



PERLE™

Clinical Studies



A Confident Choice for Life™



GC Aesthetics[®]

Total Breast Care[™] Company

GC Aesthetics[®] is an established global medical device company focused on Aesthetic, Revision and Reconstruction procedures.

Much more than a European manufacturer of high-quality implants, we are proud to support our surgeons and patients by integrating and developing solutions that are designed to support the best outcome for women's breast enhancement journey.

+40

Years of expertise
in Aesthetic and
Reconstructive
surgery¹

+70

Countries
world-wide with
GCA[®] Products²

MDR

First breast implant
on the market under
the latest
regulations
(Luna XT[™])³

10Y

Prospective and
multicentric long-
term proven safety
data⁴

17Y

Extended long-term
high patient
satisfaction data⁵

100%

Designed and
manufactured
in Europe¹

About PERLE[™]

GCA's novel Round Breast Implant with (R)evolutionary BioQ[™]-Surface technology and highly cohesive Emunomic[™] Breast Tissue Dynamic Gel



A new smooth opaque surface implant with positive skewness and kurtosis values¹ that completes GCA's portfolio.

Main features:

- Round Smooth Opaque Silicone Breast Implant¹.
- (R)evolutionary BioQ[™]-Surface designed with reverse technology for optimal harmonisation with the tissue¹.
- Dynamic Emunomic[™] Gel: 6th Generation Gel, highly cohesive it provides projection, fullness and firmness¹.
- The implant is 100% gel-filled¹.
- Enhanced GCA[®] Ultra-link shell: Optimum cross-linking in our proprietary formula for a resistant yet soft shell¹.
- Advanced RRE[™] Patch: Extremely elastic patch/shell interface properties¹.
- Versatile range of sizes and profiles¹.





“I performed this study to examine the safety of PERLE™ implants. We introduced these implants into my clinic, La Belle Forme in Glasgow, at the beginning of 2021 when I heard about the science behind them. Every empirical aspect of the implant fitted in with my idea of high quality and I wanted to test this. We followed up 374 patients, with PERLE™ implants, over an average of 18 months. Our study showed that the safety profile of these implants is comparable with other modern implants with no implant related complications and no cases of capsular contracture.”

Mr. Taimur Shoaib

MBChB, FRCSEd, DMI (RCSEd), MD, FRCS (Plast). UK.

Single-Institution Early Experience With a New, Smooth, Opaque and Round Breast Implant Over a 2-Year Period

Proven safety and performance of PERLE™

Introduction

This study performed an analysis of 2 years' experience of patient data with PERLE™ implants to evaluate the early experience of this product in patients undergoing aesthetic breast surgery.

Publication Objective

This study was undertaken to evaluate the preliminary results of a new round smooth opaque breast implant (PERLE™) from a single-institution, two centres in the UK.

Target & Main goals:

Patient Profile:



1. Primary breast augmentation
2. Secondary breast augmentation
3. Augmentation Mastopexy

Retrospective outcome data analysis:



Capsular Contracture



Infection



Revision surgery



BIA-ALCL



Other complications
(malposition, bottoming out, etc)

Zhi Yang Ng, Calum Honeyman, Taimur Shoaib, Single-Institution Early Experience With a New, Smooth, Opaque, and Round Breast Implant Over a 2-Year Period, Aesthetic Surgery Journal Open Forum, Volume 5, 2023, ojad090, <https://doi.org/10.1093/asjof/ojad090>



Study Methodology

- Multiple surgeons, single-institution, two centres in the UK.
- Conducted over two years between January 2021 and December 2022.
- 374 patients had PERLE™ implants.
- Primary and secondary breast augmentation, and augmentation mastopexy.
- Bilateral and unilateral procedures.
- Implants were placed subglandular/subfascial or dual-plane.



Single-Institution
Two centres in the UK

Surgeries performed between
January 2021-December 2022






PERLE™
was implanted to all patients

Shape:
Round

Surface:
BioQ™-Surface (Smooth Opaque, 5µm)



374 patients
Primary and secondary breast augmentation,
and Augmentation mastopexy

-  **290** Primary breast augmentation
-  **21** Secondary breast augmentation
-  **63** Augmentation mastopexy



Early experience study

Average age:
32 years
(19 – 62 years)

Mean follow up:
18 months
(6 – 30 months)

Results

This study shows low complications rates when using PERLE™ implants, showcasing:

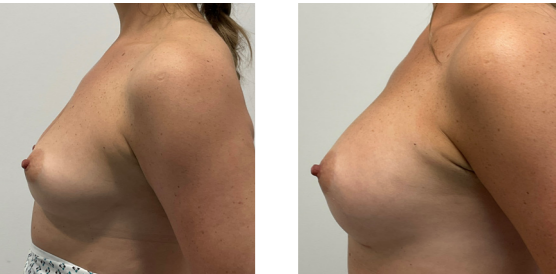


* Revision surgery included: scar revision, lower pole stretch, implant displacement, hematoma, infection and dissatisfaction of final size.

Before and after pictures courtesy of Mr. Taimur Shoaib:

Subglandular augmentation

PERLE SOR-MR 280



Before After

Augmentation mastopexy

PERLE SOR-MR 340



Before After

Subglandular augmentation

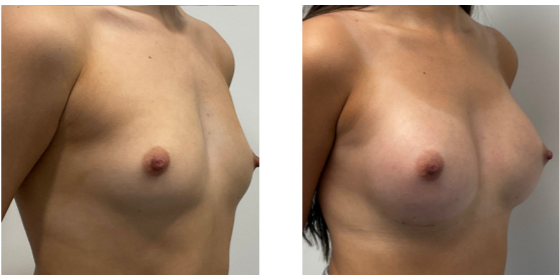
SOR-MR 340



Before After

Subglandular augmentation

PERLE SOR-MR 280



Before After

Conclusions

The authors' early, single-center experience with PERLE™implants suggests a safety profile and overall complication rate that is comparable with other modern implants. They will continue to monitor the safety and effectiveness of PERLE™ and discuss the reasons and evolution in the choice of breast implant.

Single-Institution Early Experience With a New, Smooth, Opaque and Round Breast Implant Over a 2-Year Period
Proven safety and performance of PERLE™

Led by Mr. Taimur Shoaib, MBChB, FRCSEd, DMI (RCSEd), MD, FRCS (Plast). UK



Scan to read the original study



*"I am really satisfied with the results I obtain with PERLE™.
The softness of the gel associated with HydroCone™
helped me to reduce the size of the incision of 1cm."*

Dr. Jauffret

Plastic surgeon in private practice, Marseille, France.

2 Year Follow-up Results for Breast Surgery With PERLE™ Breast Implants

A Multicentric and Retrospective Clinical Study

Introduction

For breast surgery, there are a number of implants available that offer different options, such as shape, surface characteristics, gel fillers, and size/profile to meet the diverse needs of the patient population. Each implant option has its own advantages and disadvantages, and the individual patient's needs should be taken into account when making choices.

Publication Objective

This study was undertaken to conduct an assessment of the safety, performance, and satisfaction rates through a 2-year follow-up study for the PERLE™ mammary implant.

Target & Main goals:

Patient Profile:



1. Primary Breast Augmentation
2. Medical Reason
3. Revision Surgery

Retrospective outcome data analysis:



**Capsular
Contracture**



Asymetry



**Implant
displacement**



Seroma



**Other
complications**
(malposition,
bottoming out, etc)

Jauffret JL. A Multicentric and Retrospective Clinical Study: 2 Year Follow-up Results for Breast Surgery With Perle Smooth Opaque Silicone Breast Implants. Aesthet Surg J Open Forum. 2024;6:ojae029. Published 2024 Apr 24. doi:10.1093/asjof/ojae029

Study Methodology

- A retrospective, observational, multicenter, noncomparative study.
- Conducted over 2 years between October 2020 and June 2021.
- 97 patients aged between 18 and 65 years had PERLE™ implants.
- Patients were indicated for the surgery for medical or cosmetic reasons and for revision surgery.
- Collection of data took place in 5 centers across France and Italy.



Multicentric study
5 centers across France and Italy

**Retrospective, observational,
multicentric and noncomparative**
Conducted from March 2023 to June 2023



97 patients
had bilateral surgery

France: 41 patients
Italy: 56 patients



PERLE™
was implanted to all patients

Shape:
Round

Surface:
BioQ™-Surface (Smooth Opaque, 5µm)



Results for Breast Surgery

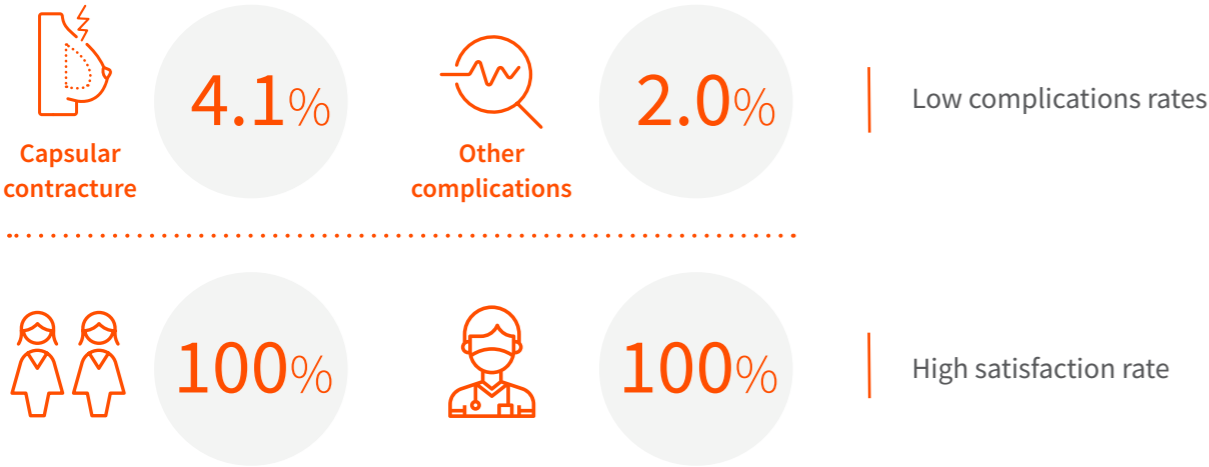
Average age:
33 years
(17 – 60 years)

Mean follow up:
26 months
(21-32 months)

Results

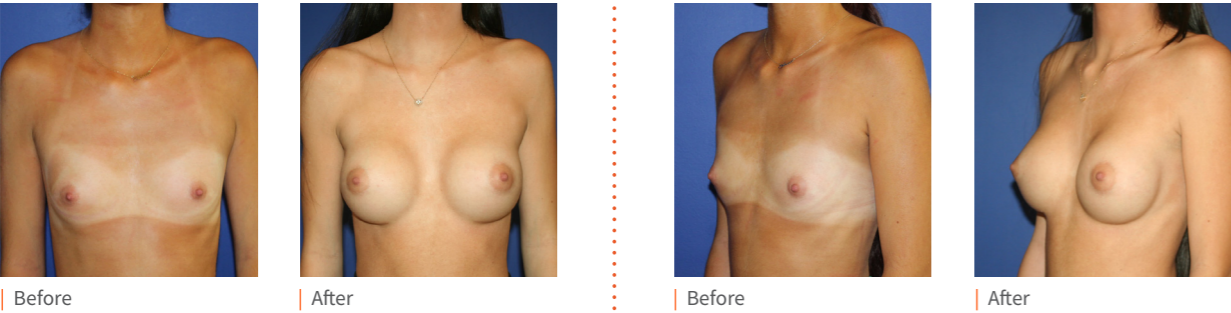
This study highlights the low complication rates and high patient satisfaction associated with PERLE™ breast implants. A total of 191 implants were used in 97 patients, with 34% of cases performed for augmentation or cosmetic purposes and 66% for reconstruction or revision surgeries. Patients with comorbidities linked cancer treatments were included in the reconstruction cohort. The key findings highlight:

Selected complications:



Before and after pictures courtesy of Dr. Jauffret:

1 year Post Surgery, 3cm under breast scar thanks to HydroCone™ retropectoral position.
SOR HR 300



Conclusions

This multicentric study showed that PERLE™ breast implants demonstrated promise with favorable outcomes and consistent complication rates. The observed safety and performance over a 2-year period suggest that this type of implant addresses current challenges and meets the needs of both patients and surgeons, as indicated by satisfaction results. The implant has a good risk/benefit balance with complication rates comprised between those expected for traditional smooth implants and textured implants.

2 Year Follow-up Results for Breast Surgery With PERLE™ Breast Implants

A Multicentric and Retrospective Clinical Study

Led by Dr. Jauffret. Plastic surgeon in private practice, Marseille, France.



Scan to read
the original study



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References:

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5. 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. Aesthet Surg J. 2022;42(5):NP282-NP292.