

The National Breast Implant Registry Annual Report 2019



THE PLASTIC SURGERY
FOUNDATION™

The data contained in this report was captured during the NBIR Phase II Pilot and the first year of registry operations (November 2017 – September 30, 2019).



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

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(November 2017 – September 30, 2019).

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Data Period

The data contained in this report was captured during the NBIR Phase II Pilot and the first year of registry operations

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Thank You!

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

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Foreword

We are very excited to present the inaugural 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 year of registry operations (October 3, 2018 – September 30, 2019). During this timeframe, the NBIR captured data on over 3,900 breast implant procedures reported by physicians across 46 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 achievement during the first year was supporting device tracking reporting/device registration through the NBIR. As of July 1, 2019, NBIR participants can simultaneously register their implants with some of the manufacturers while also submitting their data to the registry. This innovative design has streamlined the data collection process for NBIR Participants, which has helped increase participation and NBIR data collection. This is extremely important, as we need all physicians who perform breast implant procedures to participate in the NBIR in order to collect the most accurate and meaningful data on breast implants.

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



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) 2018 Procedural Statistics Report, over 313,000 breast implant procedures are performed annually in the United States. Due to the great volume of breast implant procedures that are performed, 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 nearly 20 years. The PSRN provides value to participants by allowing benchmarking of their performance to the registry aggregate, to improve their patient satisfaction, and decrease complications. Data from registries can be used to inform performance measures and clinical practice guidelines.

In 2012, The PSF initiated the beginning stages of the development of the NBIR in collaboration with the FDA, patients, and breast implant manufacturers to strengthen the post-market surveillance infrastructure for current and future breast implants in the United States.

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 an implant removal or exchange) for all patients receiving breast implants in the United States. Additional aims of the NBIR include serving as a potential infrastructure for post market studies; as well as providing 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 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 in real time!

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.

NBIR Steering Committee Composition:

- Co-Chair, NBIR Co-PI (Selected by The PSF)
- Co-Chair, NBIR Co-PI (Selected by The PSF)
- ASPS Representative
- Allergan Representative
- Mentor Representative
- Sientra Representative
- Epidemiologist/Statistician/Health Services Researcher
- Patient/Consumer
- DAPC Liaison
- FDA Representative (2)
- Analytic Center Liaison (TBD)
- Data Coordinating Center Liaison (FIGmd)
- Clinical Coordinating Center Liaison (The PSF)
- Staff Liaison (The PSF)

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.

DAPC Composition:

- | | |
|--|---|
| <ul style="list-style-type: none"> • The PSF Representative • The PSF Representative • The PSF Representative • Allergan Representative • Mentor Representative • Sientra Representative | <ul style="list-style-type: none"> • Epidemiologist/Statistician/Health Services Researcher • Analytic Center Liaison (TBD) • Data Coordinating Center Liaison (FIGmd) • Clinical Coordinating Center Liaison (The PSF) |
|--|---|

Participation

Though the NBIR has only completed one year of data collection, there has been an overwhelming push of registration from surgeons across a wide variety of practice types and locations. Of the 503 total sites registered for the NBIR, 61% of the participants were in solo practice [Fig. 1]. This was followed by private groups, academic groups, and multi-specialty groups at 22%, 8%, and 6% respectively [Fig. 1]. Figure 2 displays a gradient of registration rates across each state in the U.S. 77 sites have registered for the NBIR thus far in California. Similarly, other densely populated states such as Texas, Florida, and New York 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.

On July 1, 2019, the NBIR was compliant with the FDA's regulations for device tracking requirements (21 CFR Part 821). This allows the registry to serve as an infrastructure for the breast implant manufacturers to collect their device tracking data. Since the launch of Device Tracking, we've seen a steady increase in NBIR registration [Fig. 3.]

Figure 1: NBIR Registrants by Practice Type

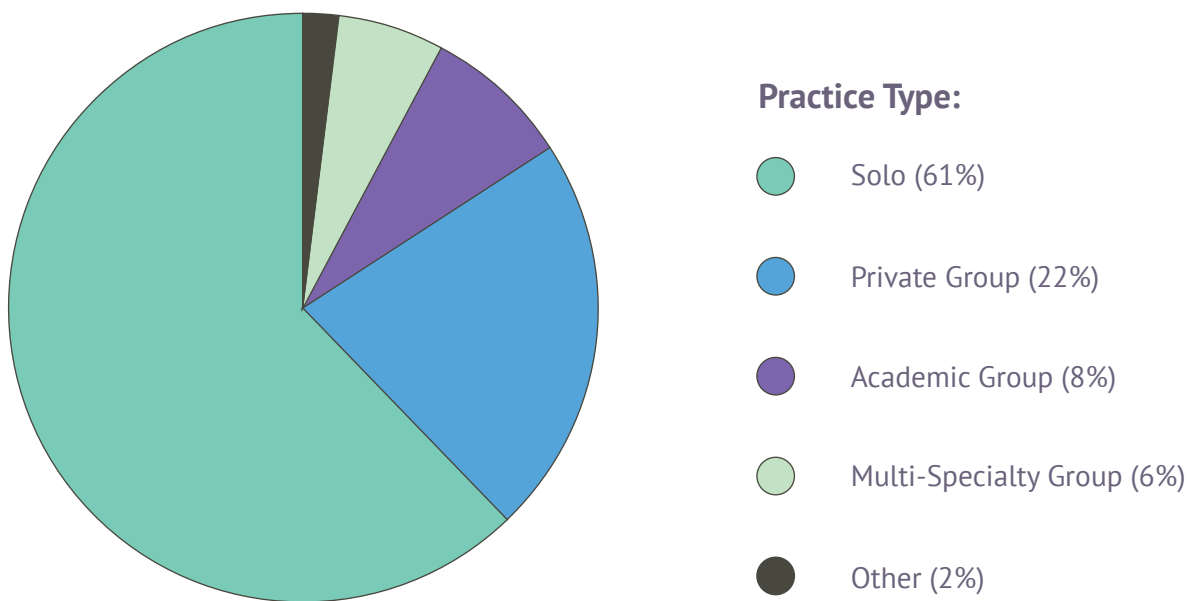


Figure 2. Registered Sites by Geographic Location

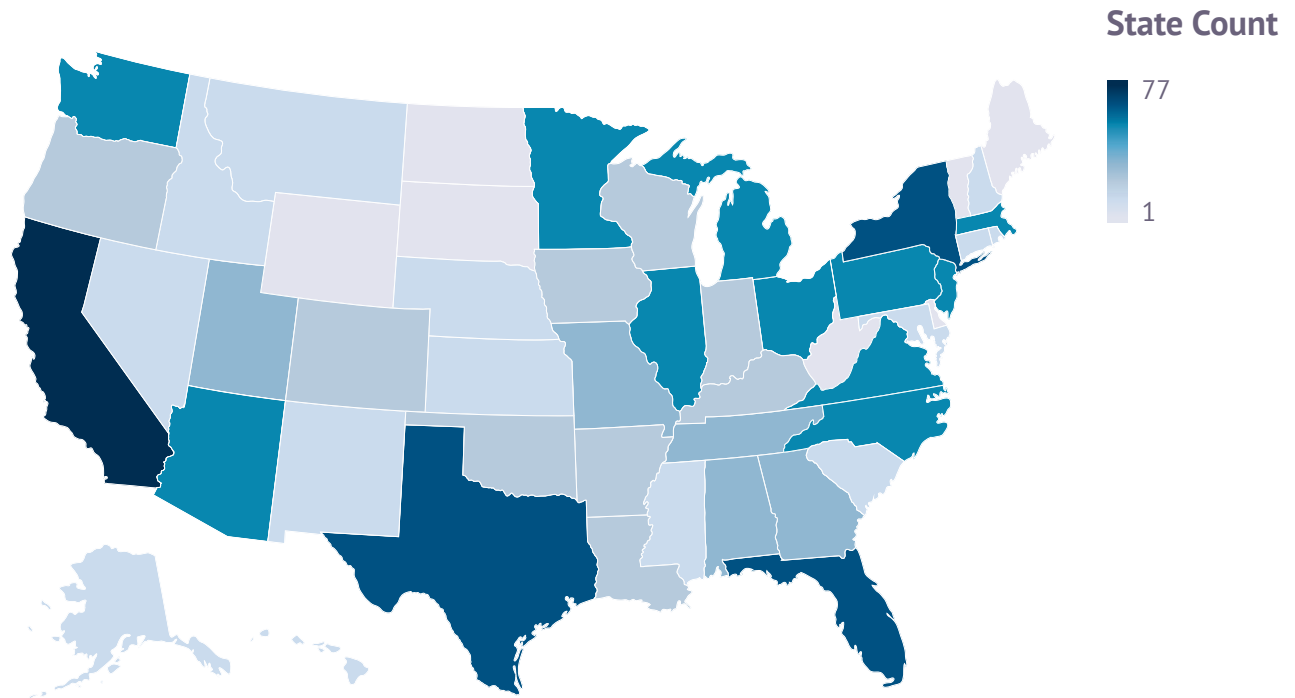
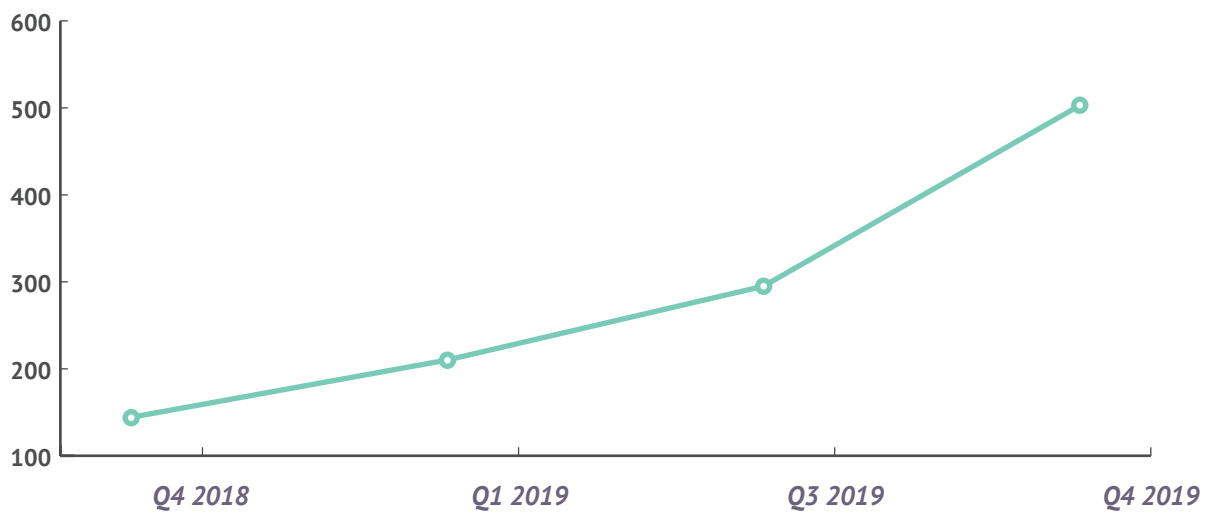


Figure 3. NBIR Registered Participants



Registry Findings

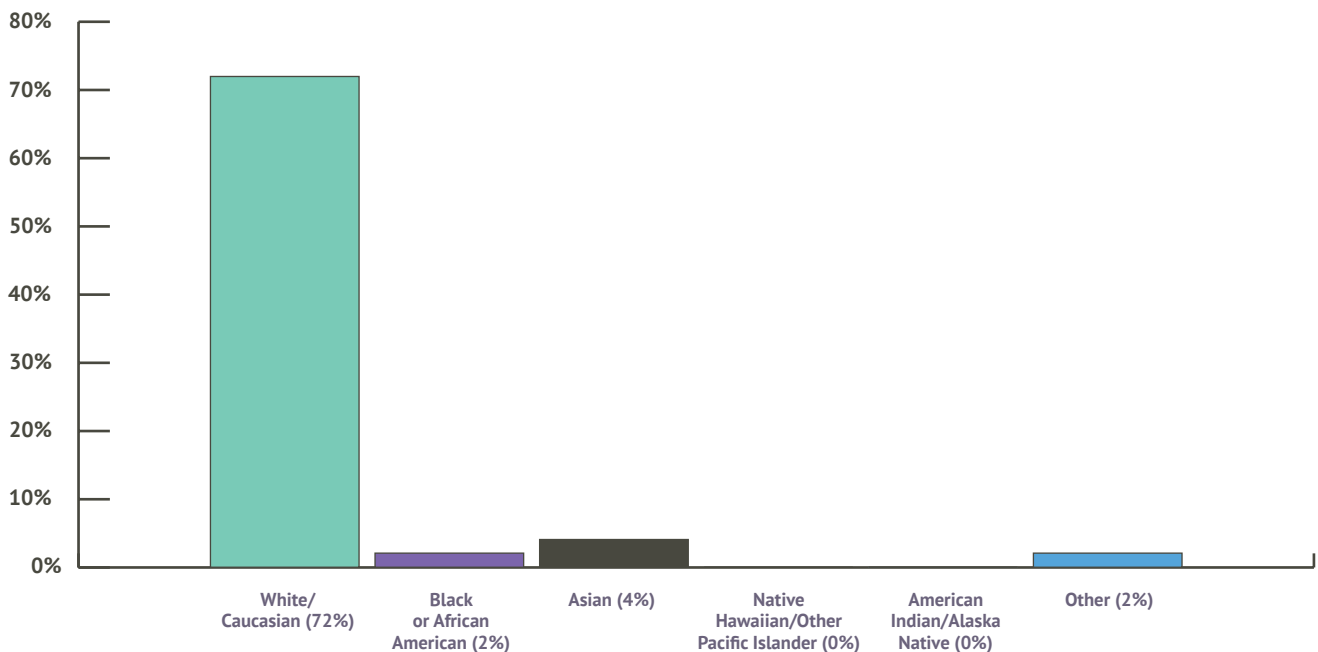
Clinical Demographics

During the first year of data collection, 3,924 cases were entered into the NBIR. For this inaugural report the analyses were performed on the entire aggregated dataset. For future reports reconstructive procedures and aesthetic procedures will be analyzed separately. The average patient age is 37 years old with a range of 19 to 87 [Fig. 4]. Of the total number of cases, 72% reported White/Caucasian race, and 55% reported an ethnicity of non-Hispanic [Fig. 5, 6]. The next predominant race reported was Asian at only 4%. Majority of cases entered involved female patients (94%), and a combined 1% involved male or transgender patients [Fig. 7].

Figure 4. Clinical case demographic variables:

Clinical Demographic Variables		
Age (years)	Range	19-87
	Mean	37.09
	Median	36
BMI (kg/m2)	Range	18.6-49.12
	Mean	23.17
	Median	22.59

Figure 5. Race



Multiple values can be selected; not a mandatory field

Figure 6. Ethnicity

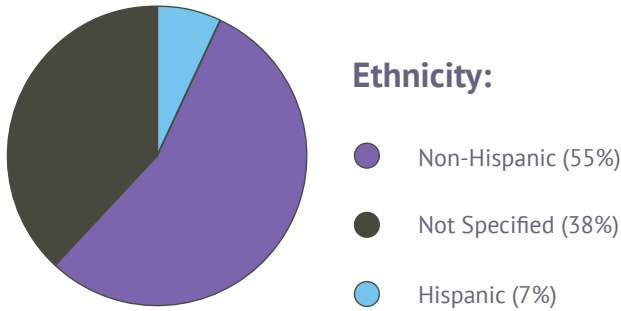
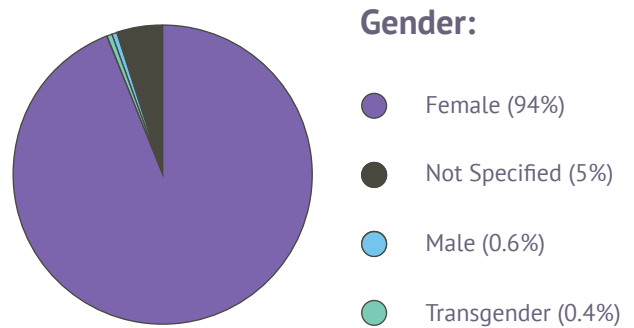
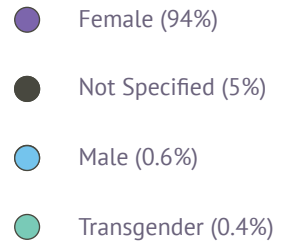


Figure 7. Gender



Gender:



History of Medical Conditions

One of the strengths of the NBIR is that it not only collects procedural information, but it also collects data on patients' medical history. Fifteen percent of cases reported a prior diagnosis of breast cancer [Fig. 8], which is in line with the total number of reconstruction cases reported (15%) [Fig. 11]. Cases often display more than one medical condition reported. 630 patient cases (16%) reported at least one medical condition in the past [Fig. 9]. It is interesting to note that 27% of cases reported a history of hypertension, while none of the other medical conditions report more than 10% of the registry population: such as diabetes, cardiac disease, and renal disease (8%, 4%, and 1% respectively). NBIR Registry Team is investigating the 73% of cases where another medical history condition was reported. If any trends are identified, the case report form will be updated accordingly. [Fig. 10].

Figure 8. History of Breast Cancer

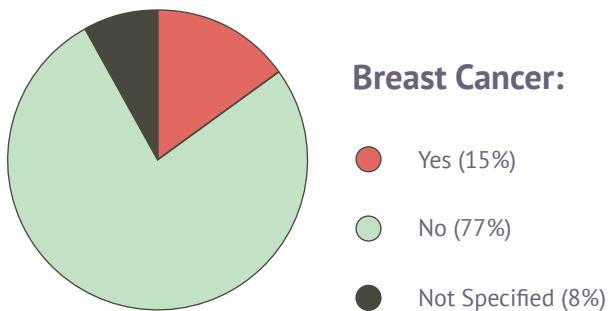


Figure 9. Presence of Prior Medical Condition

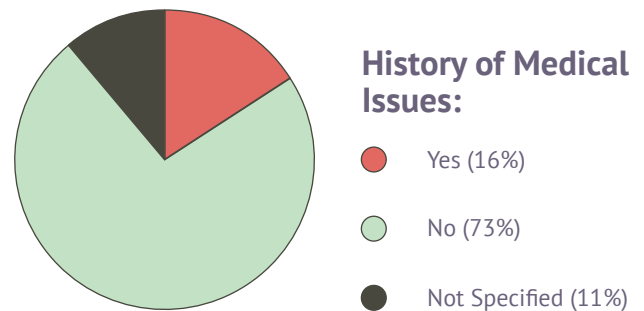
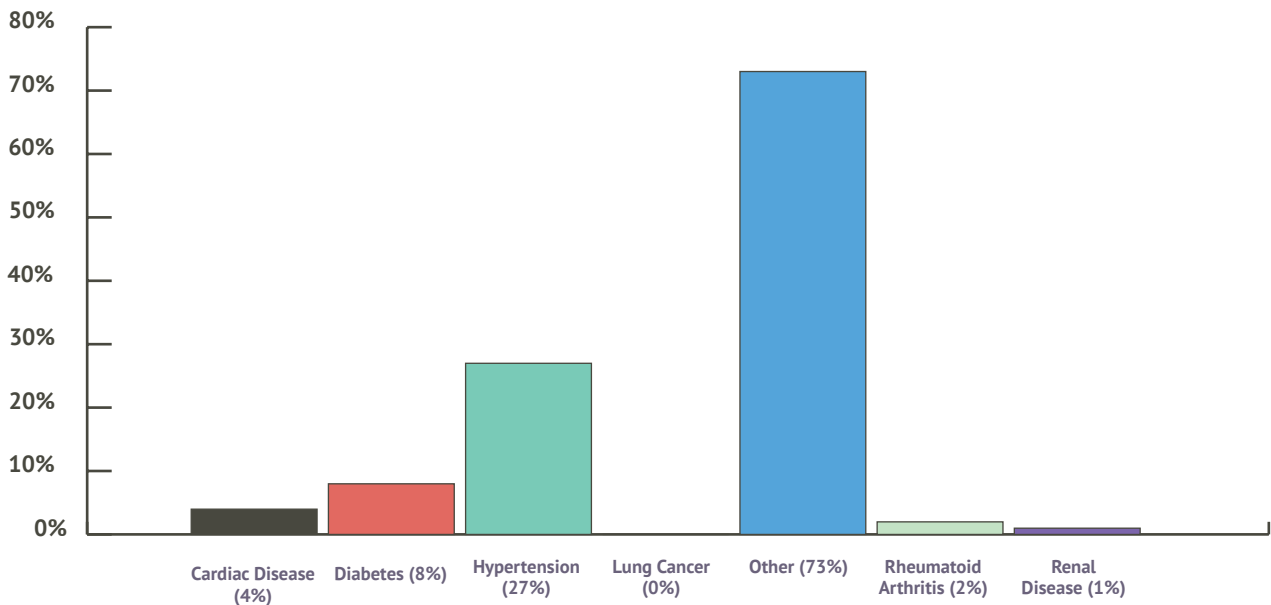


Figure 10. Medical Condition History



Multiple values can be selected; not a mandatory field

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 can 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 85% of all reported indications [Fig. 11]. Approximately 28% of the total procedures are reoperation cases and 72% involved an initial operation. [Fig. 12]. Bilateral breast implant procedures represented 94% of the cases [Fig 13]. Of the 85% of breast implant procedures that involved a breast augmentation, a combined 62% were primary augmentations or augmentation/mastopexy procedures, and 16% were revision augmentation procedures [Fig. 14]. This is comparable to the 2018 ASPS Procedural Statistic data, where 77% of the augmentations were primary augmentations, and 23% were revision augmentations. Two-thirds of the procedures entered involved a primary implant insertion. Only 2% of reported operations were implant revisions or removals, while 26% were implant replacements [Fig. 15].

The NBIR gathers additional procedural techniques regarding drains, fat grafting, surgical mesh, and acellular dermal matrices. Figures 16-19 show less than 15% of reported procedures involved these techniques: surgical mesh (2%), fat grafting (5%), drains (12%) or acellular dermal matrix (5%). Inframammary incisions made up 78% of incision types used, and submuscular/pectoral implant location made up 86% of implant location reports [Fig. 20, 21]. No other individual incision method or implant location exceeds 8% utilization by NBIR reporting surgeons.

Figure 11. Procedure by Aesthetic or Reconstruction

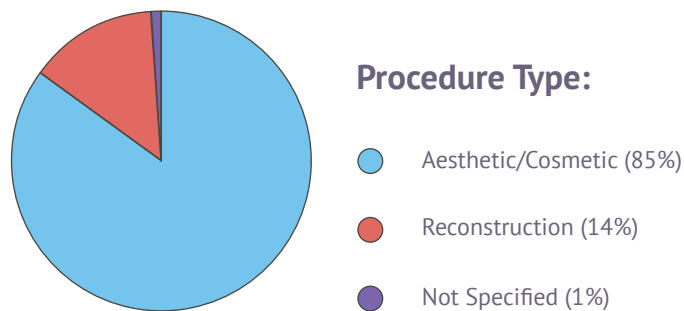


Figure 12. Procedure by Operation

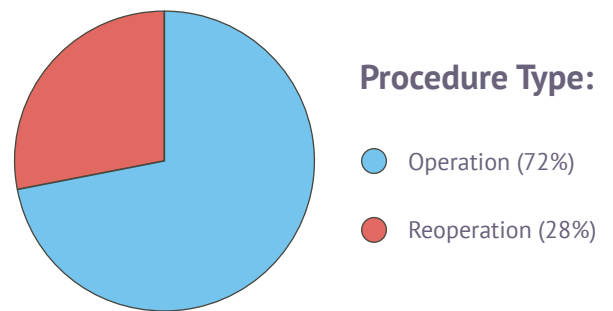


Figure 13. Procedure Location

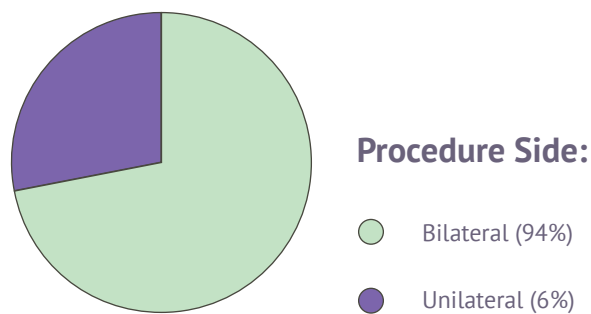


Figure 14. Procedure Indications

Indications (n=7,609)	n	%
Augmentation	3,743	49%
Augmentation/Mastopexy	1,010	13%
Reconstruction	696	9%
Revision Augmentation	1,235	16%
Revision Augmentation/Mastopexy	446	6%
Revision Reconstruction	374	5%
Other Implant Insertion	41	1%
Other Reoperation	64	1%

Includes left and right devices (n=7,609)

Figure 15. Operation Types

Operation Types (n=7,609)	n	%
Implant Insertion	4,952	65%
Implant Removal without Replacement	98	1%
Implant Revision	89	1%
Implant Replacement	1,965	26%
Capsulectomy/Capsulotomy	760	10%
Expander Removal and Implant Insertion	459	6%
Other Implant Insertion	94	1%
Other Reoperation	131	2%

Includes left and right devices (n=7,609); more than one option can be selected

Figure 16. Drains

Drains (n = 3,924)	n	%
Yes	483	12%
No	3,126	80%

Figure 17. Acellular Dermal Matrix (ADM)

ADM (n = 3,924)	n	%
Yes	200	5%
No	3,392	86%

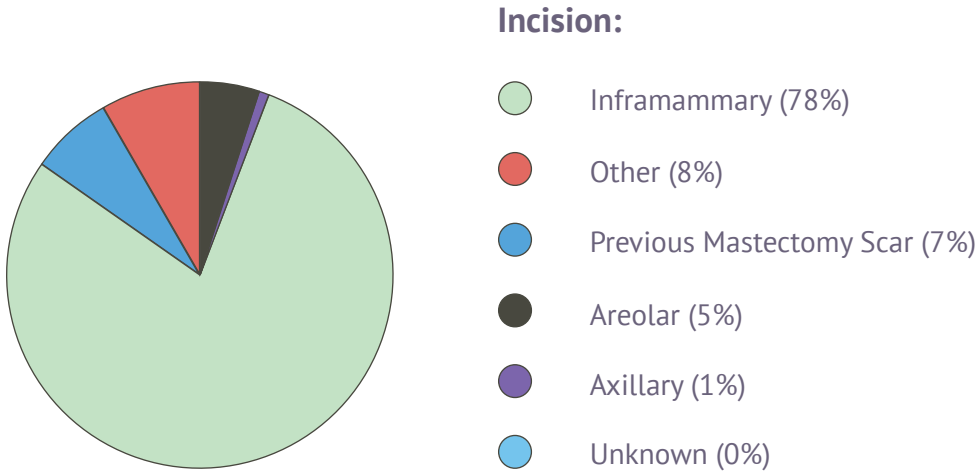
Figure 18. Surgical Mesh

Surgical Mesh (n = 3,924)	n	%
Yes	66	2%
No	3,529	90%

Figure 19. Fat Grafting

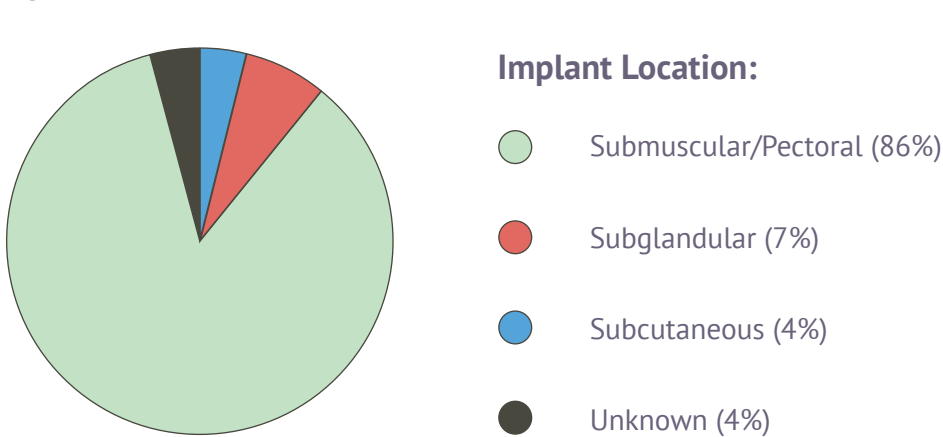
Fat Grafting (n = 3,924)	n	%
Yes	206	5%
No	3,389	86%

Figure 20. Incision



Includes left and right for all reported incision types (n = 7,046)

Figure 21. Implant Location



Includes left and right for all reported incision types (n = 7,046)

Reoperation

Reoperations are the primary endpoint for the NBIR. As reported in Figure 12, reoperations account for 28% 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 an overwhelming majority (84%) are done in response to patient request almost always regarding change in shape, size, or style [Fig. 22, 25]. Of the 24% complication-related reoperations, 90% of cases experienced capsular contracture [Fig. 23]. Other complications include hematoma, infection, seroma, skin necrosis, and wound problems. Reoperations completed in response to device issues were one of three concerns: device migration/malposition, suspected/actual rupture/deflation, or wrinkling/rippling [Fig. 24]. 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 22. Reasons for Reoperation

Reason for Reoperation (n = 2,119)	n	%
Complications	503	24%
Device Problems	767	36%
Patient Requests	1,776	84%
Other	109	5%

Includes data for left and right for each case; multiple reasons for reoperation can be selected for each case.

Figure 23. Complication-Related Reoperation

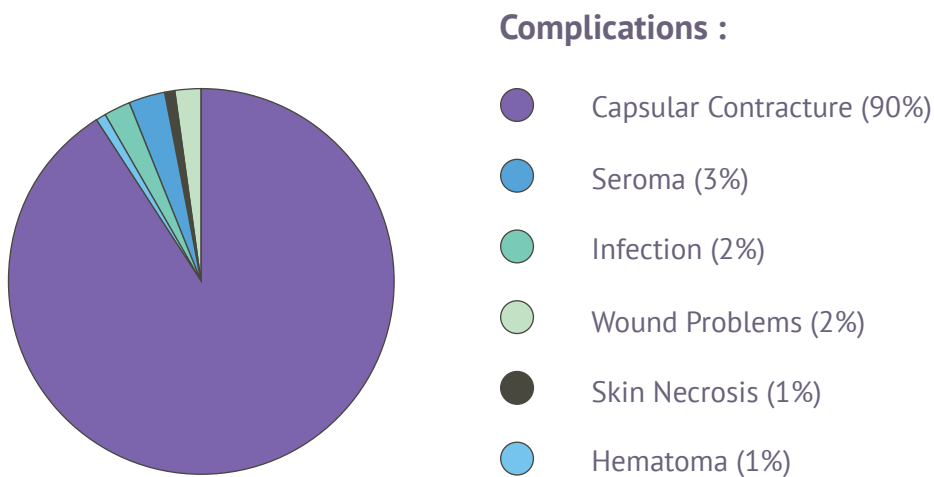


Figure 24. Device-Related Reoperation

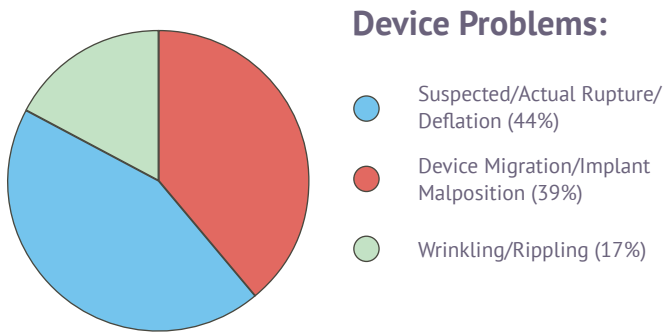
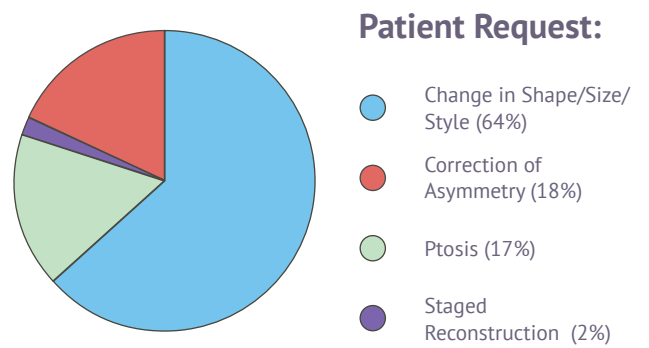
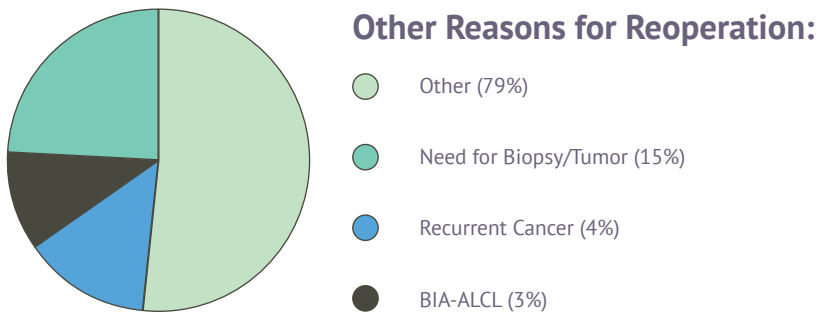


Figure 25. Patient Requests for Reoperation



User can select more than one

Figure 26. Other Reasons for Reoperation



Implant Information

There are a variety of implant types reported in the registry, with certain devices predominating. Surgeons reported use of smooth implants in 98% and round implants in 97% respectively [Fig. 27, 28]. Silicone is the typical implant fill (84%) followed by 14% filled with saline. [Fig. 29].

Figure 27. Implant Texture

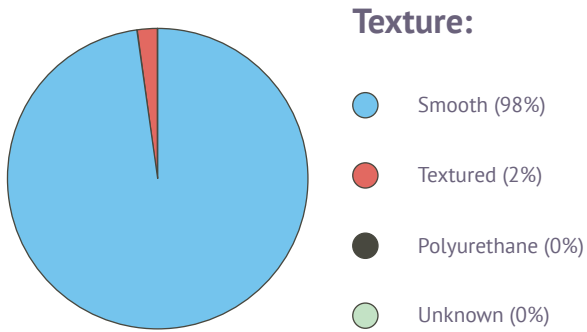


Figure 28. Implant Shape

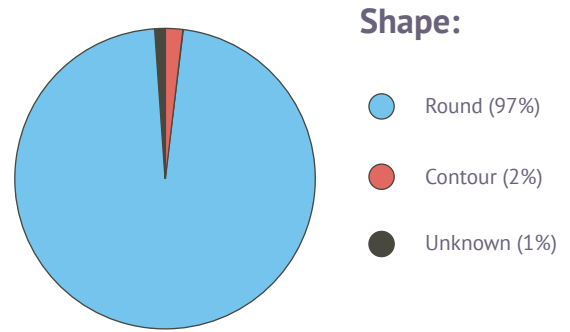
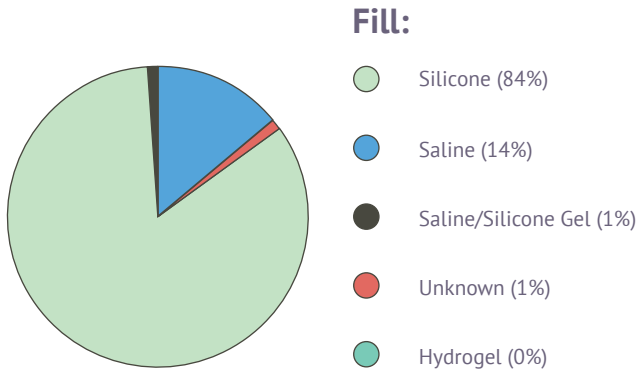


Figure 29. Implant Fill



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, and the development of an electronic medical record integration implementation plan, additional resources for NBIR Participants, and an aggressive awareness campaign.

The PSF will 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. This will also include the expansion of device tracking through the NBIR to all silicone breast implant manufacturers in 2020.

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. Upon completion of a Delphi Panel to identify these common symptoms, 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.

