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Comparing 200,000 Breast Implants and 85,000 Patients over Four National Breast Implant Registries

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PATIENT
SAFETY

Background: Growing awareness about breast implant-related adverse events has stimulated the demand for large, independent data resources. For this, data from breast implant registries could be combined. However, that has never been achieved yet.

Methods: Real-world data from four currently active national breast implant registries were used. All permanent breast implants from the Australian, Dutch, Swedish, and American registries were included. A subpopulation present across all registries between 2015 and 2018 was subsequently selected, including only permanent breast implants inserted during primary surgery for breast reconstruction or augmentation in patients without previous breast device surgery. Nationwide coverage, patient and implant characteristics, infection control measures, and revision incidences were analyzed.

Results: A total of 207,189 breast implants were registered. Nationwide coverage varied between 3% and 98%. The subpopulation included 111,590 implants (7% reconstruction, 93% augmentation). Across the registries, mean patient age varied between 41 and 49 years ($P < 0.001$) for reconstruction and 31 and 36 years ($P < 0.001$) for augmentation. Variation was observed in implant preferences across the countries and over the years. Infection control measures were most frequently registered in Australia. Cumulative revision incidence at 2 years ranged from 6% to 16% after reconstruction and from 1% to 4% after augmentation.

Conclusions: For the first time, independent, national, registry-based data from four breast implant registries were combined. This is a powerful step forward in optimizing international breast implant monitoring, evidence-based decision-making, and patient safety. (*Plast. Reconstr. Surg.* 152: 307, 2023.)

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Over the past three decades, a lack of reliable implant data has had a negative impact on patients with breast implants

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during controversies about breast implant safety, silicone safety, and postmarket implant surveillance. This paucity of good data has led to a new generation of well-designed, independent national breast implant registries to generate better evidence-based information that will ultimately improve patient safety.¹⁻⁷ These registries have united in the International Collaboration of Breast Registry Activities (ICOBRA), which was founded by the Australasian Foundation for Plastic Surgery in 2012 to harmonize registry efforts internationally.^{8,9}

The goals of ICOBRA are to enhance collaboration between breast implant registries worldwide, improve breast device monitoring, and optimize patient safety. To this end, ICOBRA developed a harmonized data set containing standardized and well-defined core data points incorporated by the involved breast implant registries.¹⁰ The use of a harmonized data set by different registries facilitates collaborative international projects, specifically for uncommon events such as breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL), for which answers on cause are yet to be found.

Although data have been collected in the separate registries and annual reports have been published, until now, data have not been combined for analysis.¹¹⁻¹⁵ Therefore, this study aimed to evaluate the potential of sharing data from active breast implant registries using the ICOBRA harmonized data set. Included topics per registry were as follows: nationwide coverage, number of registered implants, patient characteristics, implant characteristics, use of infection control measures (ICMs), and cumulative revision incidence.

PATIENTS AND METHODS

Breast Implant Registries

This observational study compiled data from the Australian Breast Device Registry (ABDR), the Breast Implant Register (BRIMP) from Sweden, the Dutch Breast Implant Registry (DBIR), and the National Breast Implant Registry (NBIR) from the United States. The BRIMP started collecting data in 2014, the ABDR and the DBIR in 2015, and the NBIR in October of 2018. All four registries include permanent breast implants for breast reconstruction and breast augmentation. The ABDR and the DBIR include (temporary) tissue expanders as well. The registries use opt-out consent for patients and are united in the ICOBRA.⁸ More details about the registries may be found in previous work.^{2,3,6,11,13,15-18}

Study Population

For this observational cohort study, only permanent breast implants were included; temporary tissue expanders were excluded, as the BRIMP and the NBIR do not register these devices. Subsequently, two selection steps were made (Fig. 1). First, all permanent breast implants that had been prospectively registered as insertion or revision surgery between the start of each registry and December 31, 2018, were included. Second, a subpopulation present across all four registries was selected to ensure uniformity of the gathered information. These included only permanent breast implants inserted during primary surgery for breast reconstruction or breast augmentation in patients without a previous breast implant or tissue expander between 2015 and 2018.

Outcomes

The included outcomes were based on the existing overlap in the annual reports of the registries. From the essential topics registry validation, patient characteristics, implant characteristics, surgery techniques, and postoperative outcomes, the following six outcomes were included: (1) nationwide coverage of each registry; (2) total number of registered permanent breast implants; (3) patient age and body mass index (BMI); (4) implant shape, shell, and fill; (5) use of ICMs; and (6) cumulative revision incidence.

Definitions

Nationwide coverage of each registry was defined as the number of participating institutions in relation to the eligible number of institutions performing breast implant surgery in each country in 2018. In Sweden, the eligible number of institutions could not be obtained. Implant insertion was defined as the insertion of a new breast implant in a breast without an implant or as replacement of an in situ device. Primary implant surgery was defined as the first operation recorded in the registry in which a new breast implant was inserted in a patient without any previous breast implant or tissue expander insertion. Revision surgery was defined as the first reoperation after insertion in which an implant was repositioned, explanted, or replaced with a new implant or autologous tissue, regardless of the revision indication. Breast reconstruction included a reconstruction after mastectomy because of breast cancer or genetic predisposition and after a congenital deformity such as tuberous breasts or benign conditions such as gender-affirming surgery. Breast augmentation was defined as a unilateral

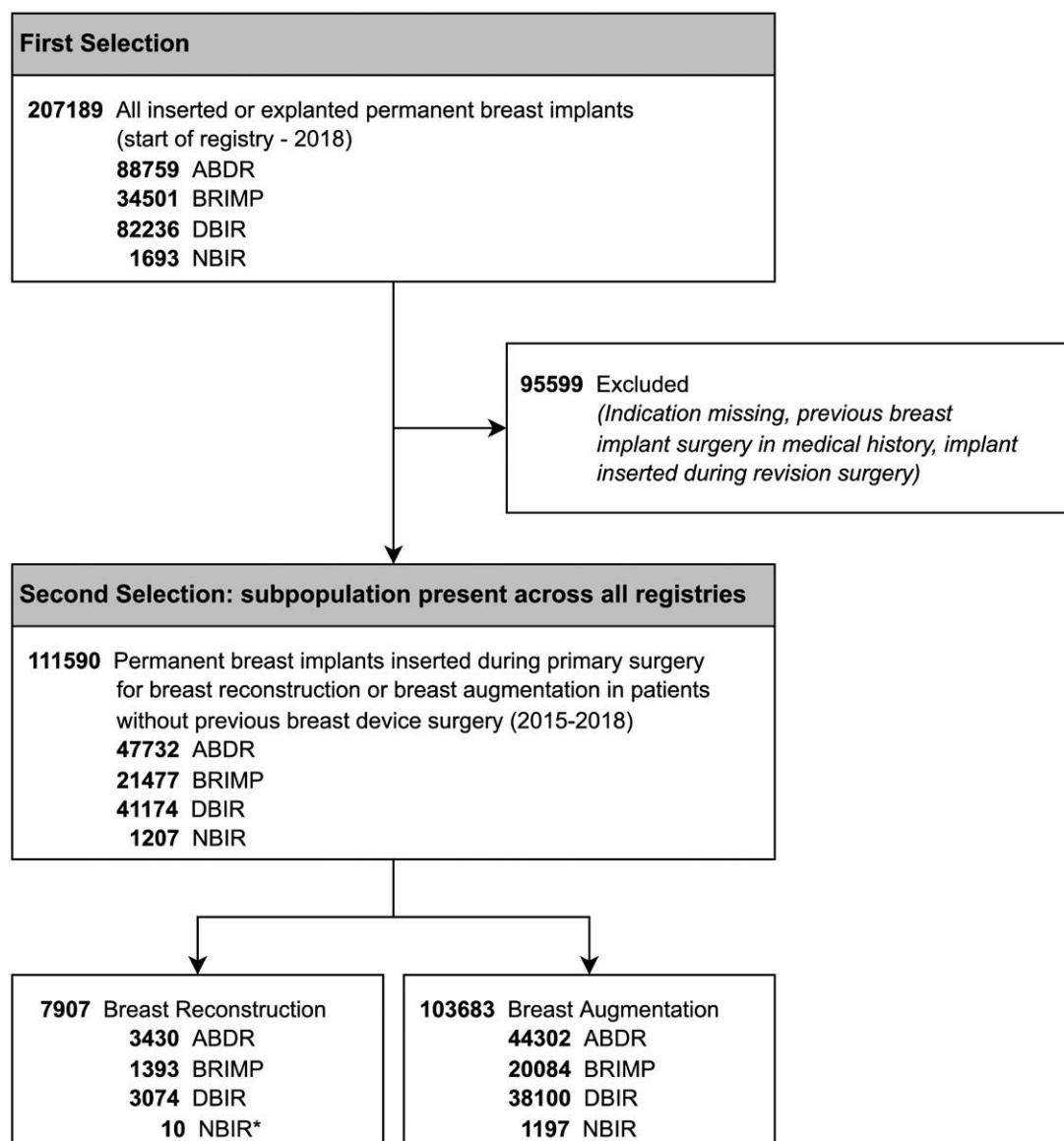


Fig. 1. Flow chart of implant selection. *Because of the low number of reconstructive records, reconstructive data from the NBIR were not further included in the study.

or bilateral procedure for enlarging the breast(s). Exact definitions of all variables used for analysis are based on the ICOBRA harmonized data set.¹⁰ (See Table, Supplemental Digital Content 1, which shows definitions of the variables used for this study, derived from the ICOBRA harmonized data set, <http://links.lww.com/PRS/F942>.)

Combining Data

The scripts for the analyses were developed collaboratively by the registries' data analysts. Subsequently, analyses were performed at the registry level, after which the results were anonymously combined in aggregated analyses. Using this technique, data from each registry were

protected for transfer across international borders according to the General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act.

Statistical Analysis

Analyses were performed with breast implants as the unit of analysis. Missing data were left untouched to reflect the actual data that were present in the registries.

The total number of registered permanent breast implants in each registry was calculated by counting all inserted and explanted breast implant records. Mean patient age was compared between the registries using a one-way analysis of

variance test (normal distribution) and a Kruskal-Wallis test (nonnormal distribution). Differences in patient median BMI were compared between the registries using a Kruskal-Wallis H test, with BMI as the ordinal dependent variable. Two-sided values of $P < 0.050$ were considered statistically significant.

Characteristics of the breast implants used were evaluated by implant shape, shell, and fill and were visualized in combined bar charts. The use of different ICMs was calculated by registry and visualized in a combined bar chart.

The crude cumulative revision incidence was analyzed using Nelson-Aalen estimates. Revision time was defined as the time from implant insertion to the first registered revision. Implants without revision surgery had their follow-up time censored at the date of data extraction. Implants without an implantation record were excluded.

No risk adjustment was undertaken for the analyses because the registries' differences in maturity do not yet allow this. Aggregated analyses were performed using R software, version 1.3.959 (© 2009-2020, RStudio, Inc.).

Cautionary Note

Although the registries are united in ICOBRA and have incorporated the minimum harmonized data set, they run independently and have different data collection forms and methods. This study represents what is registered in each registry. However, depending on registry maturity, capture rate, data completeness, and data validity, registries do not entirely reflect each country's actual practice yet. This has to be kept in mind before comparing results.

RESULTS

Nationwide Coverage

On December 31, 2018, the ABDR captured 85% of the eligible institutions ($n = 280$ of 329), the BRIMP included 46 institutions (eligible number unknown), the DBIR captured 98% of the institutions ($n = 110$ of 112), and the NBIR captured 2.5% of the institutions ($n = 156$ of 6185).

Total Number of Registrations

By the end of 2018, a total of 207,189 permanent breast implants and 85,254 patients were registered, including implantations, revisions, and explantations (Fig. 1). Of these, 88,759 implants (36,284 patients) were registered in the ABDR, 34,501 implants (14,406 patients) were registered

in the BRIMP, 82,236 implants (33,698 patients) were registered in the DBIR, and 1693 implants (866 patients) were registered in the NBIR (Fig. 2).

Patient Characteristics in Primary Implant Surgery

Subsequently, 111,590 permanent breast implants and 57,574 patients met the second selection criterion of primary breast implant insertion for breast reconstruction or augmentation between 2015 and 2018 (Fig. 1). Of these, 47,732 implants were included by the ABDR, 21,477 by the BRIMP, 41,174 by the DBIR, and 1207 by the NBIR. Because of the low number of reconstructive records in the NBIR ($n = 10$), these data were excluded for the remainder of this article. All descriptive statistics of the variables are listed. (See Table, Supplemental Digital Content 2, which shows descriptive statistics, <http://links.lww.com/PRS/F943>.)

For breast reconstruction, the mean age $\pm$ SD in the ABDR, the BRIMP, and the DBIR was 42.0 ± 14.1 , 41.3 ± 14.4 , and 48.8 ± 12.6 years, respectively ($P < 0.001$). For breast augmentation, mean age $\pm$ SD was 32.3 ± 9.2 , 32.8 ± 9.3 , 31.6 ± 9.4 , and 35.9 ± 9.8 years in the ABDR, the BRIMP, the DBIR, and the NBIR, respectively ($P < 0.001$) (Fig. 3).

Median BMI did not differ between the countries for both breast reconstruction and augmentation ($P = 0.347$ and $P = 0.080$, respectively). In the ABDR, BMI was not registered. In the BRIMP, most patients had a BMI of 25 to 29.9 kg/m² (reconstruction, 61.9%; augmentation, 78.7%). In the DBIR and the NBIR, the majority of patients had a BMI of 18.5 to 24.9 kg/m² (reconstruction, 56.0%; augmentation, 74.9%; and augmentation, 60.0%, respectively).

Implant Characteristics

Generally, a large variation in implant preference was observed. Overall, primary breast reconstruction was most frequently performed with anatomically shaped, textured, silicone-filled implants (Fig. 4). In the ABDR, 57.1% ($n = 1959$) of the implants were anatomically shaped, 73.8% ($n = 2532$) were textured, and 99.5% ($n = 3412$) were silicone-filled. In the BRIMP, this was 63.8% ($n = 889$), 89.4% ($n = 1245$), and 93.9% ($n = 1309$), respectively. In the DBIR, this was 83.0% ($n = 2550$), 86.1% ($n = 2646$), and 76.2% ($n = 2343$), respectively.

For primary breast augmentation, round, textured, silicone-filled implants were most

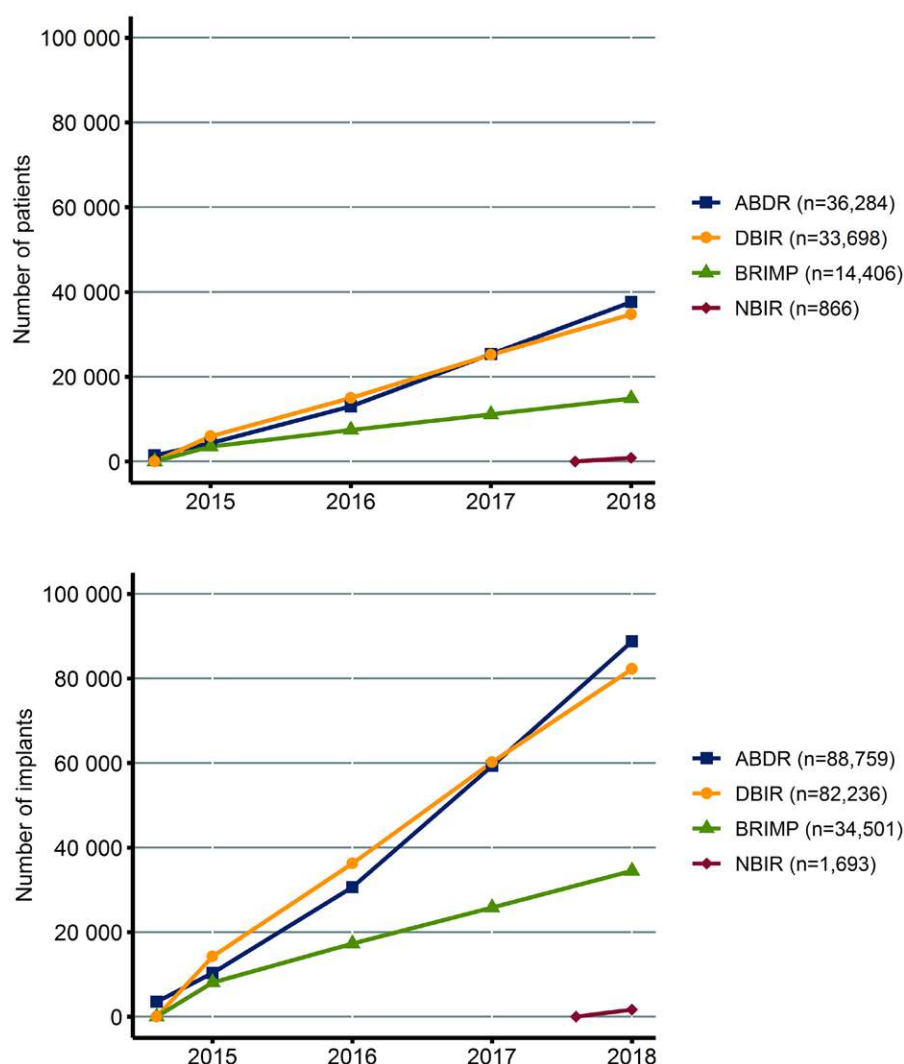


Fig. 2. Total number of registered patients and permanent breast implants since the start of each registry, including implantation and revision records. (Above) Registered patients. (Below) Registered implants.

frequently registered, except in the NBIR (Fig. 4). In the ABDR, 64.2% ($n = 28,456$) of the implants were round, 65.9% ($n = 29,173$) were textured, and 98.9% ($n = 43,827$) were silicone-filled. In the BRIMP, this was 60.0% ($n = 12,045$), 87.4% ($n = 17,570$), and 98.4% ($n = 19,784$), respectively. In the DBIR, this was 66.0% ($n = 25,160$), 89.2% ($n = 33,972$), and 97.2% ($n = 37,031$), respectively. In the NBIR, most implants were round [98.0% ($n = 1177$)], smooth [99.0% ($n = 1183$)], and silicone-filled [80.0% ($n = 962$)].

ICMs

In the ABDR, the most frequently registered ICM for primary breast reconstruction and augmentation was preoperative prophylactic

antibiotics (88.8% and 83.0%, respectively) (Fig. 5). In addition, the majority of the reconstructions and augmentations were performed with postoperative prophylactic antibiotics, antiseptic irrigation, and glove change. Antibiotic irrigation was used in approximately 50% of all procedures; the combination of antiseptic and antibiotic irrigation was not registered. Nipple guards were used in 26.6% of the reconstructions and 75.2% of the augmentations. An insertion sleeve was used in 25.8% of the reconstructions and 36.1% of the augmentations.

In the BRIMP, the most frequently registered ICM was preoperative prophylactic antibiotics (up to 96%). Postoperative prophylactic antibiotics and antibiotic irrigation were registered less frequently (reconstruction, 32.4% and 14.3%;

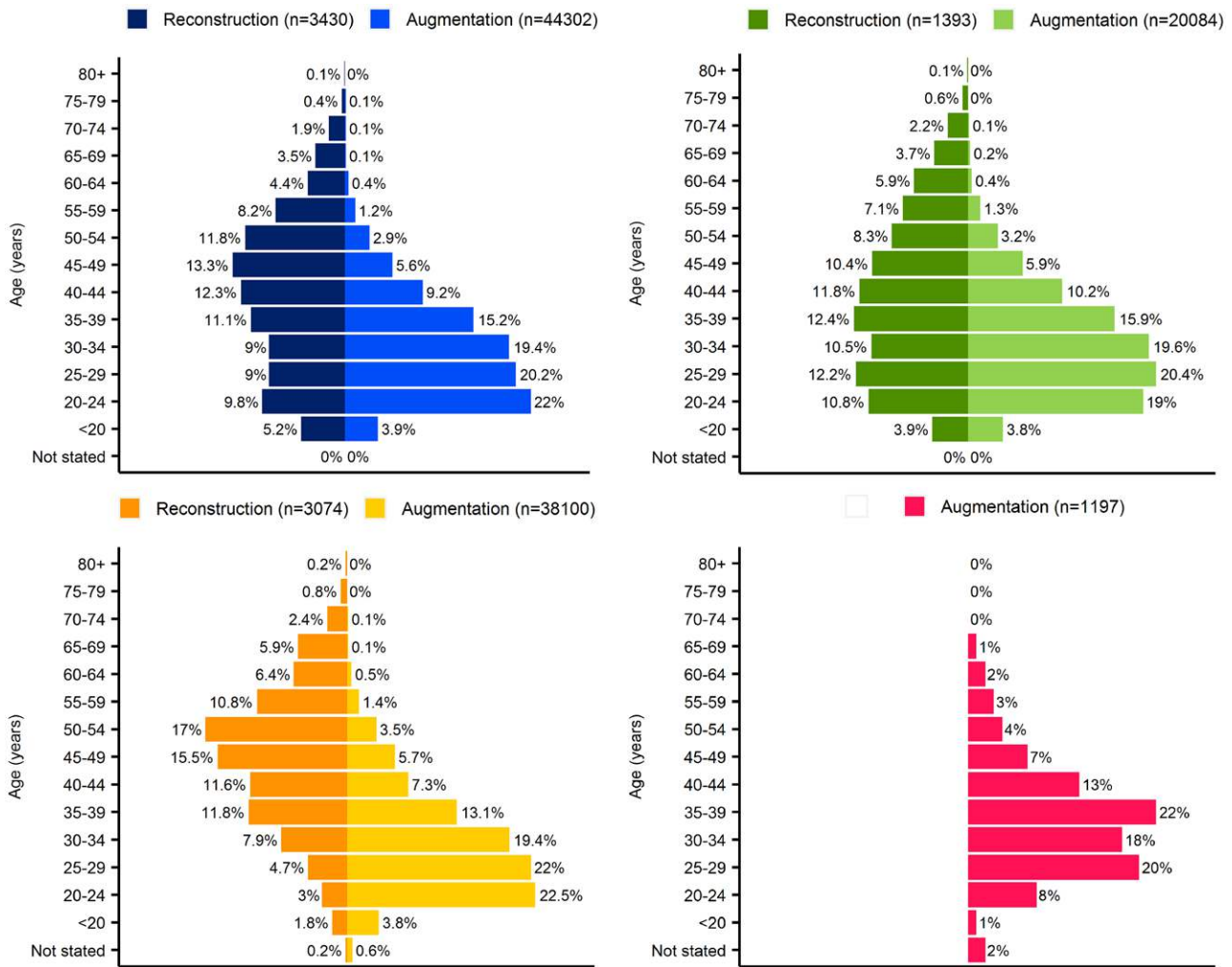


Fig. 3. Patient age distribution per primary inserted permanent breast implant: (above, left) ABDR, (above, right) BRIMP, (below, left) DBIR, and (below, right) NBIR. Difference in mean age between registries: breast reconstruction, $P < 0.001$; breast augmentation, $P < 0.001$.

augmentation, 34.1% and 23.2%, respectively). Glove change, nipple guards, and an insertion sleeve were used in clinical practice, but those ICMs were not captured in the registry.

In the DBIR, the most frequently registered ICM was preoperative antibiotics (up to 95%). Postoperative antibiotics were used after reconstructions (57.1%) but hardly after augmentations (6.7%). Glove change was registered in 87.9% of all breast reconstructions and 68.4% of all augmentations. Implant and/or pocket irrigation was more frequent with antiseptic solutions than antibiotic solutions or both. Nipple guards were used in 15.6% of the reconstructions and 45.5% of the augmentations. An insertion sleeve was hardly used in either indication (maximum, 6%). Generally, ICMs were registered more extensively in the ABDR than in the BRIMP and the

DBIR. This information is not currently captured in the NBIR.

Cumulative Revision Incidence

After primary breast reconstruction, all-cause revision incidence at 2 years was 15.8% (95% CI, 14.4% to 17.2%) in the DBIR, 11.4% (95% CI, 10.1% to 12.6%) in the ABDR, and 6.5% (95% CI, 5.2% to 7.8%) in the BRIMP (Fig. 6, above). Overall, most revisions were replacement with a new implant or autologous tissue, followed by explantation only and repositioning of the implant.

After primary breast augmentation, all-cause revision incidence at 2 years was 3.5% (95% CI, 3.3% to 3.8%) in the BRIMP, 2.8% (95% CI, 2.6% to 3.0%) in the ABDR, and 1.6% (95% CI, 1.5% to 1.8%) in the DBIR (Fig. 6, below). In the BRIMP

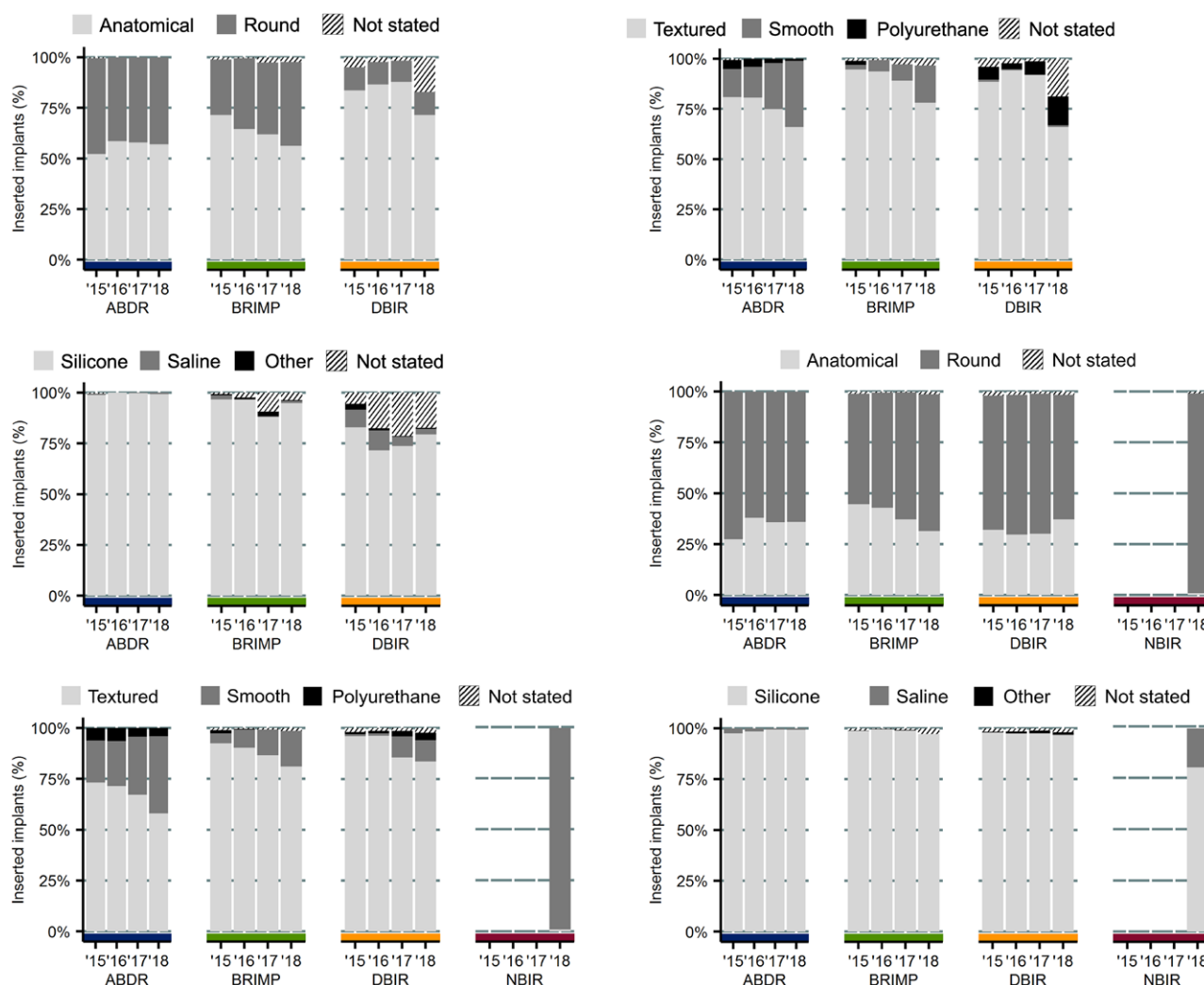


Fig. 4. Characteristics of primary inserted permanent breast implants: (above, left) reconstruction: shape; (above, right) reconstruction: shell; (center, left) reconstruction: fill (the NBIR did not have enough data to be included in the reconstructive figures); (center, right) augmentation: shape; (below, left) augmentation: shell; and (below, right) augmentation: fill. "Other" includes hydrogel-filled implants or a combination of silicone and saline. '15, 2015; '16, 2016; '17, 2017; '18, 2018.

and the DBIR, most revisions were replacement with a new implant or autologous tissue, followed by explantation only and repositioning of the implant. In the ABDR, most revisions were replacement with a new implant or autologous tissue, followed by a repositioning of the implant and explantation only.

DISCUSSION

This multinational study combined anonymized aggregate data from breast implant registries in Australia, the Netherlands, Sweden, and the United States. By the end of 2018, the registries together captured over 200,000 permanent breast implant records. Across the registries, 111,590 breast implants and 57,574 patients were selected

to analyze patient characteristics, implant characteristics, the use of ICMs, and all-cause revision incidence. These numbers are unprecedented in any publication on breast implants. Moreover, internationally combining breast implant data is considered a major breakthrough in accelerating independent knowledge to patients, surgeons, legislators, and industry.

The ABDR, the BRIMP, and the DBIR had high nationwide coverage and high data completeness (results not shown). Therefore, the presented results very likely reflect current clinical practice for the selected subpopulation in these countries.^{11–13} The NBIR has just started collecting data and covered 3% of the United States, leading to results that are not yet fully representative of American clinical practice. However, they do

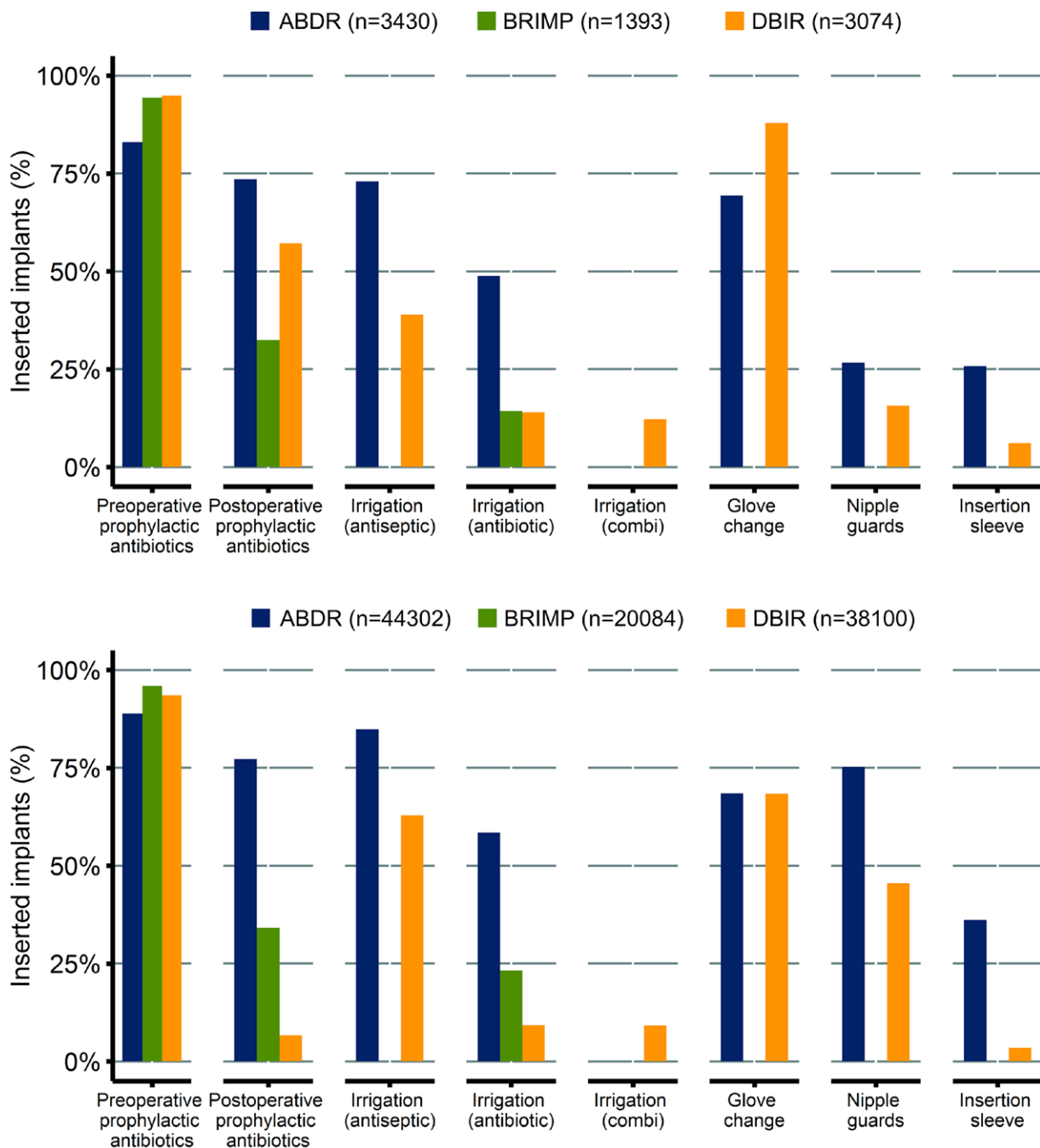


Fig. 5. ICMs used per primary inserted permanent breast implant. (Above) Breast reconstruction. (Below) Breast augmentation. In Sweden, glove change, nipple guards, and an insertion sleeve are applied but not captured in the BRIMP and therefore not included in this figure. The NBIR did not have enough data to be included in this figure.

highlight the future potential of the NBIR once embraced in daily breast implant surgery practice.

In Australia, Sweden, and the Netherlands, breast reconstruction was most frequently performed with anatomically shaped, textured, silicone-filled implants; and augmentation was most frequently performed with round, textured, silicone-filled implants. Interestingly, an increase in the proportion of round, smooth implants was

observed over time, which could be explained by the increasing concern about BIA-ALCL and its association with textured implants rather than smooth implants.^{19,20} However, the effect of different breast implant types on the outcomes will be evaluated in future combined studies; differences in implant brands and manufacturing practices across the countries need to be kept in mind as well.

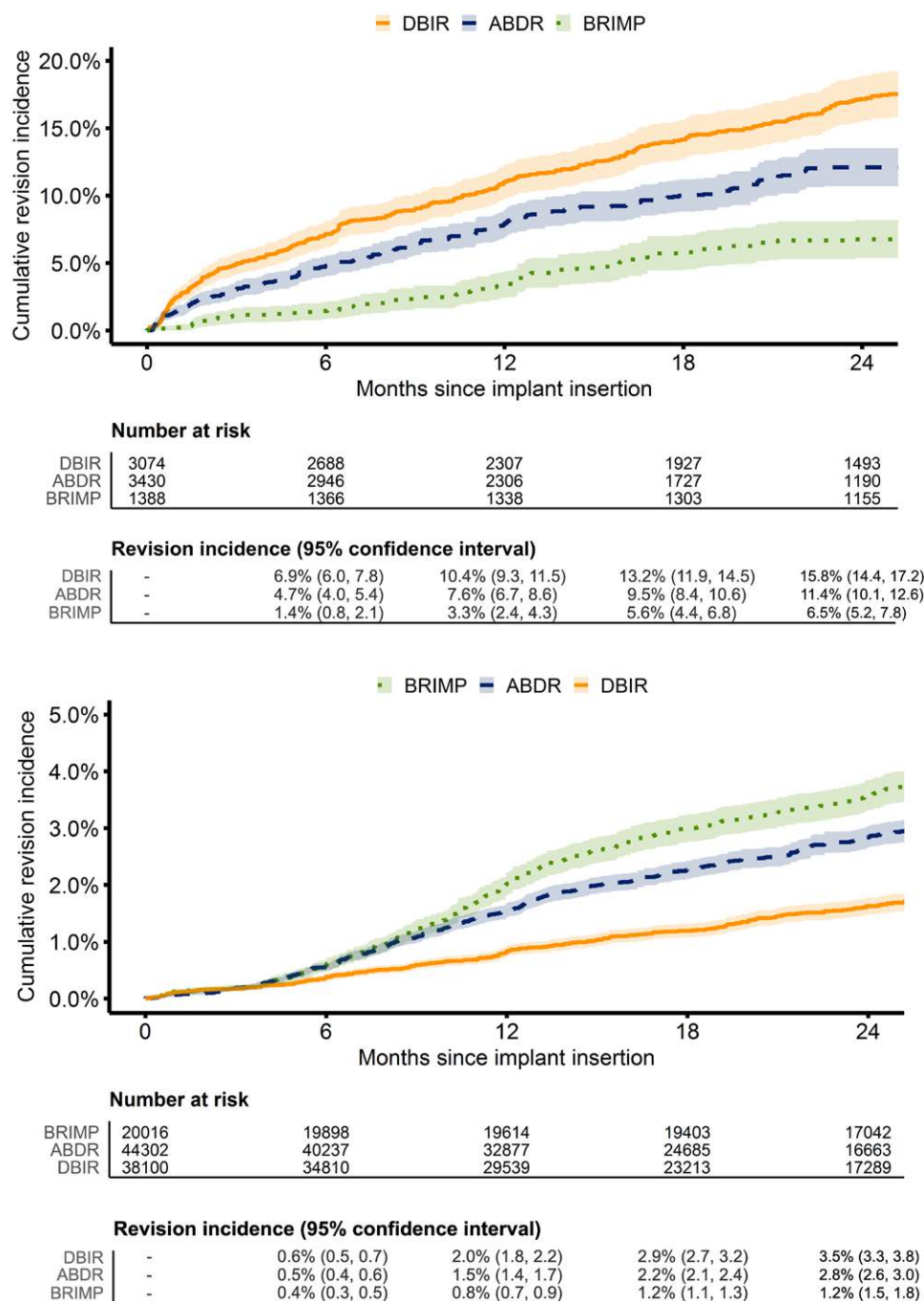


Fig. 6. Cumulative all-cause revision incidence of primary inserted permanent breast implants (2015 to 2018). (Above) Breast reconstruction. (Below) Breast augmentation. Different scales on the y axis. The NBIR did not have enough data to be included in this figure.

The most frequently registered ICM was preoperative prophylactic antibiotics. The registration of other ICMs varied between and within the countries, which most likely reflects the lack of epidemiologically sound evidence for these interventions, and resultant variation in national guidelines. For example, Swedish guidelines advise against using an antiseptic solution for pocket

and/or implant irrigation.²¹ In the Netherlands, the use of antiseptic irrigation, glove change, and nipple shields are left to the surgeons' discretion because of their low costs and no real drawbacks.^{22,23} In Australia, there is high use of intraoperative and postoperative antibiotics, but substantial regional variation in the use of other ICMs.^{24,25}

Cumulative revision incidence ranged from 6% to 16% after breast reconstruction and 1% to 4% after augmentation. Depending on each registry's maturity, these revision rates reflect registered revisions rather than actual revisions. Furthermore, no adjustment for confounding factors was performed. In addition, underreporting of revisions might be present, especially in the registries' earliest years. Finally, differences between the countries in patients' attitudes toward cosmetic reoperation and differences in health policy aspects could have affected revision incidence. The exact revision indications are captured by the registries, but they were beyond the scope of this article. Providing insight into the underlying reasons for the observed variation, the exact revision indications, and revision incidence per implant type are interesting topics for future collaborative projects.

Future Perspectives

By presenting combined results from different breast implant registries, this study confirms three crucial findings: (1) data can be combined using the ICOBRA harmonized data set, (2) differences and similarities between countries can be identified, and (3) trends over time can be recognized. This is just the start, and it portends a whole new spectrum of future collaborative projects. For example, when focusing on BIA-ALCL, several theories on cause have arisen. However, as the search for evidence has been challenged by differences in implant preference, surgical techniques, and patient characteristics, combining data from different national registries can be key to an earlier clarification of cause. In addition, early detection of malfunctioning breast devices can be accelerated using information from several breast implant registries (eg, using "BREAST-Q Implant Surveillance module" results).²⁶

Furthermore, this study addresses the importance of sharing data safely and considering the FAIR principles of data (findability, accessibility, interoperability, and reusability).¹⁶ The GDPR does not allow sharing of deidentified patient-level data. Therefore, this study used anonymous aggregated analyses. However, to properly conduct high-quality research on breast implant safety and early detection of malfunctioning breast devices, deidentified patient-level data are required. Therefore, the impact of the current GDPR on (breast implant) registries, its impact on future research, and the options to safely share data need to remain serious topics of discussion.

Finally, one of the benefits of this international collaboration is that knowledge on registry governance and strategies on increasing registries' capture rates can be easily exchanged. For example, one registry implemented an online dashboard for all participating health care institutions that provides insight into registration completeness and results. Another registry personally contacts institutions with missing or incorrect data. Diving into these different strategies helps unravel why some registries are more successful in capturing cases than others.

Strengths and Limitations

This is the first study combining real-world data from four breast implant registries, including breast reconstructions and breast augmentations. Comparing data from different registries can be difficult because of limited overlapping variables.²⁷ However, the ICOBRA harmonized data set makes comparisons more manageable and reliable. In addition, the scripts for the analyses have been made collaboratively by data analysts from each registry, which prevents differences in interpretation and data selection.

However, this study is not exempt from limitations. Data from tissue expanders could not be included because the BRIMP and the NBIR do not capture these implant types. Second, because of the recent coronavirus disease of 2019 pandemic, registry data from 2019 was not finished in time to be included in this report and will be included in future studies.

CONCLUSIONS

Growing awareness about breast implant-related adverse events has resulted in the demand for independent data resources by patients, surgeons, legislators, and industry. This is the first study combining objective, population-based data from four breast implant registries with over 200,000 breast implants. The possibility of internationally combining data and revealing similarities and variations between countries is a powerful and essential step forward in breast implant monitoring. It lays the foundation for evidence-based decision-making and optimizes patient safety in the current debates on breast implant surgery.

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APPENDIX

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REFERENCES

- Hopper I, Ahern S, Nguyen TQ, et al. Breast implant registries: a call to action. *Aesthet Surg J*. 2018;38:807–810.
- Hopper I, Ahern S, Best RL, McNeil J, Cooter RD. Australian Breast Device Registry: breast device safety transformed. *ANZ J Surg*. 2017;87:9–10.
- Rakhorst HA, Mureau MAM, Cooter RD, et al. The new opt-out Dutch National Breast Implant Registry: lessons learnt from the road to implementation. *J Plast Reconstr Aesthet Surg*. 2017;70:1354–1360.
- Prantl L, von Fritschen U, Liebau J, et al. Concept for a national implant registry to improve patient safety (in German). *Handchir Mikrophir Plast Chir*. 2016;48:320–329.
- NHS Digital. Breast and Cosmetic Implant Registry. Available at: <https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry#top>. Accessed September 29, 2020.
- The Plastic Surgery Foundation. The National Breast Implant Registry (NBIR). Available at: <https://www.thepsf.org/research/registries/nbir>. Accessed September 29, 2020.
- Registercentrum Västra Götaland. BRIMP Bröstimplantatregistret. Available at: <https://brimp.registercentrum.se/om-brimp/om-broestimplantatregistret/p/BkuO2oSQS>. Accessed September 29, 2020.
- Cooter RD, Barker S, Carroll SM, et al. International importance of robust breast device registries. *Plast Reconstr Surg*. 2015;135:330–336.
- Cooter R, Barnett R, Deva A, et al. In defense of the International Collaboration of Breast Registry Activities (ICOBRA). *Aesthet Surg J*. 2016;36:NP225–NP227.
- Spronk PE, Begum H, Vishwanath S, et al. Toward international harmonization of breast implant registries: ICOBRA global common dataset. *Plast Reconstr Surg*. 2020;146:255–267.
- Hopper I, Parker E, Pellegrini B, et al. *The Australian Breast Device Registry 2018 Annual Report*. Melbourne, Victoria, Australia: Monash University, Department of Epidemiology and Preventive Medicine; 2019.
- BRIMP. *BRIMP: Breast Implant Register Annual Report 2018*. Gothenburg, Sweden: Register Centrum Västra Götaland; 2019.
- Becherer BE, Rakhorst HA, Mureau MAM, et al. *Dutch Breast Implant Registry (DBIR): Annual Report 2018*. Leiden,

- The Netherlands: Dutch Institute for Clinical Auditing; 2019.
14. Clinical Audit and Registries Management Service. Breast and Cosmetic Implant Registry: July 2018 to June 2019 - Report v1.1. NHS Digital. Available at: <https://digital.nhs.uk/data-and-information/clinical-audits-and-registries/breast-and-cosmetic-implant-registry#top>. Accessed xxx.
 15. The Plastic Surgery Foundation. *The National Breast Implant Registry Annual Report 2019*. Arlington Heights, IL: The Plastic Surgery Foundation; 2020.
 16. Bargon CA, Becherer BE, Young-Afat DA, et al. Moving breast implant registries forward: Are they FAIR and functional? *J Plast Reconstr Aesthet Surg*. 2021;74:4–12.
 17. Hopper I, Best RL, McNeil JJ, et al. Pilot for the Australian Breast Device Registry (ABDR): a national opt-out clinical quality registry for breast device surgery. *BMJ Open* 2017;7:e017778e017778.
 18. BRIMP. *BRIMP: Breast Implant Register Annual Report 2019*. Gothenburg, Sweden: Register Centrum Västra Götaland; 2020.
 19. U.S. Food and Drug Administration. Anaplastic large cell lymphoma (ALCL) in women with breast implants: preliminary FDA findings and analyses. Available at: <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm>. Accessed March 21, 2017.
 20. U.S. Food and Drug Administration. Questions and answers about breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). Available at: <https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl>. Accessed October 23, 2019.
 21. Livsmedelsverket: Swedish Food Agency (website). Available at: <https://www.livsmedelsverket.se/bestall-ladda-ner-material/2020>. Accessed September 29, 2020.
 22. Nederlandse Vereniging voor Plastische Chirurgie. Richtlijn Borstprothesechirurgie. Available at: https://richtlijnen database.nl/richtlijn/borstprothesechirurgie/startpagina_-_borstprothesechirurgie.html#:~:text=De%20richtlijn%20borstprothesechirurgie%20is%20bedoeld,een%20goede%20keus%20te%20maken. Accessed September 29, 2020.
 23. Mureau MAM; Breast Reconstruction Guideline Working Group. Dutch breast reconstruction guideline. *J Plast Reconstr Aesthet Surg*. 2018;71:290–304.
 24. Hopper I, Pellegrini B, Gartoulla P, et al. *The Australian Breast Device Registry 2019 Annual Report*. Melbourne, Victoria, Australia: Monash University, Department of Epidemiology and Preventive Medicine; 2020.
 25. Vishwanath S, Pellegrini B, Parker E, et al. Breast device surgery in Australia: early results from the Australian Breast Device Registry. *J Plast Reconstr Aesthet Surg*. 2021;74:2719–2730.
 26. Ng S, Pusic AL, Parker E, et al. Patient-reported outcome measures for breast implant surgery: a pilot study. *Aesthet Surg J*. 2019;39:NP314–NP321.
 27. Kamali P, van Bommel A, Becherer B, et al. Immediate breast reconstruction in The Netherlands and the United States. *Plast Reconstr Surg*. 2019;144:565e–574e.