA	23 (52.3)	0 (0)	2 (5.0)	0 (0)
A	15 (34.1)	0 (0)	21 (52.5)	0 (0)
B	4 (9.1)	8 (18.2)	7 (17.5)	0 (0)
C	1 (2.3)	20 (45.5)	6 (15)	15 (37.5)
D	1 (2.3)	9 (20.5)	2 (5.0)	17 (42.5)
E	0 (0)	2 (4.5)	0 (0)	7 (17.5)
F	0 (0)	3 (6.8)	1 (2.5)	1 (2.5)
G	0 (0)	1 (2.3)	0 (0)	0 (0)
Band size				
Unknown	5 (11.4)	3 (6.8)	1 (2.5)	1 (2.5)
65	1 (2.3)	0 (0)	0 (0)	0 (0)
70	16 (36.4)	5 (11.4)	5 (12.5)	2 (5.0)
75	17 (38.6)	18 (40.9)	22 (55.0)	11 (27.5)
80	2 (4.5)	10 (22.7)	6 (15.0)	11 (27.5)
85	3 (6.8)	7 (15.9)	4 (10.0)	10 (25.0)
90	0 (0)	0 (0)	0 (0)	2 (5.0)
95	0 (0)	1 (2.3)	2 (5.0)	3 (7.5)

[a]Variables are described with n, (%).

module "satisfaction with outcome" (P = 0.034). The visibility and palpability of the implants were also significantly different (P = 0.023 and P = 0.019, respectively).

Cumulative Incidence of Revision Surgery

Figure 2 shows the Kaplan-Meijer cumulative survival graph for patients with their original implants. No significant difference was found between implant sites in revision surgery with new implants (P = 0.097). Figure 3 shows a similar graph for all patients without the need for any revision surgery, which also was not significantly different (P = 0.192).

DISCUSSION

This study analyzed the "very" long-term (average follow-up, 17.03 years; range, 15-19 years) patient satisfaction and revision rate of round micro-textured Eurosilicone Cristalline Paragel breast implants from a single center and a single surgeon's experience. Looking at the BREAST-Q scores, high scores of patient satisfaction rates (67%-100% for 0- to 100-scale variables, and 66.0%-77.3% of the patients scored "very satisfied" on categorical variables) were found without clinically significant differences of note between patients with dual-plane–placed implants and subglandular-placed implants. The overall revision rate was 29.8% without significant differences between dual-plane and subglandular placement of breast implants. The baseline characteristics regarding age, implant size, and smoking are a representative display of patients wishing primary breast augmentation compared with other studies.[7-12]

Long-term satisfaction studies after breast augmentation are scarce, with most describing a maximum follow-up of approximately 5 years.[13,14] Our satisfaction rates suggest comparable results after 15 to 19 years. Mundy et al analyzed patient satisfaction of 1211 women without breast

Table 3. BREAST-Q Scores 15 to 19 Years After Primary Breast Augmentation[a]

BREAST-Q chapter	Dual-plane (n = 44)	Subglandular (n = 40)	Total (n = 84)	*P* (Mann-Whitney-U and χ^2)
Psychosocial well-being (0-100)	75.5 (47-100)	71 (35-100)	74 (35-100)	0.031
Sexual well-being (0-100)	67 (25-100)	67 (20-100)	67 (20-100)	0.705
Satisfaction with breasts (0-100)	69 (35-100)	78.5 (41-100)	71 (35-100)	0.461
Equality of breasts (1-4)				
1: Very dissatisfied	4 (9.1 %)	2 (5.0 %)	6 (7.1 %)	0.542 (χ^2)
2: Somewhat dissatisfied	2 (4.5 %)	4 (10.0 %)	6 (7.1 %)	
3: Somewhat satisfied	10 (22.7 %)	6 (15 %)	16 (19.0 %)	
4: Very satisfied	28 (63.6 %)	28 (70.0 %)	56 (66.7 %)	
Physical well-being: chest (0-100)	95.5 (27-100)	100 (14-100)	100 (14-100)	0.578
Satisfaction with implants				
Visible rippling (1-4)				
0: Not applicable	1 (2.3 %)	1 (2.5 %)	2 (2.4 %)	0.879 (χ^2)
1: Very dissatisfied	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	
2: Somewhat dissatisfied	6 (13.6 %)	8 (20.0 %)	14 (16.7 %)	
3: Somewhat satisfied	3 (6.8 %)	3 (7.5 %)	6 (7.1 %)	
4: Very satisfied	34 (77.3 %)	28 (70.0 %)	62 (73.8 %)	
Palpable rippling (1-4)				
0: Not applicable	1 (2.3 %)	2 (5.0 %)	3 (3.6 %)	0.758 (χ^2)
1: Very dissatisfied	1 (2.3 %)	2 (5.0 %)	3 (3.6 %)	
2: Somewhat dissatisfied	6 (13.6 %)	7 (17.5 %)	13 (15.5 %)	
3: Somewhat satisfied	9 (20.5 %)	5 (12.5 %)	14 (16.7 %)	
4: Very satisfied	27 (61.4 %)	24 (60.0 %)	51 (60.7 %)	
Satisfaction with outcome (0-100)	75 (10-100)	81 (41-100)	81 (10-100)	0.555
Satisfaction with information (0-100)	67 (41-100)	77 (55-100)	72 (41-100)	0.108
Satisfaction with surgeon (0-100)	96.5 (26-100)	100 (63-100)	100 (26-100)	0.753
Satisfaction with medical team (0-100)	100 (45-100)	100 (41-100)	100 (41-100)	0.352
Satisfaction with office staff (0-100)	100 (0-100)	100 (59-100)	100 (0-100)	0.459

[a]Categorical (1-4) variables are described with n, (%) and 0-100 scores with mean (min-max).

surgery to create normative data.[15] When comparing our data with Mundy et al, higher BREAST-Q scores regarding satisfaction with breasts, psychosocial well-being, sexual well-being, and even physical well-being were found in our study. The literature suggests that physical well-being can be lower after breast-augmentation surgery due to the pain or discomfort caused by the implants, though this was not the case in our study.[16]

Duteille et al described long-term safety data employing Eurosilicone's round and anatomical silicone gel breast implants; overall, their revision rate was 2.78% at 5 years and 11.9% at 10 years after primary augmentation.[2,3] Other studies, looking at different kinds of implants, suggested a revision rate of 19% after a mean follow-up of 3 years.[17] Our study showed a total revision rate of just 29.8% after 15 to 19 years, evidently significantly higher but not extreme

Table 4. Indications for Revision Surgery Employing the DBIR Replacement/Removal Indications

Indications for revision surgery	Dual-plane (n = 44)	Subglandular (n = 40)	Total (n = 84)	*P* (χ^2)
No revision surgery[a]	33 (75.0)	26 (65)	59 (70.2)	0.317
Revision surgery[a]	11 (25.0)	14 (35)	25 (29.8)	
Status of implants at follow-up, no.				
Original implants in situ	33	26	59	0.142
Same implants re-implanted	3	0	3	
New implants	7	13	20	
Explantation of implants	1	1	2	
Indications for revision surgery with reimplantation of same implants, no.				
Seroma/hematoma	2	1	3	0.614
Capsular contracture	3	0	3	0.093
Indications for revision surgery with implantation of new implants, no.				
Antiquity of implants	3	7	10	0.131
Capsular contracture	1	0	1	0.337
Implant rupture	0	2	2	0.133
Newly diagnosed breast cancer	0	2	2	0.133
Auto-immune syndrome induced by adjuvants	1	0	1	0.337
Patient dissatisfied with volume	1	2	3	0.501
Seroma/hematoma	0	0	0	NA
Silicone extravasation	0	0	0	NA
Device deflation/malposition	0	0	0	NA
Skin scarring problems	0	0	0	NA
Skin necrosis	0	0	0	NA
Deep wound infections	0	0	0	NA
BIA-ALCL	0	0	0	NA
Breast pain	0	0	0	NA
Asymmetry	0	0	0	NA
Other	0	0	0	NA

BIA-ALCL, breast implant–associated anaplastic large cell lymphoma; DBIR, Dutch Breast Implant Registry. [a]Variables are described with no. (%).

when considering a follow-up of 15 to 19 years. Until now, there are no publications, to our knowledge, describing such a long-term follow-up with a single type of breast implant.

The literature suggests that subpectoral placement of implants will result in a more natural appearance due to better coverage, less wrinkling, and supposedly less capsular contracture.[18,19] In contrast, patients having glandular ptosis probably benefit more from subglandular-placed implants by the possibility of expanding the deflated breast skin envelope without anatomical restrictions of the pectoralis muscle.[20] One of the very few studies analyzing and comparing the long-term revision rate of subglandular- vs subpectoral-placed implants is from Codner et al in

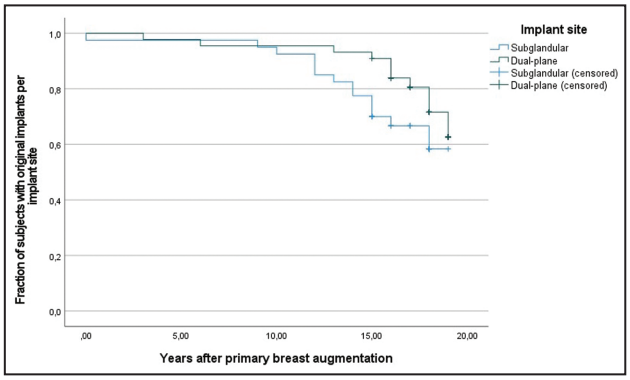

Figure 2. Kaplan-Meijer cumulative incidence of revision surgery with new implants specified for implant location.

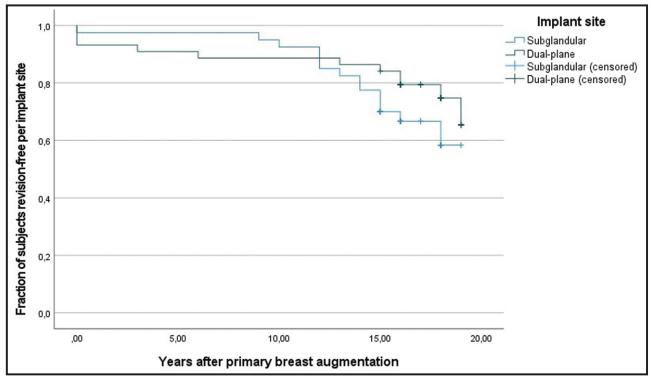

Figure 3. Kaplan-Meijer cumulative incidence of all revision surgeries specified for implant location.

2011.[21] They found an average revision rate of 21% in their study analyzing 812 patients with a follow-up of 6 years and confirmed that less wrinkling occurred in subpectoral placement, though no difference was found regarding capsular contracture. However, all these breast augmentations were performed by several plastic surgeons and had different incision locations, implant filling, implant trades, shapes, and surface textures.

The difference in BMI in our study between the dual-plane and subglandular groups may not be a surprise, because plastic surgeons preferably place implants (partially) submuscular if there is less coverage in the form of fatty and/or glandular tissue.[22] Lower BMI equals less fatty tissue and less coverage, so it is more likely the decision was made to place the implants submuscular in these patients. In the preoperative decision-making process of deciding whether implantation will be dual-plane or subglandular, tissue coverage is one of the greatest factors for the plastic surgeon to make this decision. Submuscular placement is preferable if tissue coverage is <2 cm.[23] The difference in BMI between revision and non-revision could be a reason to assume that higher BMI equals higher odds for revision surgery for all patients undergoing breast augmentation. Studies show that obesity increases the chances for complications.[24] Our study included no patients with obesity at baseline, the highest BMI being 25.18 kg/m^2. This could indicate that even with a high-normal BMI value, the chance of complications is higher.

In addition, the significant difference of implant volume within the revision surgery group can be explained by the fact that if patients desire larger implants, at some point the implant cannot easily fit in the pocket under the pectoralis muscle. These patients have the option for subglandular placement, given the condition that they have enough tissue coverage, of course. Knowing there is no significant difference in implant volume of all patients between dual-plane and subglandular groups and there is a significant difference between those groups within the revision surgeries might suggest a causality between implant volume and higher odds for revision surgery in the subglandular group.

Fischer et al demonstrated that active smoking greatly increases the chance of complications in tissue expander breast surgery ($P < 0.0001$).[25] This finding could not be confirmed with the results in our study, because no significant difference was found between revision surgery and non-revision surgery groups for smoking ($P = 0.699$).

Studies have shown that subglandular implantation makes it more difficult to breastfeed post augmentation.[26] In our study, we found no difference in breastfeeding between the 2 groups ($P = 0.137$). Within the revision group, there was also no significant difference in breastfeeding between groups ($P = 0.147$). Comparing revision vs non-revision also showed no significant difference for breastfeeding ($P = 0.862$).

When looking at revision vs non-revision groups, a difference was found in BMI, as stated before, patient satisfaction with the outcome of the surgery ($P = 0.034$), visibility of the implants ($P = 0.023$), and palpability of the implants ($P = 0.019$). Patients with revision surgery are clearly less content with the outcome. The significant difference in visibility and palpability of the implants might be an indicator that, although not always the reason for revision surgery, there is a higher grade of capsular contracture in the revision group. After all, Baker II and higher capsular contracture include palpability of the implant, and Baker III and IV capsular contracture include visibility of the implant.[27]

To determine and analyze the cumulative incidence of revision surgery with or without implantation of new implants, a Kaplan-Meijer analysis was performed. Survival of the implants is approximately the same until 10 years postsurgery as shown in Figure 2. After that period, dual-plane surgery shows a tendency, although not significant ($P = 0.097$), of higher survival of the same implants. Figure 3 shows an intersection of dual-plane and subglandular lines for all revision surgeries. This might indicate a possible better outcome for subglandular placement in early stages (approximately the

first 10-12 years postsurgery) and better outcomes for dual-plane placement after a significantly longer period of time. Possibly, in a larger study, this difference can be explained by a higher early revision rate due to the incision of the muscle when implanting submuscular (dual-plane). This might cause higher hematoma rates, for example, as shown by Yang et al, where more hematomas occurred in subpectoral implantation than prepectoral implantation ($P = 0.038$).[28]

It should be noted that no cases of breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) were noticed in our study with relatively small numbers of patients. The latest figures from the FDA show that 68% of all reported BIA-ALCL cases are from textured breast implants.[29] We realize that the registration of the reasons for revision surgery is largely based on what the included patients have reported, and therefore we cannot guarantee that no BIA-ALCL case has ever occurred in all contacted patients.

Limitations

Retrospective analysis is inherent in this very long-term, single-center, single-surgeon's follow-up study but is by nature not as strong as a prospective study design. Only 84 of the 209 patients could be included, which is still a lot concerning the time of follow-up (15-19 years) but might have resulted in underpower of the analyzes. Selection bias might also have occurred because "satisfied' patients with no or few revision surgeries seem to be more inclined to fill out the questionnaire.

In this study, only 4/84 patients had capsular contracture Baker grade 3 or higher (4.8%), whereas 10-year safety data for Eurosilicone even report an incidence of 13.1% for patients who underwent primary breast augmentation surgery.[3] This might either confirm selection bias or simply indicate the single surgeon's specific experience.

Strengths

This is significantly one of the longest follow-up studies (average follow-up, 17.03 years; range, 15-19 years) regarding breast augmentation in a single-center, single-surgeon setting employing round micro-textured Eurosilicone Cristalline Paragel breast implants in a dual-plane or a subglandular location.

CONCLUSIONS

This study showed high patient satisfaction rates and relatively low revision rates after 15 to 19 years of follow-up (average, 17.03 years) of round micro-textured Eurosilicone Cristalline Paragel breast implants in a single-surgeon experience. No clinically important significant differences were found between dual-plane and subglandular placement of implants. Analyses of larger series of dual-plane vs subglandular breast augmentation might elucidate differences that we could not find.

Supplemental Material

This article contains supplemental material located online at www.aestheticsurgeryjournal.com.

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