



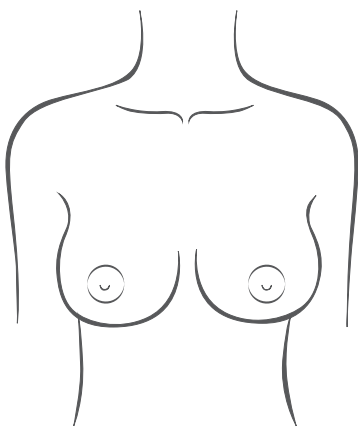
Extended long-term data published for Round Collection™ breast implants

High patient satisfaction rates and relatively low revision rates after 15 to 19 years of follow-up

Kooiman et al. 2021

Introduction

Breast augmentation is the most popular and frequently performed aesthetic procedure with a long and successful record of satisfying women who wish to enhance, regain or restore balance to their figures¹.



It has been shown that over time the cumulative risk of capsular contracture increases so a significant longer-term evaluation study definitely **adds important data to literature**².

In this study, the authors investigated **extended long-term safety**, patient satisfaction and revision rates in patients who had primary augmentation with the Round Collection™ breast implants by GC Aesthetics®.

Key findings of the study:

- ✓ Average 17 years follow-up. Extended long-term data available for breast implants.
- ✓ This study showed high patient satisfaction rates and low revision rates.
- ✓ High satisfaction rates were found, with BREAST-Q scores in the range of 67% to 100%.
- ✓ A significant difference between dual-plane and subglandular groups was found in psychosocial well being in favour of the dual plane group.
- ✓ No clinically significant differences were found between dual-plane and subglandular placement of implants.
- ✓ No cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) were found in the study as an indication for revision surgery.

Publication Objective

This study was undertaken to evaluate the long-term (average follow-up 17 years) results of Round Collection™ breast implants from a single centre, single surgeon experience, regarding both patient-reported outcome measures as well as revisions.

Main goals:

1. Patient Satisfaction



2. Revision Rates



Capsular Contracture
(Grade III or IV only on the Baker Scale)



Rupture



Re-Intervention



Other Complications

About Round Collection™:



Round Collection™

Main Features:

- Round Cristalline™ Micro-Texture Silicone Breast Implant³.
- ParaGel™: highly cohesive, medical grade gel, provides controlled gel distribution³:
 - Natural Cohesive Gel** | 4 projections with 73 variations
 - Soft Cohesive Gel** | 4 projections with 80 variations
- ParaGelGard™ 360° Barrier Layer minimises gel diffusion and coverage and also present at the product patch, completely covering the implant³.
- Supported by 10-year follow up safety and performance clinical study⁴.

Study Methodology:

- A retrospective cohort study was undertaken of 84 patients who underwent primary breast augmentation with Round Collection™ by GC Aesthetics®
- BREAST-Q questionnaire was used to analyze patient satisfaction.
- Implants were placed subglandularly or dual-plane through inframammary incision
- Single surgeon and single center with a minimum follow-up of 15 years.
- All surgeries were performed between January 2001 and December 2004.
- Long follow-up study: Range 15-19 years.



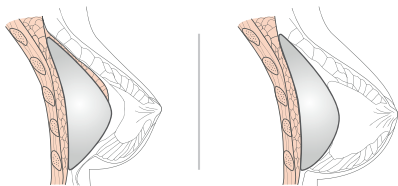
84 patients
Primary augmentation

44 Dual-plane | **40** Subglandular



Single hospital

Surgeries performed between
January 2001-December 2004



Dual-plane | Subglandular

Implants placed:
Dual-plane | Subglandular



Round Collection™
was implanted to all patients

Shape: Round | **Surface:** Micro-textured (Cristalline ParaGel™)



Long follow-up study

Average: 17.03 years | **Range:** (15-19 years)



Breast-Q

Measures what matter
to patients

Conclusion

This study (Kooiman et al. 2021) is one of the longest follow-up studies (average follow-up 17.03 years; range 15-19 years) regarding breast augmentation, in a single centre, single surgeon setting, using Round Collection™ breast implants by GC Aesthetics® in a dual-plane or a subglandular location.



Extended long-term follow-up study

Results show low revision rates and high patient satisfaction rates.

BREAST-Q Scores:

Quality of Life Results

Physical
well-being
score of

100 / 100

Psychosocial
well-being
score of

74 / 100

Sexual
well-being
score of

67 / 100

Satisfaction Results

Satisfaction
with breasts
score of

71 / 100

Satisfaction
with outcome
score of

81 / 100

Satisfaction
with care
score of

100 / 100



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References:

1. American Society of Aesthetic Plastic Surgeons (ASAPS) – Breast Augmentation Surgery.
2. Kooiman L, Torensma B, Stevens H, van der Lei B. Single Center and Surgeon's Long-Term (15-19 Years) Patient Satisfaction and Revision Rate of Round Textured Eurosilicone Breast Implants [published online ahead of print, 2021 Oct 22]. *Aesthet Surg J.* 2021;sjab373. doi:10.1093/asj/sjab373
3. Data on file, GC Aesthetics®, 2021.
4. Duteille F, et al. Ten-Year Safety Data for Eurosilicone's Round and Anatomical Silicone Gel Breast Implants. *Aesthet Surg J Open Forum.* 2019;1(2):ojz012. Published 2019 Apr 27. doi:10.1093/asjof/ojz012