The National Breast Implant Registry
Annual Report 2021

THE PLASTIC SURGERY FOUNDATION ™

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MENTOR

sientra.

NBIR
NATIONAL BREAST IMPLANT REGISTRY

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

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, 2020-SEPTEMBER 30, 2021):

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

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

Myles Cockburn, PhD | **Epidemiologist**

Joshua Der | **Mentor**

JoAnn Kuhne | **Sientra**

Jennifer Walcott | **Mentor**

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Kelly Carty | **Allergan Aesthetics**

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Megan Estes | **Mentor**

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

Sung Yoon, MD | **FDA**

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Letter From the Chairs

We are very excited to present the third 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 three years of registry operations (October 3, 2018 – September 30, 2021). During this timeframe, the NBIR captured data on over 36,000 breast implant procedures reported by physicians across the United States.

This report includes a detailed summary of data pertaining to 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.
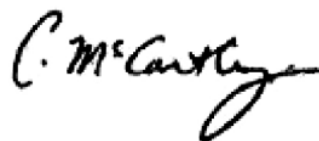
Our greatest achievements during this third year of registry operations was the successful launch of the new NBIR Device Tracking App in November 2020 and as well as the substantial growth we saw in registry participation and case collection. We appreciate the commitment to patient safety from our NBIR participants, and we look forward to their continued participation in this very important initiative.

We hope that this report will not only serve as a guide to current progress and data highlights but will also serve 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

Colleen McCarthy, MD, FRCS(C)
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) 2020 Procedural Statistics Report, over 300,000 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 improve satisfaction of their patients, and by decreased complications. Data from registries can also be used to inform clinical practice guidelines 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 an operation 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) is designed to include data required for device tracking, a federally mandated requirement of manufacturers of breast implants. As of July 1, 2019, the NBIR launched a 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 one of the NBIR mobile barcode scanning applications, HIPAA-compliant apps available for all Apple and Android devices. The apps connect 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. Responsibilities include:

- Develop and implement the strategic goals of the NBIR
- Establish and prioritize the objectives and goals of the NBIR
- Provide input into NBIR operations and processes
- Provide strategic direction for the NBIR
- Monitor quality improvement, research and other clinical objectives
- Review recommendations for data analysis that come from the Data Access and Publications Committee (DAPC).

The NBIR Steering Committee is comprised of representatives from ASPS, The PSF, the FDA, patients, researchers, and industry.

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

Though the NBIR has only completed three full years of data collection, there has been an overwhelming push of registration from surgeons across a wide variety practice types and locations. Of the 1125 total sites registered for the NBIR, 54% of the participants were in solo practice [Fig. 1]. This was followed by private groups, multi-specialty groups and academic practices at 23%, 11%, 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 160 sites. Similarly, other densely populated states such as Texas, Florida, New York, and Pennsylvania produced the highest numbers of registrants for the NBIR. Figure 3 shows the ranking of case volume collected by state in the NBIR, where Texas has the highest case collection totals. The rest of the Top 5 states for data collection include Florida, California, Louisiana and Arizona.

While 2020 had an uphill battle with most plastic surgery practices closed for a period of time due to COVID-19, we saw exponential growth in data collection and registration for NBIR during this time. We continued to see growth in 2021 despite additional waves of COVID-19.

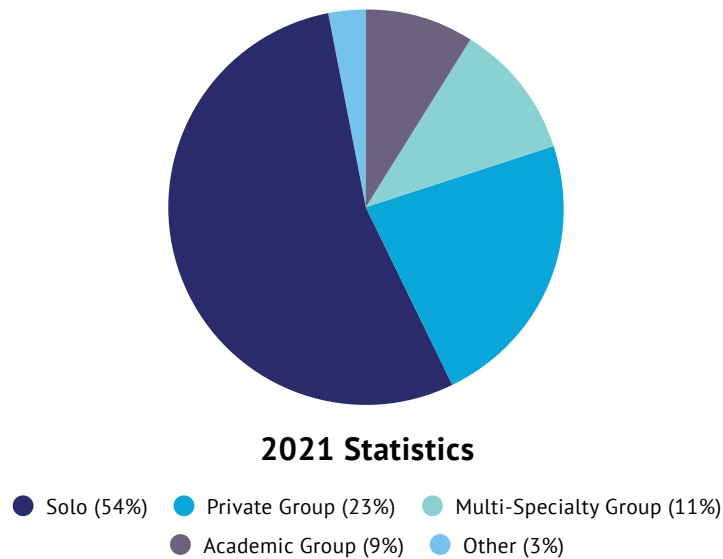**Figure 1 –** *NBIR Registrants by Practice Type*

2021 Statistics

- Solo (54%)
- Private Group (23%)
- Multi-Specialty Group (11%)
- Academic Group (9%)
- Other (3%)

Figure 2 – *Registered Sites by Geographic Location*

Registered Users:

160

0
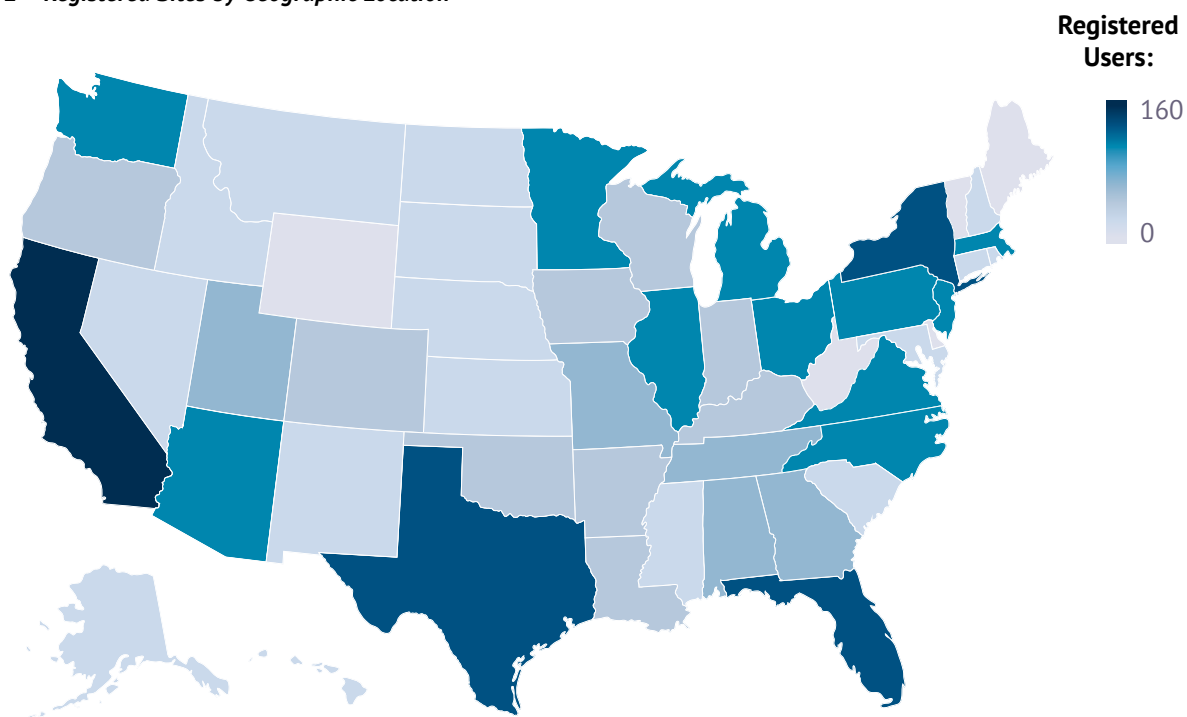
Figure 3 – *Cases Entered by Geographic Location*
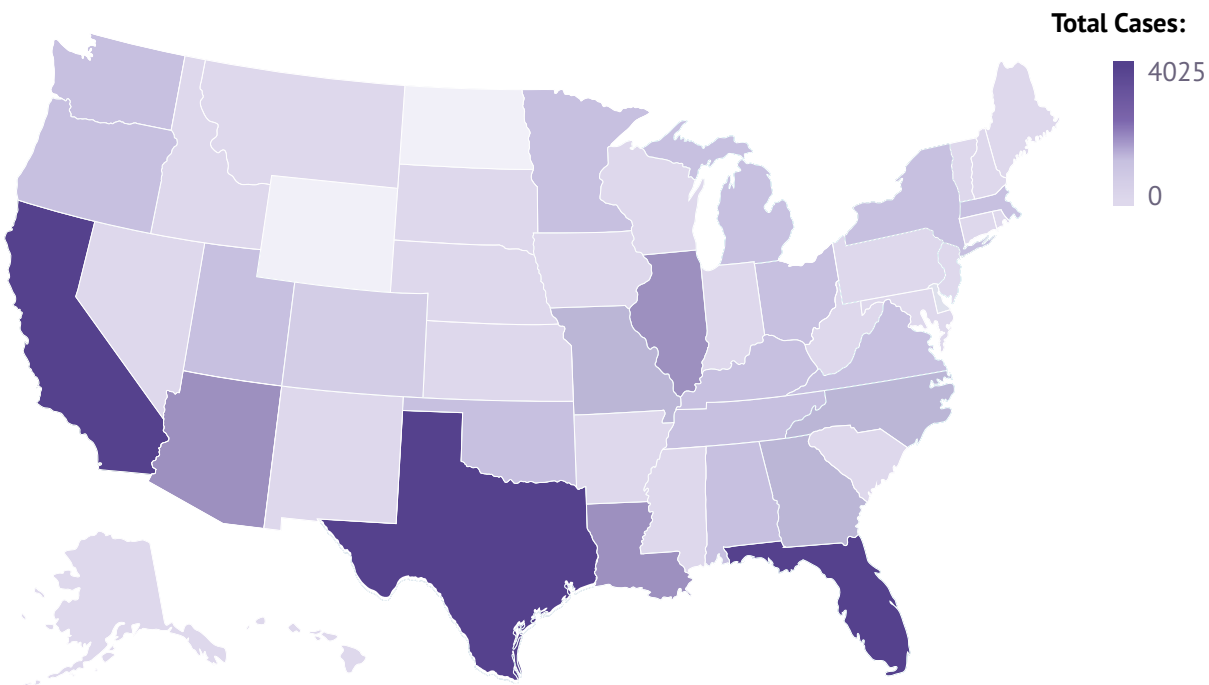

Total Cases:

4025

0

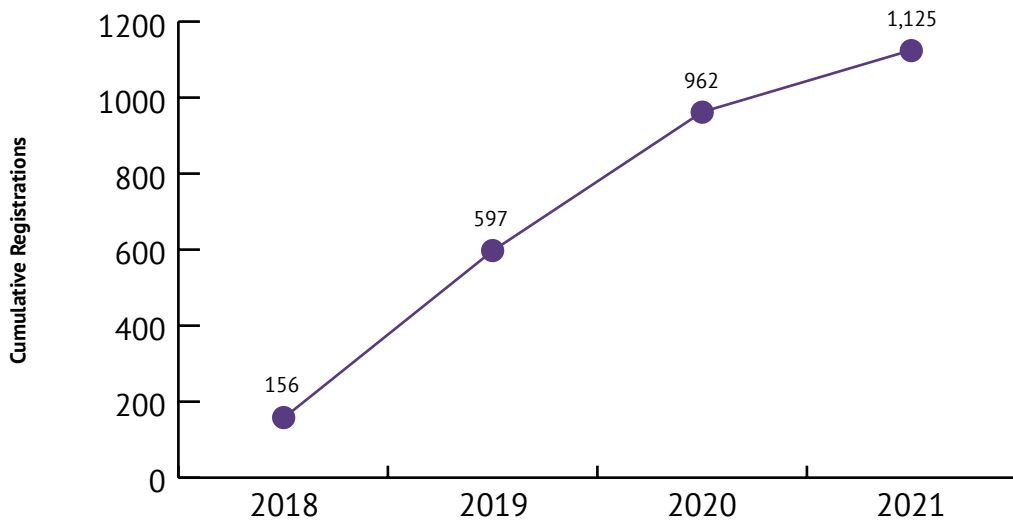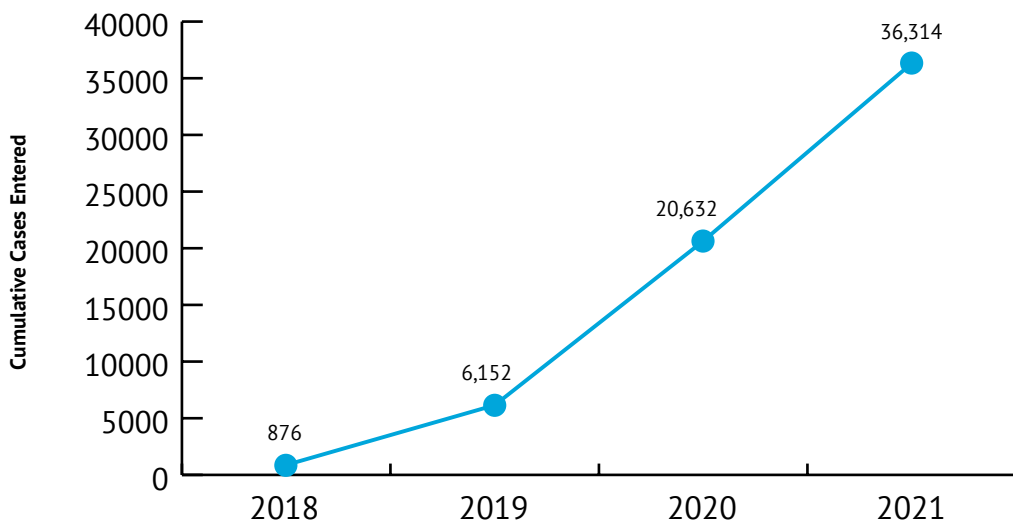**Figure 4 – *NBIR Registered Participants***

Figure 5 – *NBIR Cases Entered*
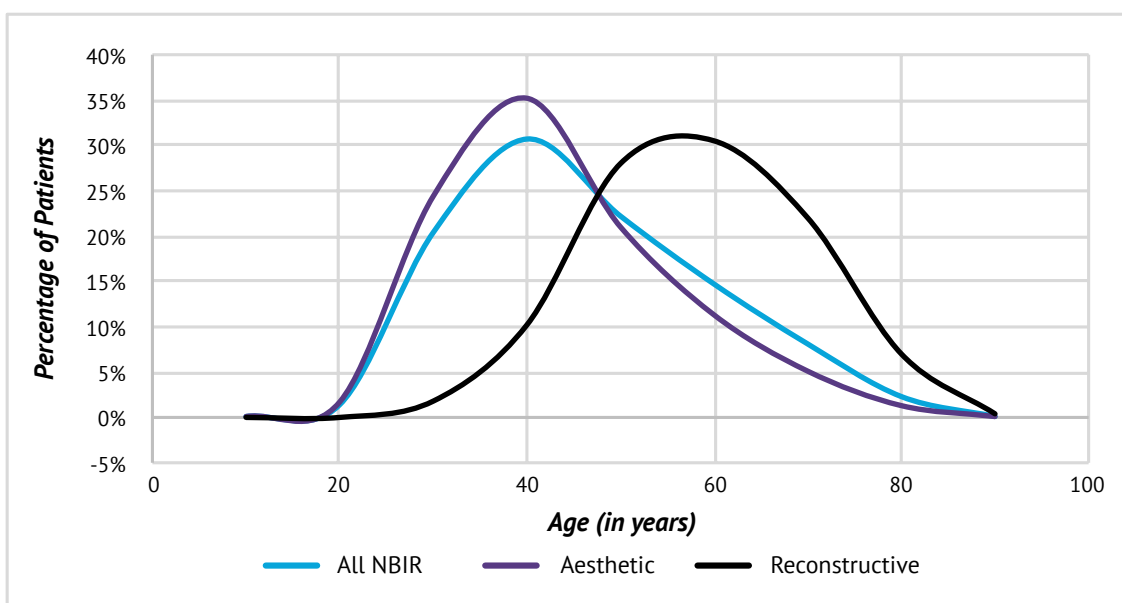
Registry Findings

Clinical Demographics

The average patient age is 42 years old with a range of 11 to 89 years old. (Table 1). The median patient age was 39 years old. Aesthetic patients tended to be younger (median: 37 years old), than reconstructive patients (median: 53 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 89% reported an ethnicity of non-Hispanic [Fig. 7,8]. African American and Asian patients made up 3.9% and 3.1% respectively. Majority of cases entered involved female patients (99%), and a combined 1% involved male or transgender patients [Fig. 9]. Race was only reported in 48% of patients, while ethnicity was only reported in 39% of patients. Gender was reported in 63% of patients.

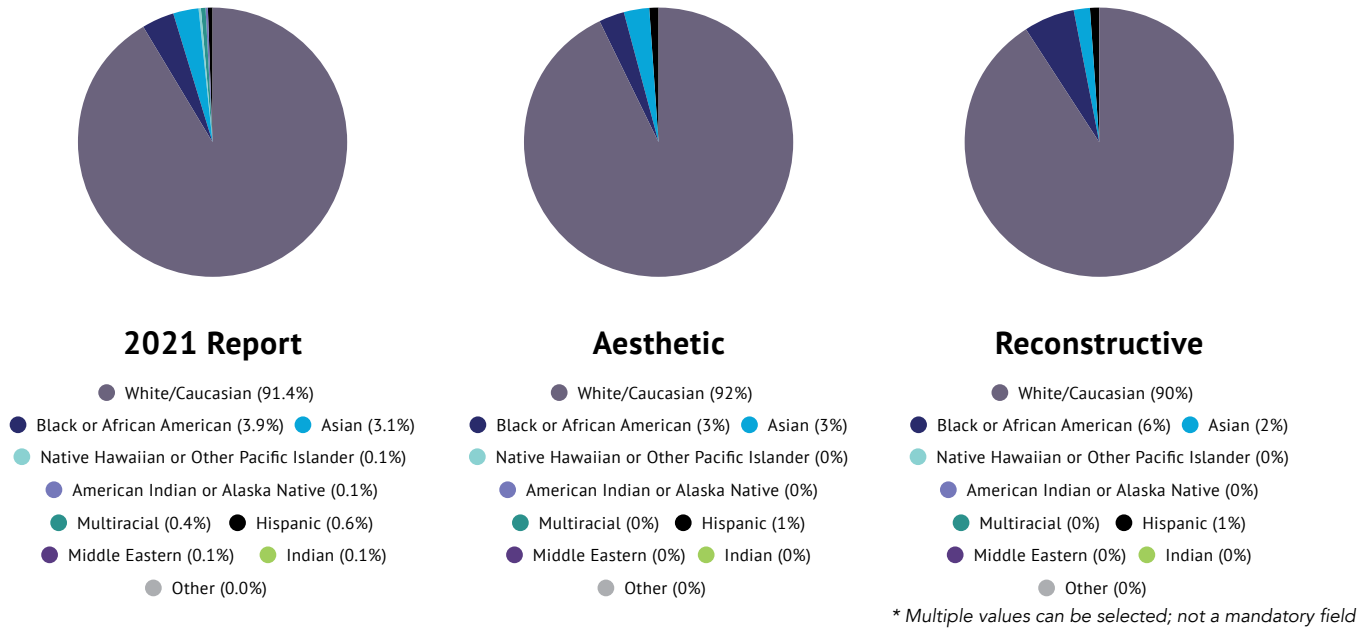**Table 1** – *Age of NBIR participants variables*

Age (years)		2021 Report	Aesthetic	Reconstructive
	Range	11-89	11-86	15-89
	Average	41.6	38.9	53.6
	Median	39.0	37.0	53.0

Figure 6 – *Age Range*

Figure 7 – *Race (n=17,587)*

2021 Report

- ● White/Caucasian (91.4%)
- ● Black or African American (3.9%)   ● Asian (3.1%)
- ● Native Hawaiian or Other Pacific Islander (0.1%)
- ● American Indian or Alaska Native (0.1%)
- ● Multiracial (0.4%)   ● Hispanic (0.6%)
- ● Middle Eastern (0.1%)   ● Indian (0.1%)
- ● Other (0.0%)

Aesthetic

- ● White/Caucasian (92%)
- ● Black or African American (3%)   ● Asian (3%)
- ● Native Hawaiian or Other Pacific Islander (0%)
- ● American Indian or Alaska Native (0%)
- ● Multiracial (0%)   ● Hispanic (1%)
- ● Middle Eastern (0%)   ● Indian (0%)
- ● Other (0%)

Reconstructive

- ● White/Caucasian (90%)
- ● Black or African American (6%)   ● Asian (2%)
- ● Native Hawaiian or Other Pacific Islander (0%)
- ● American Indian or Alaska Native (0%)
- ● Multiracial (0%)   ● Hispanic (1%)
- ● Middle Eastern (0%)   ● Indian (0%)
- ● Other (0%)

* Multiple values can be selected; not a mandatory field

Figure 8 – *Ethnicity (n=14,252)*

2021 Report

- ● Non-Hispanic (89.3%)
- ● Hispanic (10.7%)

Aesthetic

- ● Non-Hispanic (89.0%)
- ● Hispanic (11.0%)

Reconstructive

- ● Non-Hispanic (90.0%)
- ● Hispanic (10.0%)

* Not a mandatory field

Figure 9 – *Gender (n=22,761)*

2021 Report

● Female (99%) ● Male (0%)

● Transgender (0%)

Aesthetic

● Female (99%) ● Male (0%)

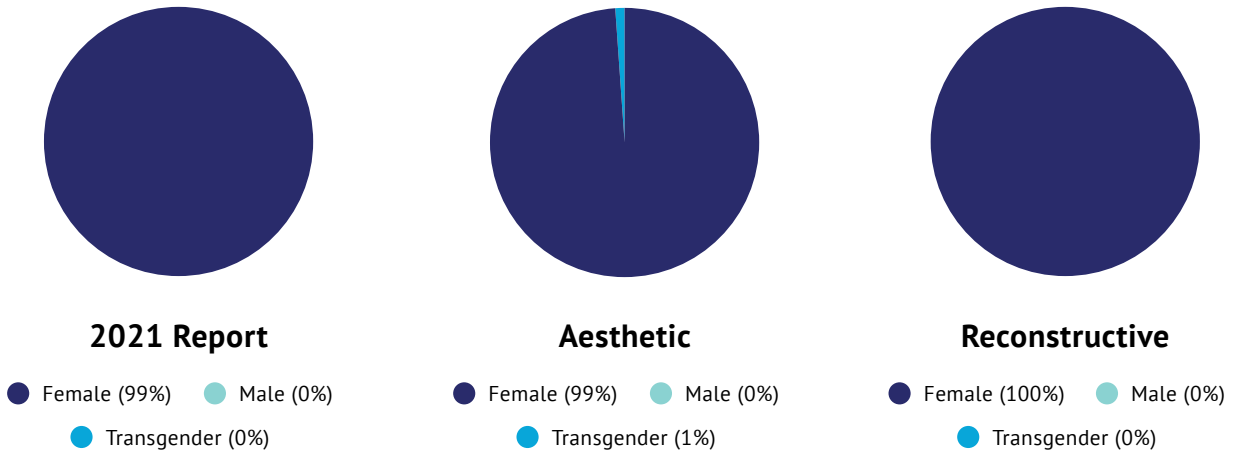● Transgender (1%)

Reconstructive

● Female (100%) ● Male (0%)

● Transgender (0%)
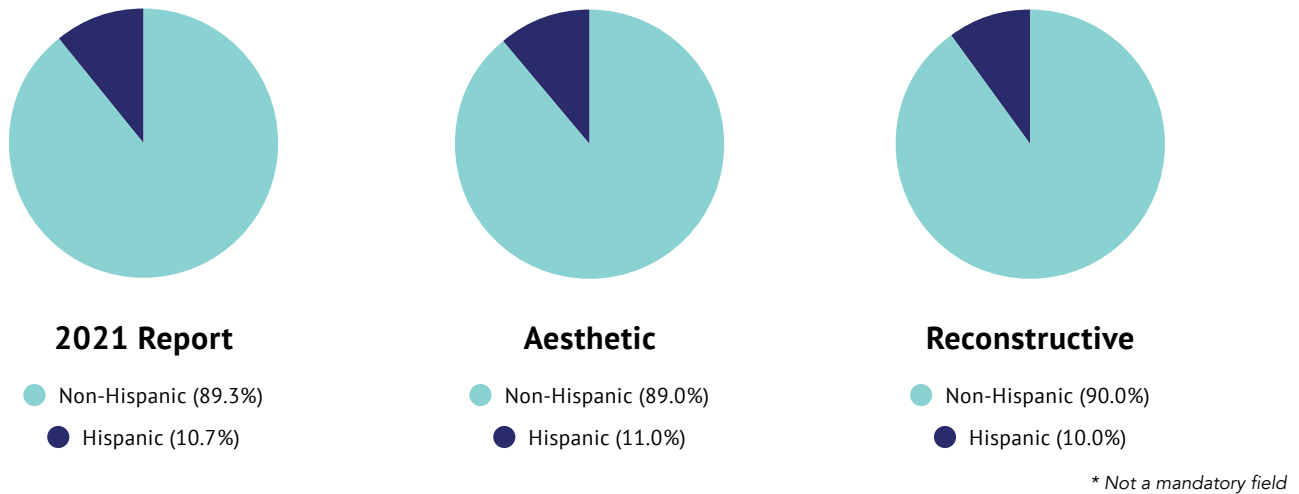
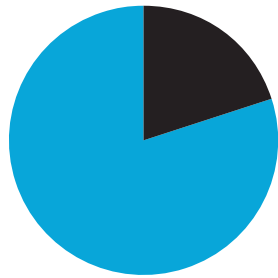** Not a mandatory field*

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. Eighteen percent of cases reported a prior diagnosis of breast cancer [Fig. 10], which is in line with last year's report (16%). 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. Twenty percent of cases reported at least one medical condition in the past [Fig. 11]. Hypertension and thyroid issues are the most common co-morbidities for Registry patients, representing 6% and 3% of the registry population respectively [Fig. 12]. Only 7 percent of NBIR cases are reported current smokers [Fig. 13].
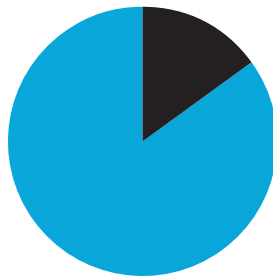
Figure 10 – *History of Breast Cancer*

2021 Report

● Yes (18%) ● No (82%)

Aesthetic

● Yes (1%) ● No (99%)

Reconstructive

● Yes (88%) ● No (12%)
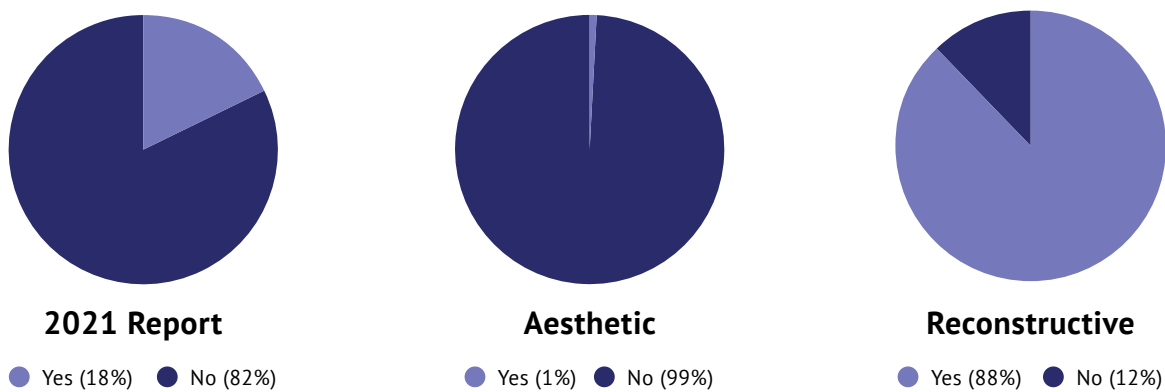
* Not a mandatory field

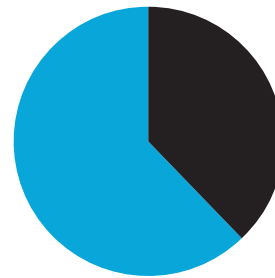**Figure 11 – *Presence of Prior Medical Condition***

2021 Report

● Yes (20%) ● No (80%)

Aesthetic

● Yes (15%) ● No (85%)
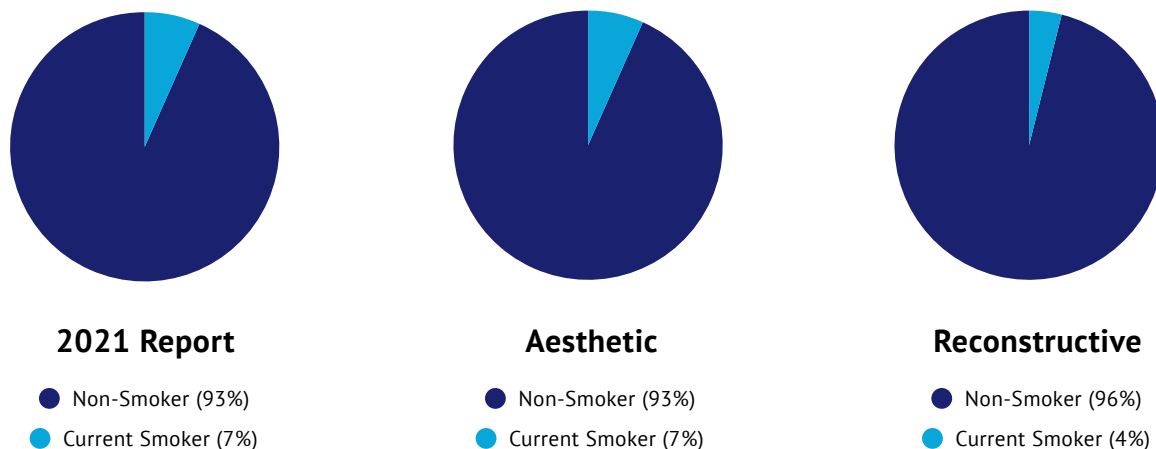
Reconstructive

● Yes (38%) ● No (62%)

Table 12 – *Medical Issues Identified*

History of Medical Issues	2021 Report
Hypertension	6.1%
Thyroid Issues, Disease, Disorder (ex. Hypothyroid)	3.2%
Cardiac Disease	2.0%
Cancer	1.9%
Diabetes	1.8%
Asthma	1.7%
Depression	1.6%
Anxiety	1.1%
GERD/ Reflux	1.1%
Elevated Cholesterol/Lipids	1.0%
Infection	0.9%
Migraines	0.9%
Autoimmune (Non-Specified and RA)	0.7%
Arthritis	0.5%
ADD/ADHD	0.4%
Anemia	0.4%
Clotting Disorder or History of Blood Clots	0.4%
Prior Surgeries	0.4%
Fibromyalgia	0.3%
IBS	0.3%
Renal Disease	0.3%
Sleep Apnea	0.3%

* User can select more than one field.
No other medical issues had greater than 0.25% response

Figure 13 – *Smoking Status*

2021 Report

● Non-Smoker (93%)
● Current Smoker (7%)

Aesthetic

● Non-Smoker (93%)
● Current Smoker (7%)

Reconstructive

● Non-Smoker (96%)
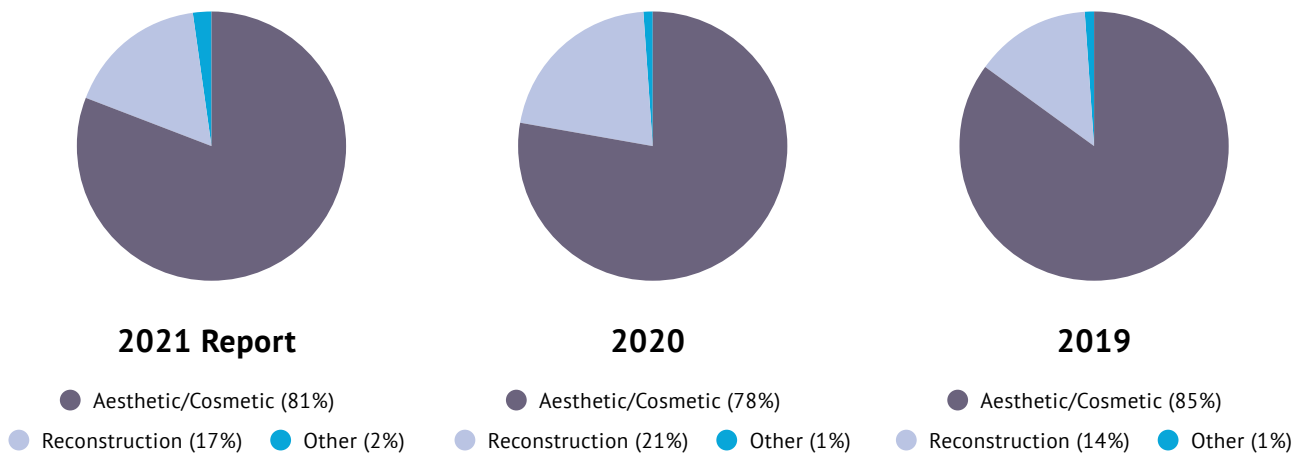● Current Smoker (4%)

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 collect data on more than one device. This is why data provided for procedure type appears inflated in comparison to raw case counts, as these figures include the left and/or right breast for each case.

There are two main categories for procedure type reported in the NBIR, Aesthetic/Reconstruction and Operation/Reoperation. Aesthetic procedures represented 81% of all reported indications [Fig. 14]. Approximately 27% of the total procedures are reoperation cases and 73% involved an initial operation. [Fig. 15]. Of note, reconstructive procedures have a higher percentage of revision or reoperations than do aesthetic procedures. Figure 16 highlights that 73% of all procedures involve the placement of a breast implant, while less than 1 percent of all procedures in the registry are for explanting devices. The most common reoperation is the implant exchange/replacement occurring in 25% of all procedures. Implant exchange refers to implant removal with implant replacement. This does not include the removal of expander with placement of an implant.

The NBIR gathers additional procedural techniques regarding drains, fat grafting, surgical mesh, and acellular dermal matrices. Figures 17-20 show less than 14% of reported procedures involved these techniques: surgical mesh (2%), fat grafting (5%), drains (13%) or acellular dermal matrix (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 81% of incision types used and are more common in aesthetic patients, than in reconstructive patients. Inframammary incisions made up 88% of incision types used for aesthetic patients, while

mastectomy incision/scar made up 56% of incision types used for reconstructive patients [Fig 21]. No other individual incision method or implant location exceeds 9% utilization by NBIR reporting surgeons. The submuscular/pectoral implant location made up 86% of implant location reports. The submuscular/pectoral implant location is more common in aesthetic patients and made up 93% of implant placement locations. The submuscular/pectoral implant location made up of 51% of implant placement locations in reconstructive patients, followed by subcutaneous and subglandular at 38% and 11% respectively [Fig 22].

Figure 14 – *Procedure Indication*

2021 Report

● Aesthetic/Cosmetic (81%)
● Reconstruction (17%)   ● Other (2%)

2020

● Aesthetic/Cosmetic (78%)
● Reconstruction (21%)   ● Other (1%)

2019

● Aesthetic/Cosmetic (85%)
● Reconstruction (14%)   ● Other (1%)

Figure 15 – *Operation Indication*

2021 Report

● Operation (73%)
● Reoperation (27%)

Aesthetic

● Operation (75%)
● Reoperation (25%)

Reconstructive

● Operation (68%)
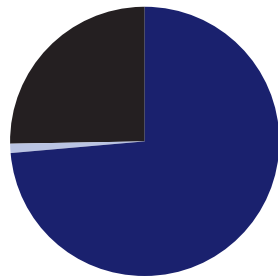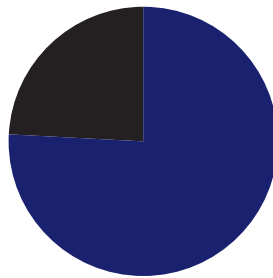● Reoperation (32%)
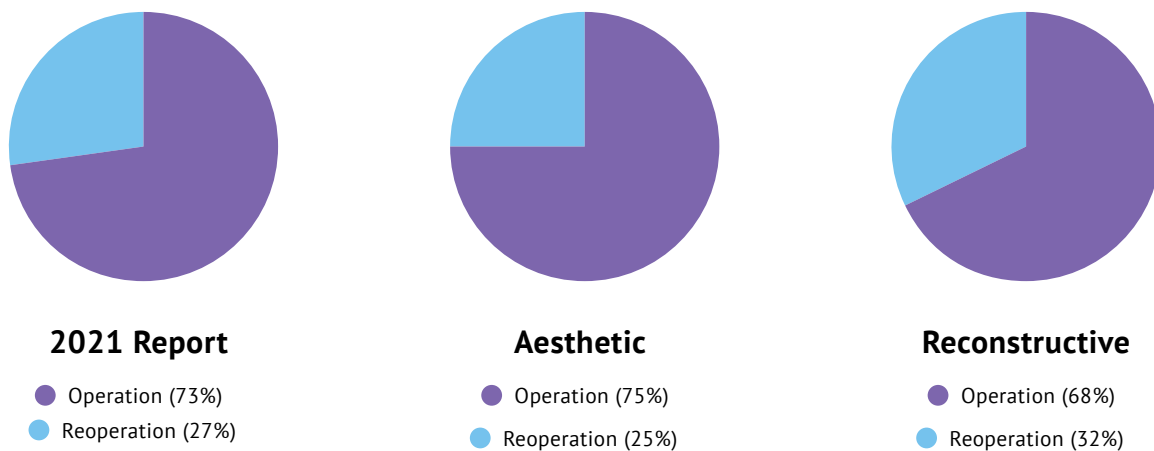
Figure 16 – *Operation Types**

2021 Report

- Implant Placement (73%)
- Explant Only (1%)
- Implant Revision (0%)
- Implant Exchange (25%)
- Capsule Procedure Only (0%)
- Mastopexy Only (0%)
- Tissue Expander Placement (0%)
- Other (0%)

Aesthetic

- Implant Placement (76%)
- Explant Only (0%)
- Implant Revision (0%)
- Implant Exchange (24%)
- Capsule Procedure Only (0%)
- Mastopexy Only (0%)
- Tissue Expander Placement (0%)
- Other (0%)
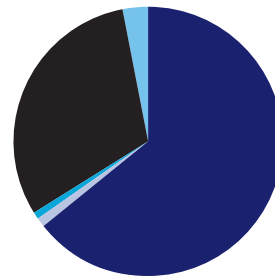
Reconstructive

- Implant Placement (65%)
- Explant Only (1%)
- Implant Revision (1%)
- Implant Exchange (31%)
- Capsule Procedure Only (0%)
- Mastopexy Only (0%)
- Tissue Expander Placement (3%)
- Other (0%)

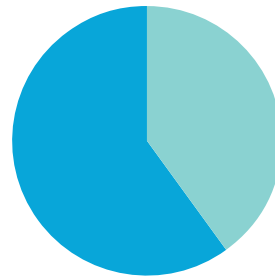** More than one option can be selected*

Figure 17 – *Drain Usage*
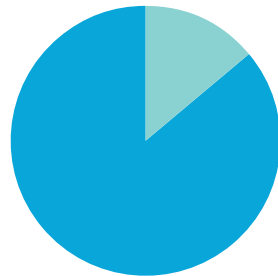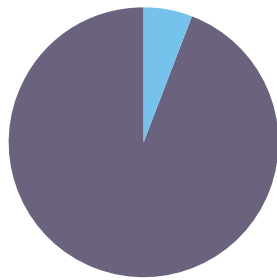

2021 Report

- No (87%)
- Yes (13%)
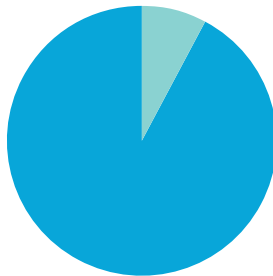
Aesthetic
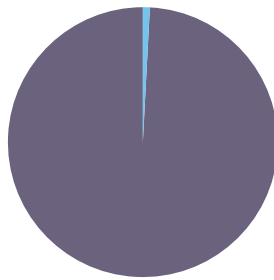
- No (94%)
- Yes (6%)

Reconstructive

- No (59%)
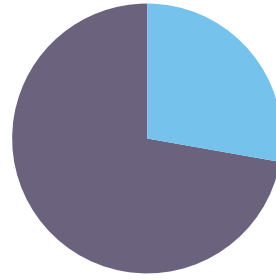- Yes (41%)

Figure 18 – *Acellular Dermal Matrix (ADM)*

2021 Report	Aesthetic	Reconstructive
● No (94%) ● Yes (6%)	● No (99%) ● Yes (1%)	● No (74%) ● Yes (26%)

Figure 19 – *Surgical Mesh*
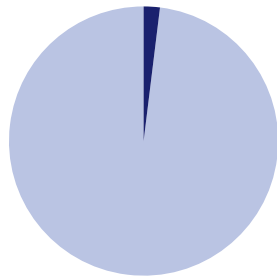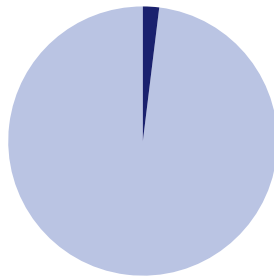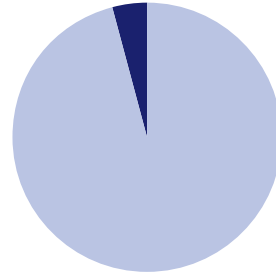
2021 Report	Aesthetic	Reconstructive
● No (98%) ● Yes (2%)	● No (98%) ● Yes (2%)	● No (96%) ● Yes (4%)

Figure 20 – *Fat Grafting*
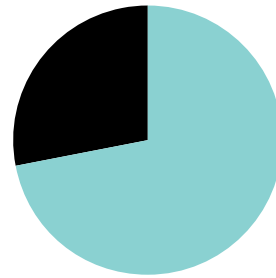
2021 Report	Aesthetic	Reconstructive
● No (95%) ● Yes (5%)	● No (99%) ● Yes (1%)	● No (72%) ● Yes (28%)

Figure 21 – *Incision Type*

2021 Report

- Anchor (1%)　Areolar (4%)
- Axillary (2%)　Inframammary (81%)
- Lollipop (0%)　Mastectomy Incision/Scar (9%)
- Mastopexy Incision (1%)
- Previous Surgical Scar (0%)
- Transverse (0%)　Vertical (2%)
- Wise (1%)　Other (0%)

Aesthetic

- Anchor (1%)　Areolar (4%)
- Axillary (2%)　Inframammary (88%)
- Lollipop (0%)　Mastectomy Incision/Scar (0%)
- Mastopexy Incision (1%)
- Previous Surgical Scar (0%)
- Transverse (0%)　Vertical (2%)
- Wise (1%)　Other (0%)

Reconstructive

- Anchor (0%)　Areolar (1%)
- Axillary (0%)　Inframammary (38%)
- Lollipop (0%)　Mastectomy Incision/Scar (56%)
- Mastopexy Incision (0%)
- Previous Surgical Scar (1%)
- Transverse (1%)　Vertical (1%)
- Wise (1%)　Other (1%)

Figure 22 – *Implant Placement Location*

2021 Report

- Submuscular/Pectoral (86%)
- Subglandular (8%)
- Subcutaneous (6%)

Aesthetic

- Submuscular/Pectoral (93%)
- Subglandular (7%)
- Subcutaneous (1%)

Reconstructive

- Submuscular/Pectoral (51%)
- Subglandular (11%)
- Subcutaneous (38%)
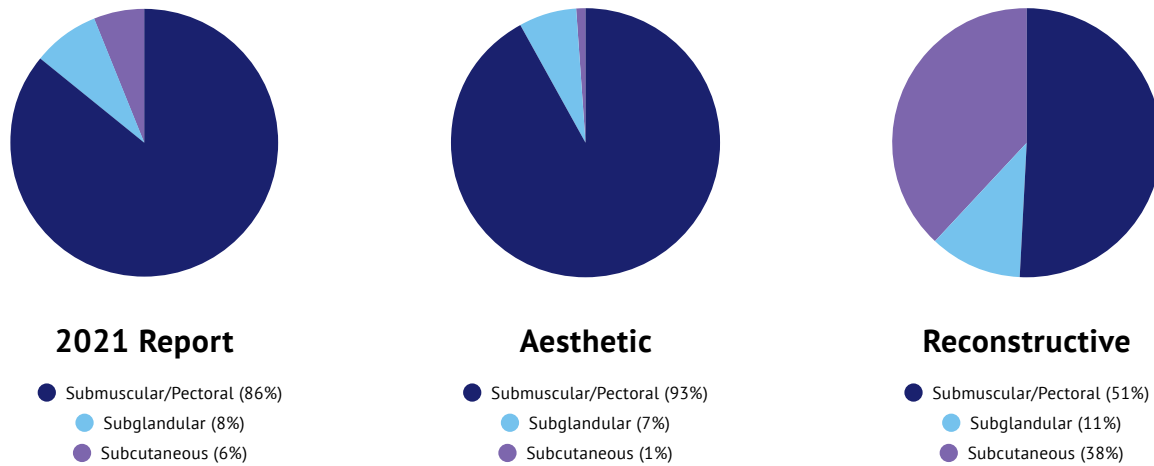
Device Information

A variety of implant types have been reported in the registry, with certain devices predominating. Surgeons reported use of smooth implants in 99% and round implants almost 100% respectively [Fig. 23, 24]. Silicone is the typical implant fill (88%) followed by 12% filled with saline. [Fig. 25].
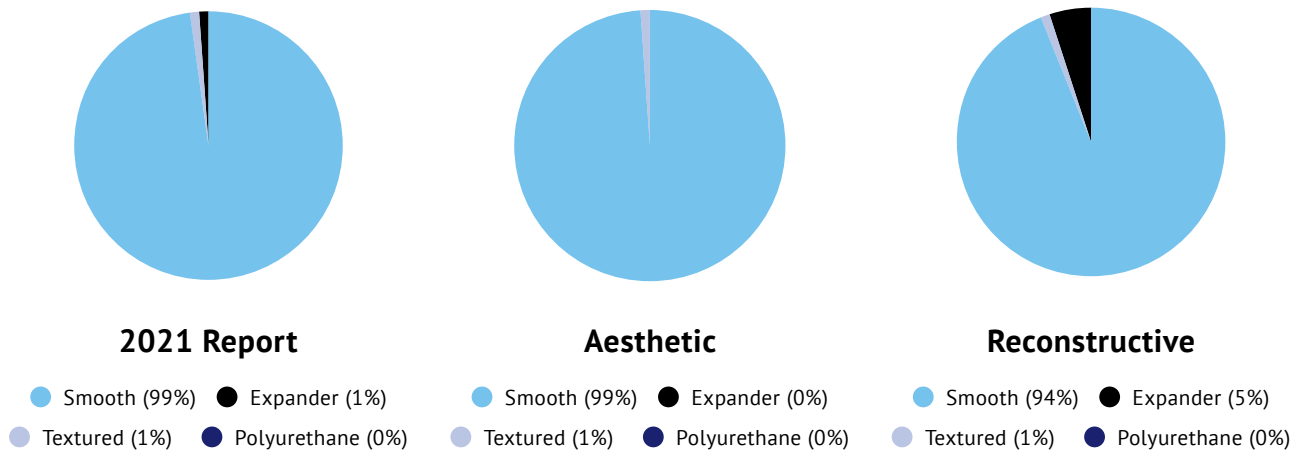
Figure 23 – *Device Texture*

2021 Report	Aesthetic	Reconstructive
● Smooth (99%) ● Expander (1%)	● Smooth (99%) ● Expander (0%)	● Smooth (94%) ● Expander (5%)
● Textured (1%) ● Polyurethane (0%)	● Textured (1%) ● Polyurethane (0%)	● Textured (1%) ● Polyurethane (0%)

Figure 24 – *Device Shape*

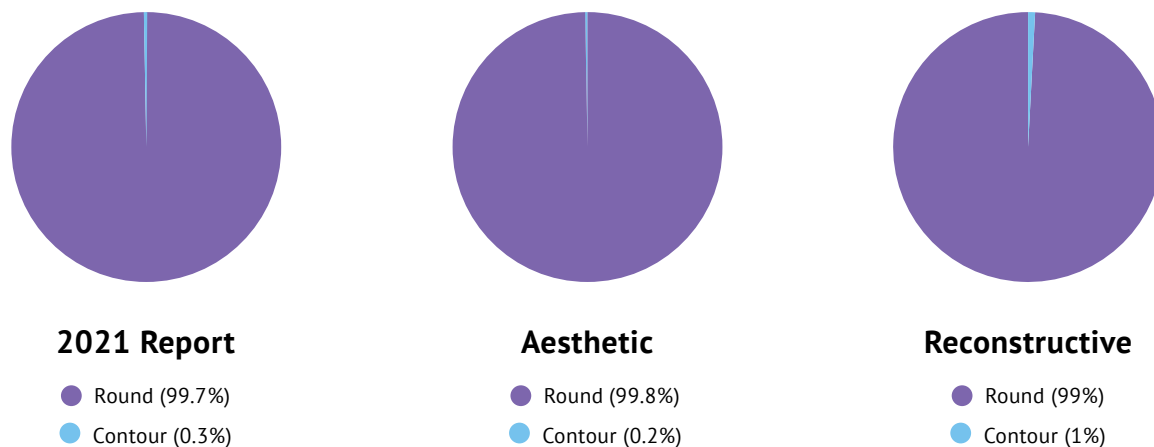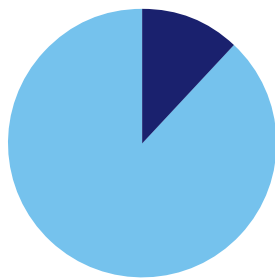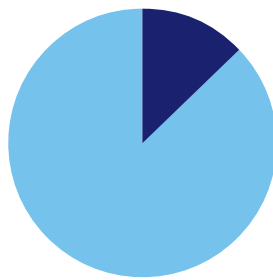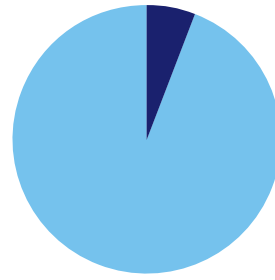| 2021 Report	Aesthetic	Reconstructive
● Round (99.7%)	● Round (99.8%)	● Round (99%)
● Contour (0.3%)	● Contour (0.2%)	● Contour (1%)

Figure 25 – *Device Fill*

2021 Report

● Saline (12%) ● Silicone (88%)
● Saline/Silicone Gel (0%)

Aesthetic

● Saline (13%) ● Silicone (87%)
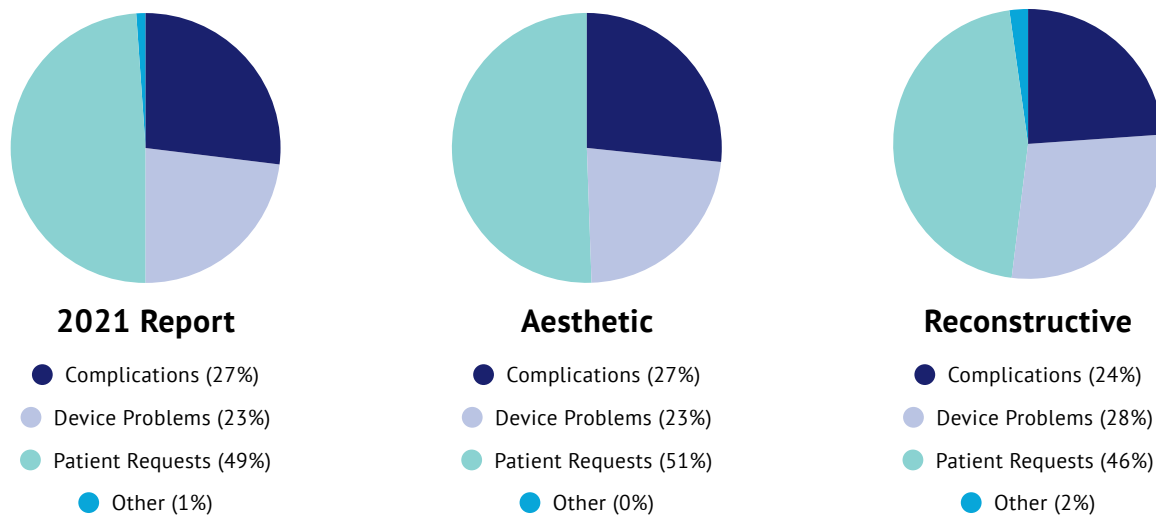● Saline/Silicone Gel (0%)

Reconstructive

● Saline (6%) ● Silicone (94%)
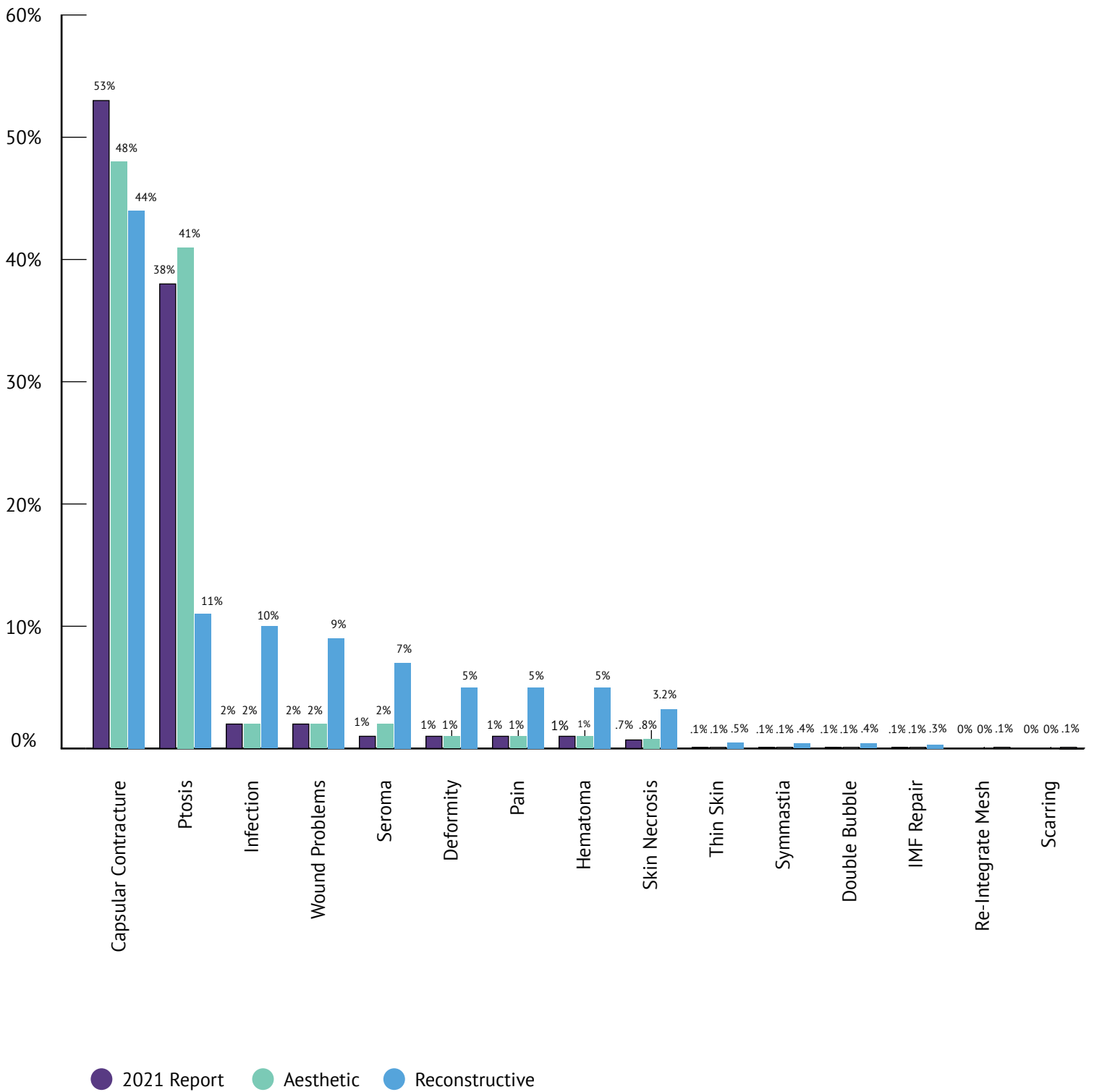● Saline/Silicone Gel (0%)

Reoperation

Reoperations are the primary endpoint for the NBIR. As reported in Figure 15, reoperations account for 27% 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 done for a wide variety of reasons including complications associated with the surgery and device problems, but the majority (49%) are done in response to patient request mostly regarding change in shape, size, or style [Fig. 26]. Figure 27 lists all the complications reported, with a breakdown by indication. Of the 15% complication-related reoperations, 53% of cases experienced capsular contracture [Fig. 27]. Other complications include ptosis, hematoma, infection, would problems and seroma. Reoperations completed in response to device issues were one of three concerns: device migration/malposition, suspected/actual rupture/deflation, or wrinkling/rippling [Fig. 28]. Of the other reasons for reoperations reported, 8% 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*

2021 Report

● Complications (27%)
● Device Problems (23%)
● Patient Requests (49%)
● Other (1%)

Aesthetic

● Complications (27%)
● Device Problems (23%)
● Patient Requests (51%)
● Other (0%)

Reconstructive

● Complications (24%)
● Device Problems (28%)
● Patient Requests (46%)
● Other (2%)

Figure 27 – *Complication-related Reoperation*

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Figure 28 – *Device-related Reoperation*

2021 Report
- Rupture/Deflation (45%)
- Device Migration (40%)
- Wrinkling/Rippling (15%)

Aesthetic
- Rupture/Deflation (49%)
- Device Migration (37%)
- Wrinkling/Rippling (13%)

Reconstructive
- Rupture/Deflation (29%)
- Device Migration (50%)
- Wrinkling/Rippling (21%)
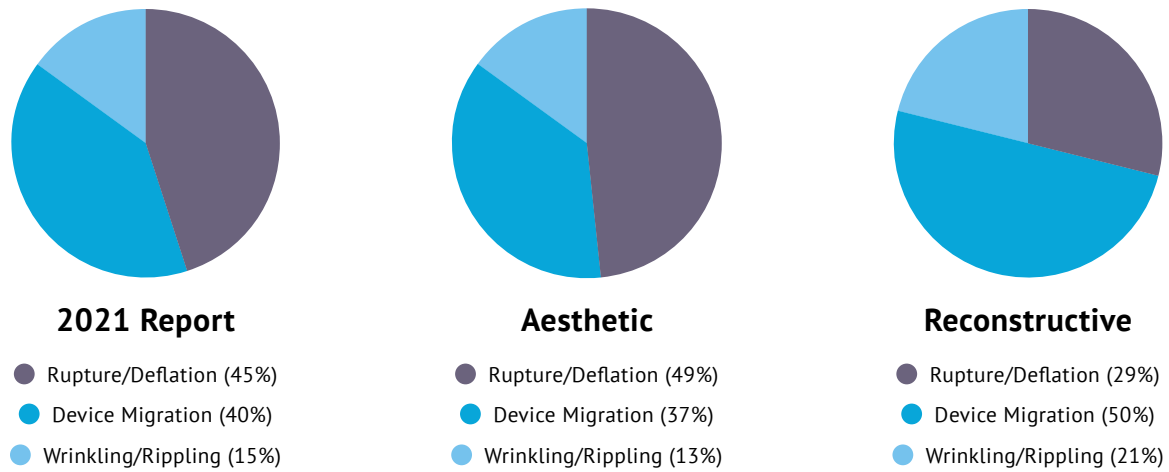
Figure 29 – *Patient Requests for Reoperation*

- 2021 Report
- Aesthetic
- Reconstructive
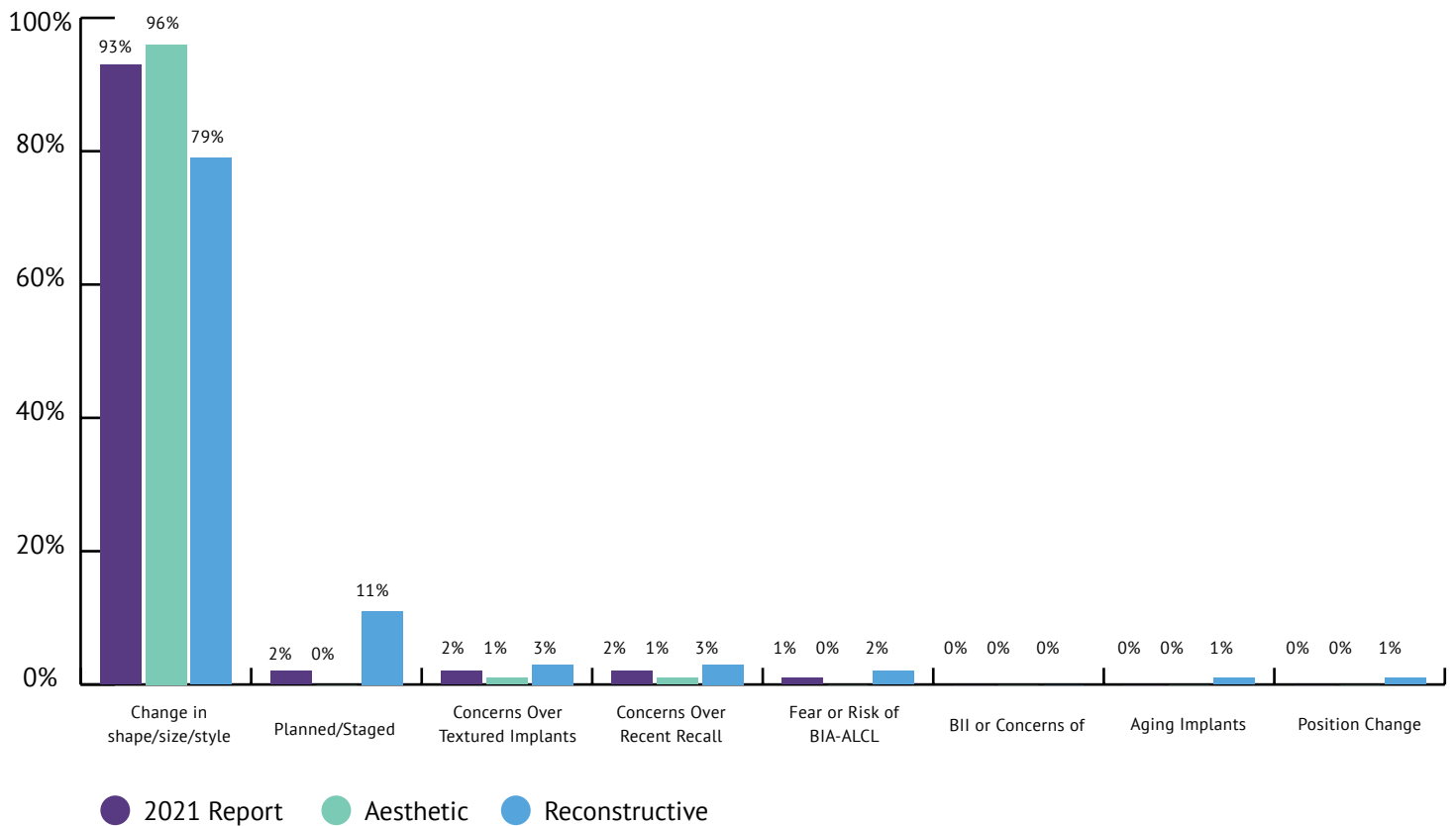
Figure 30 – *Other Reasons for Reoperation*

2021 Report

- Recurrent Cancer (11%)
- Breast Cancer (12%)
- Need for biopsy/tumor (37%)
- BIA-ALCL (8%)
- Other Health Issues (15%)
- Other (17%)

Aesthetic

- Recurrent Cancer (2%)
- Breast Cancer (11%)
- Need for biopsy/tumor (50%)
- BIA-ALCL (11%)
- Other Health Issues (13%)
- Other (13%)

Reconstructive

- Recurrent Cancer (19%)
- Breast Cancer (11%)
- Need for biopsy/tumor (31%)
- BIA-ALCL (5%)
- Other Health Issues (11%)
- Other (24%)
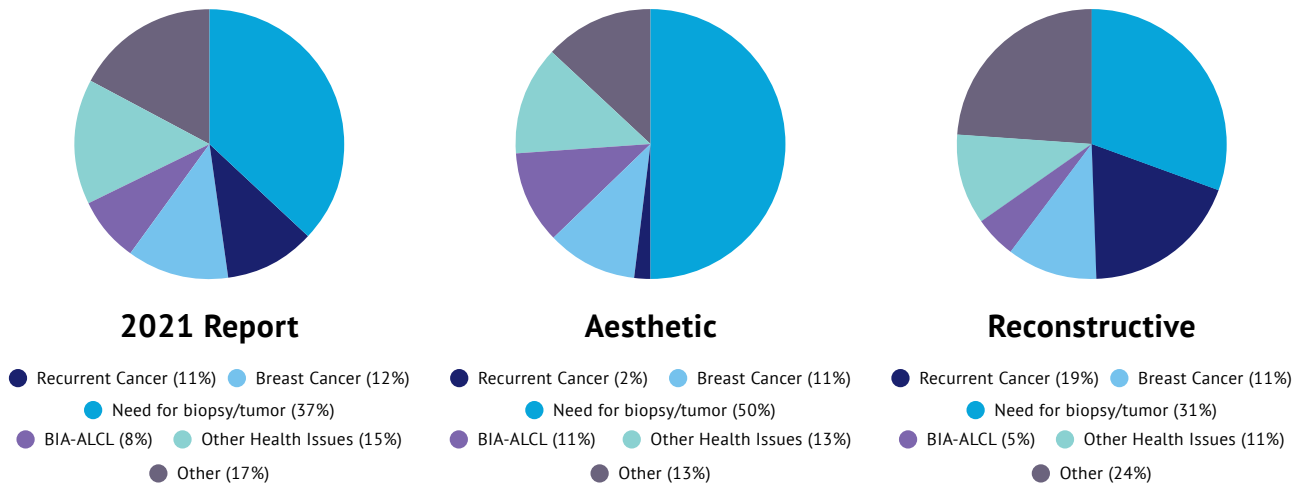
Figure 31 – *Correction of Asymmetry*

2021 Report

- Yes (88.8%)
- No (11.2%)
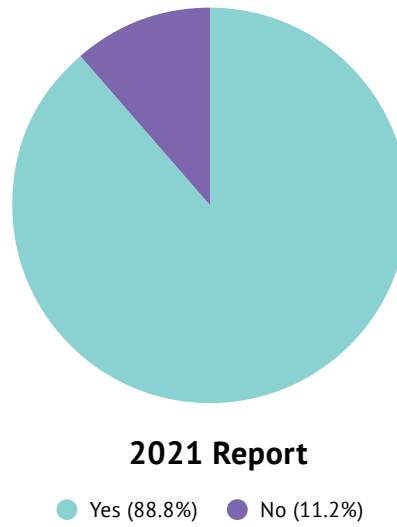
Future Perspectives

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. The PSF will also continue to work with the breast implant manufacturers to promote the use of device tracking/registration using the NBIR to help increase NBIR participation and data collection.

Patient Reported Outcomes

In the upcoming year, the NBIR will begin piloting a Patient Reported Outcome (PRO) component of the NBIR. The PSF is in the process of developing a breast implant 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.

NBIR Manuscript

In the upcoming year, the first NBIR manuscript will be published summarizing the results of the first 50,000 cases entered in the NBIR.

Acknowledgements: