

The National Breast Implant Registry Annual Report 2020



The data contained in this report was captured during the NBIR Phase II Pilot and the first two years of registry operations (November 2017 – September 30, 2020).

Allergan Aesthetics
an AbbVie company



sientra.



This publication was produced by the National Breast Implant Registry (NBIR).

Any inquiries or comments regarding this publication should be directed to:

National Breast Implant Registry
Attn: Katie Sommers, Director of
Research and Scientific Affairs
444 East Algonquin Road
Arlington Heights IL 60005
ksommers@plasticsurgery.org

During the second year of registry operations, support was provided by The Plastic Surgery Foundation, Allergan Aesthetics, Mentor Worldwide LLC and Sientra.

Data published in this report is copyright protected and may not be published or used without permission.

Thank You!

The National Breast Implant Registry (NBIR) Steering Committee has played a crucial role in the development, launch, and growth of the NBIR. We would like to thank all NBIR Steering Committee representatives for their time, effort, and participation in this very important initiative.

NBIR STEERING COMMITTEE REPRESENTATIVES (OCTOBER 1, 2019–SEPTEMBER 30, 2020):

*Andrea Pusic, MD (Co-Chair) | **The PSF***

*Kelly Carty | **Allergan Aesthetics***

*Myles Cockburn, PhD | **Epidemiologist***

*Megan Estes | **Mentor***

*JoAnn Kuhne | **Sientra***

Charles Verheyden, MD, PhD (Co-Chair)

*Danica Marinac-Dabic, MD | **FDA***

*Colleen McCarthy, MD, MS | **ASPS/PSF***

*Jennifer Walcott | **Mentor***

*Sung Yoon, MD | **FDA***

Table of Contents

LETTER FROM THE CHAIRS	5
BACKGROUND	6
REGISTRY PARTICIPATION	9
REGISTRY FINDINGS	12
Clinical Demographics.....	12
Patient Medical History.....	14
Procedure Information.....	16
Device Information.....	21
Reoperations	23
FUTURE DIRECTIONS	27

Letter From the Chairs

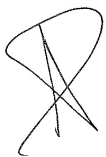
We are very excited to present the second Annual Report of The Plastic Surgery Foundation's (PSF) National Breast Implant Registry (NBIR). The NBIR is a collaborative effort between The PSF, the United States Food and Drug Administration (FDA), patients and breast implant manufacturers to strengthen the post-market surveillance infrastructure for current and future breast implants in the United States. This report includes data submitted to the NBIR during Phase II of our NBIR Pilot (November 2017 – May 2018), as well as the first two years of registry operations (October 3, 2018 – September 30, 2020). During this timeframe, the NBIR captured data on over 15,500 breast implant procedures reported by physicians across the United States.

This report includes a detailed summary of patient demographic, risk/co-morbidity, procedural, and complication/adverse event data related to breast implants. The PSF continues to work with surgeons, patients, the FDA, breast implant manufacturers and other stakeholders to effectively utilize this data in strengthening national quality surveillance efforts.

Our greatest achievement during this second year of registry operations was the tremendous growth we saw in registry participation and case collection, especially during these unprecedented times of COVID-19. We saw an increase of more than 12,000 cases entered and over 300 new users were enrolled, all demonstrating the commitment of plastic surgeons to patient safety. We look forward to this continued growth and continued innovation of the registry.

We hope this report will not only serve as a guide to current progress, but also as a call for future participants to join this national quality improvement effort. We look forward to continuing to evolve the NBIR to further benefit patients and physicians.

Sincerely,



Andrea L. Pusic, MD
Co-Chair
NBIR Steering Committee



Charles N. Verheyden, MD, PhD
Co-Chair
NBIR Steering Committee

Background

Registries are a powerful means to understand real-world patient outcomes and identify safety signals through systematic data collection and ongoing surveillance. Registries are particularly important for learning more about the safety of breast implants because the majority of these devices are placed for cosmetic reasons in healthy women who may not be seen regularly by a physician. The time between when the implant is placed and the development of an adverse event may be many years, further complicating efforts to collect accurate implant data. According to the American Society of Plastic Surgeons (ASPS) 2019 Procedural Statistics Report, over 400,000 breast implant procedures are performed annually in the United States. Due to this volume of breast implant procedures, there is a need to further study these devices to ensure patient safety.

The ASPS and The PSF are committed to patient safety. Through the Plastic Surgery Registries Network (PSRN), ASPS/PSF have been fully invested in clinical data registries for over 20 years. The PSRN provides value to participants by allowing benchmarking of personal performance to the registry aggregate, by demonstrating pathways to improved satisfaction of their patients, and by decreased complications. Data from registries can also be used to inform clinical practice guideline and performance measure development.

The NBIR is a prospective, non-interventional, population-based, outcomes and safety surveillance registry and quality improvement initiative that collects clinical, procedural and outcomes data at the time of an implant operation and any subsequent reoperations (requiring implant removal or exchange) for all patients receiving breast implants in the United States. The NBIR, a collaboration that The PSF started with the FDA and the breast implant manufacturers in 2012, also provides an infrastructure for device manufacturers to facilitate the post-implant component of their device tracking data collection.

Registry Design

The NBIR is an all-comers, opt-out registry for both reconstructive and cosmetic procedures involving breast implants. The registry collects patient demographic, risk/co-morbidity, procedural, and complication/adverse event data related to breast implants. Data is entered into the NBIR at the time of implant placement and at the time of reoperation. The NBIR is designed to link a reoperation case to the initial implant procedure using minimal patient identifiable information. Collecting this information at these two timepoints, across reporting physicians, allows for a better understanding of the frequency and reasons for reoperation.

The NBIR case report form (CRF) includes data fields required for device tracking, a federal mandate for breast implant manufacturers. As of July 1, 2019, the NBIR launched the technology which allows the NBIR to serve as an infrastructure for the breast implant manufacturers to collect their device tracking data. This allows NBIR participants to simultaneously register their implants with the manufacturers while also submitting their data to the registry.

Data Collection Model

Data is collected by physicians or their designated staff and entered directly into the NBIR web portal via manual data entry and the use of a mobile barcode scanning application.

The following data elements are entered manually:

- Physician/Reporter Information
- Patient Information
- Procedure Information
- Explanted Device Information
- Reasons for Reoperation

It is important to note that the data pertaining to the physician/reporter is populated automatically by the NBIR, since this data was previously entered by the physician during their NBIR registration; however, the data that was automatically populated can be edited if needed. The data pertaining to the implanted device is electronically captured using the NBIR mobile barcode scanning application, a HIPAA-compliant app available for all Apple and Android devices. The app connects to the FDA's Global Unique Device Identifier Database (GUDID), allowing it to scan and decode the Unique Device Identifier (UDI) barcode/QR code for all breast implants and push this data to the NBIR CRF. This technology was implemented to allow for more accurate and complete data entry. It also allows for physicians to enter their device information right from the operating room.

Governance

The NBIR Steering Committee is the governing body that oversees all registry operations including the successful implementation, monitoring and management of resources and activities. The Steering Committee is responsible for:

- Development and implementation of the strategic goals of the NBIR
- Establishing and prioritizing the objectives and goals of the NBIR
- Providing input into NBIR operations and processes
- Providing strategic direction for the NBIR
- Monitoring quality improvement, research and other clinical objectives
- Reviewing recommendations for data analysis that come from the Data Access and Publications Committee (DAPC).

Data Access and Publications Committee

The DAPC is responsible for overseeing all activities related to data reporting, research and publications on aggregate NBIR data and will address issues of access to NBIR data for analysis and potential research.

The DAPC is comprised of three representatives from The PSF, one representative from each breast implant manufacturer sponsoring the NBIR, and one epidemiologist/statistician/health services researcher.

Registry Participation

Although only in its second full year of data collection, there has been an overwhelming growth in registration from surgeons across a wide variety of practice types and locations. Of the 818 total sites registered for the NBIR, 56% of the participants were in solo practice [Fig. 1]. This was followed by private groups, multi-specialty groups and academic practices at 23%, 10%, and 9% respectively [Fig. 1]. Figure 2 displays a gradient of registration rates across each state in the U.S. California leads NBIR registration with 125 sites. Similarly, other densely populated states such as Texas, Florida, New York, and Michigan produced the highest numbers of registrants for the NBIR. This data mirrors the practice patterns of ASPS' member surgeons, which represents 93% of all board-certified plastic surgeons. Figure 3 shows the case volume collected by state in the NBIR, where California again has the highest case collection totals. The rest of the Top 5 states for data collection include Florida, Texas, Arizona, and Louisiana.

While the primary boosts to 2019's registration included FDA's hearing on breast implant safety and the launch of device tracking for breast implant manufacturers, 2020 had an uphill battle with most plastic surgery practices closed for a period of time due to COVID-19. We are thrilled to report, however, that we saw exponential growth in data collection and registration for NBIR during this time, as seen below in Figures 4 and 5.

Figure 1 – NBIR Registrants by Practice Type

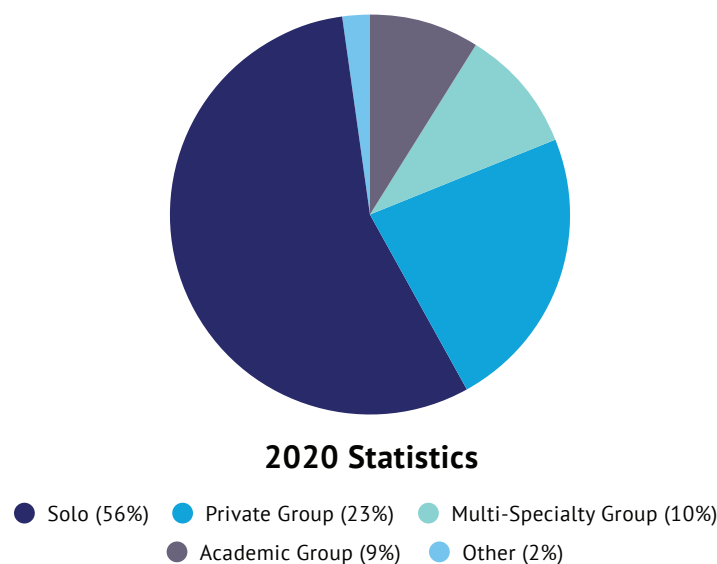


Figure 2 – Registered Sites by Geographic Location

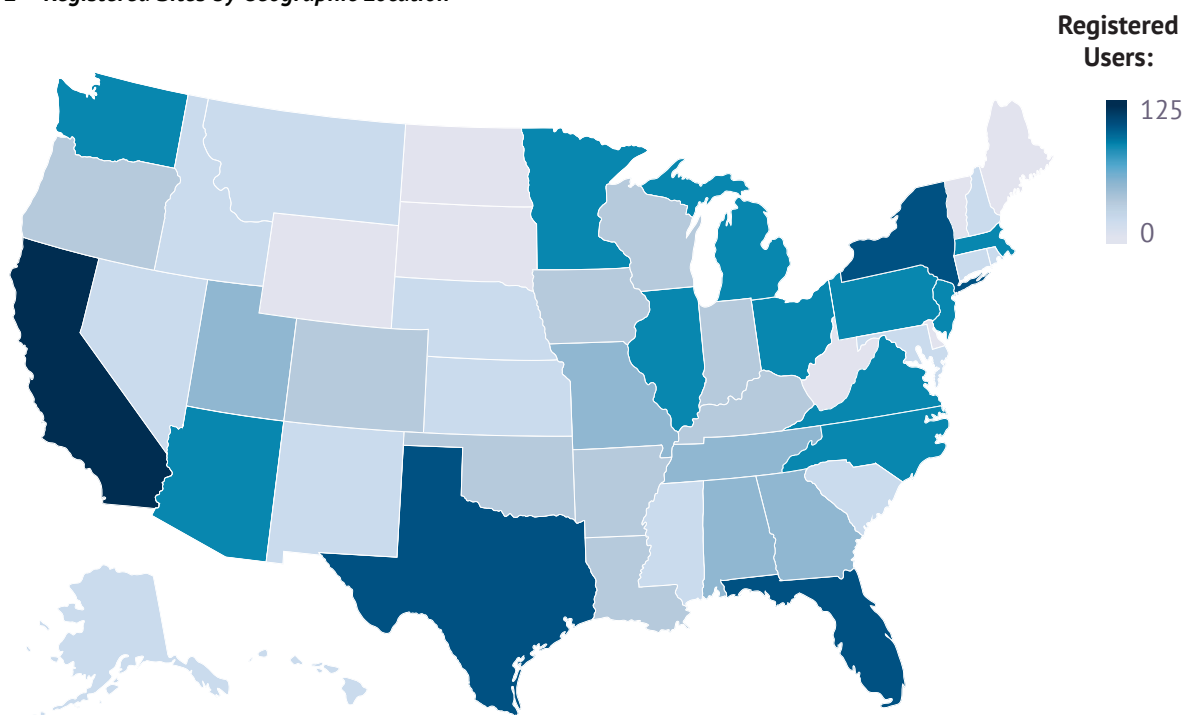


Figure 3 – Cases Entered by Geographic Location

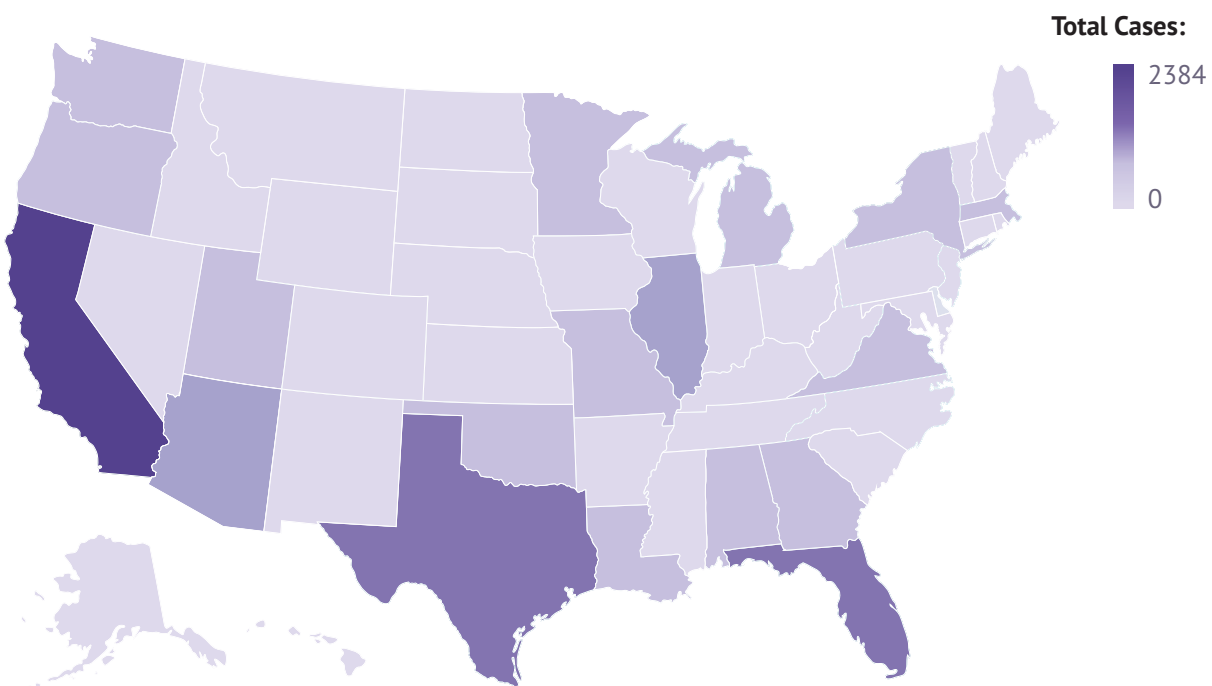


Figure 4 – NBIR Registered Participants

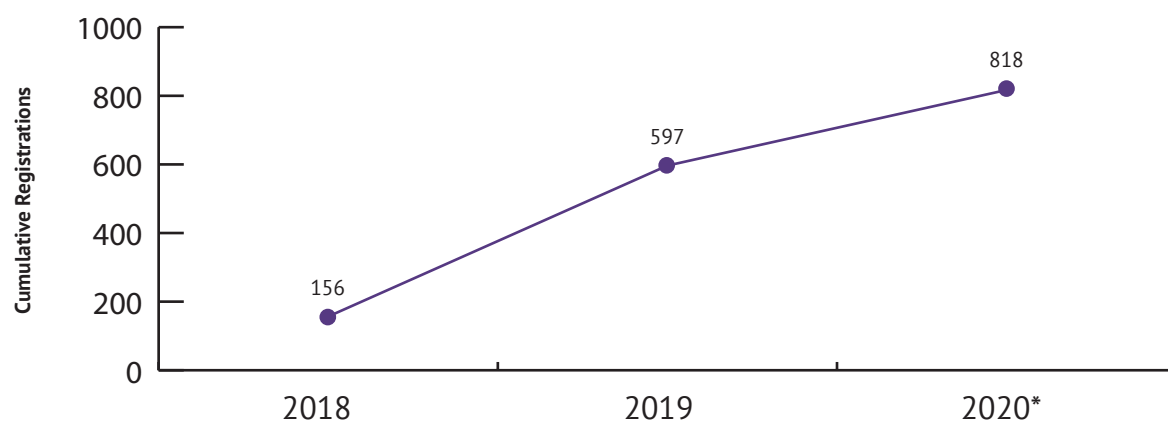
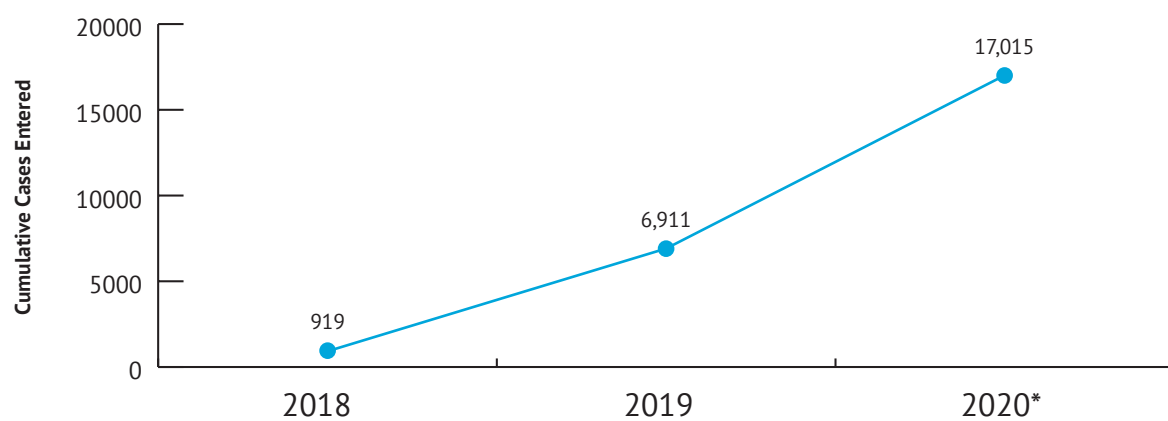


Figure 5 – NBIR Cases Entered



* Includes submitted/entered cases

Registry Findings

Clinical Demographics

The average patient age is 42 years old with a range of 16 to 86 years old. (Table 1). The median patient age was 40 years old. Aesthetic patients tended to be younger (median: 37 years old), than reconstructive patients (median: 54 years old). Figure 6 shows the age distribution of NBIR patients, indicating that reconstructive patients tended to be older than the aesthetic patients.

Of the participants with race and ethnicity reported, 91% were White/Caucasian race and 90% reported an ethnicity of non-Hispanic [Fig. 7,8]. African American and Asian patients made up 3.6% and 3.4% respectively. The majority of cases entered involved female patients (99%), and a combined 1% involved male or transgender patients [Fig. 9]. Race was only reported in 68% of patients, while ethnicity was only reported in 54% of patients. Gender was reported in 88% of patients.

Table 1 – Age of NBIR participants variables

Age (years)	NBIR		Aesthetic	Reconstructive
	Range	16-86	16-86	16-86
	Average	41.9	39.1	54
	Median	40	37	54

Figure 6 – Age Range

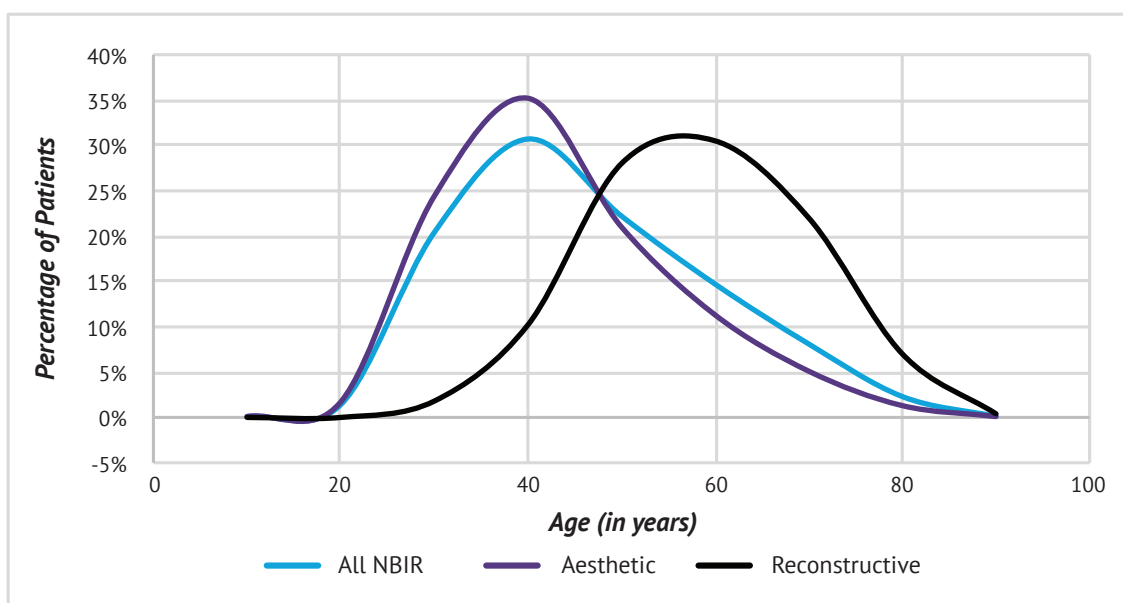
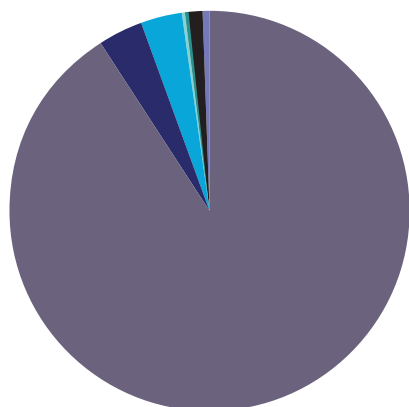


Figure 7 – Race (n=10,648)

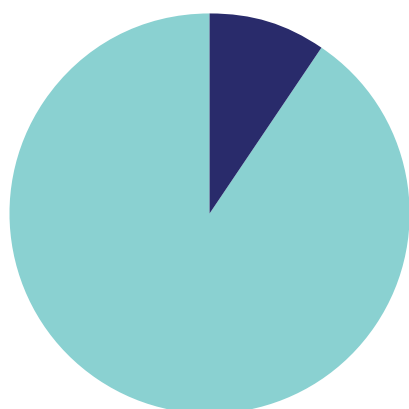


NBIR

- White/Caucasian (90.9%)
- Black or African American (3.6%)
- Asian (3.4%)
- Native Hawaiian or Other Pacific Islander (0.1%)
- American Indian or Alaska Native (0.1%)
- Multiracial (0.4%)
- Other (1.5%)

* Multiple values can be selected; not a mandatory field

Figure 8 – Ethnicity

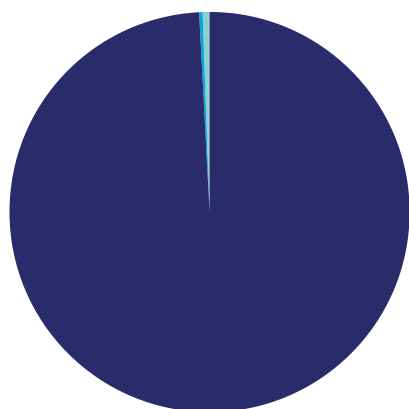


NBIR

- Non-Hispanic (90.3%)
- Hispanic (9.7%)

* Not a mandatory field

Figure 9 – Gender



NBIR

- Female (99.1%)
- Male (0.4%)
- Transgender (0.4%)

* Not a mandatory field

Patient Medical History

One of the greatest strengths of the NBIR is that it not only collects procedural information, but it also collects data on patients’ medical history. Average BMI for NBIR participants is in a “healthy” weight range (Table 2), while reconstructive patients average BMI is in the “overweight” category. Sixteen percent of total cases reported a prior diagnosis of breast cancer [Fig. 10], which is in line with last year’s report (15%). Patients often had a history of more than one medical condition. Data was analyzed to look for trends within the “other” field, and those fields have been added to this report. 2,276 patient cases (19%) reported at least one medical condition [Fig. 11]. Hypertension and thyroid issues are the most common co-morbidities for Registry patients, representing 5% and 3% of the registry population respectively (Table 3). Seven percent of participants have at least one “other” item in their medical history. Only 7% of NBIR cases are reported current smokers (Fig. 12).

Table 2 – BMI of NBIR participants

BMI	NBIR			
	Aesthetic		Reconstructive	
	Range	14.1-53.2	14.1-49.3	16.0-53.2
	Average	24.2	23.6	26.9
	Median	23.3	22.9	25.8

Figure 10 – History of Breast Cancer

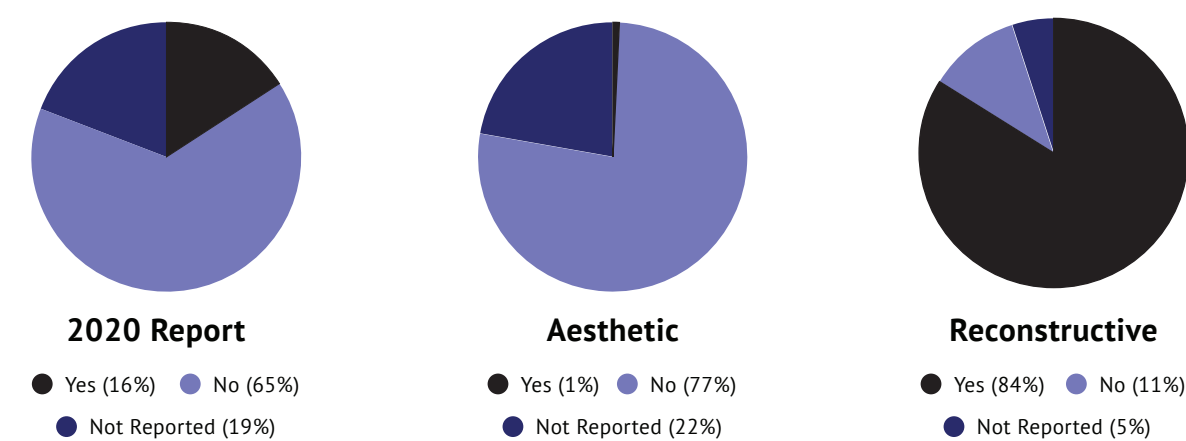


Figure 11 – Presence of Pre-existing Medical Condition

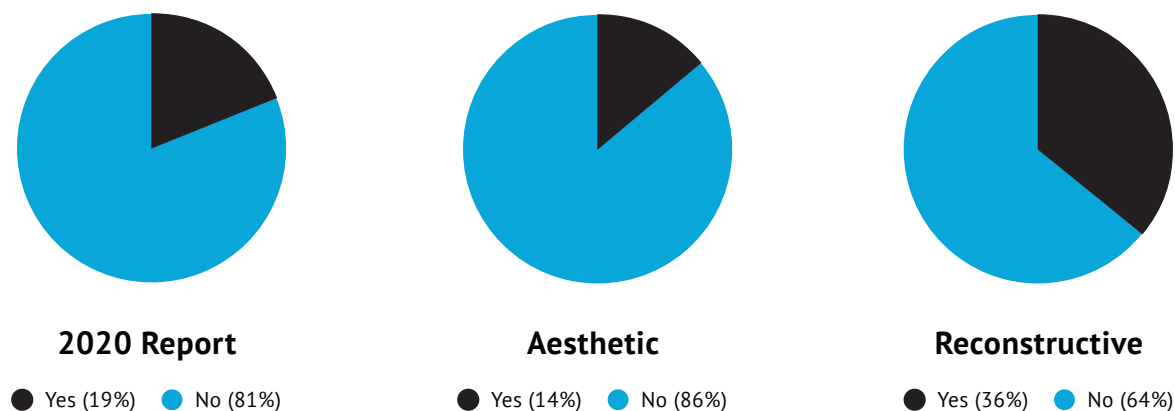
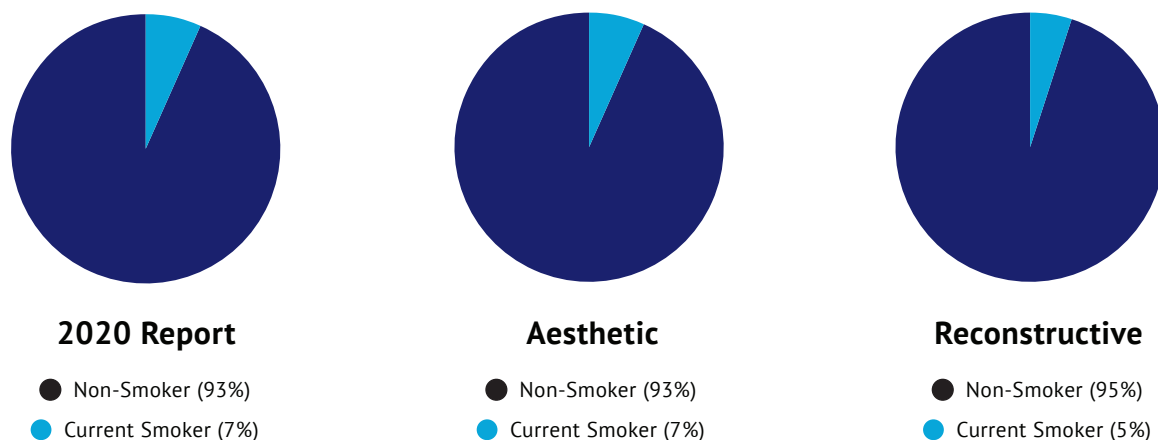


Table 3 – Medical Issues Identified

History of Medical Issues	2020 Report
ADD/ADHD	0.3%
Allergies	0.1%
Anxiety	0.9%
Arthritis	0.4%
Asthma	1.3%
BRCA+	0.1%
Cancer	1.4%
Cardiac Disease	0.8%
Depression	1.2%
Diabetes	1.2%
Fibromyalgia	0.2%
GERD/ Reflux	0.7%
Hypertension	4.5%
Lung Cancer	0.1%
Migraines	0.8%
Renal Disease	0.1%
Rheumatoid Arthritis	0.3%
Thyroid Issues, Disease, Disorder (ex. Hypothyroid)	2.2%
Other	7.9%

* User can select more than one field

Figure 12 – Smoking Status



Procedure Information

It is important to note that results for procedure information are calculated using the total number of implants documented, as opposed to the total number of cases collected, since one case often collects data on more than one device. Data provided for procedure type may appear inflated in comparison to raw case counts, but this is because these figures include the left and/or right breast for each case, since the procedure can vary by breast.

There are two main categories for procedure type reported in the NBIR: Aesthetic/Reconstruction and Operation/Reoperation. Aesthetic procedures represented 78% of all reported indications [Fig. 13]. Approximately 30% of the total procedures are reoperation cases, and 70% involved an initial operation [Fig. 14]. Of note, reconstructive procedures have a higher percentage of revision or reoperations than aesthetic procedures. Figure 15 breaks down the type of procedure. Figure 16 highlights that 62% of all procedures involve the placement of a breast implant (Implant Insertion and Expander Removal and Implant Insertion), while less than 1% of all procedures in the registry are for explanting devices without reimplantation. The most common reoperation is the implant exchange/replacement reported for 25% of all procedures.**

The NBIR gathers additional procedural information regarding drains, fat grafting, surgical mesh, and acellular dermal matrices (ADM). Figures 17-20 show less than 14% of reported procedures involved these techniques: surgical mesh (2%), fat grafting (5%), drains (14%) or ADM (6%). Drain usage is much less common in aesthetic patients than in reconstructive patients (Fig 17). This is the case for ADM usage and Fat Grafting as well (Fig 18, 20). Inframammary incisions made up 80% of incision types used, and submuscular/pectoral implant location made up 82% of implant location reports [Fig. 21, 22]. No other individual incision method or implant location exceeds 9% utilization by NBIR reporting surgeons.

*** At this early stage of the registry, most of the reoperation procedures would have been done on initial operations before the NBIR launch, even many years ago.*

Figure 13 – Procedure Indication

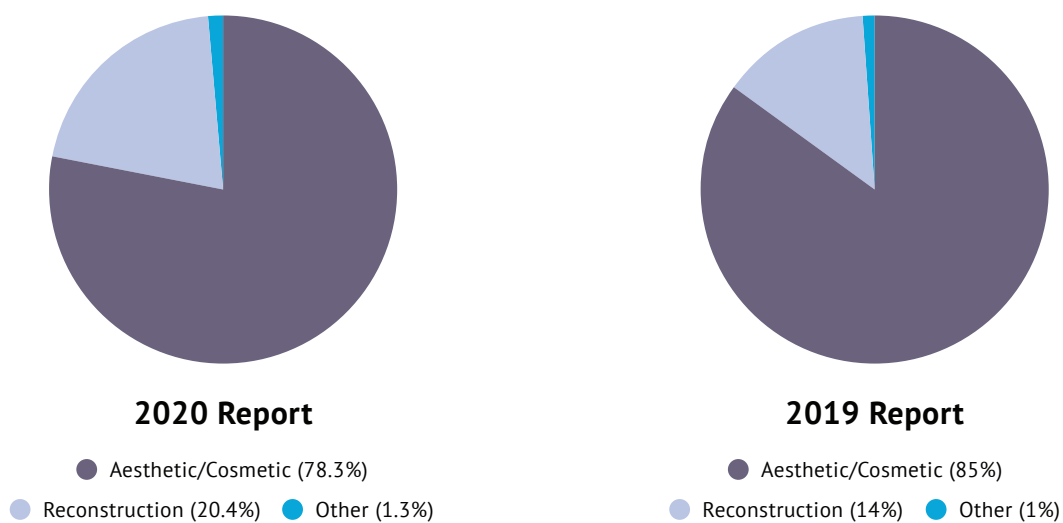


Figure 14 – Operation Indication

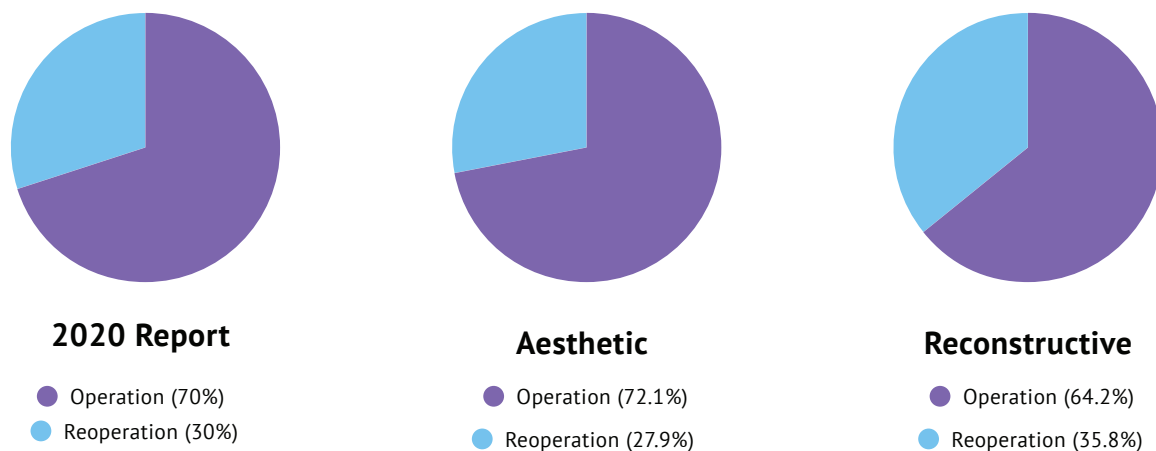


Figure 15 – Indication Type

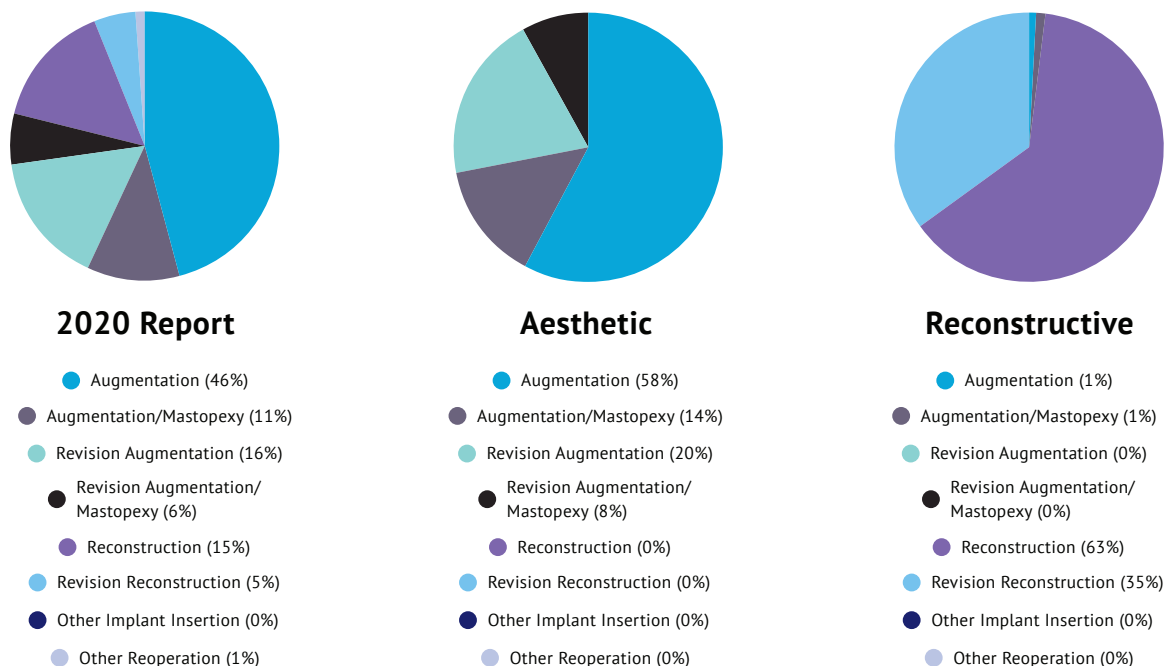
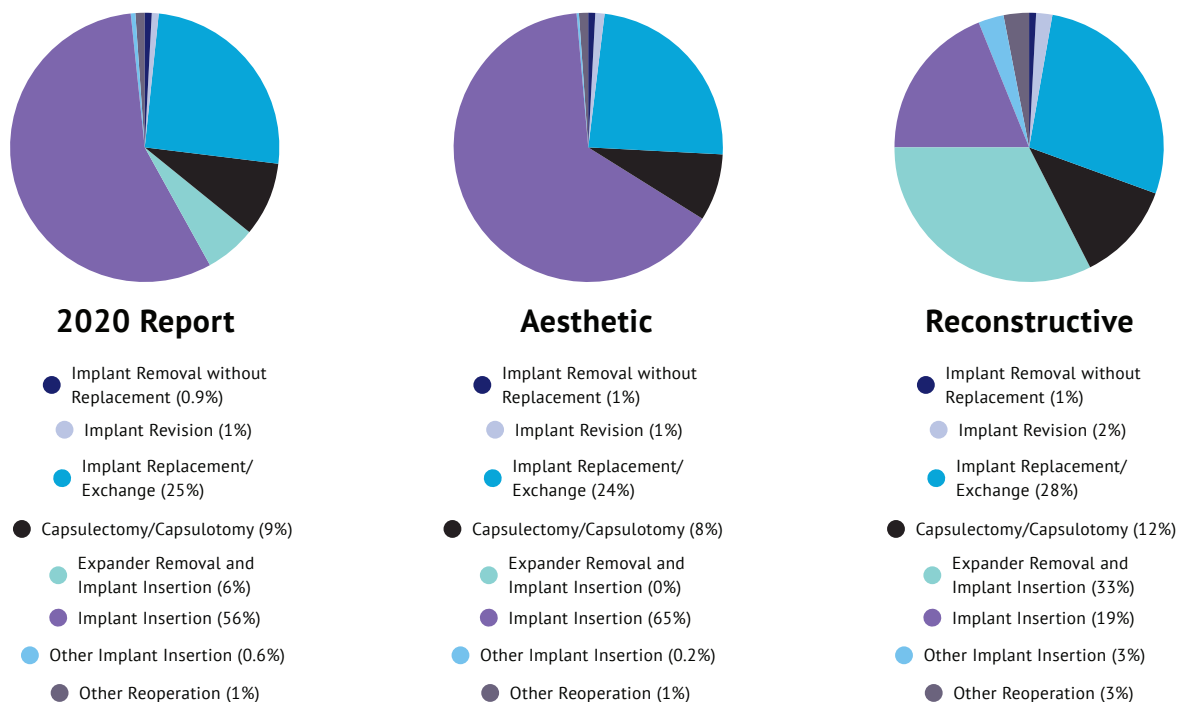


Figure 16 – Operation Types*



* More than one option can be selected

Figure 17 – Drain Usage

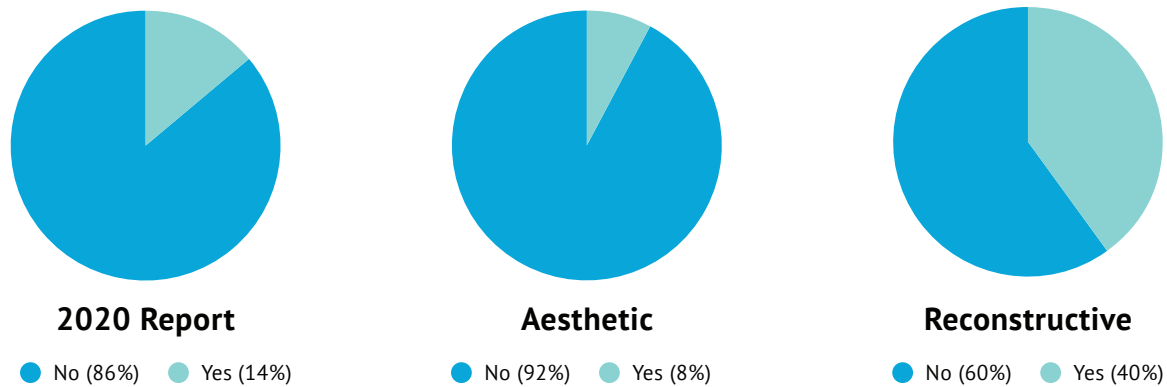


Figure 18 – Acellular Dermal Matrix (ADM)

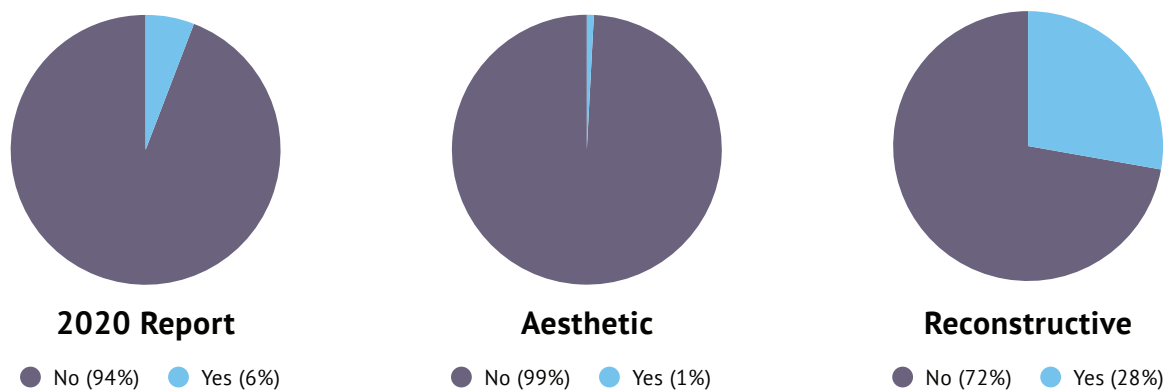


Figure 19 – Surgical Mesh

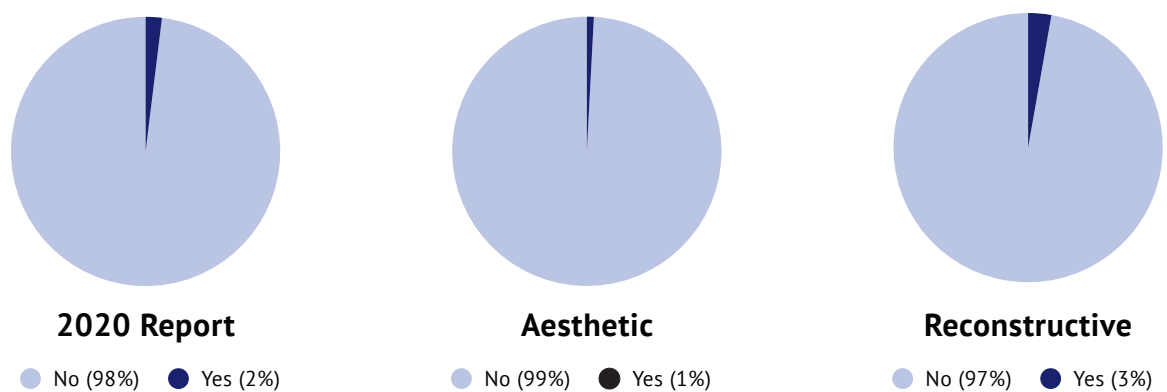


Figure 20 – Fat Grafting

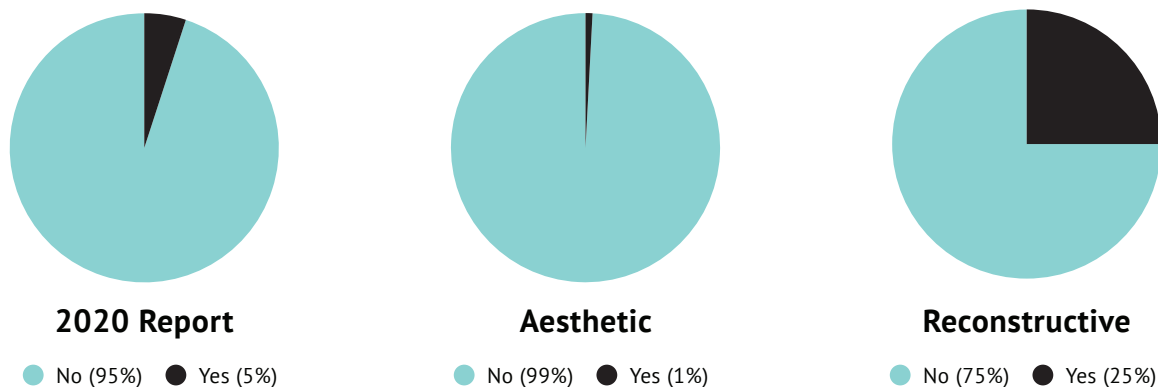


Figure 21 – Incision Type

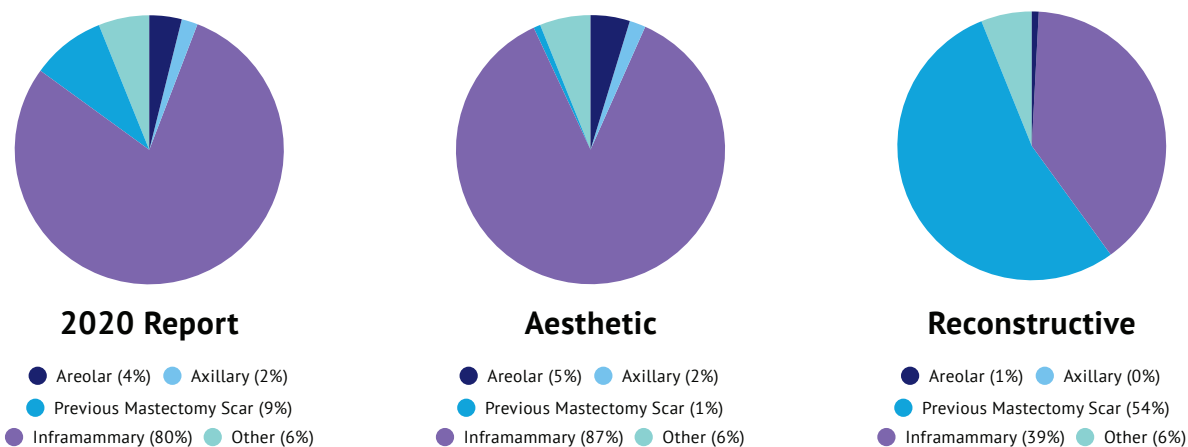
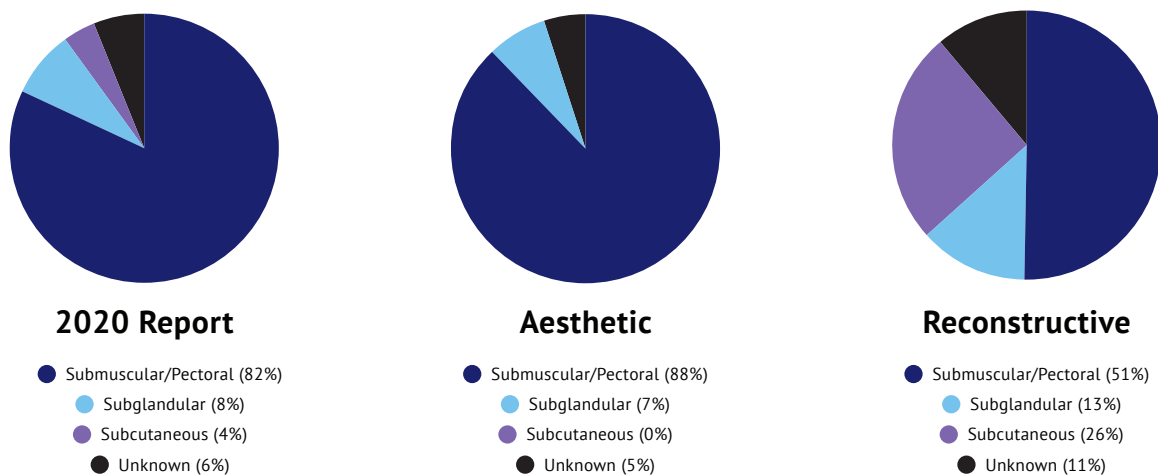


Figure 22 – Implant Placement Location



Device Information

There are a variety of implant types reported in the registry, with certain devices predominating. Surgeons reported use of smooth implants in 99% of cases and round implants in 98% of cases respectively [Fig. 23, 24]. Silicone is the typical implant fill (85%), followed saline (13 %). [Fig. 25].

Figure 23 – Device Texture

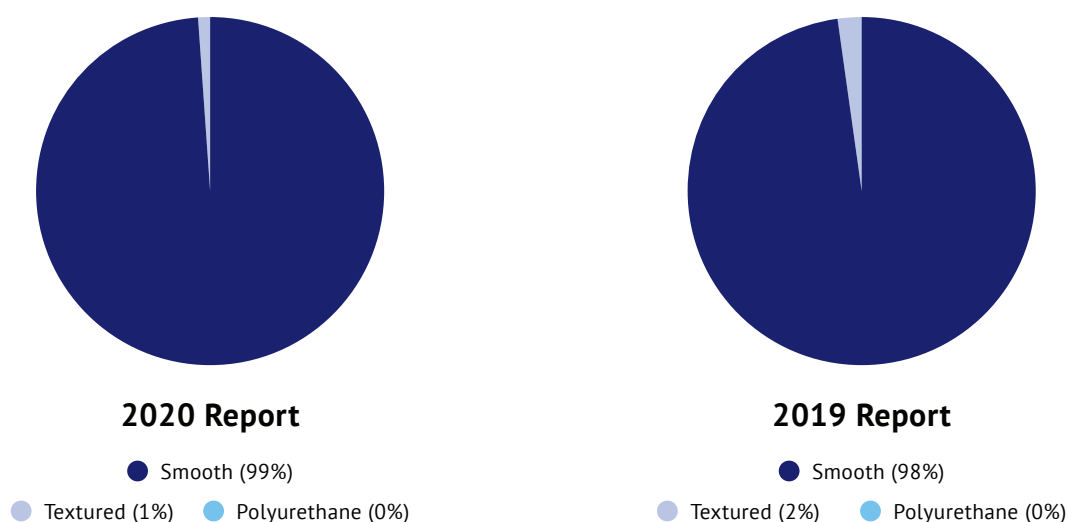


Figure 24 – Device Shape

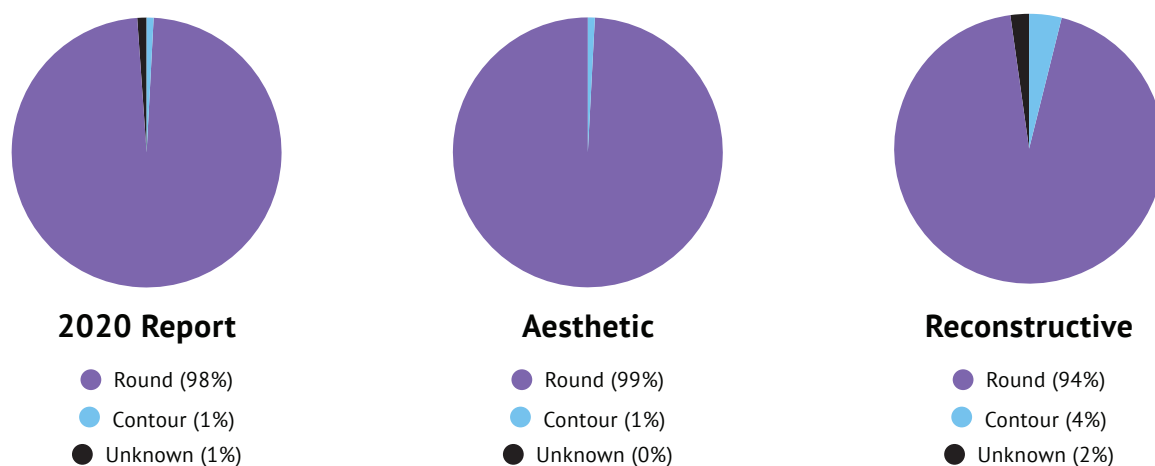
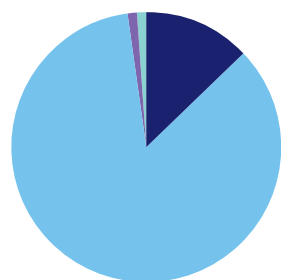
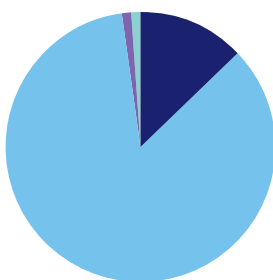


Figure 25 – Device Fill



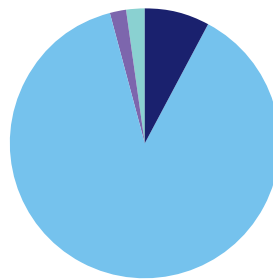
2020 Report

● Saline (13%) ● Silicone (85%)
● Saline/Silicone Gel (1%)
● Hydrogel (0%) ● Unknown (1%)



Aesthetic

● Saline (13%) ● Silicone (85%)
● Saline/Silicone Gel (1%)
● Hydrogel (0%) ● Unknown (1%)



Reconstructive

● Saline (8%) ● Silicone (88%)
● Saline/Silicone Gel (2%)
● Hydrogel (0%) ● Unknown (2%)

Reoperation

Reoperation is the primary endpoint for the NBIR. As reported in Figure 15, reoperation accounts for 30% of procedures reported to the NBIR. This includes data for both the left and right implants within each case. It is important to note that each case can have multiple reasons for reoperation reported.

Reoperations are performed for a variety of reasons, including complications associated with the surgery and device problems; but the majority (59%) are performed in response to patient request, primarily to change shape, size, or style of implant [Fig. 26]. Figure 31 lists all the complications reported, with a breakdown by indication. Of the 15% complication-related reoperations, 89% of cases reported capsular contracture [Fig. 27]. Other complications include hematoma, infection, seroma, skin necrosis, and wound problems. Reoperations performed in response to device issues reported one of three concerns: device migration/malposition, suspected/actual rupture/deflation, or wrinkling/rippling [Fig. 28]. Of the other reasons for reoperations reported, 3% involved a case of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). These cases will be reported to The PSF's Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE) Registry.

Figure 26 – Reasons for Reoperation

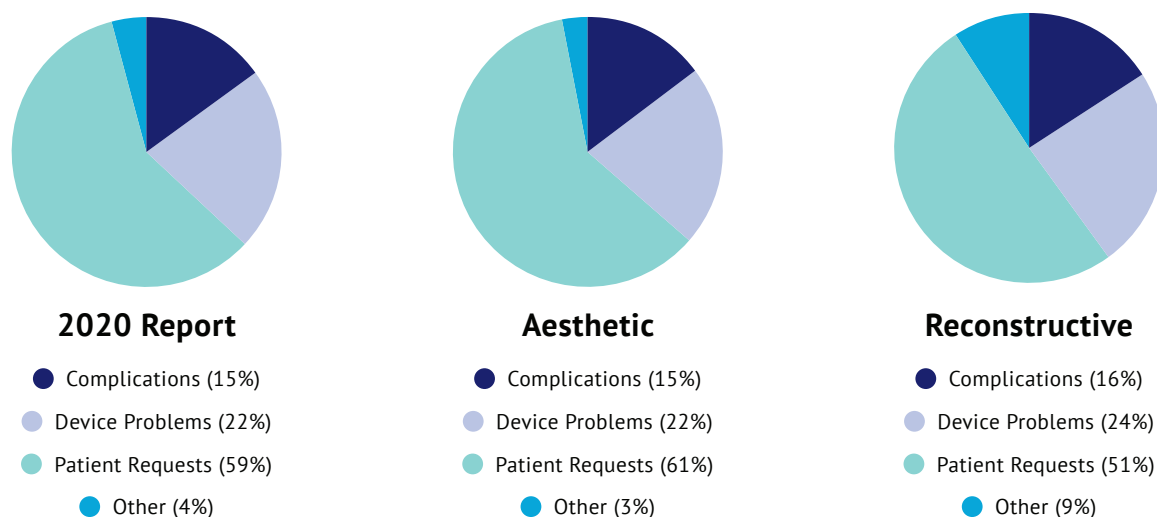
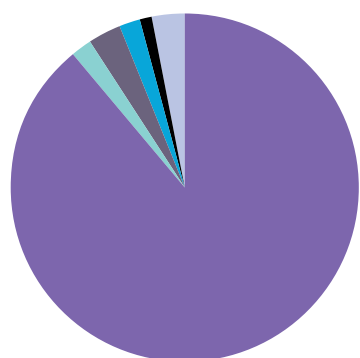
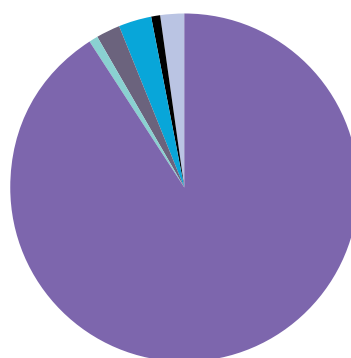
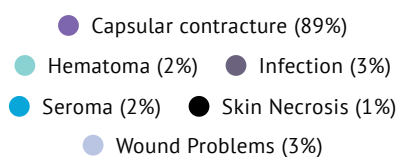


Figure 27 – Complication-related Reoperation



2020 Report



2019 Report

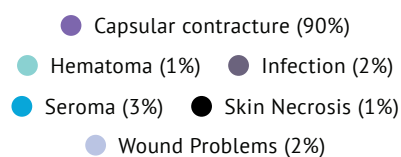
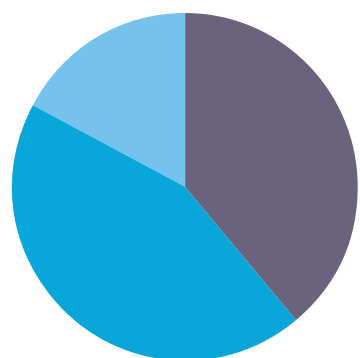
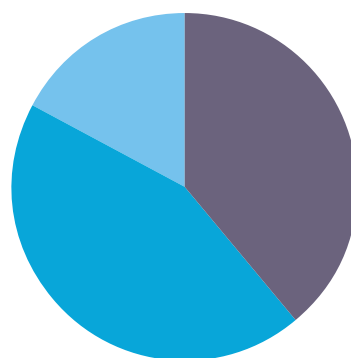
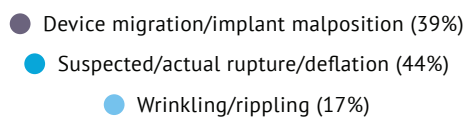


Figure 28 – Device-related Reoperation



2020 Report



2019 Report

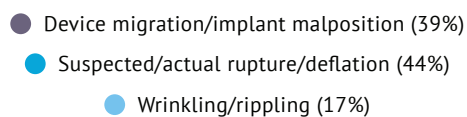


Figure 29 – Patient Requests for Reoperation

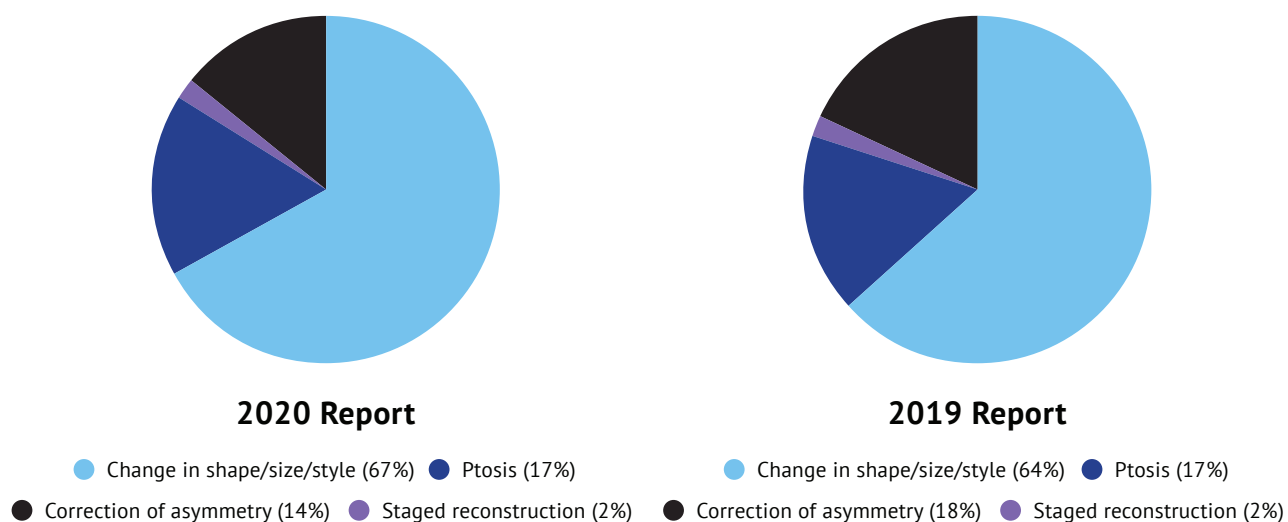


Figure 30 – Other Reasons for Reoperation

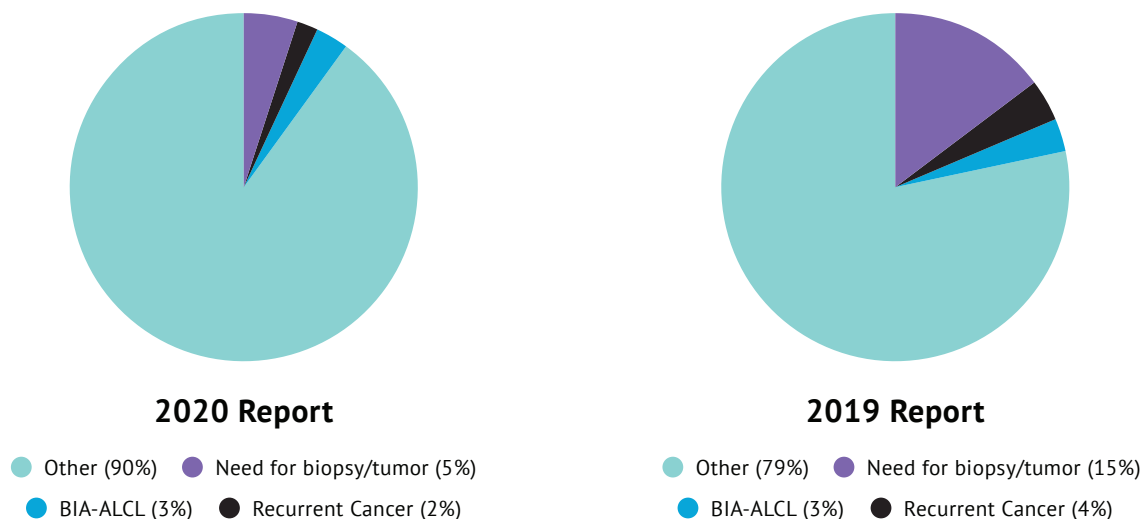
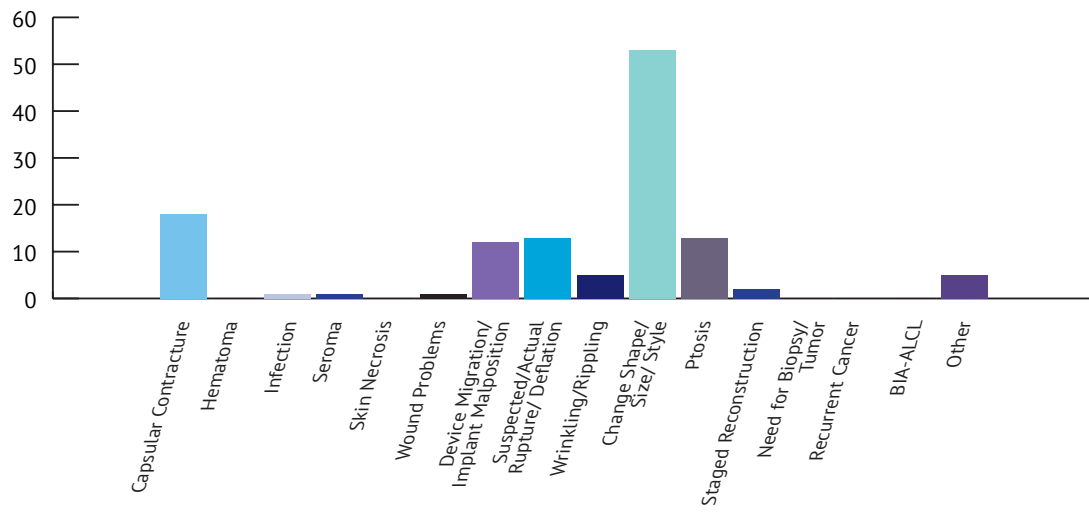
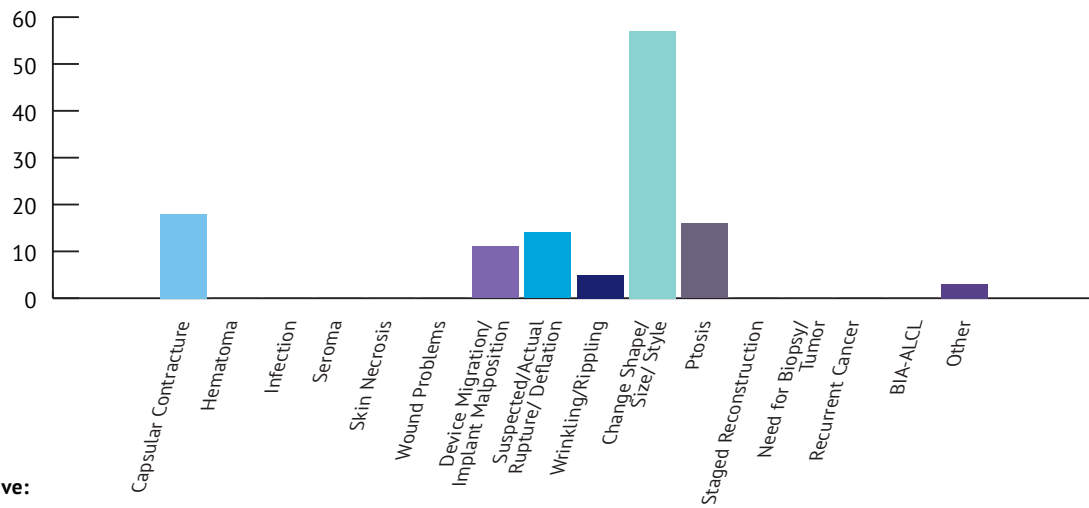


Figure 31 – List of all reasons for reoperation by Indication

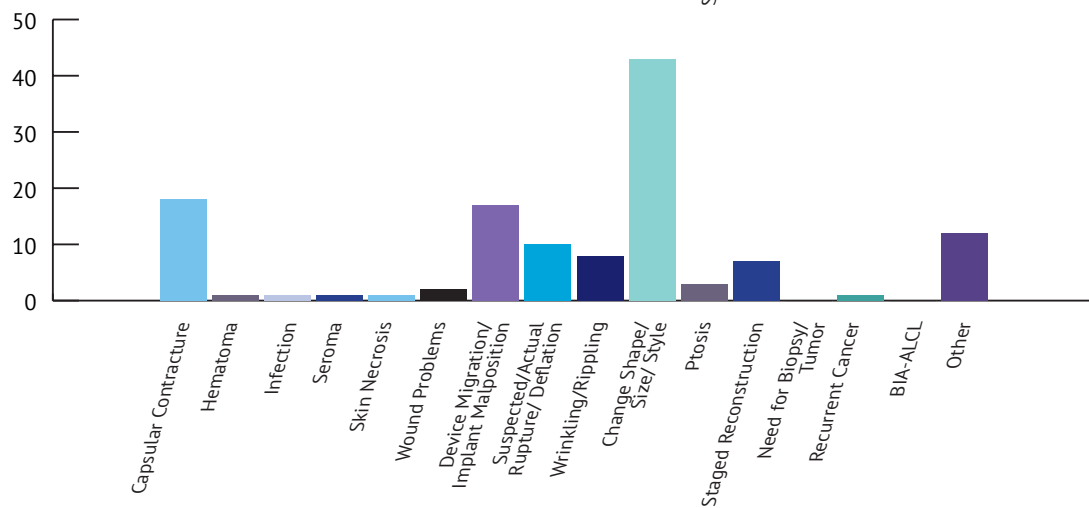
2020 Report:



Aesthetic:



Reconstructive:



Future Perspectives

Increase Registry Use

In the upcoming year, the NBIR Steering Committee will focus on developing initiatives to help increase the number of NBIR Participants and the number of cases collected in the registry. This will include making modifications to the data entry platform that will improve the user experience, the development of additional resources for NBIR Participants, and the development of an aggressive awareness campaign. We will also continue to actively promote our new Device Tracking mobile application, which launched shortly after 2020 Annual Report data collection closed.

Data Collection Model

In the upcoming year, the NBIR will pilot a Patient Reported Outcome (PRO) component. The PSF is in the process of developing a breast implant illness symptom severity scale to examine common signs and symptoms that patients receiving breast implants may encounter. The new scale will be piloted within the NBIR. Upon successful completion of the pilot, PROs will be permanently included as a part of NBIR data collection.



Acknowledgements:

The work on this annual report would not be possible without the tremendous contributions from ASPS/PSF Staff and Physician leadership. On behalf of the NBIR Steering Committee, we wish to thank Erin Mullen, Katie Sommers, Priya Patel, Keith Hume, Gina McClure, Surinder Kaur, and Angela Bochucinski for their efforts to support the National Breast Implant Registry, as well as the development of this report.

