MONASH University

AUSTRALIAN BREAST DEVICE REGISTRY

2021 REPORT

AUSTRALIAN Breast Device REGISTRY

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Data Period

The data contained in this document were extracted from the ABDR database 22 May 2022 and relates to data that had been submitted from the initiation of the pilot ABDR on 19 January 2012 to 31 December 2021. As the registry does not capture data in real time, there can be a lag between occurrence of an event and capture in the ABDR.

The Australian Breast Device Registry is supported by funding from the Australian Government Department of Health.

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FOREWORD

Welcome to the 2021 Australian Breast Device Registry (ABDR) Annual Report, the registry's sixth.

This report reflects the developing maturity of the registry and provides additional analyses from previous years. Continued growth in the volume of clinical data together with device and procedure follow up by the registry has provided us the opportunity to more clearly define emerging trends in the use of breast devices in Australia. In particular, this report presents greater information regarding the devices implanted and explanted that have been recorded by the ABDR, as well as a number of emerging procedural trends, particularly in reconstructive surgery.

Importantly, the ABDR continues to report data obtained regarding Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). We encourage every surgical clinician to report all confirmed cases of BIA-ALCL to the registry, and extend thanks to those who have already provided that information. Ongoing BIA-ALCL data collection will assist the ABDR in better understanding the device profile and other possible contributing factors associated with this rare disease.

Despite the ongoing prolonged COVID-19 pandemic restrictions that primarily affected Australia's south eastern states during 2021, the registry did not observe a reduction in reported procedure numbers. To all those participating surgeons and their team members who completed their data collection (registry) forms and contributed to the ABDR during those uncertain times, thank you for your commitment!

The continued success of this important quality registry remains reliant on the generous support from the Commonwealth Department of Health (DOH), for which the ABDR is most grateful. The registry team continues to work closely with the Therapeutic Goods Administration (TGA), ensuring that the ABDR remains aligned with TGA regulatory activities, including developing the use of unique device identifiers (UDIs) for breast devices being established by the TGA. Additionally, as the registry's dataset continues to mature, it continues to attract ongoing interest from researchers and industry.

The ABDR also supports hundreds of breast device recipients who every year contact the registry seeking breast device information. Further, we extend our thanks to all those women who participated in the registry's Patient Reported Outcome (PROMs) activities, providing their feedback following breast device surgery.

We hope that you find this year's ABDR Annual Report of interest, and engaging reading.

ACKNOWLEDGEMENTS

The ABDR acknowledges the Australian Government Department of Health for its continued funding and support for the ABDR, and the three major Australian cosmetic and surgical societies that encourage members to contribute their procedure and device data. We gratefully acknowledge the commitment and dedication of the three ABDR Clinical Leads (representing each of the supporting craft groups) who tirelessly provide their expertise regularly throughout the year, and greatly assisting the registry with its operations.

We are most grateful for the generous time contributions made by the ABDR Steering Committee members for their invaluable guidance with registry activities, including Dr Amanda Craig (Therapeutic Goods Administration), Dr Bernadette Aliprandi-Costa (Australian Commission on Safety and Quality in Healthcare), Sally Rayner and Gwili Holme (Australian Commonwealth Department of Health), Cindy Schultz Ferguson and Jane Synnot (consumer representatives) and David Ross and Dr Jasjit Baveja (Medical Technology Association of Australia).

The ABDR and the information provided in the contents of this annual report, would not be possible if not for the ongoing contributions and support from the numerous surgeons, nurses and other hospital staff who are engaged with this registry's data collection. Sincere thanks to you all for your ongoing commitment. Finally, we would also like to thank all of the patients who recognise the importance of the ABDR, both in the short and long-term, and allow the ABDR to report their data.

Steering Committee Representative Organisations

Monash University
Australian Government Department of Health (DOH)
Australian Society of Plastic Surgeons (ASPS)
Australasian College of Cosmetic Surgery and Medicine (ACCSM)
Breast Surgeons of Australia and New Zealand (BreastSurgANZ)
Therapeutic Goods Administration (TGA)
Australian Commission on Safety and Quality in Health Care (ACSQHC)
Medical Technology Association of Australia (MTAA)
Consumers Health Forum of Australia (CHF)

During 2021, we thanked outgoing Steering Committee members including A/Prof Colin Moore (ACCSM), A/Prof Elisabeth Elder (BreastSurgANZ), David Ross (MTAA) and Cindy Schultz-Ferguson (CHF) who provided outstanding leadership during the first 5 years of the ABDR national rollout at Monash University. We welcomed new members to these roles including Mr Patrick Tansley (ACCSM), Ms Melanie Walker (BreastSurgANZ), Dr Jasjit Baveja (MTAA) and Jane Synnot (CHF). A/Prof Gillian Farrell continued as the ASPS representative.

EXECUTIVE SUMMARY

The Australian Breast Device Registry (ABDR) is overseen by a national Steering Committee comprised of members representing a broad range of stakeholder groups. A Management Committee that comprises a representative from each of the 3 participating craft groups and the ABDR leadership team further supports and guides the registry's activities.

A total of **305 sites** participated in the ABDR, of which approximately 70% are private and 30% are public. The vast majority (94%) of cosmetic surgeries were undertaken in private sites, as well as the majority (78%) of reconstructive surgeries. A total of **552 surgeons** have contributed to the ABDR since 2012, including 22 surgeons who joined in 2021. Plastic surgeons comprise 62% of total participating surgeons, breast surgeons 30% and cosmetic surgeons 8%. There is a wide variety in the surgical volume of breast device procedures undertaken by individual surgeons, with the highest proportion of surgeons performing fewer than 5 procedures per annum, followed by 11 - 50 procedures per annum. The ABDR distributed over 400 reports to individual surgeons and over 100 reports to individual sites in 2021.

As of 31 Dec 2021, the ABDR had collected information on **75,336 patients** undergoing a total of **86,040 procedures** involving **148,529 devices (implants).** The ABDR has a consistent patient opt-out rate of only 1%. Of the 75,336 patients, 72.5% have undergone cosmetic procedures, and 20.8% have undergone reconstructive procedures (with approximately 6% not recording the indication of procedure). A total of **12,303 patients, 14,384 procedures and 23,500 devices were added to the registry in 2021.**

This annual report includes some additional device information for the first time. A total of 138,510 breast devices were inserted between 2012-21, of which 99% have associated manufacturer details recorded. Almost **90% of inserted implants** over this period were from **Mentor, Motiva and Allergan,** although there was substantial variation in use of device by manufacturer over time. A total of 13,836 implant devices were removed at the time of revision, of which 70.5% included manufacturer information. The most common devices **explanted at revision were Allergan, Mentor and Motiva devices, comprising 74%.** A total of 11,001 devices were explanted without replacement, of which 62.7% had manufacturer information. The most common **explanted only devices were Allergan, Mentor and Silimed, comprising 76.3%** of explanted devices.

ABDR data continues to show a decline in the proportion of inserted devices, and an increase in the number of revisions and explants. Removal of devices without replacement increased by 4% for reconstructive patients and 7.9% for cosmetic patients from 2016 to 2021. A majority of explant procedures for both reconstructive and cosmetic patients are undertaken in private hospitals, although 27.3% of reconstructive and 6.1% of cosmetic patients have explants undertaken in public hospitals.

Reconstructive Procedures

The ABDR recorded an additional **3,395 reconstructive procedures** in 2021, a slight reduction compared with 2019 and 2020. Reconstructive procedures include procedures following breast cancer, prophylactic or risk-reducing surgery, and procedures for developmental deformity. The proportion of each has remained relatively stable over time. The proportion of direct-to-implant (DTI) vs two-stage (tissue expander then implant) procedures has changed over time, with **DTI procedures comprising 62%** of reconstructive procedures, and two-stage procedures comprising 38% in 2021. The use of a greater range of aseptic techniques has also increased over time.

Greater than 55% of patients undergoing post-cancer or risk-reducing direct-to-implant insertions had concurrent use of dermal matrices. Approximately 28% of patients receiving a tissue expander also had dermal matrices used in conjunction. The trend favouring the use of smooth shell implants for reconstructive surgery continued with over 67% of these devices used for reconstructive procedures in 2021, with the remainder having textured shells. This reflects a steady decline in the use of textured implants reported for both reconstructive and cosmetic procedures over the last 6 years.

Complications relating to breast device surgery are recorded as either a reason for revision or are found incidentally at the time of revision/explantation. The most common **complications associated with reconstructive** patient revisions or explants in 2021 were capsular contracture (37.9%), device malposition (28.8%) and device rupture (17.3%). **All-cause revision** incidence at 6 years for **reconstructive** procedures was 18.3% for risk-reducing procedures, 19.1% for post-cancer procedures, and 13.5% for developmental procedures. Respectively, 6-year **revision** incidence due to **complications** was 12.7%, 12.8% and 8.0%.

The **all-cause revision** incidence rate for reconstructive implants at 6 years since primary implant insertion by **device shell type** was 24.7% for polyurethane implants, 18.8% for textured implants and 13.6% for smooth implants. The 6-year revision incidence due to complications by **shell** was 16.7% for polyurethane implants, 12.5% for textured implants and 10.1% for smooth implants. Complications reported at revision surgeries varied depending on whether the primary implant was inserted with a **matrix.** Device malposition and capsular contracture rates for reconstruction surgery were **lower for implants with matrix,** as were rates of device rupture and deflation. However, implants with **matrix** had **higher rates** of skin scarring problems, deep wound infection and seroma/haematoma. At six-years after insertion, 21.7% of the **implants with matrix** and 16.8% without matrix had been **revised** (for **all causes**), and 16.2% of the implants with matrix and 11.0% without matrix use had been revised due to **complications.**

During 2021 complications found at the time of unplanned revision procedures involving **tissue expanders** include deep wound infection (21.1%), capsular contracture (14.6%) and seroma/haematoma at 12.4%. The **revision incidence** of reconstructive primary **tissue expander** was 8.3% for all-cause revision and 5.1% for revision due to complications at 36 months. Six-year **revision** incidence due to complications for **direct to implant** procedures was 18.6%, and 16.5% for **two-stage** procedures (with a tissue expander).

Cosmetic Procedures

Approximately 67% of devices used in cosmetic surgery in 2021 were **smooth** shelled, with the remainder (33%) being **textured.** The proportion of textured implants continues to decline dramatically since 2018. In 2021, the most common complications associated with cosmetic patient revisions/explants were capsular contracture (34.8%), device rupture (21.4%) and device malposition (19.4%). **All-cause revision** incidence at 6 years was 5.6%, and revision incidence due to complications was 3%. Revision incidence was similar for the different types of devices, although was higher for polyurethane devices from 2019.

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

The ABDR began receiving reports of new cases of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) in mid-2015, and by the end of 2021 has received reports of **60 cases** (including 13 from 2021), with 62 related devices from all states and territories of Australia. Of the cases diagnosed with BIA-ALCL, 35 procedures were cosmetic, and 21 procedures were reconstructive. Approximately 50% of BIA-ALCL cases reported to the ABDR were diagnosed between 7-10 years following implant insertion, with a range of 3 to 18 years post implant insertion. Shell characteristics that were identified for 50 of the 62 explanted devices included 36 with a textured shell and 13 with a polyurethane shell.

Patient Reported Outcome Measures (PROMs)

The ABDR has also continued conducting its **Patient Reported Outcome Measure (PROMs)** program. Since commencing in October 2018, over **65,992 patients** have been contacted by the ABDR inviting recipients of breast devices to complete a brief questionnaire. During this time there has been a decline in participant response rates, from 49-79% in 2018 to 33-47% in 2021. Response rates generally were higher for reconstructive patients than for the cosmetic cohort, with both groups exhibiting lower response rates at 5 years post implant.

Overall, patients with cosmetic implants are more satisfied and experience less pain and tightening in their breasts than patients who had reconstructive device procedures. PROMs outcomes varied slightly between reconstructive **DTI and 2-stage procedures,** and were very similar for both reconstructive and cosmetic patients regarding **device shell.** The ABDR also reports on three internationally developed Clinical Quality Indicators **(CQIs)** that continue to show high levels of compliance.

Reporting and the Future

In 2021, the ABDR provided individual **reports** to a majority of participating surgeons and sites. Four research requests for ABDR data were made in 2021, and two requests by industry for safety and quality reports.

2022 will witness some exciting new initiatives involving the ABDR including the development of a new **database** that will allow surgeons and sites access to their own data. A new **PROMs** program focusing on reconstructive patients will also be established. The ABDR will review the **CQIs** reported by the registry, and will continue its close working relationship with the TGA on its **Unique Device Identifier** project.

OVERVIEW OF THE AUSTRALIAN BREAST DEVICE REGISTRY

The Australian Breast Device Registry (ABDR) is a clinical quality registry that was established in May 2015, and has been capturing information on breast devices used in Australia for the past 6 years. Its primary purpose is to track the long-term safety and performance of breast implants, breast tissue expanders and matrices implanted, and removed (explanted) from Australian recipients. The registry also aims to identify and report on possible trends and complications associated with breast device surgery, and to identify best surgical practice to improve patient outcomes. To this end, the ABDR is tasked with collecting, analysing and reporting data on all breast device surgery taking place across Australia.[1] Information on these surgical procedures is gathered from public hospitals, private hospitals and private day surgeries.

The registry was developed from an earlier successful pilot program led by the Australasian Foundation of Plastic Surgery. The ABDR continues to work in partnership with Australian surgeons, craft groups, health service managers and theatre staff in public and private facilities, and of course patients. The registry adheres to the Australian Commission on Safety and Quality in Health Care (ACSQHC) Framework for Australian Clinical Quality Registries (2014)[2] and Operating Principles and Technical Standards for Clinical Quality Registries (2008)[3]. It complies with all applicable standards of data security and protection, and privacy.

The ABDR's activities are overseen by both a Steering Committee and a Management Committee. The former comprises members representing a broad range of stakeholders including: The Commonwealth Department of Health (DOH) incorporating the Therapeutic Goods Administration (TGA); The Medical Technology Association of Australia (MTAA); the Australian Commission on Safety and Quality in Health Care (ACSQHC), the three surgical craft groups, academic registry scientists/epidemiologist and Consumers Health Forum of Australia (CHF). Steering Committee membership is provided on page 3. The Management Committee comprises the three clinical leads and the ABDR co-ordinating centre, and meets monthly to discuss clinical issues associated with day-to-day running of the ABDR.

Endorsement from the three participating clinical craft groups, the Australian Society of Plastic Surgeons (ASPS), Breast Surgeons of Australia and New Zealand (BreastSurgANZ) and the Australian College of Cosmetic Surgery and Medicine (ACCSM) is vital in encouraging members to contribute their patients' device information to the registry. Contributing surgeons also benefit from the ABDR by having the ability to track their patient's devices, the capacity to audit their clinical practice and accumulate Continuous Medical Education (CME) points for participating in the registry. Surgeons contributing to the registry also have the opportunity to include the ABDR logo on their website demonstrating their participation to the registry and their ongoing commitment to patient safety.

The ABDR has Human Research Ethics Committee (HREC) approval in each Australian State and Territory, and site governance is obtained at all sites before data is collected. To ensure high quality data, the ABDR is an opt-out registry[4]. This process incorporates a waiver of consent that allows the treating clinician to provide patient contact details to the ABDR at the time of the procedure. Following this, the ABDR co-ordinating centre provides information (an explanatory statement) to these patients, advising them of the option to opt out of the registry at any time.

Data is collected at the time of surgery, and is captured utilising the ABDR's Data Collection Form; designed as a simple "tick and stick" one-page, double-sided paper form. Since 2017, the ABDR have employed a Patient Reported Outcome Measure (PROMs), that is conducted at one-, two-, five- and ten-years following insertion of a breast device. The instrument used is referred to as a BREAST-Q Implant Surveillance (BREAST-Q IS), that consists of five questions and is adopted from the BREAST-Q questionnaire. The questions relate to satisfaction and symptoms[5-7].

The ABDR database has been developed with tools designed to reduce data entry error and maintain high quality data, including range and reliability checks that are activated as data are entered into the registry. The ABDR Database Manager also conducts regular data audits through the database to identify any missing or incorrect data, which is then followed up by registry staff.

Access to data held by the ABDR is subject to applicable National and State privacy policies as well as specific ethics approval for research projects. Only very limited operational staff have access to identified patient data. Patients may request access to their own information by contacting the ABDR, where they will be required to provide proof of identity prior to the release of any data. Surgeons can also access their own patient data in line with the ABDR's Privacy Policy. All other requests for data must comply with the ABDR Data Access and Publications Policy, and be reviewed and approved by the ABDR Management Committee.

Outcome Assessment

The main outcomes reported is time-to-revision analysis using survival analysis methods to investigate revision incidence rates for primary reconstructive breast implants, cosmetic breast implants and matrices separately.

- Revision surgery includes the unplanned replacement, repositioning or explant of an in-situ breast device. Revision time is defined as the time from the insertion of the breast implant to the first subsequent revision procedure.
- All-cause revision incidence considers all revisions captured by the registry, whether for complication reasons, patient preference or other unknown reasons.
- A revision due to complication is defined as revisions that stated complication as the reason for revision and/or an issue was identified at revision (issues included device rupture, device deflation, capsular contracture, device malposition, skin scarring problems, deep wound infection, seroma/haematoma and BIA-ALCL).
- Crude cumulative revision incidence rates were generated using Nelson-Aalen estimates for all primary reconstructive and cosmetic breast implants captured by the ABDR from 2012 to 2021. Primary breasts without a revision procedure captured by the registry had their follow-up time censored at the date of data extraction.

CHAPTER 1: REGISTRY PARTICIPATION (2012-2021)

Site participation

The ABDR continues to encourage all hospitals and day surgeries in Australia that undertake breast device surgery, to contribute data to the registry. There is no independent record of these sites within Australia, so the precise denominator is unknown. ABDR staff also monitor changes and updates to site status, noting site closures and inviting sites that commence breast device surgery. The ABDR gained 8 additional sites throughout the past year, 2 of which were public hospitals with the remaining 6 being private sites. A total of **305 sites** have participated data to the ABDR since 2012 (Table 1.1). Figure 1.1 incorporates currently closed sites into the state/jurisdiction totals. Approximately 70% of currently active sites are private, and 30% are public.

TABLE 1.1: SITE PARTICIPATION BY STATE/TERRITORY AND SITE TYPE (PUBLIC OR PRIVATE) 2012-2021

State	Closed Sites	Participating Private Sites	Participating Public Sites	Total
NSW	7	64	25	96
VIC	4	49	21	74
QLD	7	48	13	68
WA	2	21	0	23
SA	4	17	7	28
ACT	0	6	1	7
TAS	0	4	2	6
NT	0	2	1	3
Total	**24**	**211**	**70**	**305**

Note: the value in the total includes the sites that have closed

Sites are considered participating once ethics and site governance approval has been obtained and data collection for the registry has commenced. The ABDR staff coordinate all ethics and site governance activities including submissions, amendments and progress reports on behalf of participating sites. The main reason a site is not participating is that the ethics or governance application or implementation process is not yet finalised. Public hospitals in Western Australia remain unable to contribute to the registry as they are prevented to by state legislation.

FIGURE 1.1: SITE PARTICIPATION BY STATE AND SITE TYPE

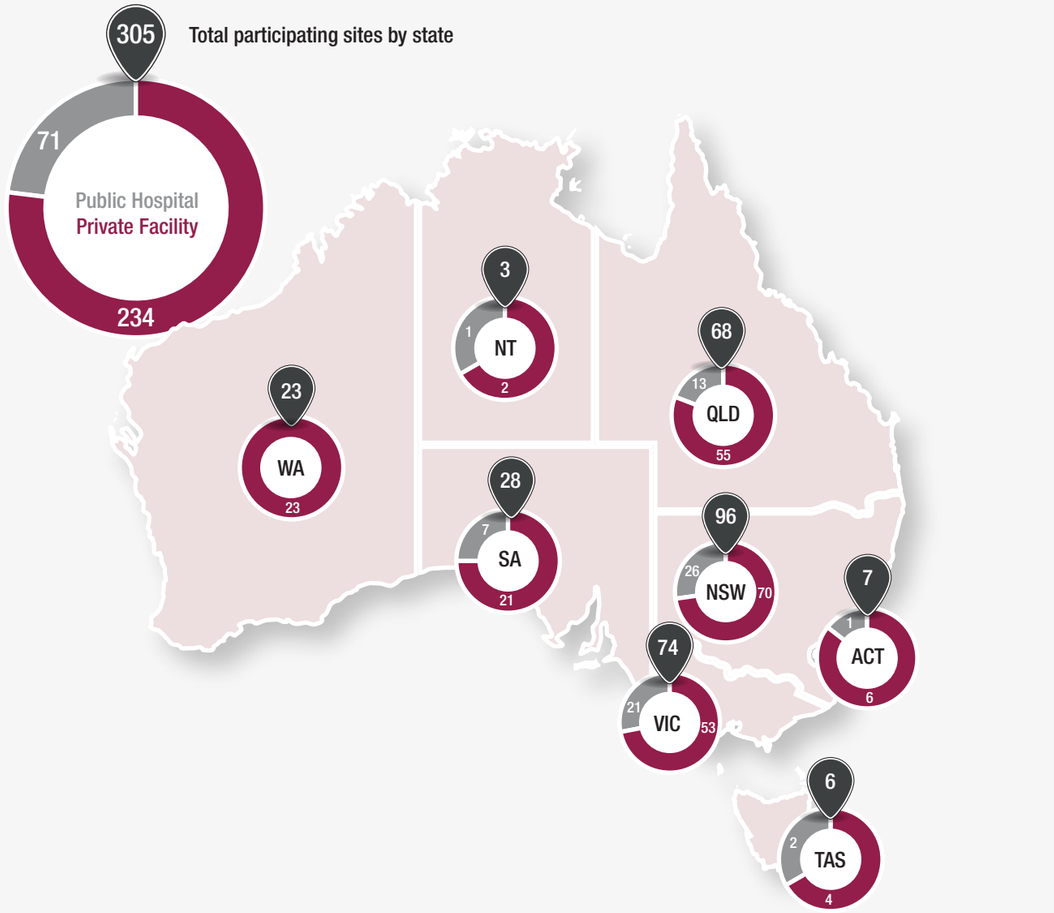


Table 1.2 identifies patient participation by state/territory, surgery indication and site type. The vast majority (94%, 57,206 patients) of cosmetic surgeries were undertaken in private sites, with a small number of patients undergoing cosmetic surgery in public sites consisting of explant only procedures (as per Figure 2.5). The majority (78%, 17,985 patients) of reconstructive surgeries were also undertaken in private sites. A total of 6,273 patients did not have their indication for surgery recorded in the ABDR comprising 7% of the total of 87,314 patients (noting some patients may be counted in both private and public sectors). These 7% of patients do not have their data reported within the reconstructive and cosmetic surgery data sections.

TABLE 1.2: PATIENT PARTICIPATION BY STATE/TERRITORY, SURGERY INDICATION AND SITE TYPE (PUBLIC AND PRIVATE) 2012-2021

State	Cosmetic		Reconstructive		Not Stated//Known		Total	
	Private	Public	Private	Public	Private	Public	Private	Public
NSW	17,148 (30.0%)	97 (24.7%)	4,468 (24.8%)	1,425 (26.1%)	1,363 (23.9%)	157 (27.8%)	22,979 (28.4%)	1,679 (26.2%)
QLD	17,151 (30.0%)	107 (27.2%)	3,037 (16.9%)	1,288 (23.6%)	1,957 (34.3%)	138 (24.4%)	22,145 (27.4%)	1,533 (23.9%)
VIC	11,871 (20.8%)	94 (23.9%)	3,802 (21.1%)	1,547 (28.3%)	1,032 (18.1%)	143 (25.3%)	16,705 (20.6%)	1,784 (27.8%)
WA	7076 (12.4%)	0 (0.0%)	3,109 (17.3%)	0 (0.0%)	927 (16.2%)	0 (0.0%)	11,112 (13.7%)	0 (0.0%)
SA	3109 (5.4%)	63 (16.0%)	2,614 (14.5%)	869 (15.9%)	292 (5.1%)	82 (14.5%)	6,015 (7.4%)	1,014 (15.8%)
TAS	564 (1.0%)	24 (6.1%)	472 (2.6%)	176 (3.2%)	96 (1.7%)	24 (4.2%)	1,132 (1.4%)	224 (3.5%)
ACT	168 (0.3%)	8 (2.0%)	375 (2.1%)	137 (2.5%)	20 (0.4%)	18 (3.2%)	563 (0.7%)	163 (2.5%)
NT	119 (0.2%)	0 (0.0%)	108 (0.6%)	15 (0.3%)	21 (0.4%)	3 (0.5%)	248 (0.3%)	18 (0.3%)
Total	**57,206 (100.0%)**	**393 (100.0%)**	**17,985 (100.0%)**	**5,457 (100.0%)**	**5,708 (100.0%)**	**565 (100.0%)**	**80,899 (100.0%)**	**6,415 (100.0%)**

Note: some patients might be counted more than once as they might undertake their procedures in both private or public sites or in different states/territories.

Surgeon participation

All surgeons representing the 3 participating craft groups identified as performing breast device surgery are encouraged to submit their data to the ABDR. At 31 December 2021, an additional 22 new surgeons joined the registry throughout the year. From 2012 to 2021, **552 individual surgeons participated** in the ABDR including **344 plastic surgeons, 164 breast/general surgeons** and **44 cosmetic surgeons** (Table 1.3). As for sites, there is no national list of data relating to surgeons/proceduralists undertaking breast device surgery. Of the total number of surgeons who contributed data in the reporting period - plastic surgeons are the largest participating craft group, comprising 62% of total participating surgeons, breast surgeons comprised 30% and cosmetic surgeons comprised 8%.

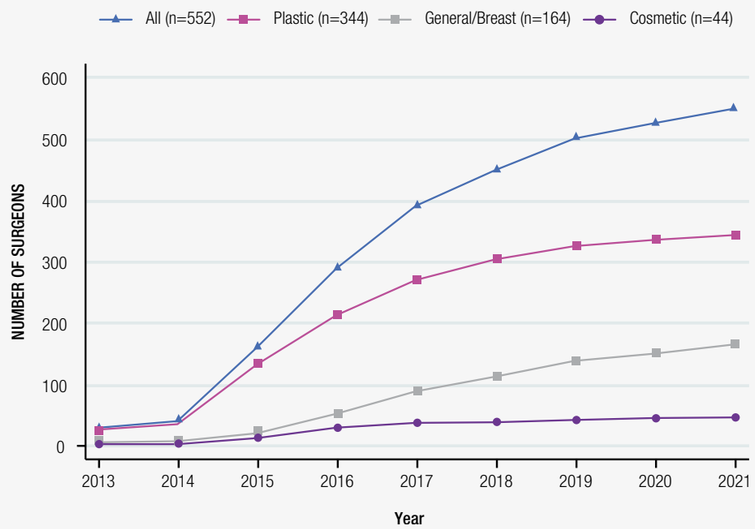
TABLE 1.3: SURGEON PARTICIPATION BY STATE AND CRAFT GROUPS (2012-2021)

State	Plastic Surgeons	General/Breast Surgeons	Cosmetic Surgeons
VIC	102 (30%)	27 (16%)	5 (11%)
NSW	93 (27%)	59 (36%)	21 (48%)
QLD	67 (19%)	42 (26%)	12 (27%)
WA	36 (10%)	16 (10%)	4 (9%)
SA	30 (9%)	11 (7%)	2 (5%)
TAS	11 (3%)	3 (2%)	0
ACT	3 (1%)	4 (2%)	0
NT	2 (1%)	2 (1%)	0
Total	**344**	**164**	**44**

Accumulation of surgeon participation

Figure 1.2 shows the timeline for recruitment of surgeons into the pilot Breast Device Registry (BDR) and ABDR. Prior to April 2015, the pilot study included accredited sites with plastic surgeons and general/breast surgeons only. In 2015, the registry became an initiative of the Australian Government Department of Health and the scope was broadened to include all medical professionals performing breast device surgery. Members of the Australasian College of Cosmetic Surgery and Medicine began participating in October 2015.

FIGURE 1.2: CUMULATIVE PARTICIPATING ABDR SURGEONS BY CRAFT GROUPS



To better understand how the ABDR could engage surgeons, the ABDR analysed the number of breast device procedures undertaken by surgeons in 2021. Table 1.4 shows wide variety in the surgical volume of these procedures undertaken by individual surgeons. The highest proportion of surgeons undertaking either cosmetic or reconstructive procedures performed less than five procedures per annum, however 9 surgeons performed over 200 procedures in the same year.

TABLE 1.4: RECONSTRUCTIVE AND COSMETIC PROCEDURES PER SURGEON (2021)

Number of procedures per surgeon	Cosmetic	Reconstructive
>200	9	0
101-200	17	1
51-100	19	13
11-50	113	77
6-10	55	71
<5	135	162
Total	**348**	**324**

Note: Some surgeons might undertake both cosmetic and reconstructive procedures

Surgeon and site reporting

The ABDR disseminated its third round of **surgeon reports** in 2021 to 417 surgeons. All surgeons with a minimum case load who contributed data in the reporting year received an individualised surgeon report regarding their ABDR outputs including 1-year PROMs results. **Site reports** were generated for the third time and provided to the top 50% of sites contributing data in 2020 (104 site reports).

Presentation of this report

Due to the different clinical profiles between patients presenting for breast reconstructive surgery and cosmetic procedures, the registry outputs have been presented separately for the two groups. This Annual Report therefore presents data analysed and recorded separately in two main sections:

- **Registry outputs: Reconstructive indications** will include procedures for post-cancer reconstruction, risk-reducing reconstruction and developmental indications.
- **Registry outputs: Cosmetic indications** will include cosmetic procedures only.

Patients whose records omitted the indication for surgery (not stated), were excluded from further analysis in this report (refer to Table 2.1 and Table 2.2). Within the two registry output sections- reconstructive and cosmetic, results have been analysed and presented across three types of procedural interventions where possible:

- **Primary insertion surgery** which captures surgery involving insertion of a new device, either a breast implant or tissue expander. Patients from the reconstructive cohort are also assigned to this group when the procedure involves inserting a first breast implant following removal of a tissue expander.
- **Revision surgery** which includes unplanned replacement or reposition procedures. The initial device insertion may or may not have been captured by the registry. Also included are reconstruction procedures involving the removal of an implant and insertion of a tissue expander or a new implant.
- **Explant only surgery** which includes the removal or explant of an in-situ device without replacement, including both tissue expanders or breast implants.

CHAPTER 2: ABDR DATA OVERVIEW

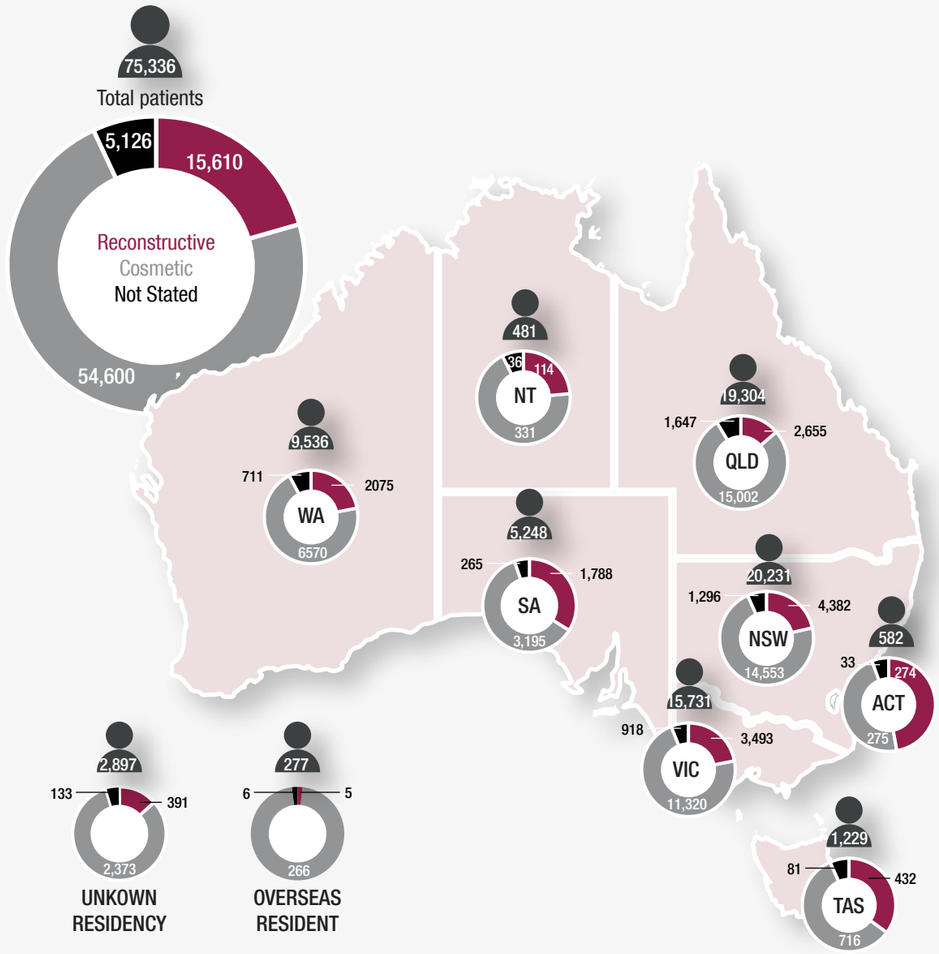
Patient, procedure and device numbers

From 2012 to 2021, the ABDR had **75,336 patients** registered, reflecting an **addition of 12,303 patients** since the previous year. A patient is considered to be participating in the ABDR from the date of their earliest ABDR recorded surgery. Due to the lag of data transfer from the surgeon to the ABDR, additional patients may have had surgery in this timeframe but are yet to be included in the database. Data from patients who chose to opt out (n=778) are not included in the reported figures.

Figure 2.1 and Tables 2.1 and 2.2 present the registered patients, procedures per patient, and procedures per breast by indication for surgery for the period between 2012-2021 and 2021 respectively. Procedure indication is assigned based on a four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental indication and then cosmetic procedures. Patients were assigned to the indication for their first procedure as recorded on the Data Collection (registry) Form submitted by surgeons and subsequently recorded in the ABDR database. When the first operation was bilateral but different procedures were undertaken on each breast, the four-tier hierarchy was applied for assigning the procedure.

Figure 2.1 shows the residency by state/territory of patients by surgical indication. Queensland and New South Wales have the highest proportion of patients having cosmetic surgery, while New South Wales and Victoria have the highest proportion of patients having reconstructive surgery.

FIGURE 2.1: PATIENT RESIDENCY BY INDICATION (2012-2021)



Note: N = 75,336 patients. This includes 277 overseas residents and 2,897 with unknown residency.
Patients with unknown residency are those who have elected email as the form of correspondence.
The ABDR did not collect data on country of residency for this report.

Of the **75,336 patients** in the ABDR, 72.5% have been entered into the registry for cosmetic procedures; 15.3% for post-cancer reconstruction, 3.3% for risk-reducing reconstruction; and 2.2% for correction of developmental anomaly (Table 2.1). The total number of procedures captured by the registry is 86,040, indicating that some patients have more than one procedure captured by the registry, particularly reconstructive patients who comprise 20.4% of total patients but 26.0% of total procedures. **Over 160,000** procedures per breast have been captured by the registry, and **148,529 devices** have been captured. The number of devices is fewer than the number of procedures per breast as some procedures may not result in a new device insertion e.g. malposition or explantation procedures. Furthermore, the number of procedures for each breast accounts for all procedures recorded by the ABDR, and thus a specific device may be included in this total more than once. Devices captured at implant are not counted again during an explant procedure. A total of **12,303 new patients,14,384 procedures per patient, 26,961 procedures per breast,** and **23,500 devices** were captured in 2021 (Table 2.2).

TABLE 2.1: THE TOTAL NUMBER AND PERCENTAGE OF REGISTERED PATIENTS, PROCEDURES PER PATIENT, PROCEDURES PER BREAST, AND TOTAL DEVICES CAPTURED BY CLINICAL INDICATION FOR SURGERY (2012-2021)

	Patients*		Procedures (total)**		Procedures (each breast) ***		Devices captured by Registry #	
	N	(%)	N	(%)	N	(%)	N	(%)
Reconstructive								
Post-cancer reconstruction	11,494	(15.3%)	16,879	(19.6%)	21,403	(13.4%)	20,679	(13.9%)
Risk-reducing reconstruction	2,462	(3.3%)	3,588	(4.2%)	10,054	(6.3%)	9,668	(6.5%)
Developmental deformity	1,654	(2.2%)	1,917	(2.2%)	3,211	(2.0%)	3,112	(2.1%)
Total reconstructive	**15,610**	**(20.4%)**	**22,384**	**(26.0%)**	**33,459**	**(21.7%)**	**33,459**	**(22.5%)**
Total cosmetic	**54,600**	**(72.5%)**	**57,406**	**(66.7%)**	**114,066**	**(71.2%)**	**108,871**	**(73.3%)**
Not stated	5,126	(6.8%)	6,250	(7.3%)	11,564	(7.2%)	6,199	(4.2%)
Total	**75,336**	**(100%)**	**86,040**	**(100.0%)**	**160,298**	**(100%)**	**148,529**	**(100%)**

Note: Indication was assigned based on a four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation.
* Patients were assigned to the indication for their first procedure recorded in the ABDR.
** The number of procedures at the patient level have been reported, where the primary reason for the procedure determines the classification by indication.
*** The number of procedures at breast level have been reported.
# Devices including primary and revision procedures, but not explants, were reported for this outcome. Missing or not reported device types were excluded.

TABLE 2.2: THE TOTAL NUMBER AND PERCENTAGE OF REGISTERED PATIENTS, PROCEDURES PER PATIENT, PROCEDURE PER BREAST, AND TOTAL DEVICES CAPTURED BY CLINICAL INDICATION FOR SURGERY (2021)

	Patients*		Procedures (total)**		Procedures (each breast) ***		Devices captured by Registry #	
	N	(%)	N	(%)	N	(%)	N	(%)
Reconstructive								
Post-cancer reconstruction	1,657	(13.5%)	2,573	(17.9%)	3,297	(12.2%)	3,118	(13.3%)
Risk-reducing reconstruction	357	(2.9%)	3,588	(3.8%)	1,527	(5.7%)	1,448	(6.2%)
Developmental deformity	227	(2.2%)	1,917	(1.9%)	474	(1.8%)	446	(1.9%)
Total reconstructive	**2,241**	**(18.2%)**	**3,395**	**(23.6%)**	**5,298**	**(19.7%)**	**5,012**	**(21.3%)**
Total cosmetic	**8,835**	**(71.8%)**	**9,461**	**(65.8%)**	**18,811**	**(69.8%)**	**17,186**	**(73.3%)**
Not stated	1,227	(10.0%)	1,528	(10.6%)	2,852	(10.6%)	1,302	(5.5%)
Total	**12,303**	**(100%)**	**14,384**	**(100.0%)**	**26,961**	**(100.0%)**	**23,500**	**(100.0%)**

Note: Indication was assigned based on a four-tier hierarchy beginning with post-cancer reconstruction, followed by risk-reducing reconstruction, developmental deformity and then cosmetic augmentation.
* Patients were assigned to the indication for their first procedure recorded in the ABDR.
** The number of procedures at the patient level have been reported, where the primary reason for the procedure determines the classification by indication.
*** The number of procedures at breast level have been reported.
# Devices including primary and revision procedures, but not explants, were reported for this outcome.
Missing or not reported device types were excluded.

Devices captured

The ABDR undertakes an annual case ascertainment of devices reported to it by participating surgeons against sales data for that year provided by the Therapeutic Goods Administration. For 2021, the TGA reported sales of 23,925 devices, of which 23,500 were captured by the ABDR, resulting in a **94% capture rate.** This is an increase on previous capture rates of approximately 75% of sales, and is due to both ongoing increased surgeon and site participation in the ABDR and reduction in total implants sold in 2021.

The following tables identify the devices captured as well as the completeness of reporting of information regarding the devices collected in the Registry from 2012-2021. Data is reported per breast. The following Tables 2.3 – 2.5 and Figure 2.3 relate to **breast implants** only, not tissue expanders or mesh/matrix devices.

TABLE 2.3: IMPLANT DEVICES INSERTED BY MANUFACTURER, PER BREAST (2012-2021)

Manufacturer	N	%
Mentor Medical Systems	69,231	50.0%
Motiva	34,835	25.2%
Allergan	19,823	14.3%
Polytech Health & Aesthetics	7,339	5.3%
Nagor	4,347	3.1%
Eurosilicone	1,944	1.4%
Silimed Industria de Implantes	604	0.4%
Group Sebbin SAS	175	0.1%
Cereplas	44	<0.1%
Total	**138,342**	**100.0%**
Completeness	**138,342**	**99.9%**

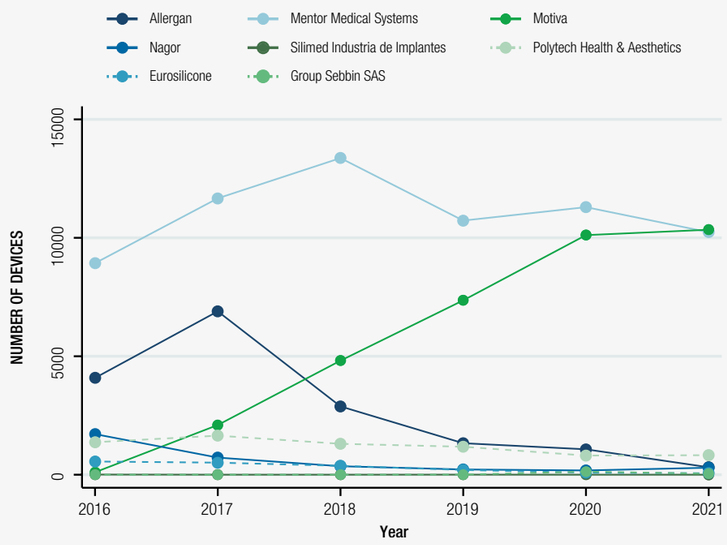
N (total) = 138,510.
Data completeness of 99.9% include 168 inserted implant devices for which manufacturer information was not completed.

Note: Inclusion criteria: 1) First implant insertion, OR 2).TE removal, revision and implant insertion OR 3) Implant or TE removal, revision or replacement AND revision type = insertion

Table 2.3 provides the breakdown of devices inserted by manufacturer for cosmetic and reconstructive purposes, where this information was provided to the registry, and is reported both by number and percentage. From 2012-2021, a total of 138,510 devices were inserted, of which 138,342 **(99%)** had manufacturer details provided. This includes implant devices from (1) a first reconstructive implant insertion (DTI), or (2) TE removal and implant insertion (two- stage), or at (3) implant or TE removal, revision or replacement with subsequent insertion. The most common inserted implant devices from 2012-2021 were Mentor, Motiva and Allergan, which combined comprised almost 90% of implants inserted.

Figure 2.2 shows the change in the number of implant devices inserted by manufacturer over the period from 2016-2021. Motiva substantially increased its share of the proportion of implanted devices over this period, whilst Allergan decreased the number of devices implanted over the same period. It should be noted that all Allergan macrotextured implants were withdrawn from use in Australia in 2019. Data collected during the pilot program 2012-2015 has not been included due to the small number of devices reported.

FIGURE 2.2: IMPLANTED DEVICES INSERTED BY MANUFACTURER, PER BREAST (2016-2021)



The most common explanted devices at the time of revision between 2012 and 2021 were Allergan, Mentor and Motiva devices, which comprised 74.2% of explanted devices (Table 2.4). This information does not necessarily reflect device performance as there are a number of reasons why a device may be revised including patient, procedure and device factors. Of a total of 13,836 recorded explanted implant devices in the ABDR, 9,756 **(70.5%)** had manufacturer information available.

TABLE 2.4: EXPLANTED IMPLANTS AT THE TIME OF REVISION (NOT INCLUDING TISSUE EXPANDERS)

Manufacturer	N	%
Allergan	3,435	35.2%
Mentor Medical Systems	2,759	28.3%
Motiva	1043	10.7%
Silimed Industria de Implantes	716	7.3%
Nagor	621	6.4%
Eurosilicone	325	3.3%
Polytech Health & Aesthetics	284	2.9%
PIP	231	2.4%
Other	157	1.6%
Dow Corning	109	1.1%
Cereplas	54	0.6%
Group Sebbin SAS	22	0.2%
Total devices	**9,756**	**100.0%**
Completeness of devices	**9,756**	**70.5%**

N (total) = 13,836. There were 4,080 devices explanted at the time of revision for which manufacturer information was not completed.

Note: Exclusion criteria: 1) TE at insertion OR 2) TE revision, removal OR replacement, OR 3) implant removal and TE insertion or 4) procedure type not stated. 5) included if revision type was explant.

Of a total of 11,001 implants removed (explanted) without replacement, 6,898 **(62.7%)** had manufacturer information available (Table 2.5). The most commonly explanted devices were Allergen, Mentor and Silimed, comprising 76.3% of total explanted only devices.

TABLE 2.5: EXPLANTED IMPLANTS AT THE TIME OF REVISION WITHOUT REPLACEMENT (NOT INCLUDING TISSUE EXPANDERS)

Manufacturer	N	%
Allergen	2,925	42.4%
Mentor Medical Systems	1,643	23.8%
Silimed Industria de Implantes	698	10.1%
Nagor	496	7.2%
Eurosilicone	281	4.1%
PIP	231	3.3%
Cereplas	158	2.3%
Other	157	2.3%
Motiva	126	1.8%
Dow Corning	109	1.6%
Cereplas	54	0.8%
Group Sebbin SAS	20	0.3%
Total devices	**6,898**	**100.0%**
Device completeness	**6,898**	**62.7%**

N (total) = 11,001. There were 4,103 devices explanted without revision for which manufacturer information was not completed.

Note: Exclusion criteria: 1) TE at insertion OR 2) TE revision, removal, or replacement, OR 3) implant removal and TE insertion OR 4) procedure type not stated AND 5) excluded if revision included replacement, or 6) Inclusion criteria revision type was “explant”

ABDR devices include breast implants as well as tissue expanders. Of the 160,298 devices registered with the ABDR, **93.3% are breast implants, 6.2% are tissue expanders,** and 0.6% are not defined (Table 2.6).

TABLE 2.6: BREAKDOWN OF DEVICE BY PROCEDURE TYPE

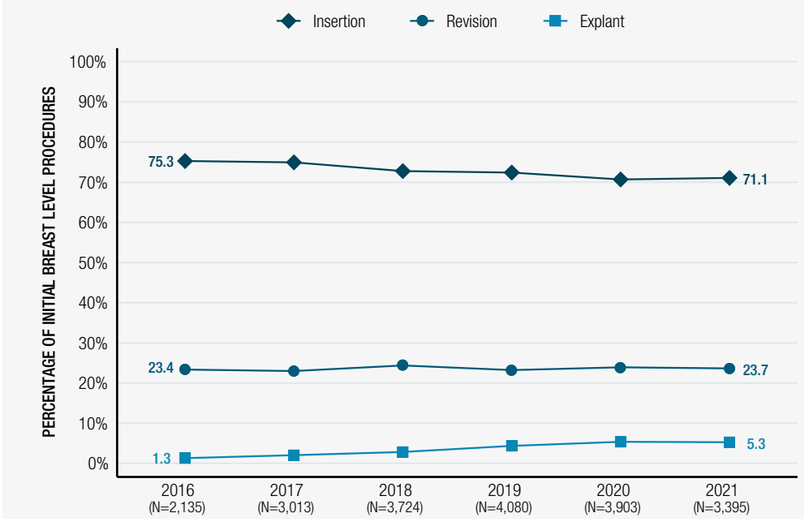
	N	%
Implants inserted	138,510	86.4%
Implants explanted only	11,001	6.9%
Tissue expanders inserted	9,284	5.8%
Tissue expanders explanted only	605	0.4%
Not defined	900	0.6%
Total	**160,298**	**100.0%**

Insertion, revision and explant procedures

Figures 2.3 and 2.4 reflect the number of implant insertion, revision and explant surgery procedures over a 6-year period for both reconstructive and cosmetic initial procedures at breast level. There was a 4.2% and 13.4% decrease in the proportion of initial insertion procedures for reconstructive and cosmetic procedures, respectively, from 2016 to 2021. Conversely, there was an increase in explant procedures over the same period, rising by 4% for the reconstructive cohort (1.3% to 5.3%) and by 7.9% for the cosmetic cohort (0.6% to 8.5%) from 2016 to 2021.

During 2021, 2,413 patients underwent a reconstructive insertion procedure, with 803 undergoing revision and 179 undergoing an explant procedure (total = 3,395 procedures). Patients were assigned according to their first procedure, as recorded in the ABDR.

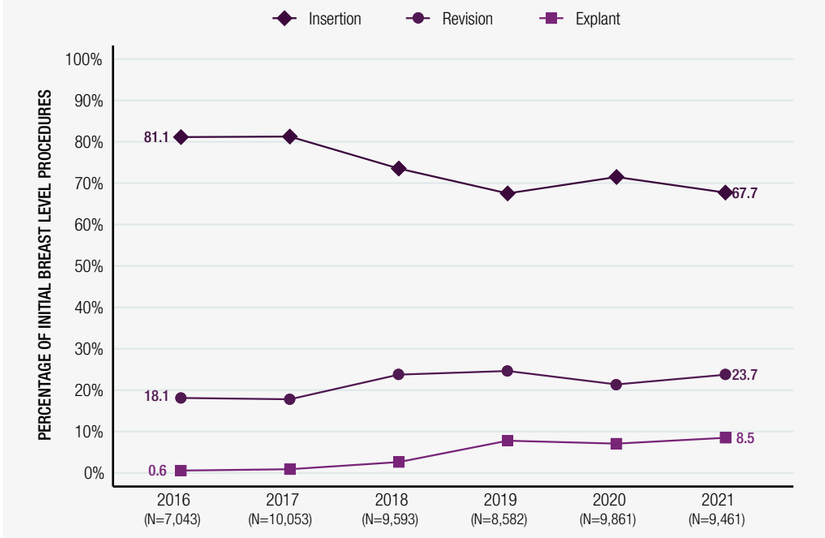
FIGURE 2.3: INITIAL INSERTION, REVISION AND EXPLANT PROCEDURES PER PATIENT OVER TIME (2016-2021) – RECONSTRUCTIVE GROUP



Note: Data at the patient level for the first (initial) procedure captured by the registry.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
Procedural hierarchy, or primary reason for procedure determines indication.

During 2021, 6,409 patients underwent a cosmetic insertion procedure, with 2,247 undergoing a revision procedure and 805 undergoing an explant procedure (total 9,461 procedures). Patients were assigned according to their first procedure, as recorded in the ABDR.

FIGURE 2.4: INITIAL INSERTION, REVISION AND EXPLANT PROCEDURES PER PATIENT OVER TIME (2016-2021) – COSMETIC GROUP



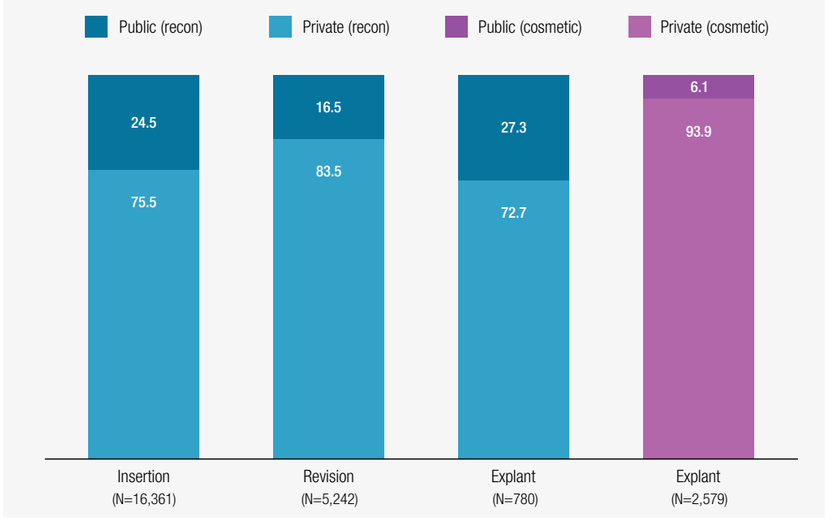
Note: Data at the breast level for the first (initial) procedure captured by the registry.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.

Procedures by indication, procedure type and site type

Figure 2.5 shows that overall, the majority of breast device procedures recorded by the ABDR are performed in private facilities, regardless of whether they are reconstructive or cosmetic.

The first three bars represent reconstructive procedures, as no cosmetic insertions or revisions are performed in public facilities. Bar 4 represents cosmetic explants only, of which 93.9% are undertaken in private and 6.1% are performed in public facilities.

FIGURE 2.5: PROCEDURE BY SITE TYPE FOR RECONSTRUCTION (BY INDICATION) AND COSMETIC (EXPLANTS ONLY) PROCEDURES DURING 2012-2021



Note: Insertion, revision and explant procedures for any indication have been analysed independently.
Both unilateral and bilateral procedures are included.
Only explants have been provided for cosmetic procedures, as all insertions and revisions are performed in private hospitals only.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.
Procedures with unknown type (insertion, revision, explant) have not been included.

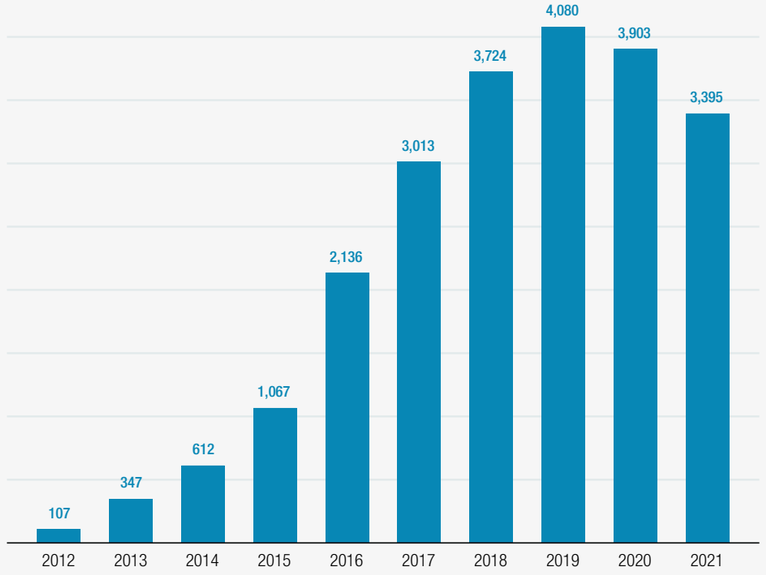
CHAPTER 3: REGISTRY OUTPUTS – RECONSTRUCTIVE INDICATIONS

Reconstructive procedure numbers

The ABDR has captured a total of **22,384 procedures** involving breast devices for reconstructive surgery, where reasons for reconstruction surgery included post-cancer reconstruction, risk-reducing reconstruction and developmental deformity.

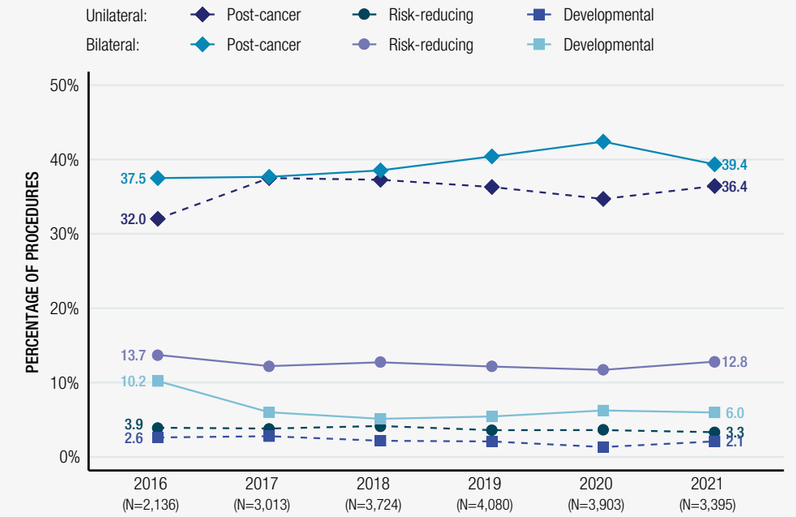
Figure 3.1 shows a steady rise in the annual number of reconstructive procedures captured in each year since registry commencement except for the past 2 years where a slight decline is noted. In **2021, 3,395** reconstructive procedures were captured as opposed to 3,903 captured in 2020. This may reflect a subtle shift away from the use of breast devices in favour of fat grafting and use of autologous flaps in reconstructive procedures. Alternatively, this slight reduction may also be a carry-over from the impact of the COVID-19 pandemic on elective surgery in some states of Australia, and subsequent restrictions on some elective surgeries that continued throughout 2021.

FIGURE 3.1: REGISTERED PROCEDURES (2012-2021) – RECONSTRUCTIVE PROCEDURES



In 2021, of a total of 3,395 procedures, 1,338 (39.4%) were bilateral post-cancer and 1,236 (36.4%) were unilateral post-cancer; 435 (12.8%) were bilateral risk-reducing and 112 (3.3%) were unilateral risk-reducing; and 204 (6.0%) were bilateral developmental with 71 being (2.1%) being unilateral developmental procedures. Over time, the proportion of bilateral and unilateral post-cancer reconstruction procedures exhibit a slight increase, while the proportion of both bilateral and unilateral procedures for risk-reducing indications have remained relatively stable. Surgery for bilateral developmental indications have slightly decreased during the same reporting period (Figure 3.2).

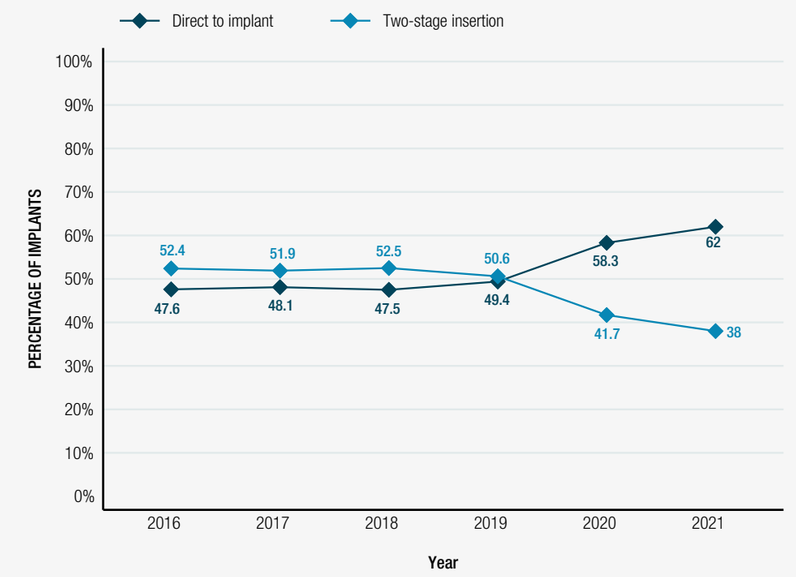
FIGURE 3.2: REGISTERED PROCEDURES (2016-2021) – RECONSTRUCTIVE PROCEDURES



Note: A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast. Primary reason for procedure has been applied for all patients

Figure 3.3 demonstrates that the proportion of **direct to implant procedures** conducted has increased in 2020 and 2021, whereas the relative proportion of **two-stage insertions,** (where after the initial insertion and subsequent removal of a tissue expander, an implant procedure is conducted) has decreased over the same period.

FIGURE 3.3: PROPORTION OF DIRECT TO IMPLANT VS TWO-STAGE INSERTION PROCEDURES PERFORMED DURING 2016-2021

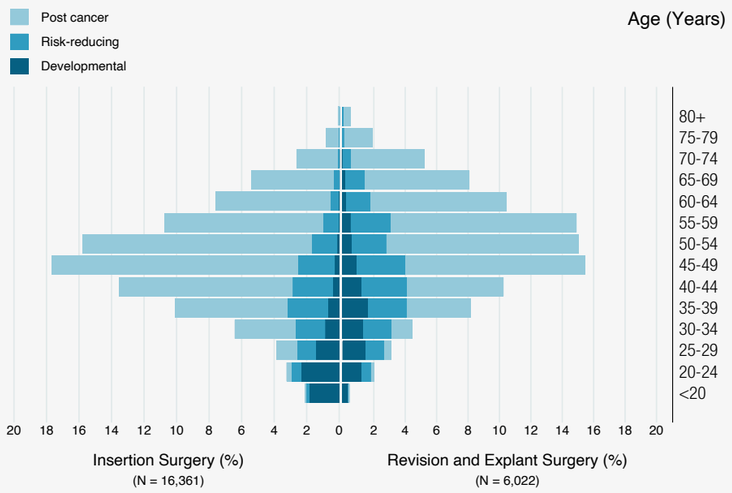


Note: Data was collected at the breast level for primary insertion or TE removal and subsequent implant insertion. Revision or Explant were not included in the analyses.

Patient age at reconstructive procedures

The age distribution at the time of reconstructive procedure is shown in Figure 3.4 and Table 3.1. Age differences can be seen by the indication for procedure and whether the procedure involved device insertion, revision or explant. In 2012-2021, the median age for post-cancer reconstruction was approximately 50 years for insertion surgery, 55 years for revision surgery and 55 for explant surgery. Patient age was slightly lower for risk-reducing reconstruction, and lowest for developmental deformity where the median for insertion surgery was 25 years.

FIGURE 3.4: AGE DISTRIBUTION AT TIME OF PROCEDURE (2012-2021) – RECONSTRUCTION PROCEDURES



Note: Insertion and revision (including explant) procedures have been analysed independently.
Both unilateral and bilateral procedures have been included.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procdure type detail per breast.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.

TABLE 3.1: SUMMARY STATISTICS FOR AGE AT TIME OF PROCEDURE (2012-2021) – RECONSTRUCTIVE PROCEDURES

	Insertion Surgery		Revision Surgery		Explant Only	
	N	Median Age (IQR)	N	Median Age (IQR)	N	Median Age (IQR)
Post-cancer	12,674	50.2 (43.4, 57.9)	3,661	54.5 (47.3, 62.5)	543	55.0 (48.2, 62.9)
Risk-reducing	2,361	41.9 (34.8, 49.8)	1,050	47.4 (38.8, 57.5)	177	43.7 (35.9, 55.3)
Developmental	1,326	24.7 (20.4, 32.2)	531	36.1 (27.7, 45.4)	60	38.8 (28.7, 45.9)
Total	**16,361**		**5,242**		**780**	

Note: Insertion, revision and explant only procedures have been analysed independently.
Both unilateral and bilateral procedures have been included.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
The interquartile range reports observed patient age at the 25th and 75th percentiles.

Reconstructive procedures aseptic techniques

The ABDR collects data on **intra-operative aseptic techniques** used by contributing surgeons. More than one intra-operative technique can be used and recorded per procedure. Table 3.2 and Figure 3.5 show the intra-operative techniques used during breast reconstruction surgery. The use of intra-operative and post-operative antibiotics are reported together for 2012-2021 as these data were not collected separately until 2015. Overall, the use of a range of aseptic techniques has increased during this period.

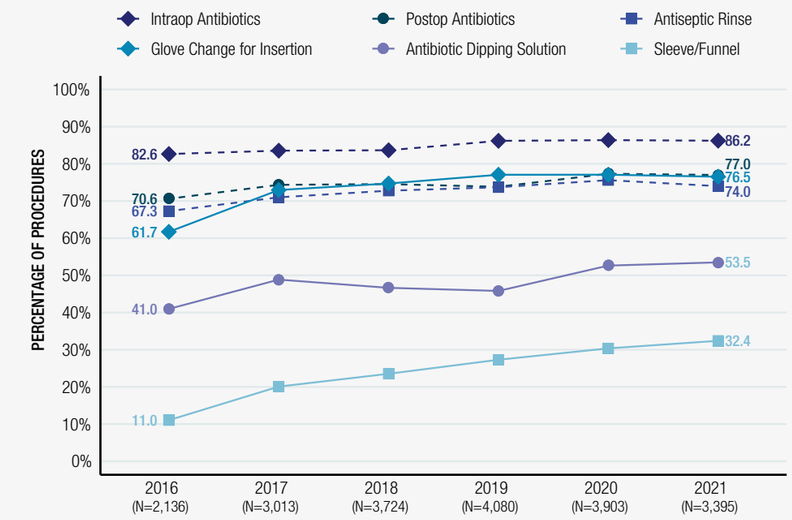
TABLE 3.2: INTRAOPERATIVE TECHNIQUES (2012-2021) – RECONSTRUCTIVE PROCEDURES

	2012-2021	
	N	(%)
Intraop/postop antibiotics	19,381	(86.6%)
Antiseptic rinse	16,234	(72.5%)
Glove change for insertion	16,324	(72.9%)
Antibiotic dipping solution	10,500	(46.9%)
Sleeve/funnel	5,229	(23.4%)
Not stated	2,589	(11.6%)
Total number of procedures	**22,384**	

Note: More than one intraoperative technique can be used and recorded per procedure.

In 2021, 2,926 patients were given intraoperative antibiotics; 2,614 were post-operative antibiotics, 2,597 had glove change for insertion, 2,512 had antiseptic rinse, 1,816 received antiseptic dipping solution, and 1,100 had a sleeve or funnel during reconstructive procedures.

FIGURE 3.5: INTRAOPERATIVE TECHNIQUES (2016-2021) – RECONSTRUCTIVE PROCEDURES



Note: Information regarding intraoperative and postoperative antibiotics have been collected separately since 2015.
Procedures were determined at the patient level, where procedural hierarchy was applied.

The registry report also records details regarding other surgical elements and techniques used during each breast procedure. These are summarised in Table 3.3. Trends observed over time include reduced insertion site from the previous mastectomy scar, and increased insertion site from the inframammary region; reduced use of the subpectoral/dual plane and increased use of the sub-glandular/subfascial plane; increased use of axillary surgery; increased use of fat grafting; increased use of nipple guard; reduced absent nipples; and increased nipple sparing surgery.

TABLE 3.3: SURGICAL ELEMENTS (2016-2021) – RECONSTRUCTIVE BREAST LEVEL PROCEDURES

	2016	2017	2018	2019	2020	2021
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Incision site*						
Previous mastectomy scar	1,519 (45.2%)	1,903 (41.4%)	2,130 (37.3%)	2,084 (33.0%)	1,857 (30.2%)	1,512 (28.5%)
Inframammary	1,166 (34.7%)	1,444 (31.4%)	1,927 (33.8%)	2,425 (38.4%)	2,555 (41.6%)	2,204 (41.6%)
Areola	209 (6.2%)	414 (9.0%)	558 (9.8%)	656 (10.4%)	555 (9.0%)	513 (9.7%)
Mastopexy/reduction scar	217 (6.5%)	434 (9.4%)	536 (9.4%)	528 (8.4%)	522 (8.5%)	470 (8.9%)
Axillary	12 (0.4%)	49 (1.1%)	66 (1.2%)	47 (0.7%)	27 (0.4%)	30 (0.6%)
Other	121 (3.6%)	176 (3.8%)	222 (3.9%)	281 (4.4%)	270 (4.4%)	187 (3.5%)
Not stated	189 (5.6%)	317 (6.9%)	404 (7.1%)	468 (7.4%)	552 (9.0%)	568 (10.7%)
Surgical plane						
Sub-pectoral/ Dual plane	1,997 (59.4%)	2,672 (58.2%)	3,350 (58.7%)	3,449 (54.6%)	3,024 (49.2%)	2,475 (46.7%)
Sub-flap	314 (9.3%)	454 (9.9%)	488 (8.6%)	549 (8.7%)	493 (8.0%)	514 (9.7%)
Sub-glandular/ sub-fascial**	332 (9.9%)	339 (7.4%)	461 (8.1%)	709 (11.2%)	873 (14.2%)	847 (16.0%)
Other	30 (0.9%)	69 (1.5%)	105 (1.8%)	267 (4.2%)	358 (5.8%)	300 (5.7%)
Not stated	600 (17.8%)	900 (19.6%)	1,083 (19.0%)	1,139 (18.0%)	1,131 (18.4%)	924 (17.4%)
Axillary surgery						
Yes	356 (10.6%)	708 (15.4%)	945 (16.6%)	1,132 (17.9%)	1,190 (19.4%)	1,032 (19.5%)
Concurrent mastectomy						
Yes	8,36 (24.9%)	1,415 (30.8%)	1,835 (32.2%)	2,168 (34.3%)	2,134 (34.7%)	1,897 (35.8%)
Concurrent mastopexy						
Yes	219 (6.5%)	322 (7.0%)	432 (7.6%)	390 (6.2%)	386 (6.3%)	419 (7.9%)
Flap cover						
Yes	295 (8.8%)	382 (8.3%)	472 (8.3%)	499 (7.9%)	460 (7.5%)	420 (7.9%)
Previous mastopexy						
Yes	119 (3.5%)	217 (4.7%)	225 (3.9%)	228 (3.6%)	244 (4.0%)	230 (4.3%)
Fat grafting						
Yes	132 (3.9%)	342 (7.4%)	448 (7.9%)	552 (8.7%)	501 (8.2%)	442 (8.3%)
Drain use						
Yes	1,728 (51.4%)	2,524 (54.9%)	2,914 (51.1%)	3,290 (52.0%)	3,149 (51.3%)	2,642 (49.9%)
Nipple guard						
Yes	503 (15.0%)	764 (16.6%)	940 (16.5%)	1,166 (18.4%)	1,207 (19.6%)	1,089 (20.6%)
Nipple absent						
Yes	1,599 (47.5%)	2,259 (49.2%)	2,725 (47.8%)	2,790 (44.1%)	2,525 (41.1%)	2,051 (38.7%)
Nipple sparing						
Yes	606 (18.0%)	976 (21.2%)	1,277 (22.4%)	1,626 (25.7%)	1,757 (28.6%)	1,490 (28.1%)
Total Procedures	**3,363**	**4,594**	**5,706**	**6,322**	**6,144**	**5,298**

Note: Details are at the breast procedure level.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
Matrix includes acellular dermal and synthetic matrices.
*More than one incision site can be recorded; row percentages are shown.
**This includes sub-cutaneous placement after mastectomy per data reported to the registry.

Matrix use in reconstructive procedures

Matrices are almost exclusively used in conjunction with reconstructive breast surgery. The registry captures the use of matrices when used concurrently with a tissue expander or breast implant. Table 3.4 reports matrix usage during reconstructive surgery involving breast implants and tissue expanders.

Matrix was used during 55.8% of direct-to-implant insertions for post-cancer reconstruction and 55.7% of risk-reducing reconstructions. It was minimally used for the second stage of two-stage procedures. Matrix use involving the insertion of tissue expanders was 27.5% for post-cancer and 28.5% for risk-reducing reconstructions. Matrix was used in between 9-12% of implant and tissue expander revisions for cancer-related procedures.

TABLE 3.4: MATRIX USE (2012-2021) – RECONSTRUCTION BREAST LEVEL PROCEDURES

	Total number of procedures (N)	Number of procedures with matrix use (N)	Proportion of procedures with matrix use (%)
BREAST IMPLANTS			
Direct to implant insertion			
Post cancer	4,106	2,293	55.8%
Risk-reducing	2,763	1,539	55.7%
Developmental	1,979	1	0.1%
Total	**8,848**	**3,833**	**43.3%**
Two-stage insertion* (2nd stage)			
Post cancer	6,154	149	2.4%
Risk-reducing	2,167	48	2.2%
Developmental	168	0	0.0%
Total	**8,489**	**197**	**2.3%**
Revision (not explant)			
Post cancer	4,494	393	8.7%
Risk-reducing	2,149	198	9.2%
Developmental	847	24	2.8%
Total	**7,490**	**615**	**8.2%**
TISSUE EXPANDER			
Insertion			
Post cancer	5,633	1,551	27.5%
Risk-reducing	2,520	717	28.5%
Developmental	121	1	0.8%
Total	**8,274**	**2,269**	**27.4%**
Revision (not explant)			
Post cancer	323	35	10.8%
Risk-reducing	82	10	12.2%
Developmental	1	0	0.0%
Total	**406**	**45**	**11.1%**
Total Procedures	**33,507**	**6,959**	**20.8%**

Note: Details are at the breast procedure level.
Insertion and revision procedures have been analysed independently.
Explant only and procedures with unknown procedure type (insertion, revision or explant) have not been included.
Matrix includes acellular dermal and synthetic matrices.
*Two-stage refers to use of matrix at the time of definitive implant surgery, i.e. when the tissue expander is removed and implant is inserted.

Device characteristics for breast reconstruction

The registry captures information about **breast devices (breast implants, tissue expanders and matrices)** used during procedures in Australia. Table 3.5 provides information regarding device shell/texture, shape, and fill characteristics for breast implants and tissue expanders used for breast reconstruction during an insertion procedure or a replacement revision procedure. Of the total reconstructive breast implants used, 57.6% were textured, 40.7% were smooth and 1.6% polyurethane. Round breast reconstructive implants were the most common at 51.3%, followed by shaped/anatomical implants at 48.5%. In terms of device fill for reconstructive breast implants, 97.7% were silicone filled, 1.3% silicone/saline filled and 0.8% with saline.

The majority of tissue expanders were textured, with 0.1% having a smooth shell. In addition, the majority of tissue expanders were shaped/anatomical with 0.3% being round. Approximately 2.5% of tissue expanders were silicone filled and 89.8% filled with saline. A further 7.2% were filled with carbon dioxide (these expanders are no longer available).

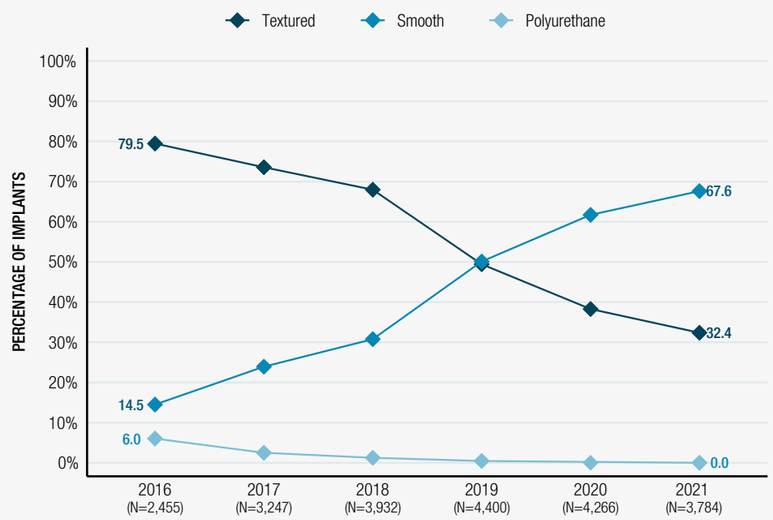
TABLE 3.5: DEVICE CHARACTERISTICS (2012-2021) – RECONSTRUCTIVE BREAST DEVICES

	Implant		Tissue Expander		Explant	
	N	(%)	N	(%)	N	(%)
Shell/ Texture						
Textured	14,054	(57.6%)	8,842	(99.6%)	3,859	(43.7%)
Smooth	9,926	(40.7%)	13	(0.1%)	3,433	(38.8%)
Polyurethane	382	(1.6%)	0	(0.0%)	178	(2.0%)
Not stated	45	(0.2%)	26	(0.3%)	1,371	(15.5%)
Shape						
Round	12,510	(51.3%)	31	(0.3%)	4,552	(51.5%)
Shaped/anatomical	11,846	(48.5%)	8,681	(97.7%)	2,903	(32.8%)
Not stated	51	(0.2%)	169	(1.9%)	1,386	(15.7%)
Fill						
Silicone	23,851	(97.7%)	220	(2.5%)	6,978	(78.9%)
Saline	190	(0.8%)	7,973	(89.8%)	440	(5.0%)
Silicone/ Saline	321	(1.3%)	0	(0.0%)	26	(2.9%)
Carbon dioxide	0	(0.0%)	639	(7.2%)	25	(2.8%)
Not stated	45	(0.2%)	49	(0.6%)	1,372	(15.5%)
Total	**24,407**	**(100%)**	**8,881**	**(100%)**	**8,841**	**(100%)**

Note: Device characteristics are reported for all reconstructive breast devices during an insertion, replacement revision or explant procedures.
Implant procedures included first implant insertion, TE removal and implant insertion, or implant revision as replacement.
Tissue expander procedures were determined as either TE insertion, Implant removal and TE insertion, or TE removal and replacement at revision.
Explants were determined as either implant or TE revision determined as explant only.

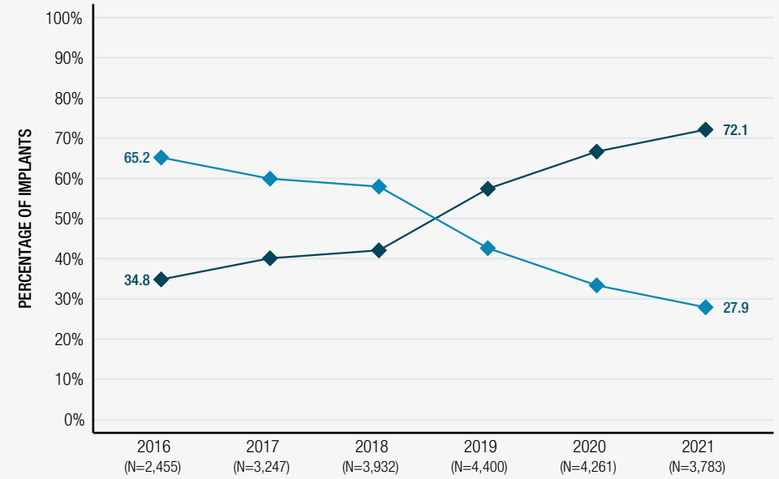
Figures 3.6 and 3.7 provide the trends in device shell/texture and shape use from 2016 to 2021. For the reconstructive cohort, from 2016 to 2021 there has been a substantial decrease in use of textured implants from 79.5% to 32.4% and polyurethane implants from 6.0% to 0%. This trend reflects the changes in use of textured implants preceding and since the TGA action to suspend some textured implants in 2019. Over time, the use of smooth implants has increased from 14.5% to 67.6%. During 2021, 2,558 patients received a smooth device shell implant with 1,226 receiving a textured device.

FIGURE 3.6: DEVICE SHELL (2016-2021) – RECONSTRUCTIVE IMPLANTS



Note: Device texture is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shell type have not been included.

FIGURE 3.7: DEVICE SHAPE (2016-2021) – RECONSTRUCTIVE IMPLANTS



Note: Device shape is reported for new implants during an insertion procedure or a replacement revision procedure. Implants with an unknown shape have not been included.

Since 2016 the use of round implants has more than doubled, with 72% of these devices being used in preference to shaped/anatomical implants. During 2021, 2,728 patients received a round implant with 1,056 receiving a shaped/anatomical device.

Complications and revision incidence – Breast implants for reconstruction

The registry collects details of issues and complications that are found at the time of a revision procedure involving breast devices. Revision surgery includes the unplanned replacement, reposition or explant of an in-situ breast device. Table 3.6 reports the issues identified at all reconstructive breast implant revisions, including revisions for breasts where the insertion of the initial implant may or may not have also been captured by the registry. Please note, this table does not represent complication rates. Complication rates are described in the following section using the Kaplan Meier (survival) curves. The table indicates only the most common complications that are reported to the registry.

TABLE 3.6: ISSUES IDENTIFIED AT REVISION PROCEDURE – RECONSTRUCTIVE BREAST IMPLANTS

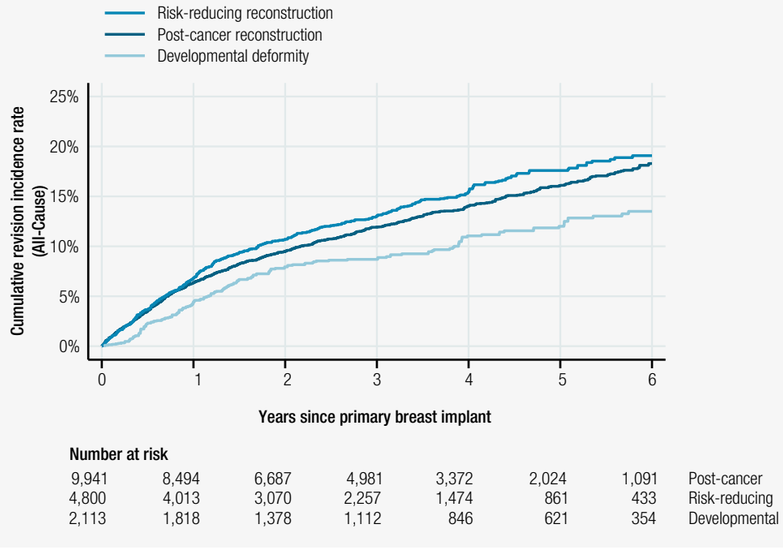
Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2021		2021	
	N	(%)	N	(%)
Capsular contracture	3,106	(37.9%)	516	(37.9%)
Device malposition	2,428	(29.6%)	393	(28.8%)
Device rupture	1,319	(16.1%)	236	(17.3%)
Device deflation	580	(7.1%)	93	(6.8%)
Skin scarring problems	573	(7.0%)	90	(6.6%)
Seroma/ haematoma	342	(4.2%)	60	(4.4%)
Deep wound infection	220	(2.7%)	31	(2.3%)
Total revision procedures	**8,198**		**1,363**	

Note: Listed in order of frequency are issues identified during reconstructive breast implant revision procedures.
Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure.
The crude percentage attached to each issue identified at revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a complication rate.

Multiple issues can be recorded at the time of revision surgery, and issues are either identified as a reason for the revision or found incidentally during the revision procedure. In 2021, capsular contracture was the most common issue identified and reported at approximately 37.9% of reconstructive breast implant revisions, followed by device malposition reported at 28.8% of revisions and device rupture reported at 17.3% of revisions. This pattern has remained relatively stable over time.

Figure 3.8 below, demonstrates an **all-cause revision** incidence curve for the three reconstructive indications. At 6-years after the date of primary implant insertion, 19.1% of implants for risk-reducing reconstruction, 18.3% for post-cancer reconstruction and 13.5% of primary implants used for developmental deformity were revised for the first time.

FIGURE 3.8: ALL-CAUSE REVISION INCIDENCE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Note: All–cause revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

Figure 3.9 provides revision incidence **due to complication** curve for the three reconstructive indications. At 6 years after the date of primary implant insertion, revision incidence due to complications was 12.8% risk-reducing reconstruction, 12.7% post-cancer reconstruction and 8.0% for developmental deformity.

FIGURE 3.9: REVISION INCIDENCE DUE TO COMPLICATION BY INDICATION – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

Note: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

Table 3.7 showcases revision incidence due to the **most common complications** identified over a 6-year time interval for the **three reconstructive indications.** The most common complications requiring revision were capsular contracture (slightly increasing over time to just over 5% at 6 years) and device malposition (approximately 5% at 6 years). Other complications had a lower 6-year incidence. At 6 years after the date of primary implant insertion, revision incidence due to complication was 5.4% capsular contraction, 5.2% device malposition, 1.4% skin scarring, 1.2% deflation/rupture, 1.1% deep wound infection and 0.8% seroma/haematoma.

Note that revision incidence total number and percentage per complication are calculated both for the total proportion for each complication, and also for post-cancer, risk-reducing and developmental complications separately, within each revision type.

TABLE 3.7: REVISION INCIDENCE BY SPECIFIC COMPLICATION BY CLINICAL INDICATION – RECONSTRUCTION PRIMARY BREAST IMPLANTS

	N	N	Revision Incidence											
	Primary breast implant	Revised	N	1 Year	N	2 Years	N	3 Years	N	4 Years	N	5 Years	N	6 Years
Revision due to capsular contracture														
Post-cancer	9,941	331	8,494	1.1%	6,687	2.2%	4,981	3.2%	3,372	4.1%	2,024	4.9%	1,091	5.9%
Risk-reducing	4,800	140	4,013	1.1%	3,070	2.1%	2,257	2.6%	1,474	3.7%	861	4.6%	433	5.2%
Developmental	2,113	50	1,818	0.8%	1,378	1.9%	1,112	2.0%	846	2.9%	621	2.9%	354	3.7%
Total	**16,854**	**521**	**14,325**	**1.1%**	**11,135**	**2.1%**	**8,350**	**2.9%**	**5,692**	**3.8%**	**3,506**	**4.5%**	**1,878**	**5.4%**
Revision due to device malposition														
Post-cancer	9,941	336	8,494	1.6%	6,687	2.6%	4,981	3.4%	3,372	4.3%	2,024	4.7%	1,091	5.2%
Risk-reducing	4,800	177	4,013	1.9%	3,070	3.2%	2,257	4.2%	1,474	4.8%	861	5.2%	433	5.5%
Developmental	2,113	64	1,818	1.3%	1,378	2.8%	1,112	3.0%	846	3.6%	621	3.8%	354	4.5%
Total	**16,854**	**577**	**14,325**	**1.6%**	**11,135**	**2.8%**	**8,350**	**3.6%**	**5,692**	**4.3%**	**3,506**	**4.7%**	**1,878**	**5.2%**
Revision due to skin scarring														
Post-cancer	9,941	104	8,494	0.60%	6,687	0.80%	4,981	1.10%	3,372	1.30%	2,024	1.40%	1,091	1.40%
Risk-reducing	4,800	66	4,013	1.00%	3,070	1.30%	2,257	1.50%	1,474	1.70%	861	1.70%	433	1.70%
Developmental	2,113	10	1,818	0.00%	1,378	0.40%	1,112	0.40%	846	0.60%	621	0.60%	354	0.90%
Total	**16,854**	**180**	**14,325**	**0.70%**	**11,135**	**0.90%**	**8,350**	**1.10%**	**5,692**	**1.30%**	**3,506**	**1.40%**	**1,878**	**1.40%**
Revision due to device deflation/rupture														
Post-cancer	9,941	64	8,494	0.2%	6,687	0.3%	4,981	0.4%	3,372	0.7%	2,024	1.0%	1,091	1.3%
Risk-reducing	4,800	27	4,013	0.2%	3,070	0.3%	2,257	0.4%	1,474	0.6%	861	0.8%	433	1.4%
Developmental	2,113	11	1,818	0.1%	1,378	0.3%	1,112	0.4%	846	0.7%	621	0.7%	354	0.9%
Total	**16,854**	**102**	**14,325**	**0.2%**	**11,135**	**0.3%**	**8,350**	**0.4%**	**5,692**	**0.6%**	**3,506**	**0.9%**	**1,878**	**1.2%**
Revision due to deep wound infection														
Post-cancer	9,941	114	8,494	1.00%	6,687	1.10%	4,981	1.20%	3,372	1.30%	2,024	1.30%	1,091	1.30%
Risk-reducing	4,800	46	4,013	0.90%	3,070	1.00%	2,257	1.00%	1,474	1.00%	861	1.00%	433	1.00%
Developmental	2,113	7	1,818	0.30%	1,378	0.30%	1,112	0.30%	846	0.30%	621	0.30%	354	0.30%
Total	**16,854**	**167**	**14,325**	**0.90%**	**11,135**	**1.00%**	**8,350**	**1.00%**	**5,692**	**1.10%**	**3,506**	**1.10%**	**1,878**	**1.10%**
Revision due to seroma/haematoma														
Post-cancer	9,941	67	8,494	0.60%	6,687	0.60%	4,981	0.70%	3,372	0.70%	2,024	0.80%	1,091	0.80%
Risk-reducing	4,800	39	4,013	0.70%	3,070	0.70%	2,257	0.80%	1,474	0.90%	861	1.00%	433	1.00%
Developmental	2,113	7	1,818	0.30%	1,378	0.30%	1,112	0.30%	846	0.30%	621	0.50%	354	0.50%
Total	**16,854**	**113**	**14,325**	**0.60%**	**11,135**	**0.60%**	**8,350**	**0.70%**	**5,692**	**0.70%**	**3,506**	**0.80%**	**1,878**	**0.80%**

Note: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.

Fourteen percent of reconstructive patients had radiotherapy associated with their breast reconstructive (implant insertion) surgery. Table 3.8 provides a comparison of the number and percentage of issues identified/complication type for patients who had prior radiotherapy, compared with those who did not, for implant or tissue expander procedures. **Previous radiotherapy and tissue expander insertion** was associated with higher rates of capsular contracture, device malposition/rupture and deflation, skin scarring and seroma/haematoma; and lower rates of deep wound infection and breast cancer recurrence. If breast cancer has reoccurred it is not considered a complication. **Previous radiotherapy and implant insertion** was associated with a higher rate of capsular contracture, skin scarring problems, and seroma/haematoma; and lower rates of device malposition, device rupture/deflation, and BIA-ALCL.

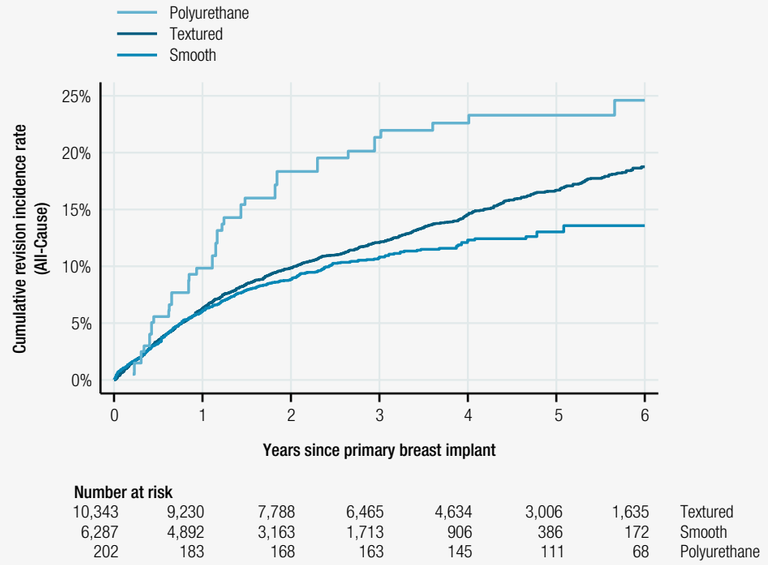
TABLE 3.8: COMPLICATION RATES FOR PATIENTS WITH PREVIOUS RADIOTHERAPY VS NO PREVIOUS RADIOTHERAPY – IMPLANTS AND TISSUE EXPANDERS.

		Previous radiotherapy and implant	No previous radiotherapy and implant	Tissue expander and previous radiotherapy	Tissue expander and no previous radiotherapy
Capsular Contracture	Yes	450 (48.2%)	1,994 (37.0%)	34 (30.1%)	60 (13.5%)
	No	374 (40.1%)	2,839 (52.7%)	52 (46.0%)	294 (66.4%)
	Not stated	109 (11.7%)	555 (10.3%)	27 (23.9%)	89 (20.1%)
Device Malposition	Yes	264 (28.3%)	1,720 (31.9%)	16 (14.2%)	54 (12.2%)
	No	551 (59.1%)	3,109 (57.7%)	70 (61.9%)	298 (67.3%)
	Not stated	118 (12.6%)	559 (10.4%)	27 (23.9%)	91 (20.5%)
Device Rupture	Yes	115 (12.3%)	923 (17.1%)	29 (25.7%)	71 (16.0%)
	No	721 (77.3%)	4,011 (74.4%)	59 (52.2%)	292 (65.9%)
	Not stated	97 (10.4%)	454 (8.4%)	25 (22.1%)	80 (18.1%)
Device Deflation	Yes	57 (6.1%)	437 (8.1%)	24 (21.2%)	56 (12.6%)
	No	752 (80.6%)	4,351 (80.8%)	63 (55.8%)	297 (67.0%)
	Not stated	124 (13.3%)	600 (11.1%)	26 (23.0%)	90 (20.3%)
Skin Scarring Problems	Yes	102 (10.9%)	363 (6.7%)	18 (15.9%)	52 (11.7%)
	No	707 (75.8%)	4435 (82.3%)	68 (60.2%)	302 (68.2%)
	Not stated	124 (13.3%)	590 (11.0%)	27 (23.9%)	89 (20.1%)
Seroma/Haematoma	Yes	39 (4.2%)	196 (3.6%)	12 (10.6%)	43 (9.7%)
	No	769 (82.4%)	4,602 (85.4%)	75 (66.4%)	310 (70.0%)
	Not stated	125 (13.4%)	590 (11.0%)	26 (23.0%)	90 (20.3%)
Deep Wound Infection	Yes	17 (1.8%)	92 (1.7%)	12 (10.6%)	75 (16.9%)
	No	793 (85.0%)	4,701 (87.2%)	75 (66.4%)	280 (63.2%)
	Not stated	123 (13.2%)	595 (11.0%)	26 (23.0%)	88 (19.9%)
Breast Cancer	Yes	21 (2.3%)	127 (2.4%)	7 (6.2%)	45 (10.2%)
	No	788 (84.5%)	4,666 (86.6%)	79 (69.9%)	308 (69.5%)
	Not stated	124 (13.3%)	595 (11.0%)	27 (23.9%)	90 (20.3%)
Anaplastic Large Cell Lymphoma	Yes	0 (0.0%)	11 (0.2%)	0 (0.0%)	0 (0.0%)
	No	805 (86.3%)	4,778 (88.7%)	86 (76.1%)	349 (78.8%)
	Not stated	128 (13.7%)	599 (11.1%)	27 (23.9%)	94 (21.2%)
Total		**2,994**	**18,727**	**947**	**7,199**

Note: Complication percentages are presented within each specific complication type hierarchy, and represent the proportion of complications this includes for matrix versus no matrix use, and may be compared across radiotherapy usage status for implant and TE procedures (2012-2021). Data has not been collected on post-mastectomy radiotherapy.

Figure 3.10 **provides the all-cause revision incidence for reconstructive implants by shell characteristics.** The all-cause revision incidence rate at **six-years since primary implant insertion** was approximately 24.7% for polyurethane implants, 18.8% for textured implants and 13.6% for smooth implants. The higher incidence of all-cause revisions for polyurethane implants at six-years may be due to women having these devices removed following the TGA device recall in 2019.

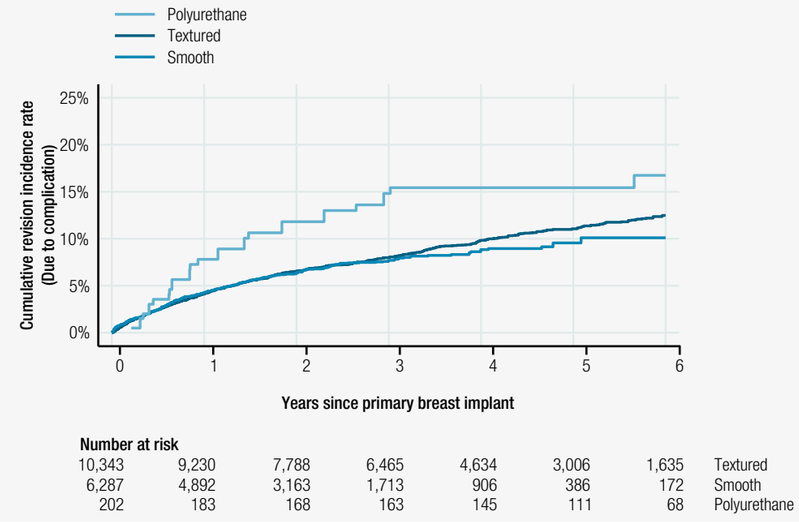
FIGURE 3.10: ALL-CAUSE REVISION INCIDENCE BY SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Note: All–cause revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.
Implants with an unknown shell have not been included.

Figure 3.11 below provides the **revision incidence due to complications for reconstructive primary implants by shell characteristics.** The revision due to complication incidence rate at **six-years since primary implant** insertion was 16.7% for polyurethane implants, 12.5% for textured implants and 10.1% for smooth implants.

FIGURE 3.11: REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Note: All–cause revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

Table 3.9 shows the **revision incidence rate for different complications identified for reconstruction primary breast implants by shell type.** The highest proportion of specific complication was **device malposition for polyurethane** implants which had a 9.1% 6-year incidence compared with devices having textured and smooth shells that had an average of approximately 5% incidence at 6 years.

TABLE 3.9: REVISION INCIDENCE FROM SPECIFIC COMPLICATIONS BY DEVICE SHELL – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

	N	N	Revision Incidence											
	Primary	Revised	1 Year		2 Years		3 Years		4 Years		5 Years		6 Years	
			N	RI	N	RI	N	RI	N	RI	N	RI	N	RI
Revision due to device malposition														
Textured	10,343	369	9,230	1.5%	7,788	2.6%	6,465	3.3%	4,634	4.1%	3,006	4.5%	1,635	4.9%
Smooth	6,287	193	4,892	1.8%	3,163	3.2%	1,713	4.0%	906	4.5%	386	4.8%	172	5.4%
Polyurethane	202	15	183	3.6%	168	4.7%	163	7.8%	145	7.8%	111	7.8%	68	9.1%
Total	**16,832**	**577**	**14,305**	**1.6%**	**11,119**	**2.8%**	**8,341**	**3.6%**	**5,685**	**4.3%**	**3,503**	**4.7%**	**1,875**	**5.2%**
Revision due to capsular contracture														
Textured	10,343	417	9,230	1.2%	7,788	2.5%	6,465	3.3%	4,634	4.4%	3,006	5.1%	1,635	6.0%
Smooth	6,287	94	4,892	0.8%	3,163	1.4%	1,713	2.1%	906	2.4%	386	2.7%	172	3.2%
Polyurethane	202	10	183	2.6%	168	3.2%	163	4.4%	145	5.0%	111	5.0%	68	6.3%
Total	**16,832**	**521**	**14,305**	**1.1%**	**11,119**	**2.2%**	**8,341**	**2.9%**	**5,685**	**3.8%**	**3,503**	**4.5%**	**1,875**	**5.4%**
Revision due to deflation/rupture														
Textured	10,343	76	9,230	0.2%	7,788	0.3%	6,465	0.4%	4,634	0.6%	3,006	0.8%	1,635	1.3%
Smooth	6,287	22	4,892	0.2%	3,163	0.3%	1,713	0.4%	906	0.7%	386	1.0%	172	1.0%
Polyurethane	202	4	183	0.5%	168	1.7%	163	2.2%	145	2.2%	111	2.2%	68	2.2%
Total	**16,832**	**102**	**14,305**	**0.2%**	**11,119**	**0.3%**	**8,341**	**0.4%**	**5,685**	**0.7%**	**3,503**	**0.9%**	**1,875**	**1.2%**
Revision due to skin scarring														
Textured	10,343	104	9,230	0.5%	7,788	0.7%	6,465	0.9%	4,634	1.2%	3,006	1.2%	1,635	1.2%
Smooth	6,287	72	4,892	0.8%	3,163	1.2%	1,713	1.4%	906	1.5%	386	1.5%	172	2.0%
Polyurethane	202	4	183	1.0%	168	1.6%	163	1.6%	145	2.2%	111	2.2%	68	2.2%
Total	**16,832**	**180**	**14,305**	**0.7%**	**11,119**	**0.9%**	**8,341**	**1.1%**	**5,685**	**1.3%**	**3,503**	**1.4%**	**1,875**	**1.4%**
Revision due to seroma/haematoma														
Textured	10,343	69	9,230	0.5%	7,788	0.6%	6,465	0.6%	4,634	0.7%	3,006	0.8%	1,635	0.8%
Smooth	6,287	37	4,892	0.6%	3,163	0.6%	1,713	0.6%	906	0.6%	386	0.6%	172	0.6%
Polyurethane	202	7	183	2.6%	168	2.6%	163	3.8%	145	3.8%	111	3.8%	68	3.8%
Total	**16,832**	**113**	**14,305**	**0.6%**	**11,119**	**0.6%**	**8,341**	**0.7%**	**5,685**	**0.7%**	**3,503**	**0.8%**	**1,875**	**0.8%**
Revision due to deep wound infection														
Textured	10,343	106	9,230	0.9%	7,788	1.0%	6,465	1.0%	4,634	1.1%	3,006	1.1%	1,635	1.1%
Smooth	6,287	59	4,892	0.9%	3,163	0.9%	1,713	1.0%	906	1.0%	386	1.0%	172	1.0%
Polyurethane	202	2	183	0.5%	168	0.5%	163	0.5%	145	1.1%	111	1.1%	68	1.1%
Total	**16,832**	**167**	**14,305**	**0.9%**	**11,119**	**1.0%**	**8,341**	**1.0%**	**5,685**	**1.1%**	**3,503**	**1.1%**	**1,875**	**1.1%**

Note: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021, and has been calculated by specific complication type.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
Time to revision was censored at the data extract date for non-revised implants.

Complications and revision incidence – Device with matrix use at revision procedure

The registry collects details of **issues and complications that are found at the time of a revision procedure** for **primary implants inserted with matrix.** Revision surgery includes the unplanned replacement, reposition or explant of an in-situ breast device. Table 3.10 reports the issues identified at revision procedure of **devices with and without matrix** accompanying insertion of primary reconstructive breast implants. Multiple issues can be recorded at the time of revision surgery, and issues are either identified as a reason for the revision or found incidentally during the revision procedure. Device malposition and capsular contracture rates were **lower for implants with matrix** (24.1% vs 30.8%; 22.9% vs 25.5% respectively) as were rates of device rupture and deflation. However, implants with matrix had **higher rates** of skin scarring problems (11.5% vs 8.5%), deep wound infection (18.8% vs 5.1%) and seroma/haematoma (10.9% vs 3.4%).

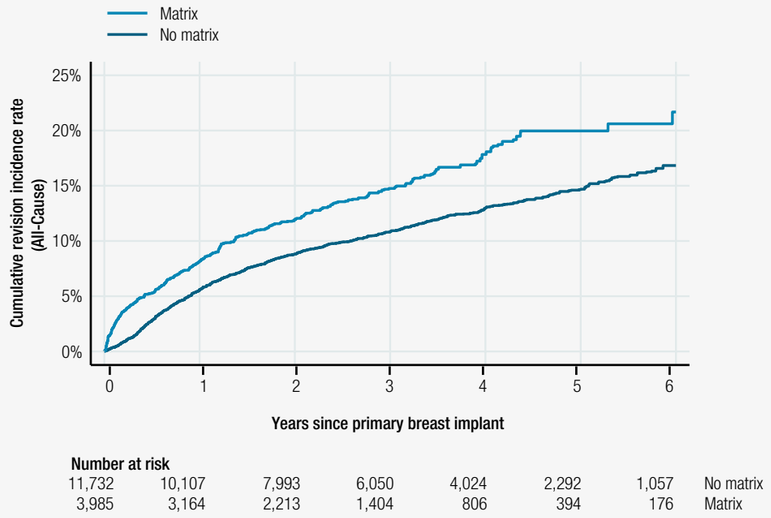
TABLE 3.10: ISSUES IDENTIFIED AT REVISION PROCEDURE OF IMPLANTS INSERTED WITH AND WITHOUT MATRIX – RECONSTRUCTIVE BREAST IMPLANTS

Complications and issues identified at revision (N.B. not complication rates)	Primary implant (without Matrix use at insertion) revisions		Primary implant (with Matrix use at insertion) revisions	
	N	(%)	N	(%)
Device malposition	402	30.8%	124	24.1%
Capsular contracture	333	25.5%	118	22.9%
Skin scarring problems	111	8.5%	59	11.5%
Deep wound infection	66	5.1%	97	18.8%
Seroma/Haematoma	45	3.4%	56	10.9%
Device rupture	62	4.8%	14	2.7%
Device deflation	30	2.3%	6	1.2%
Not stated	256	19.6%	41	8.0%
Total Revision Procedures	**1,305**	**100%**	**515**	**100%**

Note: Listed in order of frequency are issues identified during reconstructive breast implant revision procedures.
Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure.
The crude percentage attached to each issue identified at revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a complication rate.
Each reported percentage applies to the proportion of total complications accounted for by that variable specifically.
Revisions that have matrix type identified, but complication type not stated are included in the total revision procedures count.

Figure 3.12 provides an **all-cause revision incidence** curve for reconstructive primary breast implants **by matrix use.** At six-years after insertion, 21.7% of the implants with matrix and 16.8% without matrix use had been revised.

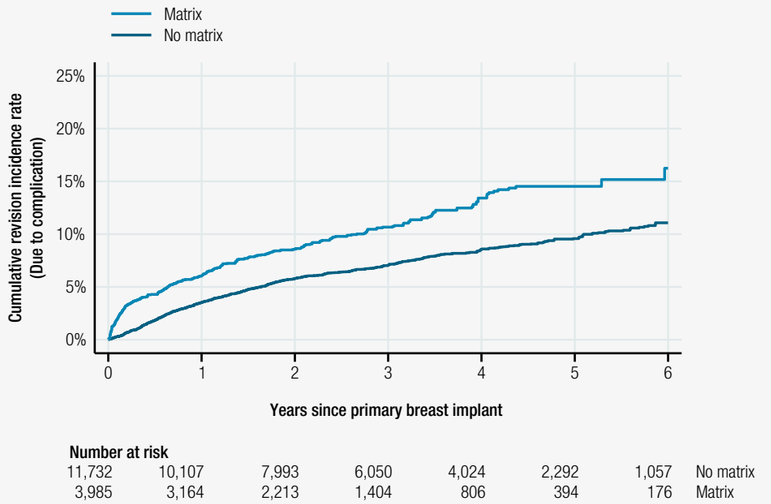
FIGURE 3.12: ALL-CAUSE REVISION INCIDENCE BY MATRIX USE – RECONSTRUCTION PRIMARY BREAST IMPLANTS



Note: All–cause revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

Figure 3.13 provides a revision due to **complication incidence curve for reconstructive primary breast implants by matrix use.** At six-years after insertion 16.2% of the implants with matrix use and 11.0% without matrix use had been revised due to complications.

FIGURE 3.13: REVISION DUE TO COMPLICATION INCIDENCE BY MATRIX USE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS



Note: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.
Implants with unknown matrix use have not been included.

Revision incidence rates due to specific complications identified at time intervals following primary implant insertion **with and without matrix** are reported in Table 3.11. This table demonstrates the number of cases and percentages for revision incidence for primary breast implants. Revision incidence is categorised by complication type, and further categorised by matrix use, within each complication type. All the specific complications had a higher incidence rates for implants associated with matrix compared to implants alone, except for device deflation/rupture which as a lower incidence for implants inserted with matrix. The highest revision incidence overall was 7.5% at 6-years due to capsular contraction and 6.5% at 6-years for device malposition with matrix.

TABLE 3.11: REVISION INCIDENCE BY MATRIX USE – RECONSTRUCTIVE PRIMARY BREAST IMPLANTS

	N	N	Revision Incidence											
	Primary	Revised	1 Year		2 Years		3 Years		4 Years		5 Years		6 Years	
			N	RI	N	RI	N	RI	N	RI	N	RI	N	RI
Revision due to device malposition														
No matrix	11,732	402	10,107	1.7%	7,993	2.8%	6,050	3.5%	4,024	4.3%	2,292	4.6%	1,057	4.9%
Matrix	3,985	124	3,164	1.5%	2,213	2.6%	1,404	3.9%	806	4.6%	394	5.4%	176	6.5%
Total	**15,717**	**526**	**13,271**	**1.6%**	**10,206**	**2.8%**	**7,454**	**3.6%**	**4,830**	**4.3%**	**2,686**	**4.7%**	**1,233**	**5.2%**
Revision due to capsular contracture														
No matrix	11,732	333	10,107	1.0%	7,993	2.0%	6,050	2.6%	4,024	3.3%	2,292	3.9%	1,057	4.7%
Matrix	3,985	118	3,164	1.1%	2,213	2.3%	1,404	3.4%	806	5.2%	394	6.1%	176	7.5%
Total	**15,717**	**451**	**13,271**	**1.0%**	**10,206**	**2.1%**	**7,454**	**2.8%**	**4,830**	**3.7%**	**2,686**	**4.3%**	**1,233**	**5.2%**
Revision due to deflation/rupture														
No matrix	11,732	74	10,107	0.2%	7,993	0.3%	6,050	0.4%	4,024	0.6%	2,292	1.0%	1,057	1.4%
Matrix	3,985	18	3,164	0.1%	2,213	0.3%	1,404	0.3%	806	0.6%	394	0.6%	176	1.2%
Total	**15,717**	**92**	**13,271**	**0.2%**	**10,206**	**0.3%**	**7,454**	**0.4%**	**4,830**	**0.6%**	**2,686**	**0.9%**	**1,233**	**1.4%**
Revision due to skin scarring														
No matrix	11,732	111	10,107	0.5%	7,993	0.8%	6,050	1.0%	4,024	1.1%	2,292	1.2%	1,057	1.3%
Matrix	3,985	59	3,164	1.2%	2,213	1.4%	1,404	1.6%	806	2.0%	394	2.0%	176	2.0%
Total	**15,717**	**170**	**13,271**	**0.7%**	**10,206**	**0.9%**	**7,454**	**1.1%**	**4,830**	**1.3%**	**2,686**	**1.4%**	**1,233**	**1.5%**
Revision due to seroma/haematoma														
No matrix	11,732	45	10,107	0.3%	7,993	0.4%	6,050	0.4%	4,024	0.4%	2,292	0.4%	1,057	0.4%
Matrix	3,985	56	3,164	1.3%	2,213	1.4%	1,404	1.5%	806	1.7%	394	1.7%	176	1.7%
Total	**15,717**	**101**	**13,271**	**0.6%**	**10,206**	**0.6%**	**7,454**	**0.7%**	**4,830**	**0.7%**	**2,686**	**0.7%**	**1,233**	**0.7%**
Revision due to deep wound infection														
No matrix	11,732	66	10,107	0.5%	7,993	0.6%	6,050	0.6%	4,024	0.6%	2,292	0.6%	1,057	0.6%
Matrix	3,985	97	3,164	2.3%	2,213	2.5%	1,404	2.6%	806	2.6%	394	2.6%	176	2.6%
Total	**15,717**	**163**	**13,271**	**1.0%**	**10,206**	**1.0%**	**7,454**	**1.1%**	**4,830**	**1.1%**	**2,686**	**1.1%**	**1,233**	**1.1%**

Note: Revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021 and compare those with matrix use to those without.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary breast implant insertion date to the first revision procedure.
Time to revision was censored at date of data extract date (whichever came first) for non-revised implants.

Complication and revision – Tissue expanders for reconstruction

The registry also collects details of **complications found at the time of unplanned revision procedures** involving **tissue expanders.** Table 3.12 reports issues identified during reconstructive tissue expander revision procedures. Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for the revision or found incidentally during the revision procedure. This table reports the issues identified at all unplanned reconstructive tissue expander revisions, including revisions for breasts where the insertion of the initial tissue expander may or may not have also been captured by the registry. In 2021, **deep wound infection** was the most commonly reported issue accounting for 21.2% of reconstructive tissue expander revisions, followed by capsular contracture at almost 14.6% and seroma/haematoma at 12.4%.

TABLE 3.12: ISSUES IDENTIFIED AT REVISION PROCEDURE – RECONSTRUCTIVE TISSUE EXPANDERS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2021		2021	
	N	(%)	N	(%)
Deep wound infection	139	(22.7%)	29	(21.2%)
Device deflation	98	(16.0%)	13	(9.5%)
Device rupture	97	(15.8%)	16	(11.7%)
Seroma/ haematoma	87	(14.2%)	17	(12.4%)
Capsular contracture	79	(12.9%)	20	(14.6%)
Skin scarring problems	56	(9.1%)	11	(8.0%)
Device malposition	60	(9.8%)	15	(10.9%)
Total number of procedures	**613**		**137**	

Note: Listed in order of frequency are issues identified during unplanned reconstructive tissue expander revision procedures.
Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure.
The crude percentage attached to each issue identified at revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a complication rate.

Table 3.13 shows that the average revision rate for reconstructive primary tissue expanders was 8.3% for all-cause revision and 5.1% for revision due to complication at 36 months.

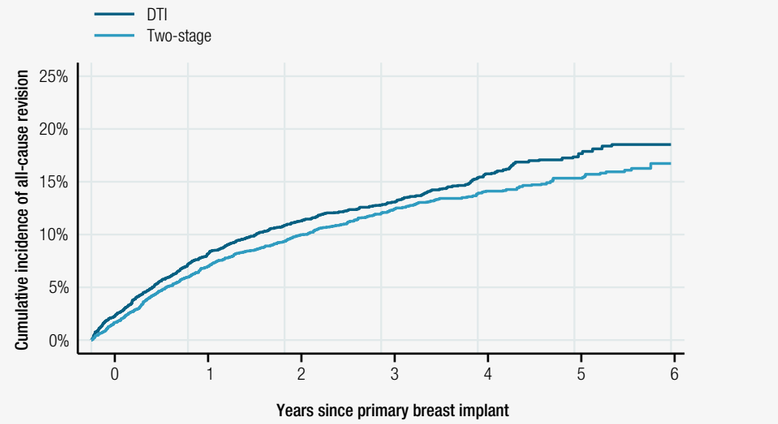
TABLE 3.13: REVISION INCIDENCE – RECONSTRUCTIVE TISSUE EXPANDERS

	N	N	Revision Incidence (95% Confidence Interval)					
	Primary implant	Revised	6 Mths	12 Mths	18 Mths	24 Mths	30 Mths	36 Mths
All-cause revision								
Post-cancer	5,638	281	3.5% (3.1, 4.1)	5.5% (4.8, 6.3)	7.4% (6.4, 8.5)	7.9% (6.9, 9.0)	8.3% (7.2, 9.5)	8.8% (7.6, 10.1)
Risk-reducing	2,550	89	2.8% (2.1, 3.6)	4.0% (3.1, 5.2)	6.4% (4.9, 8.3)	6.9% (5.3, 9.0)	7.2% (5.5, 9.4)	7.2% (5.5, 9.4)
Total	**8,188**	**370**	**3.3% (2.9, 3.8)**	**5.1% (4.5, 5.7)**	**7.1% (6.3, 8.0)**	**7.6% (6.7, 8.6)**	**8.0% (7.0, 9.0)**	**8.3% (7.3, 9.5)**
Revision due to complication								
Post-cancer	5,638	186	2.6% (2.2, 3.1)	3.7% (3.2, 4.4)	4.7% (4.0, 5.6)	4.9% (4.1, 5.8)	4.9% (4.1, 5.8)	5.0% (4.2, 5.9)
Risk-reducing	2,550	74	2.6% (2.0, 3.4)	3.4% (2.6, 4.4)	4.7% (3.5, 6.2)	5.0% (3.7, 6.6)	5.3% (3.9, 7.1)	5.3% (3.9, 7.1)
Total	**8,188**	**260**	**2.6% (2.2, 3.0)**	**3.6% (3.2, 4.2)**	**4.7% (4.1, 5.4)**	**4.9% (4.2, 5.7)**	**5.0% (4.3, 5.8)**	**5.1% (4.4, 5.9)**

Note: Revision incidence is based on reconstructive primary tissue expanders inserted from 2012 to 2022.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary tissue expander insertion date to the first revision procedure.
Time to revision was censored at date of expander to implant exchange or data extract date (whichever came first) for non-revised expanders per data submitted to the registry.

Figure 3.14 (below) provides a cumulative incidence curve for **all-cause revision for direct implant procedures (DTI) and two-stage procedures,** in which a tissue expander is utilised prior to implant procedure. At six-years after insertion 18.5% of the DTI procedure implants and 16.7% of two-stage procedures had been revised due to complications.

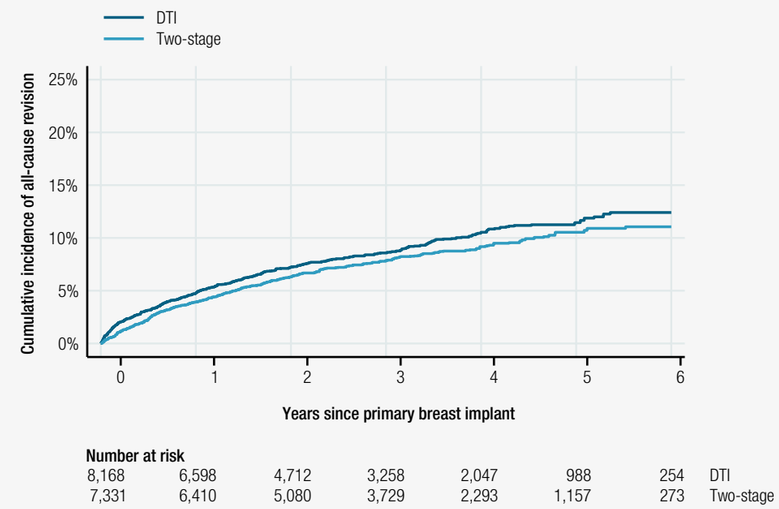
FIGURE 3.14: ALL-CAUSE REVISION INCIDENCE – RECONSTRUCTIVE DIRECT PRIMARY BREAST IMPLANTS COMPARED WITH TWO-STAGE PROCEDURES



Note: All–cause revision incidence is based on time from either primary insertion (DTI) or the insertion of implant as part of a two–stage procedure, respectively, from 2016 to 2021. Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

Figure 3.15 provides a cumulative incidence curve for **revision due to complication for direct implant procedures (DTI) and two-stage procedures,** in which a tissue expander is utilised prior to implant procedure. At six-years after insertion 12.4% of the DTI procedure implants and 11.1% of two-stage procedures had been revised due to complications.

FIGURE 3.15: REVISION INCIDENCE DUE TO COMPLICATION – RECONSTRUCTIVE DIRECT PRIMARY BREAST IMPLANTS COMPARED WITH TWO-STAGE PROCEDURES



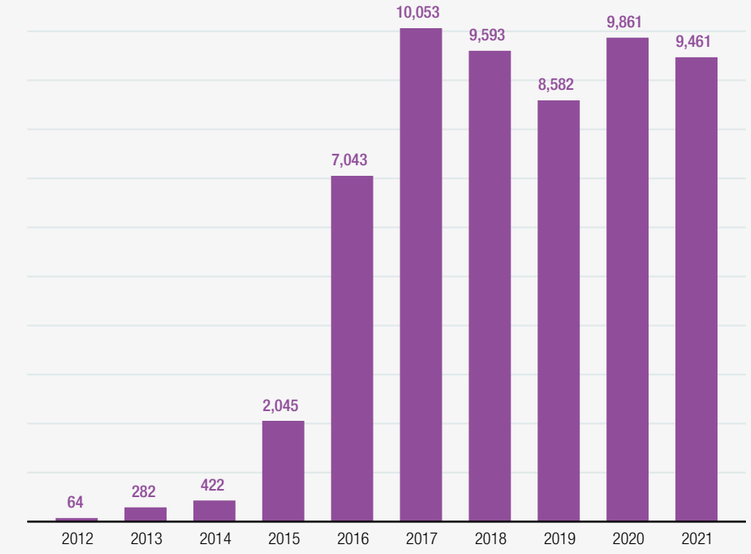
Note: Revision incidence is based on time from either primary insertion (DTI) or the insertion of implant as part of a two–stage procedure, respectively, from 2016 to 2021. Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

CHAPTER 4: REGISRTY OUTPUTS – COSMETIC INDICATIONS

Cosmetic procedure numbers

By the end of 2021, the ABDR recorded a total of **57,406** surgical procedures involving the use of breast devices for cosmetic indication (reasons). The procedures captured include surgery performed for cosmetic indication only, reported either unilaterally or bilaterally. Figure 4.1 demonstrates that in 2017 the ABDR had the greatest number of cosmetic procedures reported, followed by 2020. In 2021, **9,461** cosmetic procedures were captured.

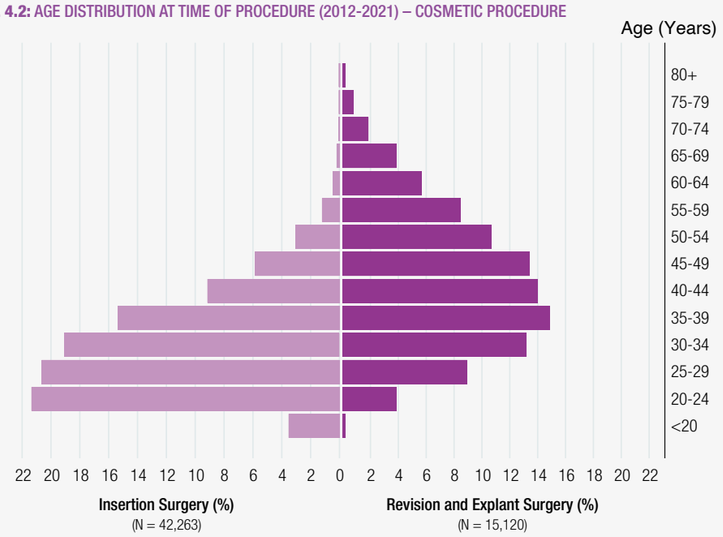
FIGURE 4.1: REGISTERED PROCEDURES (2012-2021) – COSMETIC PROCEDURES



Patient age at cosmetic procedures

The distribution of age at the time of cosmetic procedure is depicted in Figure 4.2 and Table 4.1. Overall, the median age at the time of cosmetic procedures was 31.One-year for insertion surgery, 43.0 years for revision surgery and 43.9 years for explant surgery.

FIGURE 4.2: AGE DISTRIBUTION AT TIME OF PROCEDURE (2012-2021) – COSMETIC PROCEDURE



Note: Insertion and revision (including explant) procedures have been analysed independently.
Both unilateral and bilateral procedures have been included.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procdure type detail per breast.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.

TABLE 4.1: SUMMARY STATISTICS FOR AGE AT TIME OF COSMETIC PROCEDURES

Cosmetic	Insertion Surgery	Revision Surgery	Explant Only
N	42,263	12,541	2,579
Median Age (Interquartile range)	31.1 (25.0, 38.2)	43.0 (34.6, 52.2)	43.9 (34.2, 56.0)

Note: Insertion, revision and explant only procedures have been analysed independently.
Both unilateral and bilateral procedures have been included.
A procedure indication hierarchy has been applied for bilateral procedures with different indication and procedure type details per breast.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
The interquartile range reports observed patient age at the 25th and 75th percentiles.

Cosmetic procedures aseptic techniques

Table 4.2 and Figure 4.3 show the **intraoperative techniques** used during cosmetic procedures. More than one intraoperative technique can be used and recorded during any single procedure. Overall, the use of intraoperative and/or post-operative antibiotics (90.5%), antiseptic rinse (83.2%) and glove change for insertion (70.3%) were commonly reported for cosmetic procedures and have increased over time.

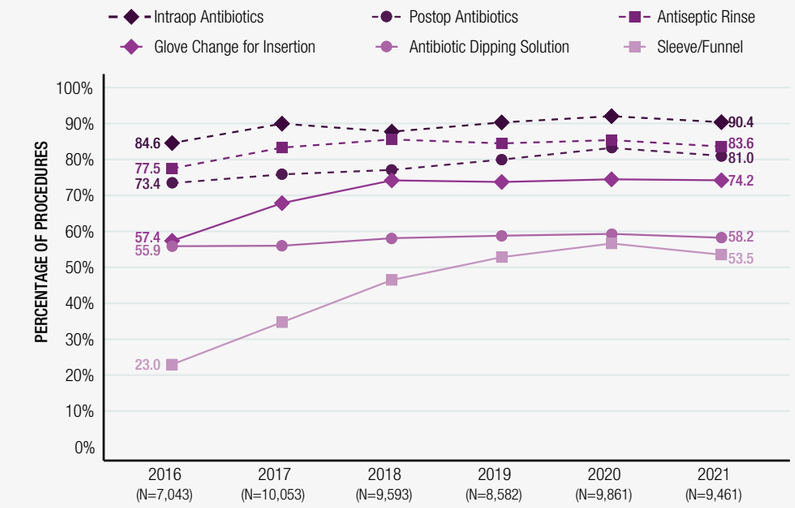
TABLE 4.2: INTRAOPERATIVE TECHNIQUES (2012-2021) – COSMETIC PROCEDURES

	2012-2021	
	N	(%)
Intraop/postop antibiotics	51,980	(90.5%)
Antiseptic rinse	47,765	(83.2%)
Glove change for insertion	40,354	(70.3%)
Antibiotic dipping solution	32,984	(57.5%)
Sleeve/funnel	25,197	(43.9%)
Not stated	3,730	(6.5%)
Total number of procedures	**57,406**	

Note: More than one intraoperative technique can be used and recorded per procedure.

In 2021, 8,553 patients were given intraoperative antibiotics, 7,909 antiseptic rinse, 7,663 post-operative antibiotics, 7,020 had glove change for insertion, 5,506 received antiseptic dipping solution and 5,062 a sleeve or funnel during cosmetic procedures.

FIGURE 4.3: INTRAOPERATIVE TECHNIQUES (2016-2021) – COSMETIC PROCEDURES



Note: Information regarding intraoperative and postoperative antibiotics have been collected separately since 2015.
Procedures were determined at the patient level, where procedural hierarchy, or primary reason for each procedure was applied.

Surgical characteristics of cosmetic procedures are presented in Table 4.3. Regarding the incision site, there has been an increase in the use of mastopexy/reduction wound, and a reduction in the use of the inframammary area, the areola and the axillary areas. There has been an increase in the use of the dual plane, in the use of concurrent mastopexy/reduction wound for incision, in fat grafting (from 0.6% in 2016 to 7.3% in 2021, and in nipple guards (from 59.8% to 73.6%). Drain use has decreased over this period.

TABLE 4.3: SURGICAL ELEMENTS (2016-2021) – COSMETIC BREAST LEVEL PROCEDURES

	2016	2017	2018	2019	2020	2021
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Incision site*						
Inframammary	11,395 (82.0%)	17,204 (86.6%)	15,319 (81.1%)	13,788 (81.3%)	15,589 (79.8%)	14,748 (78.7%)
Mastopexy/reduction wound	1,157 (8.3%)	1,419 (7.1%)	1,681 (8.9%)	1,701 (10.0%)	2,314 (11.8%)	2,225 (11.9%)
Previous mastectomy scar	151 (1.1%)	131 (0.7%)	97 (0.5%)	115 (0.7%)	124 (0.6%)	136 (0.7%)
Areola	188 (1.4%)	228 (1.1%)	263 (1.4%)	190 (1.1%)	207 (1.1%)	154 (0.8%)
Axillary	53 (0.4%)	56 (0.3%)	80 (0.4%)	36 (0.2%)	34 (0.2%)	24 (0.1%)
Other	29 (0.2%)	31 (0.2%)	36 (0.2%)	66 (0.4%)	54 (0.3%)	40 (0.2%)
Not stated	1,115 (8.0%)	1,008 (5.1%)	1,667 (8.8%)	1,260 (7.4%)	1,452 (7.4%)	1,616 (8.6%)
Surgical plane						
Sub-pectoral	10,114 (72.8%)	16,200 (81.5%)	14,475 (76.6%)	12,803 (75.5%)	14,728 (75.4%)	13,904 (74.2%)
Dual plane	249 (1.8%)	239 (1.2%)	252 (1.3%)	519 (3.1%)	689 (3.5%)	630 (3.4%)
Sub-glandular/ sub-fascial**	2,129 (15.3%)	1,999 (10.1%)	2,281 (12.1%)	2,336 (13.8%)	2,535 (13.0%)	2,682 (14.3%)
Other	30 (0.2%)	11 (0.1%)	7 (<1%)	2 (<1%)	80 (0.4%)	13 (0.1%)
Not stated	1,310 (9.4%)	1,360 (6.8%)	1,855 (9.8%)	1,251 (7.4%)	1,441 (7.4%)	1,478 (7.9%)
Concurrent mastopexy/reduction						
Yes	1,428 (10.3%)	2,169 (10.9%)	2,356 (12.5%)	2,523 (14.9%)	3,317 (17.0%)	3,283 (17.5%)
Previous mastopexy/reduction						
Yes	242 (1.7%)	407 (2.0%)	464 (2.5%)	506 (3.0%)	482 (2.5%)	545 (2.9%)
Fat grafting						
Yes	87 (0.6%)	114 (0.6%)	286 (1.5%)	790 (4.7%)	1,127 (5.8%)	1,373 (7.3%)
Drain use						
Yes	2,623 (18.9%)	2,730 (13.7%)	2,771 (14.7%)	2,581 (15.2%)	2,703 (13.8%)	2,799 (14.9%)
Nipple guard						
Yes	8,310 (59.8%)	15,579 (78.4%)	14,529 (76.9%)	12,841 (75.7%)	14,975 (76.7%)	13,794 (73.6%)
Total Procedures	**13,896**	**19,869**	**18,896**	**16,957**	**19,534**	**18,745**

Note: Details are at the breast procedure level, based on data provided to the registry at the time of analysis.
Insertion, revision and explant only procedures have been analysed independently.
Procedures with unknown procedure type (insertion, revision or explant) have not been included.
Matrix includes acellular dermal and synthetic matrices.
*More than one incision site can be recorded; row percentages are shown.
**This includes sub-cutaneous placement after mastectomy.

Device characteristics for cosmetic implants

Table 4.4 provides **device shell, shape and fill characteristics for breast implants inserted for cosmetic procedures** during an insertion procedure or replacement revision procedure. Of the total implants 50.7% were textured, 45.8% were smooth implants and 3.3% were polyurethane devices. The majority of implants were round (72.5%), followed by shaped/anatomical (27.3%). Most of devices were silicon filled (99.0%).

TABLE 4.4: DEVICE CHARACTERISTICS (2012-2021) – COSMETIC BREAST IMPLANTS

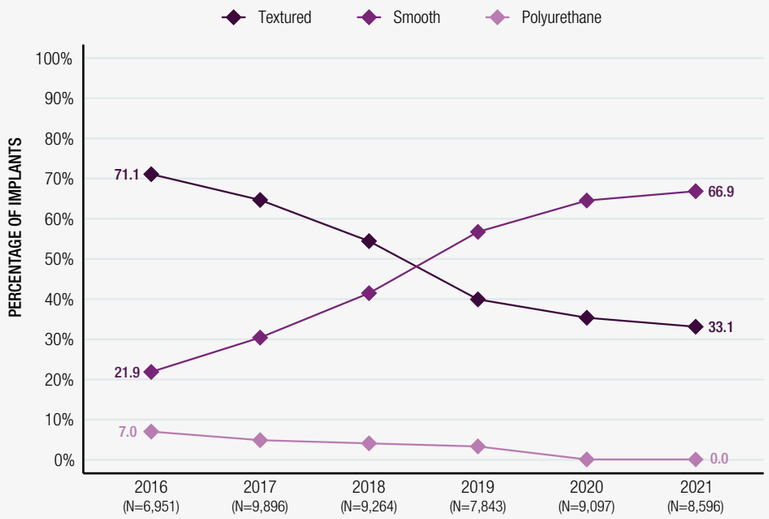
	Implant	
	N	(%)
Shell/ Texture		
Textured	54,663	(50.7%)
Smooth	49,429	(45.8%)
Polyurethane	3,604	(3.3%)
Not stated	134	(0.1%)
Shape		
Round	78,168	(72.5%)
Shaped/anatomical	29,472	(27.3%)
Not stated	190	(0.2%)
Fill		
Silicone	106,784	(99.0%)
Saline	883	(0.8%)
Silicone/ Saline	18	(0.0%)
Not stated	145	(0.1%)
Total	**107,830**	**(100.0%)**

Note: Device characteristics are reported for all new devices during an insertion procedure or a replacement revision procedure.

Figures 4.4 and 4.5 show the **trend in use of breast implants by shell and shape** respectively over time.

Figure 4.4 demonstrates the number of **textured implants has significantly reduced** from approximately 71% of devices in 2016 to 33% in 2021, with the number of smooth devices conversely increasing from approximately 22% of devices in 2016 to 67% in 2021. This represents 5,752 patients receiving a smooth implant in 2021 compared with 2,845 receiving a textured device. Polyurethane implants have not been inserted in the past 2 years.

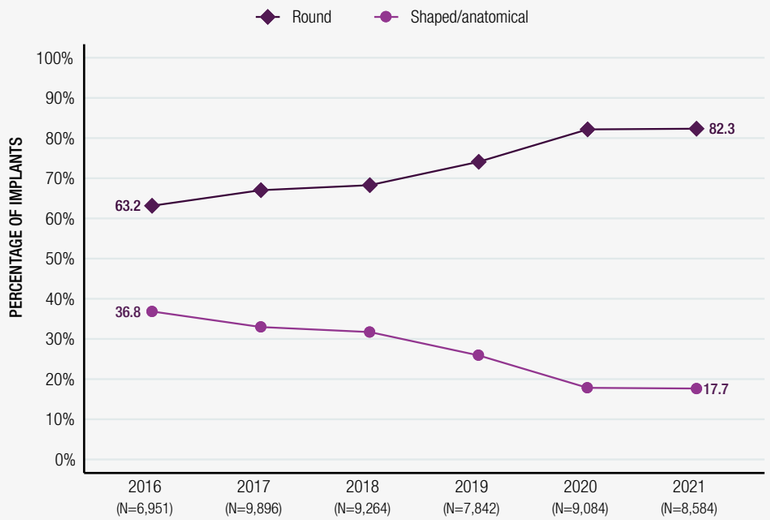
FIGURE 4.4: DEVICE SHELL (2016-2021) – COSMETIC IMPLANTS



Note: Device texture is reported for new implants during an insertion procedure or a replacement revision procedure.
Implants with an unknown shell type or TE have not been included. Explants are not included. Procedural heirarchy is applied.

Figure 4.5 highlights the continuing trend in use of **round breast implants** in cosmetic surgery. Round implants have increased from approximately 63% in 2016 to 82%, or 7,065 patients in 2021, with 1519 patients receiving a shaped/anatomical device representing only 17%.

FIGURE 4.5: DEVICE SHAPE (2016-2021) – COSMETIC IMPLANTS



Note: Device shape is reported for new implants during a primary insertion, replacement or revision procedure.
Implants with an unknown shell type or TE have not been included. Explants are not included. Procedural heirarchy is applied.

Data for both Figures 4.4 and 4.5 were recorded at the patient-procedure level, and procedure hierarchy, in which the primary reason for each procedure is used to determine procedure type. Implants with unknown shell or shape type were not included in these analyses.

Complications and revision incidence – Cosmetic breast implants

The registry collects details of **complications and issues that are found at the time of a revision procedure** involving breast devices, either identified as a **reason for the revision or found incidentally** during the revision procedure. Multiple issues can be recorded at revision surgery.

Table 4.5 reports the **complications identified at all revisions of cosmetic breast implants,** including revisions for breasts where the insertion of the initial implant may or may not have also been captured by the registry. In 2021, **capsular contracture** continues to be the most common issue identified at almost 35% of cosmetic implant revisions, followed by device rupture 21% and device malposition 19%.

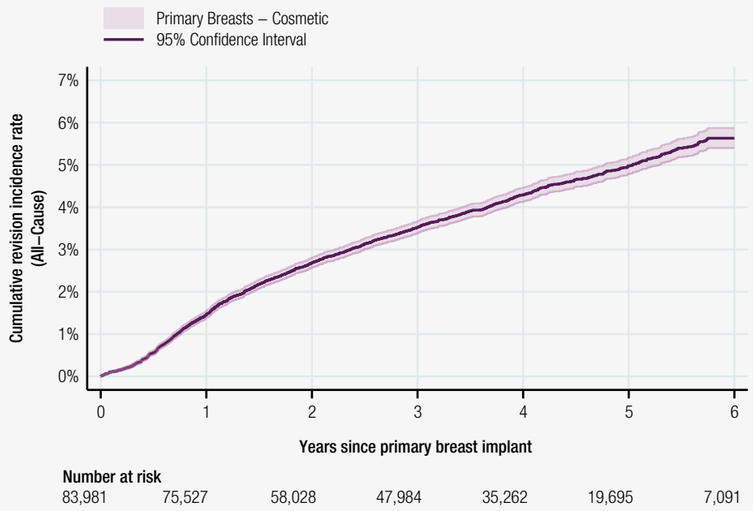
TABLE 4.5: ISSUES IDENTIFIED AT REVISION PROCEDURE – COSMETIC BREAST IMPLANTS

Complications and Issues Identified at Revision (N.B. Not complication rates)	2012-2021		2021	
	N	(%)	N	(%)
Capsular contracture	10,911	(38.0%)	2,059	(34.8%)
Device malposition	6,119	(21.3%)	1,152	(19.4%)
Device rupture	6,211	(21.6%)	1,265	(21.4%)
Device deflation	2,800	(9.7%)	565	(9.5%)
Seroma/ haematoma	800	(2.8%)	171	(2.9%)
Skin scarring problems	732	(2.5%)	116	(2.0%)
Deep wound infection	186	(0.6%)	31	(0.5%)
Total number of procedures	**28,745**		**5,923**	

Note: Listed in order of frequency are issues identified during cosmetic breast implant revision procedures.
Multiple issues can be recorded at the time of revision surgery and issues were either identified as a reason for revision or found incidentally during the revision procedure.
The crude percentage attached to each issue identified at revision is an observational proportion that has not accounted for censoring and patient follow-up time so cannot be interpreted as a complication rate.

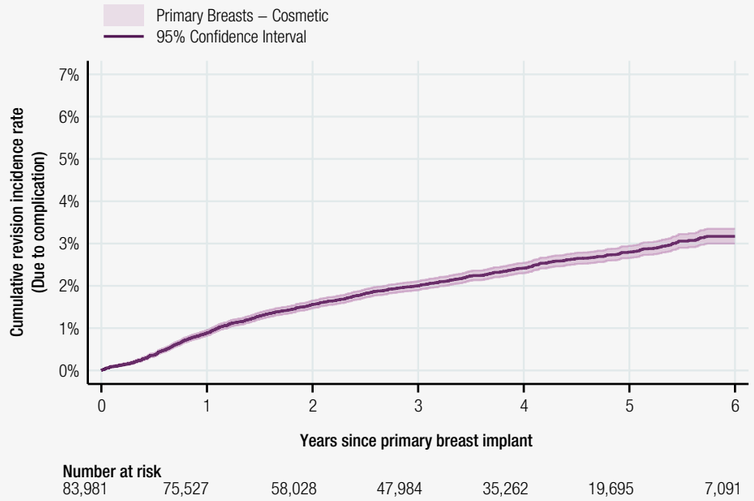
Figures 4.6 and 4.7 provide an **all-cause revision incidence** curve and revision **incidence curve due to complication** respectively for cosmetic procedures. At 6-years, just over 5.6% of cosmetic breast implants were revised after insertion, and 3% of were revised due to complications.

FIGURE 4.6: ALL-CAUSE REVISION INCIDENCE – COSMETIC PRIMARY BREAST IMPLANTS



Note: All-cause revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

FIGURE 4.7: REVISION INCIDENCE DUE TO COMPLICATION – COSMETIC PRIMARY BREAST IMPLANTS



Note: All–cause revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

Revision incidence rates due to **specific complications** are reported in Table 4.6. At six years since primary implant insertion, 1.4% of implants were revised due to device malposition, 1.3% due to capsular contraction and less than 1% for the implants were revised for other issues such as deflation/rupture, skin scarring, seroma/haematoma and deep wound infection.

TABLE 4.6: REVISION INCIDENCE – COSMETIC PRIMARY BREAST IMPLANTS

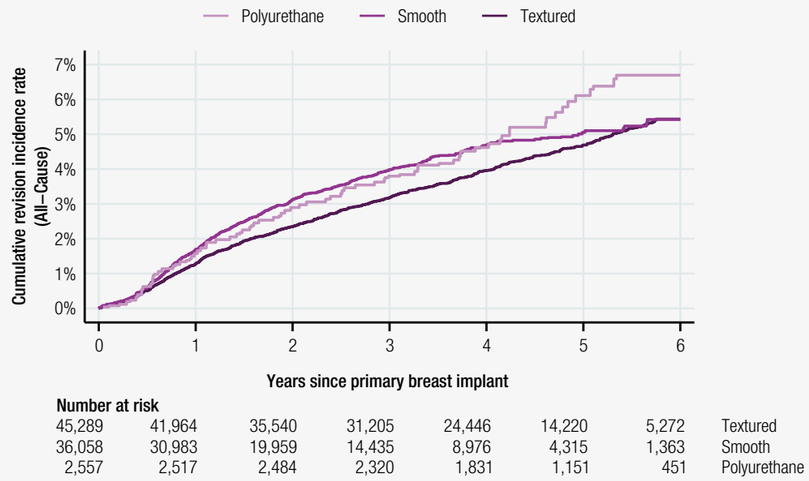
	N	N	Revision Incidence											
	Primary	Revised	1 Year		2 Years		3 Years		4 Years		5 Years		6 Years	
			N	RI	N	RI	N	RI	N	RI	N	RI	N	RI
Revision due to device malposition	83,981	856	75,527	0.50%	58,028	0.80%	47,984	1.00%	35,262	1.20%	19,695	1.30%	7,091	1.40%
Revision due to capsular contracture	83,981	670	75,527	0.30%	58,028	0.50%	47,984	0.70%	35,262	0.90%	19,695	1.10%	7,091	1.30%
Revision due to deflation/rupture	83,981	188	75,527	0.10%	58,028	0.10%	47,984	0.20%	35,262	0.20%	19,695	0.30%	7,091	0.40%
Revision due to skin scarring	83,981	104	75,527	0.10%	58,028	0.10%	47,984	0.10%	35,262	0.20%	19,695	0.20%	7,091	0.20%
Revision due to seroma/ haematoma	83,981	107	75,527	0.10%	58,028	0.10%	47,984	0.10%	35,262	0.10%	19,695	0.20%	7,091	0.20%
Revision due to deep wound infection	83,981	37	75,527	0.00%	58,028	0.00%	47,984	0.00%	35,262	0.00%	19,695	0.00%	7,091	0.00%

Note: Revision incidence is based on aesthetic primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.

Revision incidence by device characteristics

Figure 4.8 provides **all-cause revision incidence by device shell** type for primary cosmetic breast implants. The revision incidence rates are fairly similar for the three device shell types, except for an increase in polyurethane revisions at 4-5 years post insertion. At 6 years, all cause revision rates were 5.4% for both smooth and textured shells, and 6.7% for polyurethane.

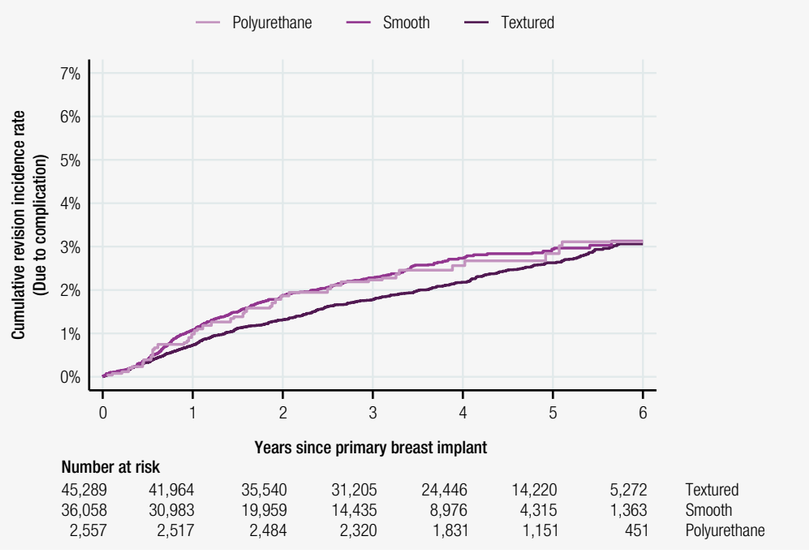
FIGURE 4.8: ALL-CAUSE REVISION INCIDENCE BY SHELL – COSMETIC PRIMARY BREAST IMPLANTS



Note: All–cause revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

Figure 4.9 provides revision incidence **due to complication** by device shell type for primary cosmetic breast implants. The revision incidence rates of 3.1% at 6 years were reported for all three shell types.

FIGURE 4.9: REVISION INCIDENCE DUE TO COMPLICATION BY SHELL – COSMETIC PRIMARY BREAST IMPLANTS



Note: All–cause revision incidence is based on reconstructive primary breast implants inserted from 2012 to 2021.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary implant insertion date to the first revision procedure.
The accompanying Table within the Figure provides the number of patients at risk of all–cause revision, following from the initial implant procedure at Year=0.

Revision incidence for specific **complications** after primary implant insertion by device shell are reported in Table 4.7. At six years after primary implant insertion, revision incidence remains low (<2%) for all device types for specific complications.

TABLE 4.7: REVISION INCIDENCE BY DEVICE SHELL – COSMETIC PRIMARY BREAST IMPLANTS

	N	N	Revision Incidence											
			1 Year		2 Years		3 Years		4 Years		5 Years		6 Years	
	Primary	Revised	N	RI	N	RI	N	RI	N	RI	N	RI	N	RI
Revision due to device malposition														
Textured	45,289	384	41,964	0.3%	35,540	0.6%	31,205	0.8%	24,446	0.9%	14,220	1.0%	5,272	1.1%
Smooth	36,058	430	30,983	0.7%	19,959	1.2%	14,435	1.4%	8,976	1.6%	4,315	1.7%	1,363	1.8%
Polyurethane	2,557	42	2,517	0.7%	2,484	1.2%	2,320	1.4%	1,831	1.6%	1,151	1.6%	451	1.9%
Total	**83,904**	**856**	**75,464**	**0.5%**	**57,983**	**0.8%**	**47,960**	**1.0%**	**35,253**	**1.2%**	**19,686**	**1.3%**	**7,086**	**1.4%**
Revision due to capsular contracture														
Textured	45,289	431	41,964	0.2%	35,540	0.5%	31,205	0.8%	24,446	0.9%	14,220	1.2%	5,272	1.4%
Smooth	36,058	210	30,983	0.3%	19,959	0.5%	14,435	0.6%	8,976	0.8%	4,315	1.0%	1,363	1.1%
Polyurethane	2,557	27	2,517	0.2%	2,484	0.5%	2,320	0.7%	1,831	0.9%	1,151	1.1%	451	1.2%
Total	**83,904**	**668**	**75,464**	**0.3%**	**57,983**	**0.5%**	**47,960**	**0.7%**	**35,253**	**0.9%**	**19,686**	**1.1%**	**7,086**	**1.3%**
Revision due to deflation/rupture														
Textured	45,289	124	41,964	0.0%	35,540	0.1%	31,205	0.2%	24,446	0.2%	14,220	0.3%	5,272	0.5%
Smooth	36,058	59	30,983	0.1%	19,959	0.1%	14,435	0.2%	8,976	0.2%	4,315	0.3%	1,363	0.3%
Polyurethane	2,557	5	2,517	0.0%	2,484	0.1%	2,320	0.1%	1,831	0.1%	1,151	0.2%	451	0.2%
Total	**83,904**	**188**	**75,464**	**0.1%**	**57,983**	**0.1%**	**47,960**	**0.2%**	**35,253**	**0.2%**	**19,686**	**0.3%**	**7,086**	**0.4%**
Revision due to skin scarring														
Textured	45,289	53	41,964	0.1%	35,540	0.1%	31,205	0.1%	24,446	0.1%	14,220	0.1%	5,272	0.1%
Smooth	36,058	50	30,983	0.1%	19,959	0.1%	14,435	0.2%	8,976	0.2%	4,315	0.2%	1,363	0.2%
Polyurethane	2,557	1	2,517	0.0%	2,484	0.0%	2,320	0.0%	1,831	0.0%	1,151	0.0%	451	0.0%
Total	**83,904**	**104**	**75,464**	**0.1%**	**57,983**	**0.1%**	**47,960**	**0.1%**	**35,253**	**0.2%**	**19,686**	**0.2%**	**7,086**	**0.2%**
Revision due to seroma/haematoma														
Textured	45,289	68	41,964	0.1%	35,540	0.1%	31,205	0.1%	24,446	0.1%	14,220	0.2%	5,272	0.2%
Smooth	36,058	31	30,983	0.1%	19,959	0.1%	14,435	0.1%	8,976	0.1%	4,315	0.1%	1,363	0.1%
Polyurethane	2,557	7	2,517	0.2%	2,484	0.2%	2,320	0.3%	1,831	0.3%	1,151	0.3%	451	0.3%
Total	**83,904**	**106**	**75,464**	**0.1%**	**57,983**	**0.1%**	**47,960**	**0.1%**	**35,253**	**0.1%**	**19,686**	**0.2%**	**7,086**	**0.2%**
Revision due to deep wound infection														
Textured	45,289	25	41,964	0.1%	35,540	0.1%	31,205	0.1%	24,446	0.1%	14,220	0.1%	5,272	0.1%
Smooth	36,058	12	30,983	0.0%	19,959	0.0%	14,435	0.0%	8,976	0.0%	4,315	0.0%	1,363	0.0%
Polyurethane	2,557	0	2,517	0.0%	2,484	0.0%	2,320	0.0%	1,831	0.0%	1,151	0.0%	451	0.0%
Total	**83,904**	**37**	**75,464**	**0.0%**	**57,983**	**0.0%**	**47,960**	**0.0%**	**35,253**	**0.0%**	**19,686**	**0.0%**	**7,086**	**0.0%**

Note: Revision incidence is based on cosmetic primary breast implants inserted from 2012 to 2022.
Rates have not been adjusted for risk factors.
Revision incidence relates to the time from primary breast implant date to the first revision procedure.
Revision procedures are categorised by complication type.

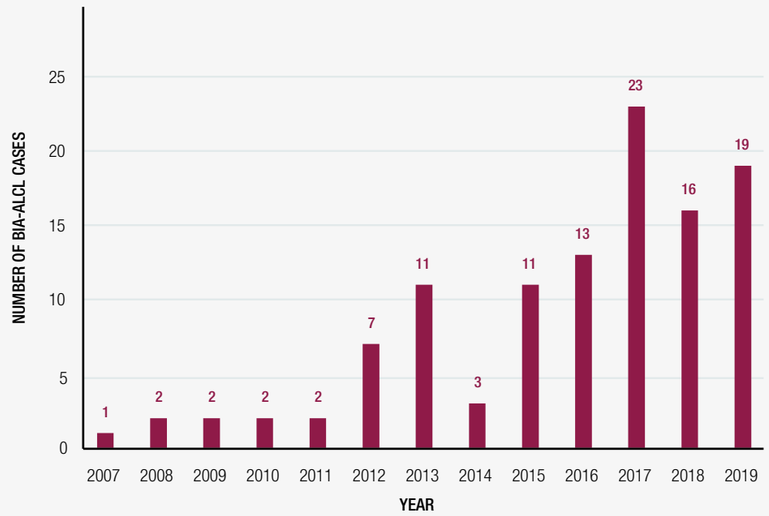
CHAPTER 5: REGISTRY OUTCOMES

Breast Implant Large Cell Lymphoma (BIA-ALCL)

Surgeons are encouraged to report all new cases of Breast Implant Associated- Anaplastic Large Cell Lymphoma BIA-ALCL to the ABDR, which together with the TGA is now the main reporting channel in Australia. Previously, cases were reported to the Macquarie University (MQU) Research Group until 2019. The data presented in this report is in two parts; (1) Data provided by MQU, and (2) Cases reported directly to the ABDR. These latter cases may overlap with some of those reported from MQU. The ABDR results include additional information regarding operation category, associated complications and explant information.

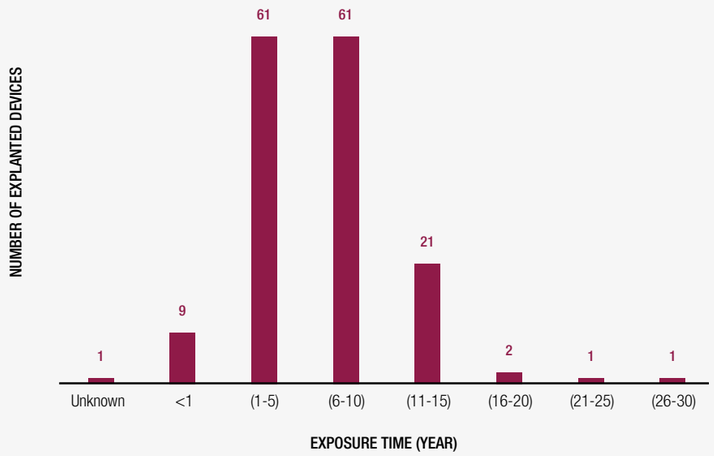
MQU data comprised **112** confirmed BIA-ALCL cases and **157** explanted devices reported between **2007-2019** (Figure 5.1).

FIGURE 5.1: NUMBER OF BIA-ALCL CASES 2007-2019 MACQUARIE UNIVERSITY (N = 112)



Of the **total 157 explanted devices captured** by MQU, 81% (127) were in situ (exposure time) for 10 years or less (Figure 5.2).

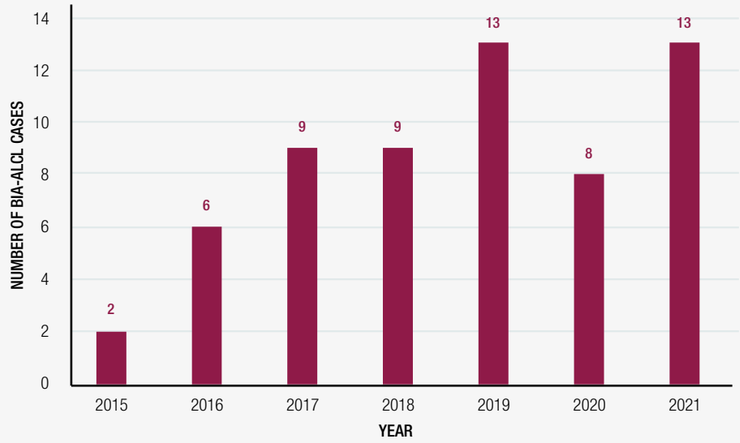
FIGURE 5.2: NUMBER OF EXPLANTED DEVICES BY EXPOSURE TIME (YEAR) 2007-2019 MACQUARIE UNIVERSITY (N = 157)



ABDR data

Confirmed cases of BIA-ALCL are reported to the ABDR irrespective of whether the surgeon is participating in the registry. New cases are then cross-referenced with the TGA's records for accuracy. By the end of 2021, the ABDR received notification of a further 13 positive diagnoses, as well as confirmation of an additional 2 cases from 2020. At the end of 2021, **60 confirmed cases of BIA-ALCL** have been reported directly to the ABDR (Figure 5.3).

FIGURE 5.3: BIA-ALCL CASES REPORTED BY YEAR ABDR 2015-2021 (N = 60)



Of the 60 cases, 58 cases were notified by surgeons as captured in the data collection form (DCF), with a further 2 cases confirmed without an accompanying DCF. One of these two cases was reported by the patient and later confirmed by the operating surgeon. Furthermore, where a DCF was not provided, the surgeons confirmed that BIA-ALCL was the reason for the device removal. For clarity we can confirm that of the 60 cases, two had bilateral BIA-ALCL reported on their DCF. The majority of BIA-ALCL cases reported are derived from Queensland, New South Wales and Victoria (Table 5.1).

TABLE 5.1: NUMBER OF BIA-ALCL PATIENTS BY STATE AND SITE TYPE- ABDR 2015-2021

State	Private	Public	Total
QLD	18	3	**21**
NSW	8	4	**12**
VIC	8	3	**11**
WA	7	0	**7**
Other/Unknown	8	1	**9**
Total	**49**	**11**	**60**

Analysis of **device and clinical characteristics** have been performed for patients where that information has been captured via the DCF. Table 5.2 shows the number of BIA-ALCL cases by indication for surgery. At breast level, the majority of BIA-ALCL cases were related to cosmetic procedures (35), followed by post-cancer reconstruction surgery (15) and benign/prophylactic surgery (5). There was 1 procedure where the type of reconstruction was not specified, and the operation category was not stated in 6 other cases.

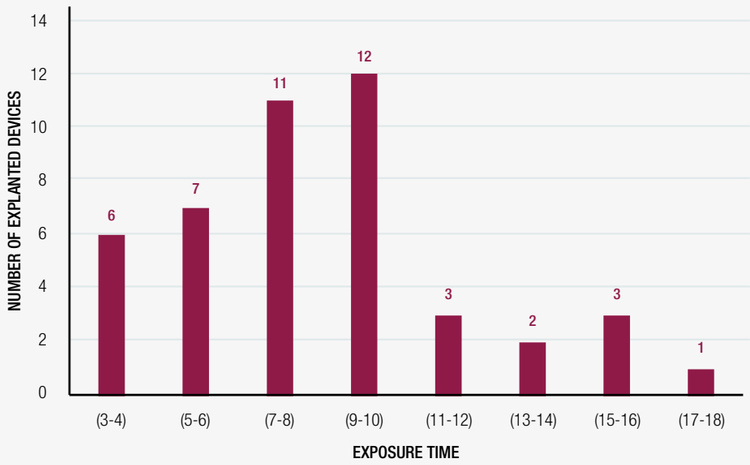
TABLE 5.2: NUMBER OF BIA-ALCL CASES (AT BREAST LEVEL) BY INDICATION FOR SURGERY – ABDR 2015-2021

Indication for Surgery	N	%
Cosmetic augmentation	35	56%
Reconstruction post cancer	15	24%
Not stated	6	10%
Reconstruction benign/prophylactic	5	8%
Reconstruction not otherwise specified	1	2%
Total	**62**	**100%**

Note: The 62 cases include 2 bilateral cases reported.

Figure 5.4 shows the duration between insertion and date of revision/explantation for the same device (where available). Of the total 60 BIA-ALCL cases at patient level, the initial insertion date of the device was recorded for only 45 patients. Fifty-one percent of reported cases that occurred between 7-10 years from the date of device insertion, with a range of 3 to 18 years post insertion.

FIGURE 5.4: NUMBER OF EXPLANTED DEVICES BY EXPOSURE TIME (YEAR) IN BIA-ALCL PATIENT ABDR 2015-2021 (N = 45)



Note: Of the total 60 BIA-ALCL cases, the initial insertion date of the device was not recorded for 15 patients.

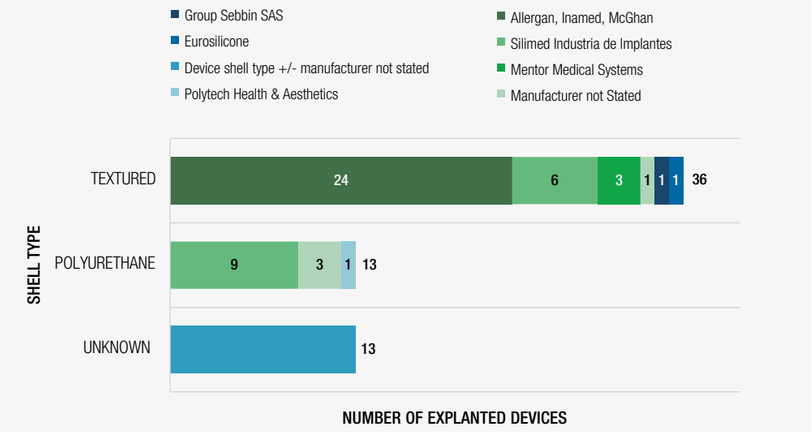
In relation to revision type, 44 procedures were recorded as **device explanation** only, whilst 18 were listed as **replacement procedures** (Table 5.3). Of the total 44 explant-only procedures, 41 included a full capsulectomy. Of 18 replacement procedures, 9 full capsulectomies and 2 partial capsulectomies were reported. As the ABDR matures, our data will reflect more accurate device and associated details as missing data on legacy procedures are reduced, and more robust recorded information analysed.

TABLE 5.3: NUMBER OF BIA-ALCL CASES (AT BREAST LEVEL) BY REVISION TYPE AND CAPSULECTOMY TYPE – ABDR 2015-2021

Revision Type	Capsulectomy Type				Total
	Full	Partial	None	Not stated/Null	
Explant only	41	0	0	3	**44**
Replacement	9	2	4	3	**18**
Total	**50**	**2**	**4**	**6**	**62**

Of the total 62 BIA-ALCL devices reported to the ABDR (Figure 5.5), the shell type of the explanted devices has been captured in 49 cases including legacy patients. Seventy-three percent of the explanted implants had textured shell (n=36), 28% were polyurethane (n=13) and shell type was not stated for 13 devices. It is to be noted that the Silimed polyurethane foam-covered implants had a manufacturing defect identified that caused surface delamination[8].

FIGURE 5.5: EXPLANTED DEVICES BY SHELL TYPE ABDR 2015-2021 (N = 62)



Similarly, device shape has been recorded for 50 cases, with 64% of the explanted devices being of anatomical shape (32), 36% being round (18), and shape not being stated for 12 of the explanted devices. The fill type of the explanted devices was recorded for 40 cases, with 95% of the explanted devices having silicon fill (38), 5% having other fill (2), and the device fill not being stated for 22 of the explanted devices. The ABDR has attempted to collect missing explanted device characteristics, and encourages all surgeons to provide as many of these details as possible so that any emerging trends can be identified and reported in the future.

Clinical presentations associated with BIA-ALCL identified at revision are noted In Tables 5.4 and 5.5. In approximately one-third of cases (23; 37%), at least one other clinical complication was reported associated with BIA-ALCL (Table 5.4). Of these, the most common was seroma/haematoma with 14 cases reporting it as a reason for revision, and a further 3 identifying a seroma/haematoma incidentally at revision (Table 5.5).

TABLE 5.4: NUMBER OF CLINICAL ISSUES ASSOCIATED WITH BIA-ALCL CASES IDENTIFIED AT REVISION – ABDR 2015-2021

Clinical issues reported	N
Only BIA-ALCL reported	36
One clinical issue reported	16
Two clinical issues reported	6
Three clinical issues reported	1
Asymptomatic	3
Total	**62**

TABLE 5.5: ADJUNCT CLINICAL ISSUES REPORTED IN BIA-ALCL CASES ABDR 2015-2021

Issue identified at revision	Reason for revision	Found incidentally
Seroma/Haematoma	14	3
Capsular contracture	4	4
Device malposition	3	1
Skin Scarring problems	1	0
Device deflation	1	0
Deep wound infection	0	0
Breast cancer	0	0

Data requests

The ABDR continued to experience an increase of enquiries from patients during this reporting period, with over 230 emails and another 223 phone calls received from patients directly. The majority of patients contacted the registry seeking their device details or information regarding personal health concerns including device recalls, Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) and Breast Implant Illness, with a small proportion requesting to opt-out.

Sixteen requests for patient and device data and site reports for case ascertainment were received from surgeons including 9 from public sites. Lists of patients and/or devices were only supplied if the request was made directly by the surgeon, or by an appropriately delegated hospital Quality Manager.

Data requests including post market clinical follow up and information on long term safety and performance of devices were also received from 2 major industry companies who supply breast devices to the Australian market. No identifiable data is ever included in these reports.

In May this year, the ABDR was further engaged by Safer Care Victoria (SCV) an administrative office of the Department of Health, to manage their patient information helpline regarding BIA-ALCL. The helpline is a unique initiative established for a one-year tenure, to support SCV's campaign aiming to successfully disseminate and support health information regarding this rare illness.

The ABDR also encourages the secondary uses of its data for research and related purposes. A total of 4 formal research data access requests were approved for the ABDR in 2021.

Date of approval	Name/ Organisation	Title of the project
01/02/2021	Ms Jessy Hansen	Development of risk-adjustment models for patient reported outcome measures associated with primary breast device implants
24/05/2021	Dr Rasa Ruseckaite	ABDR PROMs response rate evaluation
26/07/2021	Dr Robert Knight / Dr Sean Leow	Intraoperative PVP-1 (Povidone Iodine) antiseptic wash and complication rates in breast prothesis surgery, a prospective cohort study
29/07/2021	Dr Isabella Reid / Dr Ramin Shayan	Fat Grafting as an Adjunct to reconstructive and aesthetic breast surgery in Australia

CHAPTER 6: PATIENT REPORTED OUTCOME MEASURES (PROMs)

The ABDR has used the Breast-Q Implant Surveillance module (BREAST-Q IS) as a patient reported outcome measure since 2018. It comprises five questions relating to satisfaction and symptoms via questions relating to breast look, feel, rippling, pain and tightness. These questions were identified as the most likely aspects post-breast surgery to recognise device issues and performance. The BREAST-Q IS was aimed to be administered at one-, two-, five- and ten- years from the time of device insertion in all patients.

From the commencement of the PROMs program in October 2018 until end of December 2021, a total of 54,444 patients who underwent cosmetic procedures and 11,552 who had undergone breast reconstruction procedures were contacted (a total of **65,992 patients**). Response rates have been reported for the period 2019-2021 inclusive. This incorporates all complete and partial responses to the PROMs questionnaire from eligible participants, except those who chose to opt out from follow-up. A summary of the PROMs response figures from 2019 to 2021 is in Table 6.1.

TABLE 6.1: PROMS RESPONSE RATES AT YEAR 1, YEAR 2 AND YEAR 5 POST-OPERATIVE RECONSTRUCTIVE AND COSMETIC PATIENTS FROM 2019-2021

Follow-up year	2019 Reconstruction		2019 Cosmetic		2020 Reconstruction		2020 Cosmetic		2021 Reconstruction		2021 Cosmetic	
	Total Contacted N= 3,631	Total Responded 73.1%	Total Contacted N=19,326	Total Responded 55.1%	Total Contacted N= 4,587	Total Responded 52%	Total Contacted N=19,019	Total Responded 40%	Total Contacted N= 3,334	Total Responded 45.6%	Total Contacted N= 16,095	Total Responded 33%
Year 1	1,874	75.2%	9,288	58.2%	2,118	54%	7,808	41.5%	1,348	45.5%	5,773	32.3%
Year 2	1,486	72.9%	9,640	52.8%	1,933	54%	9,235	40.7%	1,430	47.3%	6,043	33.2%
Year 5	271	59.8%	398	42.7%	536	40%	1976	31.6%	556	41.4%	4,279	33.6%
Total number	**Total 22,957 contacted**				**Total 23,606 contacted**				**Total 19,429 contacted**			

Key findings are:

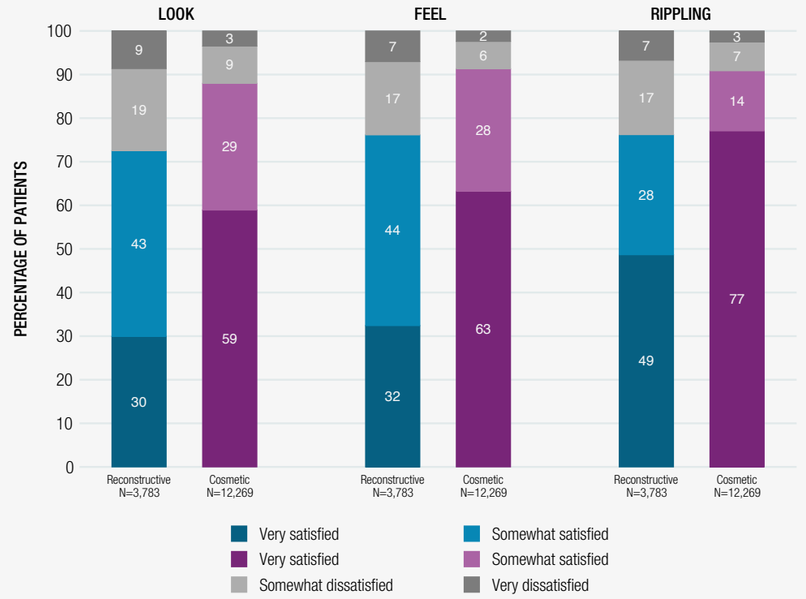
- A total of 65,992 patients were contacted to participate in the PROMs program from 2019-2021.
- In 2021 overall, 45.6% of contacted reconstructive patients and 33% of cosmetic patients responded to the survey.
- Patient response rates for reconstructive patients are higher than for cosmetic recipients.
- Reconstructive Year 1 patient response rates have reduced from 75.2% in 2019 to 45.5% in 2021, a reduction of approximately 30%.
- Cosmetic Year 1 patient response rates have reduced from 58.2% in 2019 to 32.3% in 2021, a reduction of approximately 26%.
- Response rates are highest at one-year and lowest at 5-years post-implant.
- Response rates have declined by approximately 10% each year over this time.
- Attempts to follow up non-responders were reduced in 2021 due to the lack of effectiveness of telephone calls as a method of follow up.

As a result of declining response rates, an evaluation of the PROMs program data was undertaken in 2021. This highlighted that the PROMs response rates may lead to biased reporting and may subsequently reduce the validity of the overall results. The PROMs program will therefore be paused and revised in 2022 and recommenced in 2023.

PROMs for breast implants

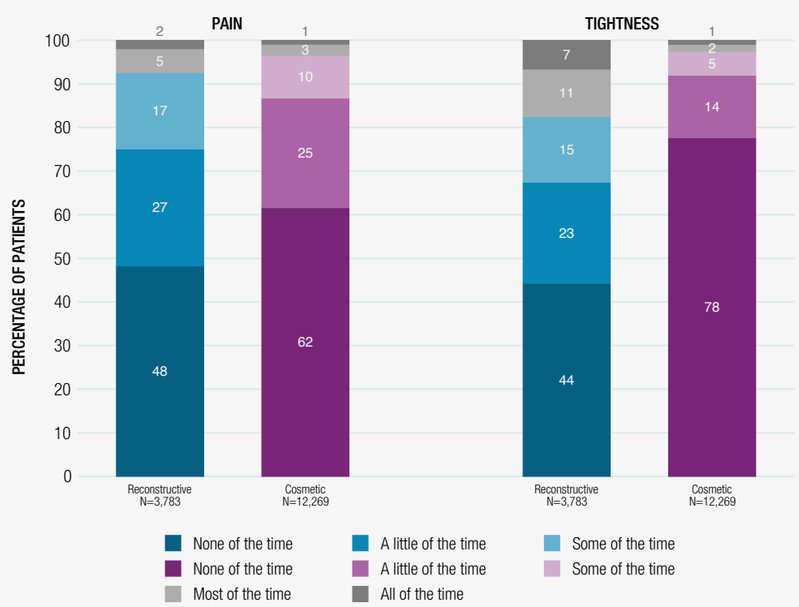
The analysis of the PROMs data comprised patients who provided complete responses to the PROMs questions. For the following analyses, data collected during 2018-2021 were analysed. The results of the Breast-Q IS with aggregate data for patients with breast reconstruction and cosmetic procedures at **one-year** post operation are shown in Figures 6.1-6.6.

FIGURE 6.1: SATISFACTION LEVEL OF BREAST RECONSTRUCTION AND COSMETIC PATIENTS AT ONE-YEAR POST-OPERATION



At **one-year** post-operation, 12% or fewer of responding patients were very or somewhat dissatisfied with implant look, feel and rippling; whereas between 24-28% of patients with breast reconstruction were dissatisfied with implant look, feel and rippling (Figure 6.1 above).

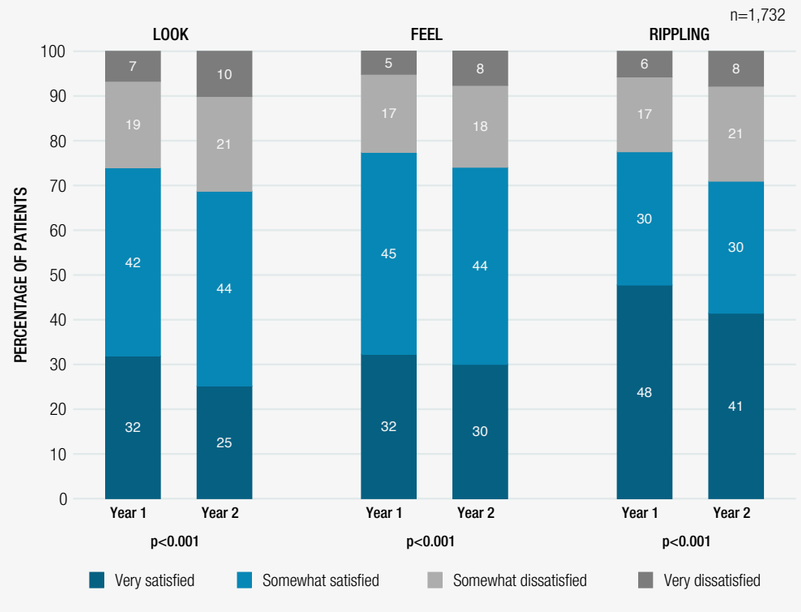
FIGURE 6.2: EXPERIENCE OF BREAST RECONSTRUCTION AND COSMETIC PATIENTS AT ONE-YEAR POST-OPERATION



At **one-year** post operation, patients with cosmetic procedures experienced less breast pain and tightness compared with patients with reconstruction procedures. Approximately 4% of cosmetic patients have experienced breast tightness most/all of the time as compared to up to 18% of reconstructive patients (Figure 6.2).

The results of the Breast-Q IS with **linked data from reconstruction** patients who answered both **Year 1 and Year 2 surveys** are shown in Figures 6.3 and 6.4 showing the patient journey over a period of time. For patients with breast reconstruction, satisfaction decreased from Year 1 to Year 2 by 5% for look, 4% for feel and 6% for rippling (Figure 6.3).

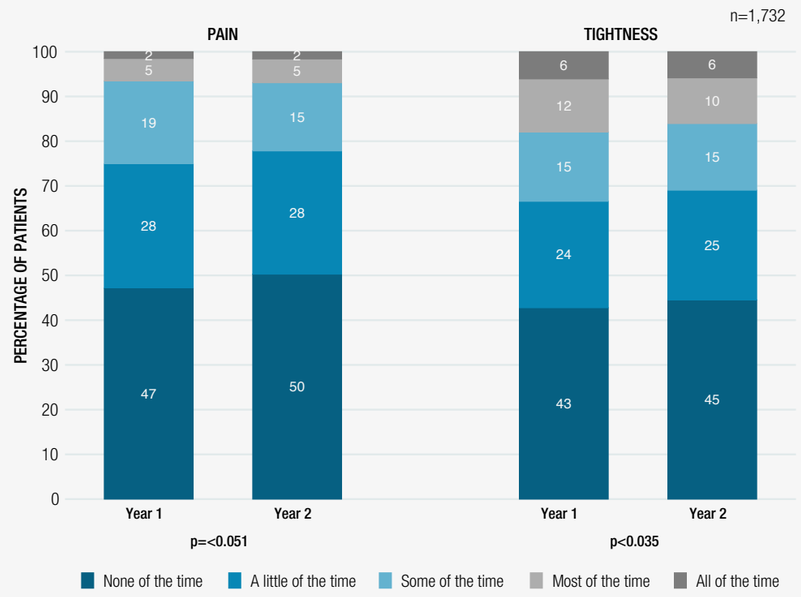
FIGURE 6.3: SATISFACTION LEVEL OF BREAST RECONSTRUCTION PATIENTS AT ONE- AND TWO-YEARS POST-OPERATION



Note: P-value from asymptotic tests for symmetry between year one and year two presented for all linked PROMs figures.

However, for reconstruction patients the proportion of patients experiencing pain and tightness 'None of the time' remained stable from Year 1 to Year 2 (Figure 6.4).

FIGURE 6.4: EXPERIENCES OF BREAST RECONSTRUCTION PATIENTS ONE- AND TWO-YEARS POST-OPERATION



The results of the Breast-Q IS with linked data from **cosmetic** procedures who answered both Year 1 and Year 2 surveys are shown in Figures 6.5 and 6.6. Overall, satisfaction with look, feel and rippling were high (Figure 6.5), however there was an increase in the proportion of women dissatisfied by; 3% for look, 2% for feel and 3% for rippling from Year 1 to Year 2. There is a very slight increase in proportion of women reporting pain most/all of the time by around 1% for pain and no change for tightness from Year 1 to Year 2 (Figure 6.6).

FIGURE 6.5: SATISFACTION LEVEL OF COSMETIC BREAST PATIENTS AT ONE- AND TWO-YEARS POST-OPERATION

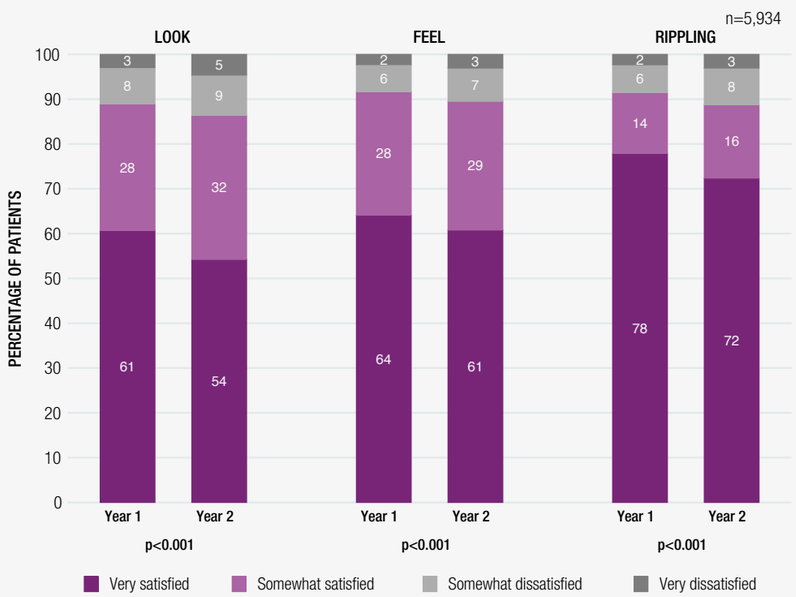
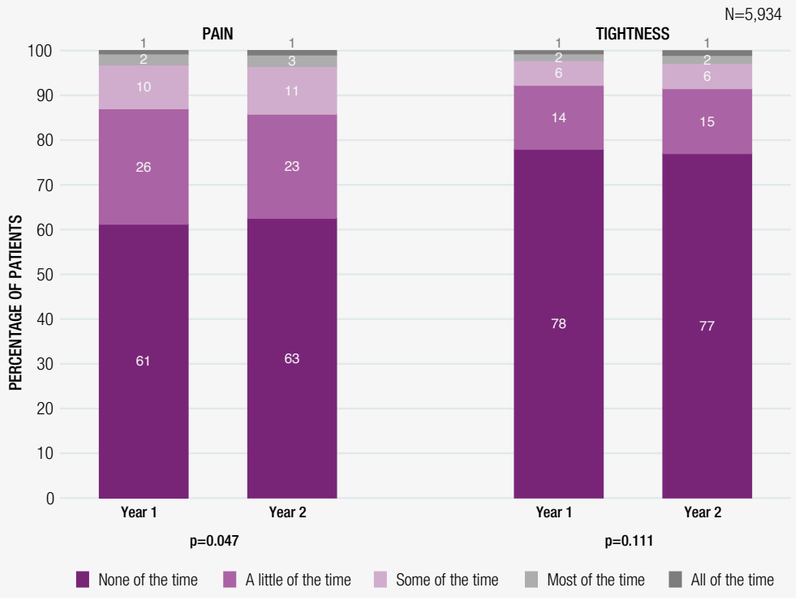


FIGURE 6.6: EXPERIENCE OF COSMETIC BREAST PATIENTS AT ONE- AND TWO-YEARS POST-OPERATION



For the first time, the ABDR has reported PROMs separately for reconstructive patients undergoing **direct to implant and two-stage insertion procedures.** Satisfaction with look and feel was slightly higher for DTI procedures (Figure 6.7). Similar satisfaction was reported for rippling and pain, however patients with DTI procedures had a slightly higher rate of tightness at one-year (Figure 6.8).

FIGURE 6.7: SATISFACTION LEVEL OF BREAST RECONSTRUCTION PATIENTS HAVING UNDERGONE DIRECT TO IMPLANT COMPARED TO TWO-STAGE INSERTION PROCEDURES, AT ONE-YEAR POST-OPERATION

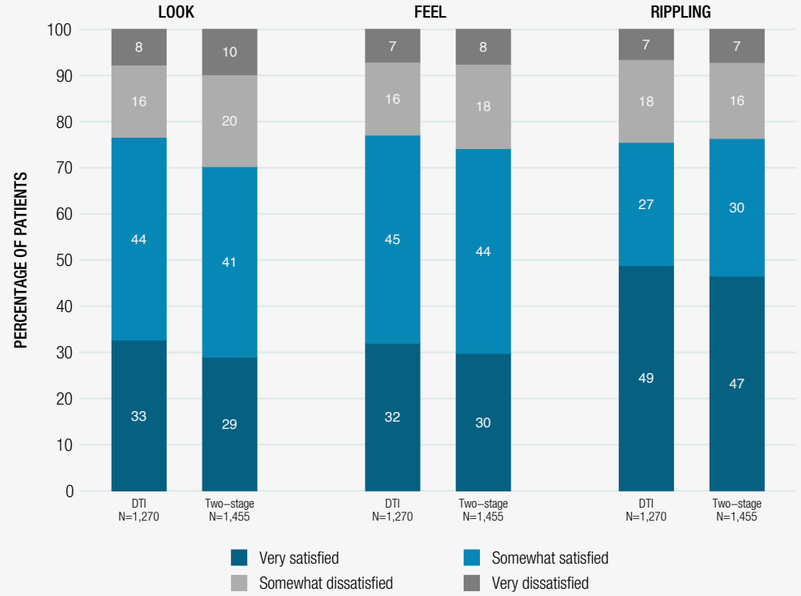
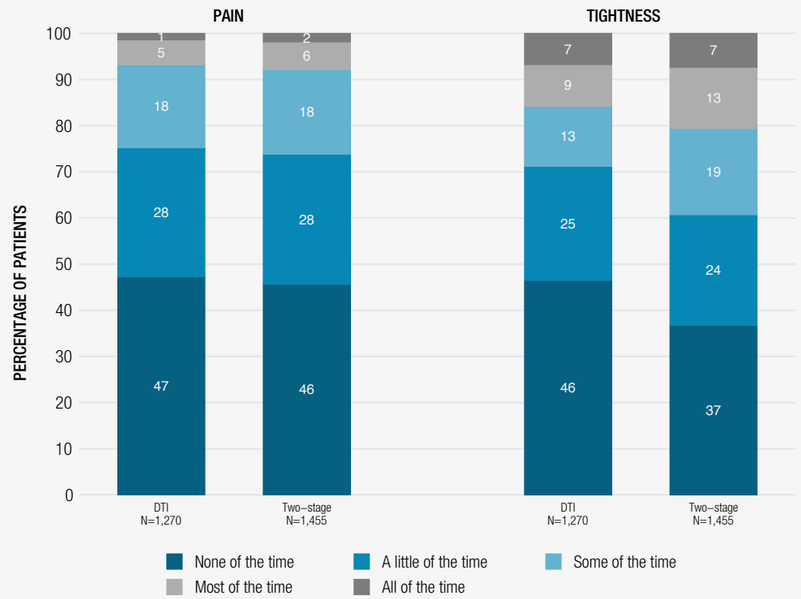


FIGURE 6.8: EXPERIENCE OF BREAST RECONSTRUCTION PATIENTS HAVING UNDERGONE DIRECT TO IMPLANT COMPARED WITH TWO-STAGE INSERTION PROCEDURES, AT ONE-YEAR POST-OPERATION



The ABDR has also reported PROMs results for reconstructive patients for the different device shells at one-year post-operation. Polyurethene shell devices have been removed from the analysis due to low numbers (< 40). Satisfaction for look, feel and rippling and pain and tightness were similar between textured and smooth devices (Figure 6.9 and 6.10).

FIGURE 6.9: SATISFACTION LEVELS OF BREAST RECONSTRUCTION PATIENTS, FOR SHELL TYPE AT ONE-YEAR POST-OPERATION

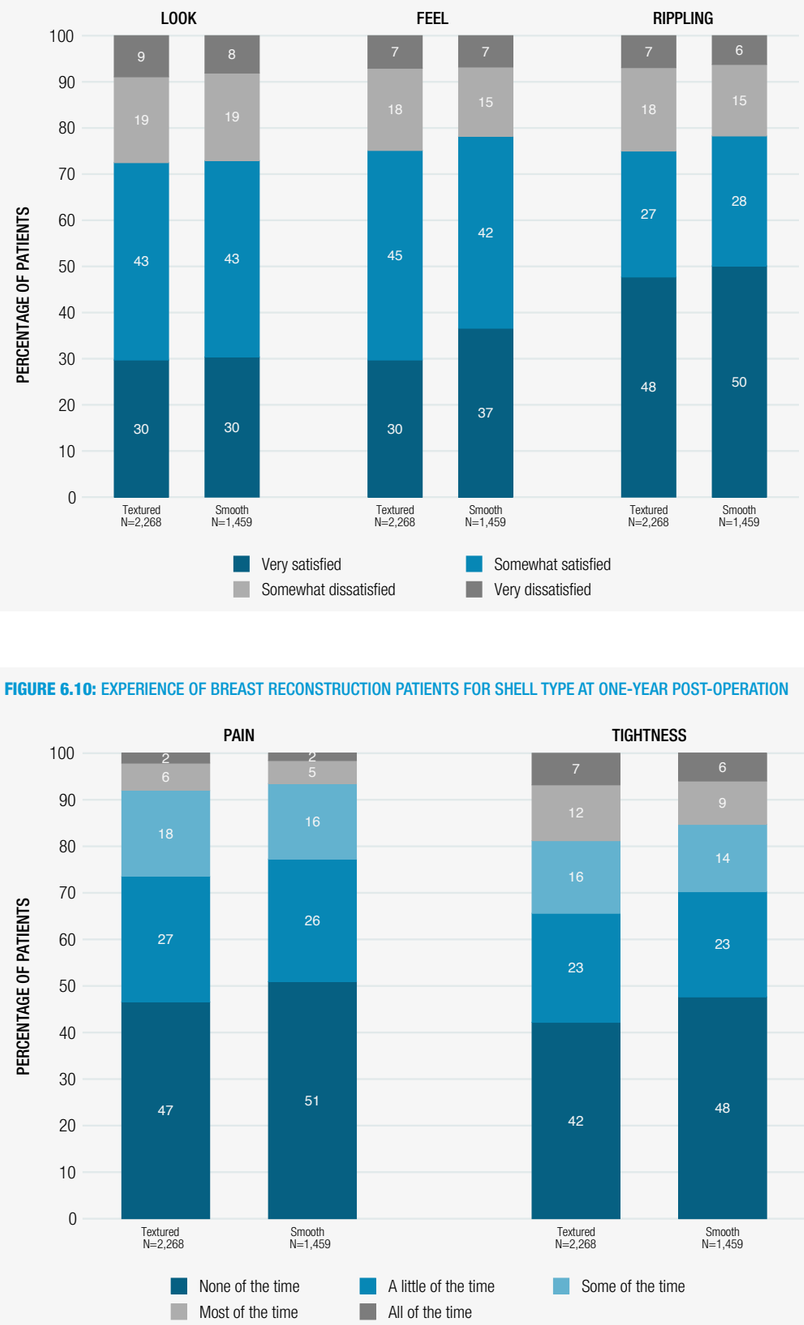


FIGURE 6.10: EXPERIENCE OF BREAST RECONSTRUCTION PATIENTS FOR SHELL TYPE AT ONE-YEAR POST-OPERATION

For cosmetic patients, all shell types were included due to a larger sample size (Figures 6.11 and 6.12). Satisfaction with look, feel, rippling, pain and tightness was similar for all device shell types at one-year post-operation.

FIGURE 6.11: SATISFACTION LEVEL OF COSMETIC BREAST PATIENTS BY SHELL TYPE AT ONE-YEAR POST-OPERATION

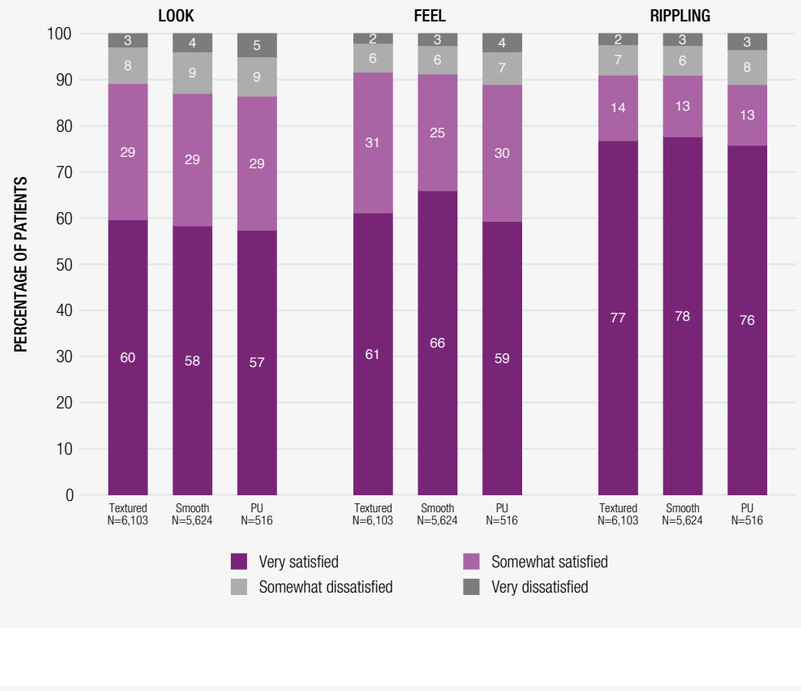
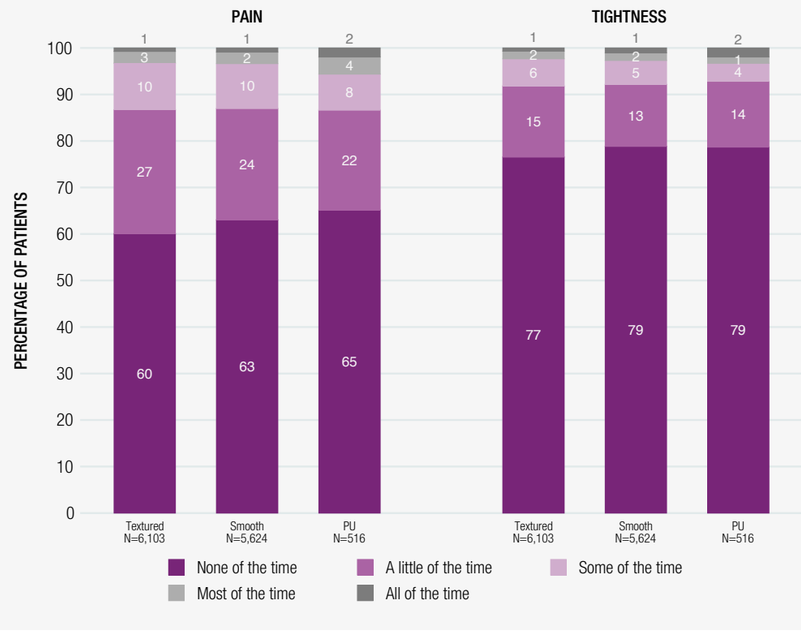


FIGURE 6.12: EXPERIENCE OF COSMETIC BREAST PATIENTS BY SHELL TYPE AT ONE-YEAR POST-OPERATION



CHAPTER 7: CLINICAL QUALITY INDICATORS (CQIs)

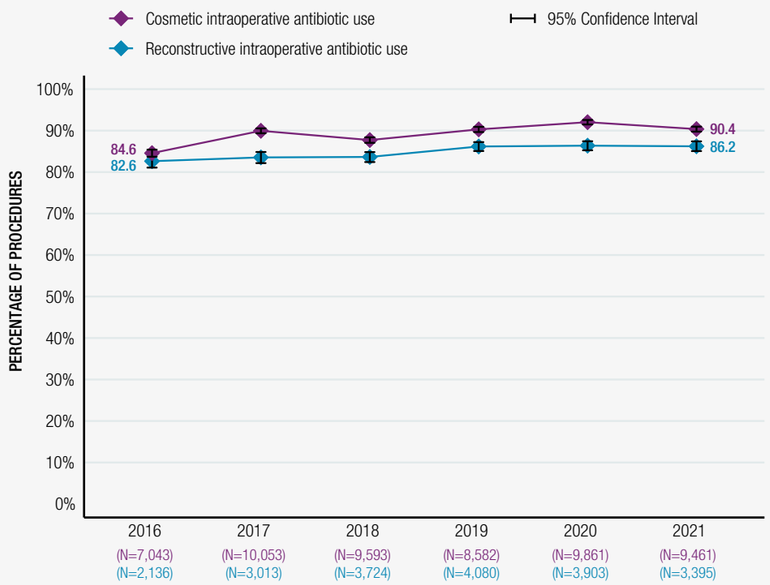
CQI 1: Intra-operative antibiotics use

As reported in the 2020 ABDR Annual Report, a scoping review was conducted to determine potential breast device quality indicators. Consensus on the final 3 quality indicators, namely pre-operative intravenous (IV) antibiotics, reoperation due to short-term complications, and patient reported outcome measures, was obtained using a modified Delphi approach[9]. The Delphi panel comprised participants from various countries and representation from surgical specialty groups including breast and general surgeons, plastic and reconstructive surgeons, cosmetic surgeons, a breast-care nurse, a consumer, a devices regulator, and a biostatistician. The 3 endorsed quality indicator measures enables breast device registries to standardize benchmarking of care for patients undergoing breast device surgery. These are reported below, as trends over the last 6 years.

Clinicians use the term 'pre-operative antibiotics' interchangeably with 'intra-operative antibiotics' use, i.e. the use of antibiotics provided IV, orally or intramuscular immediately before incision, during or within 3 hours after surgery. Therefore, the intra-operative antibiotic use has been reported in the CQI findings below.

Intra-operative antibiotic provided before skin incision to reduce complications post-surgery is presented in Figure 7.1. There has been an increasing use of intra-operative antibiotic use for both reconstructive and aesthetic groups from 2016 to 2021.

FIGURE 7.1: PROPORTION OF PROCEDURES WITH INTRA-OPERATIVE ANTIBIOTIC USE

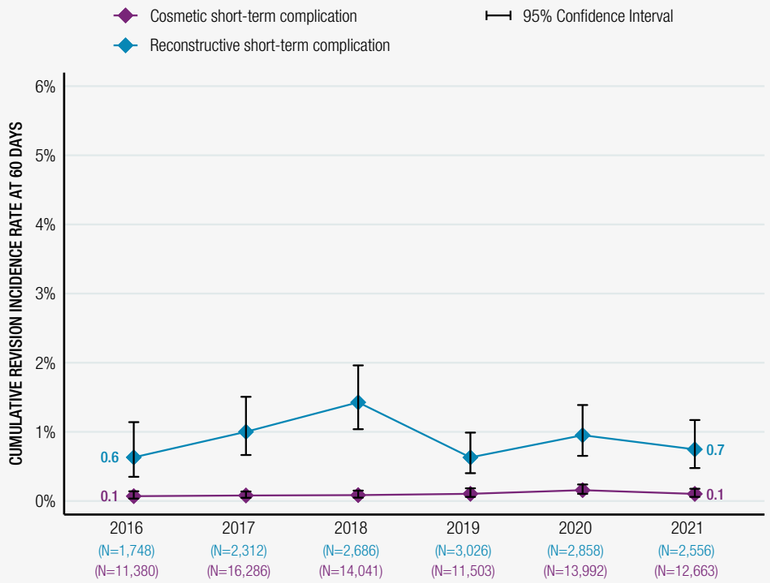


Note: Data was recorded at the patient-procedure level, and procedural hierarchy was applied

CQI 2: Revision due to short-term complication

The **reoperation rate at 60 days post-operation** due to short-term complications for the reconstructive and aesthetic cohorts are provided in Figure 7.2. The short-term complications include infection, capsular contracture, device malposition, device rupture/deflation, seroma/hematoma, and implant loss. Although implant loss is not directly captured in the Data Collection (registry) Form, it is defined as implant explantation (without replacement) for reasons other than patient preference. The revision incidence rate at 60 days post-operation due to short-term complications is very low with a slight fluctuating trend for reconstructive procedures, and has been consistently low over time for the cosmetic group at 0.1%.

FIGURE 7.2: CUMULATIVE REVISION INCIDENCE RATE AT 60 DAYS POST-OPERATION DUE TO SHORT TERM COMPLICATIONS

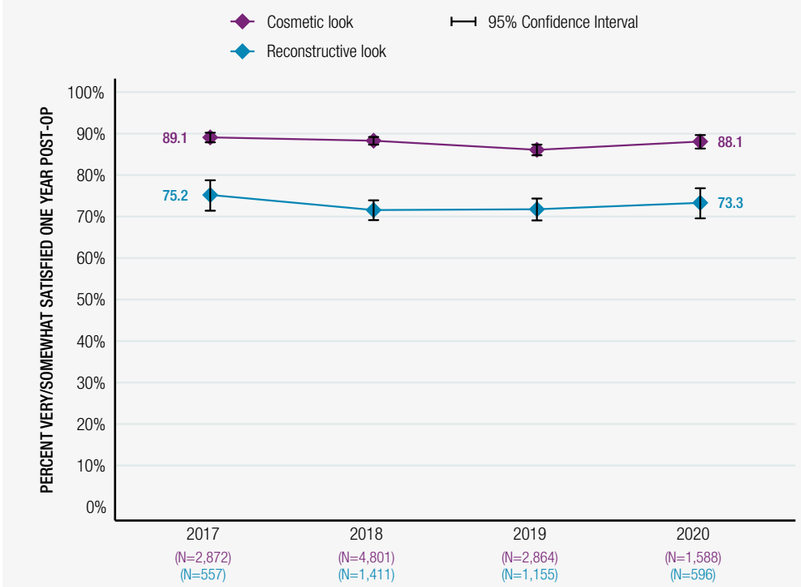


Note: Data was collected at the breast device level for primary breast implants.

CQI 3: Patient reported outcome measures (PROMs)

The CQI PROMs results for patient satisfaction with implant look, feel and rippling at one-year post-operation for reconstructive and cosmetic patients are provided. For Figures 7.3-7.7 the year reported refers to the year in which the procedure was performed, with the 12-month follow-up recorded from that date. Data was recorded at the individual patient level. Satisfaction with **implant look** is approximately 15% lower for patients who had reconstructive procedures compared with cosmetic procedures, however has not changed significantly over time. The year in each Figure represents the year the procedure was performed.

FIGURE 7.3: PROPORTION OF PATIENTS VERY OR SOMEWHAT SATISFIED WITH IMPLANT LOOK ONE-YEAR POST-OPERATION



Satisfaction with **implant feel** is approximately 10%-15% lower for reconstructive vs cosmetic procedures and has decreased by 6.5% over the last 4 years. There has also been a slight reduction (approximately 3%) in satisfaction with **implant rippling** for reconstructive procedures over the last 4 years.

FIGURE 7.4: PROPORTION OF PATIENTS VERY OR SOMEWHAT SATISFIED WITH IMPLANT FEEL ONE-YEAR POST-OPERATION

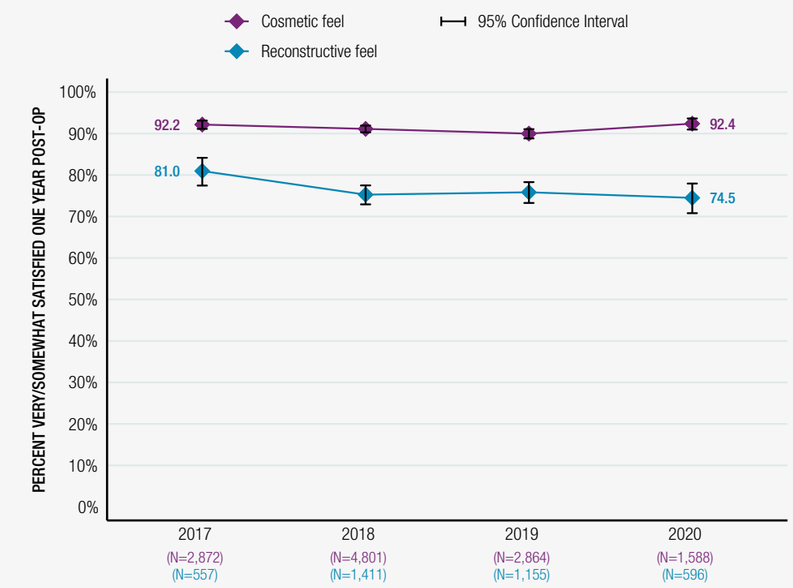
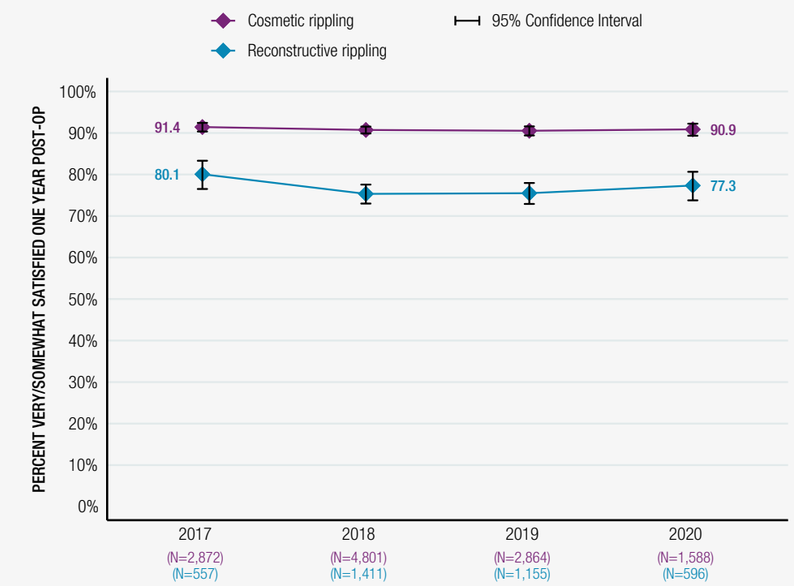
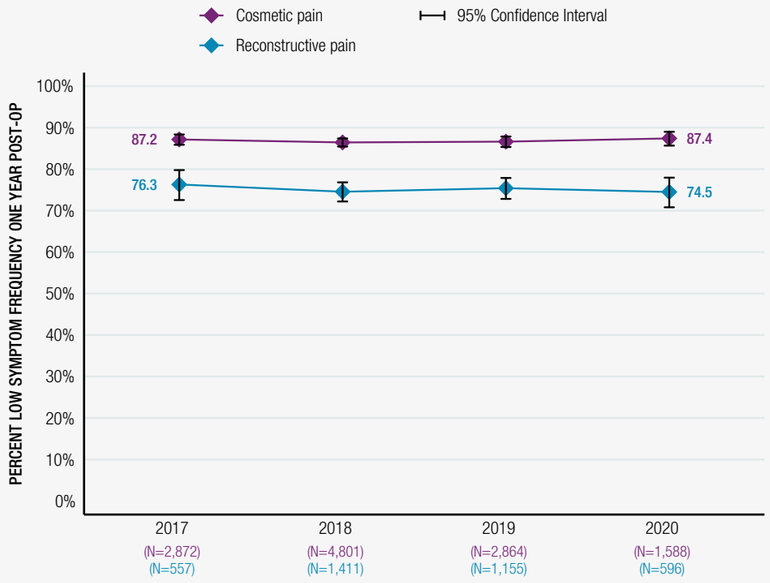


FIGURE 7.5: PROPORTION OF PATIENTS VERY OR SOMEWHAT SATISFIED WITH IMPLANT RIPPLING ONE-YEAR POST-OPERATION



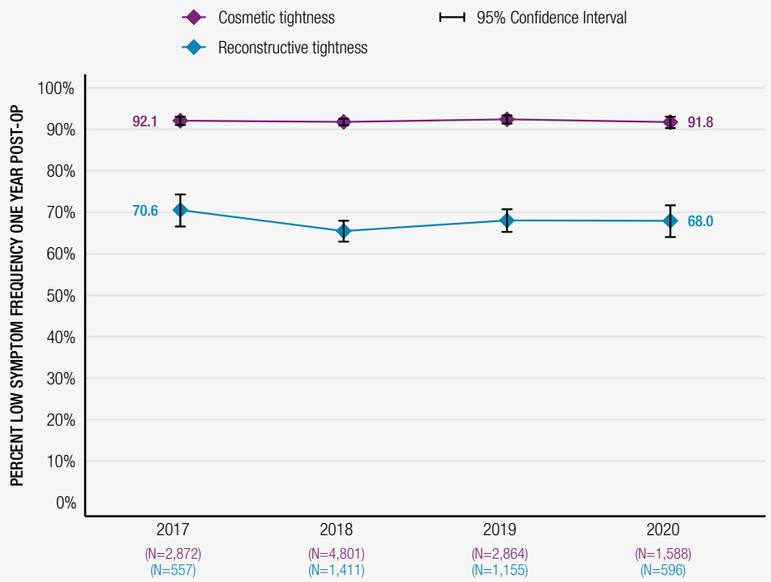
Figures 7.4 and 7.5 show the proportion of patients who reported low symptom frequency (i.e. none or little of the time) for **pain** one-year post-operation for reconstructive and cosmetic patients. Reconstructive procedures have a lower rate than cosmetic procedures, and the rates have remained steady over time.

FIGURE 7.6: PROPORTION OF PATIENTS WITH REPORTED LOW FREQUENCY (NON/A LITTLE OF THE TIME) PAIN ONE-YEAR POST-OPERATION



The proportion of patients reporting little or no **breast tightness** was lower by approximately 20% for reconstructive procedures compared with cosmetic procedures, and the values have remained relatively stable over time.

FIGURE 7.7: PROPORTION OF PATIENTS WITH REPORTED LOW FREQUENCY (NON/A LITTLE OF THE TIME) TIGHTNESS ONE-YEAR POST-OPERATION



CHAPTER 8: FUTURE INITIATIVES

The ABDR is entering an exciting phase. As the registry matures, our records will provide more robust data, with reduced amounts of missing information on legacy patients, allowing for more detailed data analysis.

The ABDR is undertaking a large project to replace the existing **database** with one where clinicians and sites can enter their patient and procedure data directly. This will provide significant benefits by enabling surgeons and sites to review their patient data at any time, allowing greater use of the data for a broader range of quality improvement and audit processes. Existing data will also be migrated into the new database so that surgeons and sites have ready availability of ABDR data to assist and communicate with their patients as needed.

The ABDR will also implement a refreshed **PROMs** program focusing on **reconstructive** patients, as this cohort experience a greater range of complications from breast device surgery. The ABDR will also review its current suite of devices collected and clinical quality indicators in light of **emerging practices** and trends in the registry. The ABDR is also working closely with the Therapeutic Goods Administration in its implementation of a **Unique Device Identifier** (UDI) for breast implants which will significantly improve the ABDR's ability to track long-term device outcomes.

CHAPTER 9: ACADEMIC OUTPUTS 2021

The ABDR produced 3 academic **publications** in 2021:

Vishwanath, Swarna, Pellegrini, Breanna, Parker, Emily, Earnest, Arul, Kalbasi, Saeid, Gartoulla, Pragya, Elder, Elisabeth, Farrell, Gillian, Moore, Colin, Cooter, Rodney D, Ahern, Susannah, McNeil, John J, & Hopper, Ingrid. (2021). Breast Device Surgery in Australia: Early Results from the Australian Breast Device Registry. Journal of Plastic, Reconstructive & Aesthetic Surgery, 74(10), 2719–2730. https://doi.org/10.1016/j.bjps.2021.03.035

Merenda, Michelle, Vishwanath, Swarna, Ng, Sze, Parker, Emily, Earnest, Arul, Klassen, Anne, Pusic, Andrea, & Hopper, Ingrid. (2021). Test-Retest Reliability of the BREAST-Q IS in the Australian Breast Device Registry. Aesthetic Surgery Journal, 41(4), NP177–NP184. https://doi.org/10.1093/asj/sjaa342

Hansen, Jessy, Ahern, Susannah, Gartoulla, Pragya, Khu, Ying, Elder, Elisabeth, Moore, Colin, Farrell, Gillian, Hopper, Ingrid, & Earnest, Arul. (2021). Identification of Predictive Factors for Patient-Reported Outcomes in the Prospective Australian Breast Device Registry. Aesthetic Surgery Journal, 42(5), 470–480. https://doi.org/10.1093/asj/sjab314

As part of our continued efforts to remain engaged with our contributors, participating site staff and patients, the ADBR previously conducted **presentations** at a variety of research, health education and advocate forums. However, due to the COVID-19 pandemic and subsequent restrictions all of our public presentations were cancelled in 2021. There were however several seminars conducted with surgeons and site theatre staff via Zoom presentations. The registry aims to re-establish more frequent presentation opportunities in the new year.

REFERENCES

1. Hopper I, Ahern S, Best RL, et al. Australian Breast Device Registry: breast device safety transformed. ANZ Journal of Surgery 2017;87(1-2):9-10. doi: 10.1111/ans.13819 [published Online First: 2017/02/06]

2. Australian Commission on Safety and Quality in Health Care, Framework for Australian Clinical Quality Registries. Sydney. ACSQHC, March 2014

3. Australian Commission on Safety and Quality in Health Care. Operating Principles and Technical Standards for Australian Clinical Quality Registries 2008

4. The Australian Senate CARC. The role of the Therapeutic Goods Administration regarding medical devices, particularly Poly Implant Prosthese (PIP) breast implants., 2012.

5. Ng S, Pusic A, Parker E, et al. Patient-Reported Outcome Measures for Breast Implant Surgery: A Pilot Study. Aesthetic Surgery Journal 2019;39(8):314-21. doi: 10.1093/asj/sjz023

6. Ng S, Kirkman M, Fisher J, et al. Establishing the acceptability of a brief patient reported outcome measure and feasibility of implementing it in a breast device registry - a qualitative study. Journal of patient-reported outcomes 2019;3(1):63. doi: 10.1186/s41687-019-0152-z

7. Ng S, Parker E, Pusic A, et al. Lessons Learned in Implementing Patient Reported Outcome Measures (PROMs) in the Australian Breast Device Registry (ABDR). Aesthet Surg J 2020 doi: 10.1093/asj/sjaa376

8. Hamdi, Moustapha. (2019). Association Between Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) Risk and Polyurethane Breast Implants: Clinical Evidence and European Perspective. Aesthetic Surgery Journal, 39(Supplement_1), S49–S54. https://doi.org/10.1093/asj/sjy328

9. Begum H, Vishwanath S, Merenda M, et al. Defining Quality Indicators for Breast Device Surgery: Using Registries for Global Benchmarking. Plastic and reconstructive surgery Global open 2019;7(8):e2348. doi: 10.1097/ gox.0000000000002348 [published Online First: 2019/10/09]

GLOSSARY

ABDR	Australian Breast Device Registry
ACCSM	Australasian College of Cosmetic Surgery and Medicine
ACSQHC	Australian Commission on Safety and Quality in Health Care
ASPS	Australian Society of Plastic Surgeons
BIA-ALCL	Breast Implant Associated-Anaplastic Large Cell Lymphoma
BREAST-Q IS	BREAST-Q Implant Surveillance module
BreastSurgANZ	Breast Surgeons of Australia and New Zealand
Contributing site	Any site that is currently contributing data to the ABDR
DOH	Department of Health
Direct-to-implant	A breast reconstruction procedure whereby an implant is inserted at the time of the mastectomy
Eligible site	A site undertaking breast device surgery as identified by ICD-10-AM code data
HREC	Human Research Ethics Committee
ICD-10-AM	Australian Modification of the International statistical Classification of Diseases and health related problems, 10th revision
IQR	Interquartile range: Quartiles divide a rank-ordered dataset into four equal parts. The values that divide each part are called the first, second and third quartiles. First, second and third quartiles correspond to the observation at the 25th, 50th and 75th percentiles, respectively. The observation from the 25th percentile to the 75th percentile is referred as the interquartile range. An observation at the 50th percentile corresponds to the median value in the dataset.
Insertion surgery	Includes procedures that involve insertion of a new device, either a tissue expander or breast implant in a patient who has or has not had previous breast device surgery. Also included are tissue expander-to-implant exchanges and implant-to-tissue expander exchange
MTAA	Medical Technology Association of Australia
Primary implant breast	A breast for which the initial insertion of a breast implant has been captured by the ABDR
Primary tissue expander breast	A breast for which the initial insertion of a tissue expander has been captured by the ABDR
Revision surgery	A procedure involving unplanned replacement or reposition procedures. The initial device insertion may or may not have also been captured by the registry. Also included procedures involving the removal of an implant and insertion of a tissue expander
Two-stage implant	A breast reconstruction procedure whereby the initial device insertion is a tissue expander, which is exchanged to a breast implant in a subsequent procedure

LIST OF FIGURES

LIST OF TABLES

APPENDIX 1 - DATA COMPLETENESS

	2019	2020	2021
Patient Characteristics (Patient Level)	**13,213**	**14,550**	**13,850**
Name	100.0%	100.0%	100.0%
Surname	100.0%	100.0%	100.0%
Medicare number	88.7%	89.9%	91.8%
Date of birth	100.0%	100.0%	100.0%
Address	97.5%	97.7%	97.8%
Telephone	88.0%	86.2%	88.8%
Surgery Characteristics (Procedure Level)	**13,943**	**15,227**	**14,384**
Operation date	100.0%	100.0%	100.0%
Hospital	100.0%	100.0%	100.0%
Surgeon	100.0%	100.0%	100.0%
Intraoperative techniques	88.1%	88.2%	86.6%
Surgery Characteristics (Breast Level)	**25,789**	**28,522**	**26,961**
Side of breast	100.0%	100.0%	100.0%
Indication for surgery	90.7%	90.4%	89.4%
Surgery type	100.0%	100.0%	100.0%
Prev radio if recon	90.6%	90.2%	88.6%
Incision site	88.6%	88.2%	86.3%
Plane	84.7%	85.0%	84.5%
Concurrent mastectomy	92.7%	91.6%	90.7%
Axillary surgery	92.7%	91.6%	90.6%
Concurrent mastopexy/reduction	92.7%	91.6%	90.7%
Concurrent flap cover	92.6%	91.5%	90.7%
Previous mastopexy/reduction	92.6%	91.5%	90.7%
Fat grafting	92.4%	91.5%	90.1%
Fat graft vol if FG	91.8%	91.7%	91.9%
Intraop fill volume if TE	67.9%	64.7%	64.3%
Revision Characteristics (Breast Level)	**9,270**	**9,529**	**10,006**
Revision surgery type	99.9%	100.0%	99.9%
Indication for revision surgery	95.6%	94.3%	95.6%
Capsulectomy	88.3%	87.7%	88.5%
Neo pocket formation	74.3%	73.1%	74.0%
Neo pocket formation details	85.2%	83.9%	85.5%
Revision overseas implant	84.6%	82.5%	83.0%
Breast cancer	95.6%	94.3%	96.0%
Device rupture	94.9%	94.2%	95.7%
Device deflation	95.5%	94.3%	95.8%
Capsular contracture	95.5%	94.3%	95.8%
Device malposition	95.6%	94.3%	96.0%
Skin scarring problems	95.6%	94.3%	95.9%
Deep wound infection	95.6%	94.3%	96.0%
Seroma/haematoma	95.7%	94.3%	96.0%
ALCL	95.7%	94.3%	96.0%
Device Characteristics (Breast Level, inserted)	**22,749**	**25,347**	**23,433**
Implant/TE device ID	99.8%	99.8%	99.8%
Matrix used	99.4%	97.0%	99.6%
Matrix device ID if ADM	99.4%	99.3%	98.5%
Device Characteristics (Breast Level, explanted)	**9,142**	**9,417**	**9,898**
Explanted device details	84.2%	84.5%	86.9%
Explanted device ID	11.2%	12.1%	11.4%
Patient opt-out rate	**1.1%**	**0.5%**	**0.8%**

APPENDIX 2 - DATA COLLECTION FORM

AUSTRALIAN BREAST DEVICE REGISTRY FORM

AUSTRALIAN Breast Device REGISTRY

MONASH University Medicine, Nursing and Health Sciences

Australian Society of Plastic Surgeons

Breast Surgeons of Australia & New Zealand

AFFIX **PATIENT** STICKER or complete details below:

Patient UR # :

Medicare # :

Surname :

First name: Middle Name:

Birth Date: / / (dd/mm/yyyy)

Address :

State: P/code:

Telephone : - Home: Business:

Mobile :

Email :

OPERATION DATE: (dd/mm/yy) / /

SITE DETAILS:

Site Name:

Suburb: State:

Surgeon name:

Is this patient a medical tourist to Australia? Yes No

RETURN FORM:

Australian Breast Device Registry,
Monash University, DEPM,
553 St Kilda Road, Melbourne 3004
email: abdr@monash.edu **fax:** (03) 9903 0277
contact phone: (03) 9903 0205

AFFIX **RIGHT DEVICE** STICKER

[COMPLETE IF NO DEVICE STICKER]

Manufacturer:
Distributor:
Reference no:
Serial no:

AFFIX **LEFT DEVICE** STICKER

[COMPLETE IF NO DEVICE STICKER]

Manufacturer:
Distributor:
Reference no:
Serial no:

AFFIX **MESH/DERMAL SHEET** STICKER

[COMPLETE IF NO DEVICE STICKER]

MESH/DERMAL SHEET: Yes No

Manufacturer:
Reference no:
Serial no:

AFFIX **MESH/DERMAL SHEET** STICKER

[COMPLETE IF NO DEVICE STICKER]

MESH/DERMAL SHEET: Yes No

Manufacturer:
Reference no:
Serial no:

PATIENT HISTORY:

RIGHT BREAST

Tick if Same Bilateral

BREAST **LEFT**

Category of operation

- Cosmetic augmentation
- Reconstruction - post cancer
- Reconstruction - benign / prophylactic
- Congenital deformity

Operation type

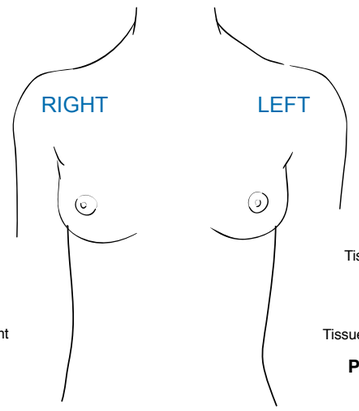
Initial (new device)

- Tissue Expander insertion
- First Implant insertion
- Tissue Expander removal & Implant insertion

Revision of in situ device

- Implant revision, removal or replacement
- Tissue Expander revision, removal, replacement

Previous Radiotherapy Yes No



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ELEMENTS OF OPERATION

RIGHT BREAST

Tick if Same Bilateral

BREAST **LEFT**

Incision site	**Plane**	**Plane**	**Incision site**
Axillary	Sub-glandular / Sub-fascial	Subglandular / Sub-fascial	Axillary
Areolar	Sub-pectoral	Sub-pectoral	Areolar
Infra-mammary	Sub-flap	Sub-flap	Infra-mammary
Previous mastectomy scar			Previous mastectomy scar
Mastopexy/reduction wound			Mastopexy/reduction wound
.....			.....

Concurrent Mastectomy	Yes No	Yes No	**Concurrent Mastectomy**
Axillary surgery incl. sentinel node biopsy	Yes No	Yes No	**Axillary surgery incl. sentinel node biopsy**
Concurrent Mastopexy / Reduction	Yes No	Yes No	**Concurrent Mastopexy / Reduction**
Concurrent Flap cover	Yes No	Yes No	**Concurrent Flap cover**
Previous Mastopexy/Reduction	Yes No	Yes No	**Previous Mastopexy/Reduction**

Fat grafting Yes Volume.....mLs No — **Fat grafting** Yes Volume.....mLs No

IF TISSUE EXPANDER, Intra Operative fill volume: .....mLs — **IF TISSUE EXPANDER,** Intra Operative fill volume: .....mLs

INTRAOPERATIVE TECHNIQUES

Intra-op prophylactic antibiotic · Antibiotic dipping solution · Post-op antibiotic · Glove change for insertion · Sleeve/funnel · Antiseptic rinse .....

RIGHT BREAST

Tick if Same Bilateral

BREAST **LEFT**

Nipple absent	Occlusive nipple shield	Occlusive nipple shield	Nipple absent
Nipple sparing	Drain used	Drain used	Nipple sparing

FOR REVISION SURGERY ONLY

RIGHT BREAST

Tick if Same Bilateral

BREAST **LEFT**

Revision Type:
Replacement Reposition existing implant Explant only

Capsulectomy ..... Full Partial None

Neo pocket formation ... Yes No Subglandular Submuscular

Explanted device: Ref.No. / Manufacturer: .....
Shell: ..... Fill: ..... Vol: ..... Date of Insert: ...../...../.....
Round Anatomical Indeterminate

Reason for Revision
Complication Asymptomatic Patient Preference

Is the operation removing an implant inserted overseas Yes No

Details : .....

Tick if Same Bilateral

Device rupture?
Yes, reason for revision Yes, found incidentally No

If yes, please indicate whether silicone extravasation was found:
Intracapsular Extracapsular Distant

Yes, reason for revision	Yes, found incidentally	No	Issue identified at revision	No	Yes, found incidentally	Yes, reason for revision
☐	☐	☐	Device deflation	☐	☐	☐
☐	☐	☐	Capsular contracture	☐	☐	☐
☐	☐	☐	Device malposition	☐	☐	☐
☐	☐	☐	Skin scarring problems	☐	☐	☐
☐	☐	☐	Deep wound infection	☐	☐	☐
☐	☐	☐	Seroma/Haematoma	☐	☐	☐
☐	☐	☐	Breast cancer	☐	☐	☐
☐	☐	☐	Anaplastic Large Cell Lymphoma	☐	☐	☐

APPENDIX 3 – ABDR STAFF

Professor Susannah Ahern, ABDR Steering Committee Chair/ABDR Academic Lead
Dr Dilinie Herbert, Research Fellow
Mr Saeid Kalbasi, Database and Data Linkage Projects Manager
Ms Judith Hankin, Relationship Manager
Ms Sally McInnes, Registry Operations Manager
Ms Ying Khu, PROMs Research Officer
Ms Trisha Nichols, Communications Officer
Ms Uma Symons, Research Officer
Mr Leonardo Morandini, Data Entry
Ms Chethana Mundanna, Data Entry
Ms Randi Jayasinghe, Data Entry
Ms Hazel Loo, PROMs telephone follow-up
Ms Renee Conroy, PROMs telephone follow-up
Ms Jessy Hansen, Data Analyst, DEPM, Monash University
Dr Craig Pickett, Data Analyst, DEPM, Monash University
A/Prof Arul Earnest, Senior Biostatistician, DEPM, Monash University
Mr Sean Smith, Research Officer
Dr Pragya Gartoulla, Research Manager
Ms Sharon Lee, Project Officer

APPENDIX 4 – LIST OF PARTICIPATING SITES AS AT END 2021

State	Site Name
ACT	Barton Private Hospital
ACT	Calvary Bruce Private Hospital
ACT	Calvary John James Hospital
ACT	Calvary Public Hospital ACT
ACT	Canberra Private Hospital
ACT	National Capital Private Hospital
ACT	Sole Vita Surgery
NSW	Aesthetic Day Surgery
NSW	Albury Wodonga Private Hospital
NSW	Alexandria Specialist Day Hospital
NSW	Auburn Hospital & Community Health Services
NSW	Australia Plastic Surgery Sydney (Closed)
NSW	Bankstown-Lidcombe Hospital
NSW	Baringa Private Hospital
NSW	Bathurst Base Hospital
NSW	Bathurst Private Hospital
NSW	Belmont Hospital
NSW	Blacktown Hospital
NSW	Bondi Junction Private Hospital
NSW	Brisbane Waters Private Hospital
NSW	Brookvale Procedure Rooms (Closed)
NSW	Calvary Mater Newcastle
NSW	Calvary Riverina Hospital
NSW	Campbelltown Private Hospital
NSW	Casino and District Memorial Hospital
NSW	Castle Hill Day Surgery (Closed)
NSW	Castlecrag Private Hospital
NSW	Charlestown Private Hospital
NSW	Chris O'Brien Lifehouse
NSW	Coffs Day Hospital
NSW	Coffs Harbour Base Hospital
NSW	Concord Repatriation Hospital
NSW	Crows Nest Day Hospital
NSW	Dalcross Adventist Hospital (Closed)
NSW	Double Bay Day Hospital
NSW	East Sydney Private Hospital
NSW	Gosford Hospital
NSW	Gosford Private Hospital
NSW	Holroyd Private Hospital
NSW	Honeysuckle Day Hospital
NSW	Hornsby Ku-Ring-Gai Hospital
NSW	Hunter Valley Private Hospital
NSW	Hunters Hill Private Hospital
NSW	Hurstville Private Hospital
NSW	Kareena Private Hospital
NSW	Kingsway Day Surgery
NSW	Lake Macquarie Private Hospital
NSW	Lakeview Private Hospital
NSW	Lingard Private Hospital
NSW	Lismore Base Hospital
NSW	Liverpool Hospital
NSW	Macquarie St Day Surgery
NSW	Macquarie University Hospital
NSW	Maitland Private Hospital
NSW	Manly District Hospital (Closed)
NSW	Mater Hospital Sydney
NSW	Mount Druitt Hospital
NSW	Nepean Hospital
NSW	Nepean Private Hospital
NSW	North Shore Private Hospital
NSW	North Shore Specialist Day Hospital
NSW	Northern Beaches Hospital
NSW	Norwest Day Hospital
NSW	Norwest Private Hospital
NSW	Peninsula Private (Dee Why NSW) (Closed)
NSW	Pittwater Day Surgery
NSW	Port Macquarie Private Hospital
NSW	Prince of Wales Hospital
NSW	Prince of Wales Private Hospital
NSW	Riverina Day Surgery
NSW	Royal Hospital for Women
NSW	Royal North Shore Hospital
NSW	Shellharbour Private Hospital
NSW	Southern Highlands Private Hospital
NSW	St George Hospital
NSW	St George Private Hospital
NSW	St Luke's Hospital
NSW	St Vincent's Private Community Hospital Griffith
NSW	St Vincent's Hospital (Darlinghurst)
NSW	St Vincent's Private Hospital (Darlinghurst)
NSW	St Vincent's Private Hospital (Lismore)
NSW	Strathfield Private Hospital
NSW	Surry Hills Day Hospital
NSW	Sydney Adventist Hospital
NSW	Sydney Children's Hospital
NSW	Sydney Day Hospital
NSW	Sydney Southwest Private Hospital
NSW	Sydney Surgical Centre
NSW	Tamara Private Hospital
NSW	The Double Bay Day Surgery
NSW	The San Day Surgery
NSW	The Skin Hospital (Darlinghurst)
NSW	The Sydney Private Hospital
NSW	The Tweed Hospital
NSW	Tweed Day Surgery
NSW	Wagga Wagga Rural Referral Hospital

State	Site Name
NSW	Waratah Private Hospital
NSW	Warners Bay Private Hospital
NSW	Westmead Hospital
NSW	Westmead Private Hospital
NSW	Wollongong Day Surgery
NSW	Wollongong Hospital
NSW	Wollongong Private Hospital
NT	Darwin Day Surgery
NT	Darwin Private Hospital
NT	Royal Darwin Hospital
QLD	Brisbane Cosmetic Clinic (Closed)
QLD	Brisbane Day Hospital
QLD	Brisbane Private Hospital
QLD	Buderim Private Hospital
QLD	Caboolture Private Hospital
QLD	Cairns Base Hospital
QLD	Cairns Day Surgery
QLD	Cairns Private Hospital
QLD	Canossa Private Hospital
QLD	Chermside Day Hospital
QLD	Far North Day Hospital
QLD	Friendly Society Private Hospital
QLD	Gold Coast Private Hospital
QLD	Gold Coast Surgical Hospital (Closed)
QLD	Gold Coast University Hospital
QLD	Greenslopes Private Hospital
QLD	Gympie Private Hospital (Closed)
QLD	Hillcrest - Rockhampton Private Hospital
QLD	Ipswich Day Hospital
QLD	Ipswich Hospital
QLD	John Flynn Private Hospital
QLD	Kawana Private Hospital
QLD	Mater Adult's Hospital
QLD	Mater Private Hospital (South Brisbane)
QLD	Mater Private Hospital Mackay
QLD	Mater Private Hospital Redland
QLD	Mater Private Hospital Springfield
QLD	Mater Private Hospital Townsville
QLD	Mater Private Hospital Townsville (Hyde Park Campus)
QLD	Mater Private Rockhampton
QLD	Mercy Health Gladstone - Mater Misericordiae Hospital Gladstone (Closed)
QLD	Miami Private Hospital
QLD	Noosa Hospital
QLD	North Lakes Day Hospital
QLD	North West Private Hospital
QLD	Pacific Day Surgery Centre
QLD	Pacific Private Day Hospital
QLD	Pindara Day Procedure Centre
QLD	Pindara Private Hospital
QLD	Precision Cosmetic Surgery (Closed)
QLD	Princess Alexandra Hospital
QLD	Queen Elizabeth II Jubilee Hospital

State	Site Name
QLD	Queensland Children's Hospital
QLD	Redland Hospital
QLD	Renaissant Aesthetic Health
QLD	Robina Hospital
QLD	Rockhampton Base Hospital
QLD	Royal Brisbane & Women's Hospital
QLD	Samford Road Day Hospital
QLD	South Bank Day Hospital
QLD	Southport Day Hospital
QLD	Spring Hill Specialist Day Hospital
QLD	St Andrew's Ipswich Private Hospital
QLD	St Andrew's Toowoomba Hospital
QLD	St Andrew's War Memorial Hospital
QLD	St Stephen's Hospital Hervey Bay
QLD	St Vincent's Private Hospital Brisbane
QLD	St Vincent's Private Hospital Northside
QLD	St Vincent's Private Hospital Toowoomba
QLD	Sunnybank Private Hospital
QLD	Sunshine Coast Day Surgery
QLD	Sunshine Coast University Private Hospital
QLD	The Cosmetic Surgery and Skin Cancer Centre (Closed)
QLD	The Wesley Hospital
QLD	Toowoomba Surgicentre
QLD	Townsville University Hospital
QLD	Varsity Lakes Day Hospital
QLD	Westside Private Hospital
SA	Adelaide Day Surgery
SA	Ashford Community Hospital
SA	Brighton Day Surgery
SA	Calvary Adelaide Hospital
SA	Calvary North Adelaide Hospital
SA	Calvary Wakefield Hospital (Closed)
SA	Calvary Wakefield Surgicentre
SA	Flinders Medical Centre
SA	Flinders Private Hospital
SA	Glenelg Community Hospital
SA	Hamilton House Day Surgery
SA	Lyell McEwin Hospital
SA	Memorial Hospital
SA	Modbury Hospital
SA	Noarlunga Health Service
SA	North Adelaide Day Surgery Centre
SA	North Eastern Community Hospital
SA	Norwood Day Surgery
SA	Parkside Cosmetic Surgery (Closed)
SA	Parkwynd Private Hospital (Closed)
SA	St Andrew's Hospital INC
SA	Stirling Hospital INC
SA	The Burnside War Memorial Hospital
SA	The Queen Elizabeth Hospital
SA	The Royal Adelaide Hospital
SA	Waverley House Plastic Surgery Centre
SA	Western Hospital (SA)

State	Site Name
SA	Womens and Childrens Hospital
TAS	Calvary - St John's Hospital
TAS	Calvary - St Vincent's Hospital
TAS	Hobart Private Hospital
TAS	Launceston General Hospital
TAS	North Tas Day Hospital
TAS	Royal Hobart Hospital
VIC	Austin Health - Austin Hospital
VIC	Austin Health - Heidelberg Repatriation Hospital
VIC	Ballarat Health Services (Base Hospital)
VIC	Barwon Health - Geelong Hospital Campus
VIC	Beleura Private Hospital
VIC	Bellbird Private Hospital
VIC	Bendigo Day Surgery
VIC	Bendigo Health - The Bendigo Hospital
VIC	Box Hill Hospital
VIC	Cabrini Brighton
VIC	Cabrini Malvern
VIC	Casey Hospital
VIC	Chelsea Heights Day Surgery and Endoscopy
VIC	Corymbia Day Hospital
VIC	Cotham Private Hospital
VIC	Dandenong Hospital
VIC	Dr Lanzer & Associates Cosmetic Day Hospital
VIC	Eastlink Surgical & Specialist Centre (Closed)
VIC	Epworth Cliveden
VIC	Epworth Eastern
VIC	Epworth Freemasons
VIC	Epworth Geelong
VIC	Epworth Hawthorn
VIC	Epworth Richmond
VIC	Frances Perry House
VIC	Frankston Hospital
VIC	Glenferrie Private Hospital
VIC	Holmesglen Private Hospital
VIC	John Fawkner Private Hospital
VIC	Knox Private Hospital
VIC	Linacre Private Hospital
VIC	Linley Clinic (Closed)
VIC	Maroondah Hospital
VIC	Maryvale Private Hospital
VIC	Masada Private Hospital
VIC	Mitcham Private Hospital
VIC	Monash House Private Hospital
VIC	Monash Medical Centre - Moorabbin Campus
VIC	Mulgrave Private Hospital
VIC	Northpark Private Hospital
VIC	Peninsula Private Hospital (VIC)
VIC	Peter MacCallum Cancer Centre
VIC	Ringwood Private Hospital
VIC	Royal Melbourne Hospital - City Campus
VIC	Sir John Monash Private Hospital
VIC	South West Healthcare-Warrnambool Campus

State	Site Name
VIC	St John of God Ballarat Hospital
VIC	St John of God Bendigo Hospital
VIC	St John of God Berwick Hospital
VIC	St John of God Geelong Hospital
VIC	St John Of God Warrnambool Hospital
VIC	St Kilda Day Hospital
VIC	St Vincent's Private Hospital East Melbourne
VIC	St Vincent's Private Hospital Fitzroy
VIC	St Vincent's Private Hospital Kew
VIC	St Vincent's Private Hospital Werribee
VIC	Stonnington Day Surgery
VIC	Sunshine Hospital
VIC	Tarietta Day Surgery (Closed)
VIC	The Alfred
VIC	The Avenue Private Hospital
VIC	The Bays Hospital
VIC	The Melbourne Eastern Private Hospital
VIC	The Northern Hospital
VIC	The Royal Childrens Hospital
VIC	The Royal Women's Hospital
VIC	VCI Day Surgery
VIC	Vermont Private Hospital
VIC	Warringal Private Hospital
VIC	Waverley Private Hospital
VIC	Western Hospital (VIC)
VIC	Western Private Hospital
VIC	Williamstown Hospital
VIC	Windsor Private Hospital
WA	Bethesda Hospital
WA	Bunbury Day Hospital
WA	Cambridge Day Surgery
WA	Colin Street Day Surgery (Closed)
WA	Concept Day Hospital
WA	Glengarry Private Hospital
WA	Hollywood Private Hospital
WA	Joondalup Health Campus
WA	McCourt Street Day Surgery
WA	Mount Hospital
WA	Peel Health Campus - Private
WA	Southbank Day Surgery
WA	St John of God Bunbury Hospital
WA	St John of God Geraldton Hospital
WA	St John of God Hospital, Subiaco
WA	St John of God Midland Public & Private Hospital
WA	St John of God Mt Lawley Hospital
WA	St John of God Murdoch Hospital
WA	St John of God Wembley Day Surgery
WA	Subiaco Private Hospital
WA	Sundew Day Surgery
WA	Waikiki Private Hospital
WA	West Leederville Private Hospital

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