Quality assurance in breast cancer care and breast implant surgery

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CHAPTER 7

How to improve patient safety and quality of care in breast implant surgery? First outcomes from the Dutch Breast Implant Registry (2015 – 2017)

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ABSTRACT

Background: Although the use of breast implants is generally considered to be safe, breast implants are associated with short- and long-term complications. To evaluate and improve the quality of breast implant surgery, and increase our knowledge of implant performance, the national Dutch Breast Implant Registry (DBIR) was established in 2015. DBIR is one of the first up-and-running breast implant registries worldwide and follows an opt-out structure.

Objective: This article provides an overview of the first outcomes and experiences of the DBIR.

Methods: The national coverage of DBIR was studied, using data from the Dutch Health and Youth Care Inspectorate. For 2016 and 2017 the incidence rate of breast implants was calculated, and patient, device, and surgery characteristics were compared between cosmetic breast augmentations or reconstructive indications. Four infection control measures were selected to demonstrate the variation in the Dutch clinical practice.

Results: In 2016, 95% of the hospitals and 78% of the private clinics participated in DBIR. Between 2015 and 2017, a total of 15,049 patients and 30,541 breast implants were included. A minimum breast implant incidence rate of 1 woman per 1,691 women could be determined for 2017. The majority of devices was inserted for a cosmetic indication (85.2%). In general, patient, device, and surgery characteristics differed per indication group. Substantial variation was seen in the use of infection control measures (range 0-100%).

Conclusion: Preliminary results obtained from DBIR show high national participation rates and support further developments towards the improvement of breast implant surgery and patient safety.

INTRODUCTION

Since the introduction of breast implant surgery approximately six decades ago, numerous studies have evaluated the health effects and safety of breast implants.[1] These studies suggested that breast implants are to be considered safe. Nonetheless, a variety of surgical complications may occur following breast implant surgery, such as infection, implant rupture or deflation, late seroma, and capsular contracture.[2,3,4]

Recently, an association between Anaplastic Large Cell Lymphoma (ALCL) of the breast has been found.[5,6,7] Furthermore, the debate on possible associations between silicone exposure and various autoimmune diseases or connective tissue diseases continues (e.g., ASIA, an autoimmune/inflammatory syndrome induced by adjuvants)[8,9,10,11,12] Therefore, the outcomes of 'real world' data are becoming of increasing scientific and clinical importance to assess the effect of various intraoperative techniques and the use of different types of breast implants, while controlling for confounding factors adequately.[13,14]

In response to this, several countries have developed breast devices registries, among which the Dutch Breast Implant Registry (DBIR).[15,16,17,18,19,20] In April 2015, the DBIR started to register all patients undergoing breast implant surgery in the Netherlands (both implantations and explantations).[21] Currently, the audit provides hospitals and private clinics with weekly updated, benchmarked information on their performance. Additionally, the registry can be used as a track-and-trace system in case of an implant recall and identify patients who have the implant(s) of interest. DBIR follows an opt-out construct, which is unique compared to other breast implants registries worldwide.

Recent research has shown that the estimated prevalence of women with breast implants was 3,3% in the Netherlands in 2015.[5] However, incidence rates and further details on surgery techniques used, types of inserted devices, and national trends are not known yet. By using data of the DBIR, this study aims to provide more insight into the patient characteristics of women undergoing breast implant surgery in the Netherlands, the different types of inserted devices, and the nationwide variation in surgical techniques used.

METHODS

A: Registry Methods

Governance

The Dutch Breast Implant Registry (DBIR), founded in 2014, was an initiative of the Netherlands Society for Plastic Surgery (NVPC).[22] It provides an audit system for plastic surgeons on outcomes of breast implant surgery and serves as a track-and-trace system for breast implants. More information on the establishment, organization, and funding of the registry can be found in the paper of Rakhorst et al. and the annual report.[21,23]

Quality indicators

The primary purpose of the DBIR is to provide healthcare providers with reliable, benchmarked information on structure, process and outcome parameters. These quantitative measures cover different aspects of breast implant surgery: patient characteristics, information about intraoperative techniques, and short- and long-term outcomes of implants. A first set of quality indicators was defined by the DBIR group and external stakeholders (e.g., Dutch Health and Youth Care Inspectorate (IGJ), healthcare insurance companies, the Federation of hospitals, and patient advocates). For 2018, three quality indicators will be made publically transparent for all hospitals and private clinics performing breast implant surgery in the Netherlands: (1) Participation in the registry, (2) Percentage of registered breast implants compared to the actual inserted/explanted devices, and (3) Percentage of completely registered records.

Data collection

Registration in the DBIR is done using an internet-based program and data are stored at a central server.[24] The dataset consists of four levels: (1) General patient information (e.g. anonymized patient identification number, age), (2) Patient characteristics during surgery (e.g. date of surgery, ASA classification, smoking, Body Mass Index (BMI), (3) Surgery techniques on breast level (e.g. indication, incision site, flap cover, or when applicable the indication for revision), and (4) Implant characteristics (e.g. manufacturer, serial number, lot number, texture, fill, shape).

Data verification and participation rate

The quality of the DBIR database is evaluated on three levels: (1) National coverage: the participation of all Dutch hospitals and private clinics participating in breast implant surgery, (2) Completeness: the number of registered procedures versus the actual number of procedures performed at each center, and (3) Validity: the quality of the data compared to the electronic patient records in the hospitals.

In this study, the national coverage was assessed by comparing the number of institutions in DBIR to the number of eligible institutions known by the Dutch Health and Youth Care Inspectorate (IGJ).

No gold standard is known for the evaluation of completeness of the DBIR yet. By now, data from the industry is far from complete, and national insurance data does not include cosmetic procedures. Therefore, this could not be determined in the current study.

B: Study Methods

Patient selection

Per record (i.e., breast), information on the date of birth, date of surgery, type of surgery (insertion/ replacement/explantation only), and device type was minimally required to be eligible for analysis. The minimum incidence rate was calculated using the total number of women between 20 and 80 years of age in the Netherlands, in 2016 and 2017.[25]

For further analysis, all patients who had received a breast implant from the start of the DBIR on April, 1st 2015 until the end of the second complete registration year at December, 31st 2017, with a known indication (either reconstructive or cosmetic), were included. Patients who had received a tissue expander were excluded from the analysis. The population was divided into two cohorts: cosmetic and reconstructive. The cosmetic group included all patients with a breast augmentation. The reconstructive group included all patients with the following indication: reconstruction post (prophylactic) mastectomy, reconstruction for a benign condition or reconstruction for a congenital deformity. To identify differences between hospital/clinics, and to identify where improvement can be made, four examples of used infection control measures

were selected: glove change prior to implant handling, antiseptic rinse before insertion, the use of postoperative drains, and the use of prophylactic antibiotics.

Analyses

Differences in patient characteristics, device characteristics, and surgical techniques are described using percentages, means, and medians (depending on the distribution). Records with a missing indication (either cosmetic or reconstructive) are presented separately. Categorical variables were analyzed using the chi-square test, and continuous variables were analyzed using Student's t-test. Nationwide variation in the use of the four selected operative techniques was calculated in percentages per hospital per year and is visualized by scatterplots including the national mean. All analyses were performed using SPSS version 24.0 (SPSS Inc Chicago, IL, USA).

RESULTS

Nationwide participation rate DBIR

In the first full registration year (2016), 101 institutions were included in DBIR, of which 73 hospitals and 28 private clinics. This means coverage of 95% of the hospitals, and 78% of the private clinics when compared to the number of the eligible institutions known by the Dutch Health and Youth Care Inspectorate (IGJ) (**Figure 1**).

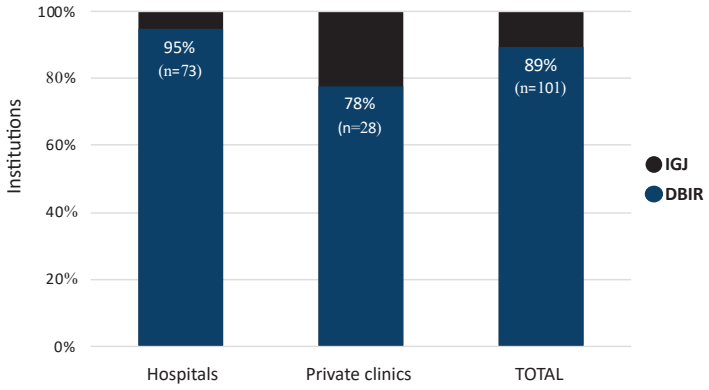


Figure 1. Nationwide participation rate DBIR (2016)
IGJ = Dutch Health & Youth Care Inspectorate.

Patients and minimum breast implantation incidence rates

In total, 48,493 records (i.e., breasts) have been registered with an operation date between the start of DBIR on April 1st, 2015 and December 31st, 2017, of which 48,026 (99.0%) were eligible for analysis (**Supplementary Figure 1)**. Of these, 41,919 were registered for the insertion of a breast implant. In 2016, 7,528 women received one or more permanent breast implant(s), accounting for a minimum incidence rate of one woman per 1,649 women. In 2017, the minimum incidence rate was one per 1,691 women (number of insertions: 7,391).

For further analysis, the indication for surgery needed to be known (either reconstructive or cosmetic). Therefore, 11,378 of the 41,919 records (27.1%) were excluded (36.8% in 2015, 32.8% in 2016, 15.1% in 2017). Eventually, 15,049 unique patients, 16,574 surgical procedures, and 30,541 breasts were included (**Figure 2**).

Patient characteristics

Patient characteristics per unique surgical procedure are presented in **Table 1**. In general, patients who had undergone a cosmetic breast augmentation were younger and had a lower ASA score compared with patients who received a breast reconstruction (all *p's* <0.001). Information on smoking and Body Mass Index (BMI) has been collected since September 2017. However, this information was missing in more than 5% of the records for both indications. **Supplementary Table 1a** contains all patient characteristics of the records in which no indication was specified.

Device characteristics

Between April 2015 and December 2017, 26,036 (85.2%) breast implants were inserted for a cosmetic breast augmentation, and 4,505 (14.8%) for a breast reconstruction. In both cosmetic and reconstructive indications, most devices had a textured shell (93.1% and 92.5%, respectively) with a silicone coating (96.3% and 91.6%, respectively), and with silicone filling (97.2% and 82.6%, respectively). Implants used in reconstructive indications were more often anatomically shaped instead of round (86.0% versus 30.6%, *p* <0.001). The median volume of inserted implants was higher in the reconstructive group (415cc, IQR 325-520) compared to the cosmetic group (350cc, IQR 300-405; *p* <0.001).

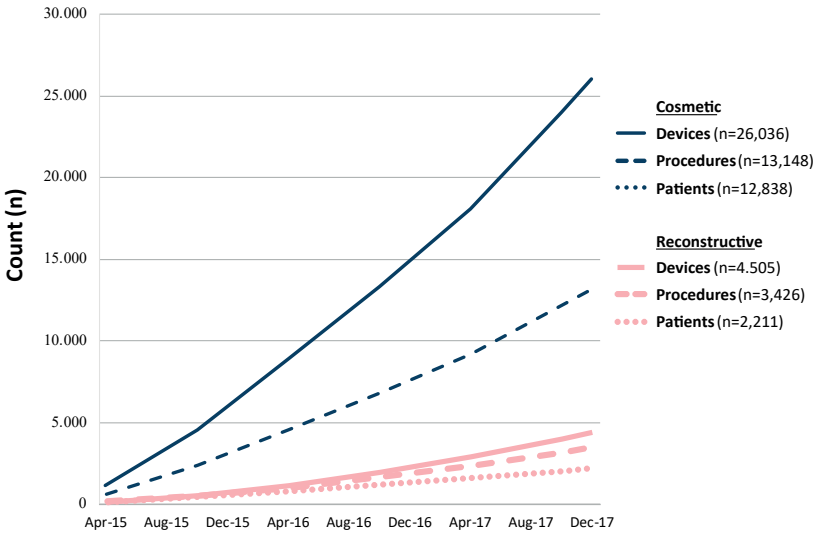


Figure 2. Cumulative number of registered patients, procedures and inserted breast implants (2015-2017)

Between 2016 and 2017, a decrease in the use of textured implants was seen for both indication groups (cosmetic: 96% to 89%, $p < 0.001$; reconstructive: 94% to 92%, $p = 0.04$) (**Figure 3)**. A similar trend was observed for the use of silicone coated devices (cosmetic: 98% to 95%, $p < 0.001$; reconstructive: 95% to 90%, $p < 0.001$). Furthermore, in the reconstructive group, an increase in the use of round implants (11% to 15%, $p < 0.001$) and silicone filled implants (78% to 85%, $p < 0.001$) was found. Characteristics of the 11,378 devices inserted for no specified indication are listed in **Supplementary Table 1b**.

Surgery characteristics

In the patients with a known indication for surgery, 26,036 (85.2%) breast implants were inserted for a cosmetic breast augmentation. Almost all cosmetic procedures were performed bilaterally (99.0%). Patients in the reconstructive group, however, more frequently underwent a unilateral procedure (52.1%, 2,349 of the 4,505 devices). As shown in **Table 2**, the incision site for a cosmetic breast augmentation was most frequently the inframammary fold (93.7%), while in reconstructive procedures the mastectomy scar was used in most cases (53.1%). For both cosmetic and reconstructive

Table 1. Patient characteristics per surgical procedure, presented on patient level (2015-2017)

	Cosmetic		Reconstructive		
	n	%	n	%	*P*
Patients[A]	13,148		3,426		
Age					<0.001
<30	6,227	47.4	205	6.0	
30-39	4,140	31.5	488	14.2	
40-49	1,794	13.6	876	25.6	
50-59	783	6.0	1,112	32.5	
>60	204	1.6	745	21.7	
ASA classification					<0.001
I	12,493	95.0	2,235	65.2	
II	532	4.0	1,040	30.4	
III-IV	30	0.2	90	2.6	
Unknown	*93*	*0.7*	*61*	*1.8*	
Smoking[B]					<0.001
Yes	218	10.5	61	9.9	
No	1,028	49.5	383	62.1	
Unknown	*830*	*40.0*	*173*	*28.0*	
BMI[B] (kg/m^2)					<0.001
<18.5	109	5.3	11	1.8	
18.5-25	1,529	73.7	273	44.2	
25 - 30	218	10.5	148	24.0	
>=30	32	1.5	55	8.9	
Unknown	*188*	*9.1*	*130*	*21.1*	

[A] *Patients per unique surgical procedure, no unique patients.*
[B] *Registered since September 2017. Percentages are calculated for a smaller population: n=2.076 (cosmetic), n=617 (reconstructive).*
ASA: American Society of Anesthesiologists. BMI: Body Mass Index.

indications, most devices were placed with full coverage of the pectoral muscle (26.2% and 39.6%, respectively) or dual plane (47.4% and 33.6%, respectively). Autologous flap cover, fat grafting or a MESH or Acellular Dermal Matrix (ADM) were not often used for both indications. See **Supplementary Table 1c** for all surgery characteristics of the records in which no indication was specified.

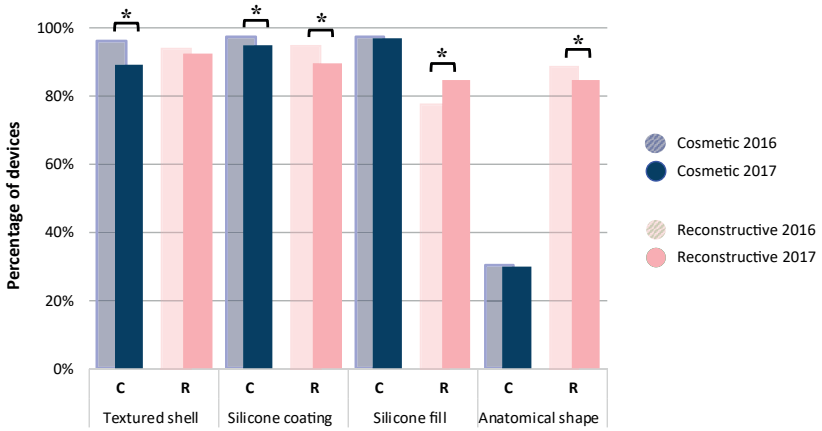


Figure 3. Device characteristics per inserted device (2015-2017) Textured vs Smooth shell, Silicone vs Polyurethane coating, Silicone vs Saline fill, Anatomical vs Round shape. NB. 2015 was not a complete registration year, and is therefore not included in this figure. Cosmetic (2016 n=8,995; 2017 n=11,253), Reconstructive (2016 n=1,546; 2017 n=2,175), <5% missing characteristics. * $p < 0.001$.

National variation in the use of infection control measures

A wide variation was observed between hospitals/clinics in the use of four selected perioperative infection control measures (all ranged 0-100%) (**Figure 4**). From 2016 to 2017, the proportion of procedures (per breast) in which surgeons changed their gloves before the insertion of an implant increased from 88% to 89% in reconstructive indications, and from 61% to 80% in cosmetic augmentations. Furthermore, an increase was observed regarding rinsing the breast implant with an antiseptic solution before insertion (from 70% to 78% (reconstructive), and from 78% to 85% (cosmetic)). Increased use of prophylactic intravenous antibiotics before the incision was noticed too; from 95% to 97% (reconstructive) and from 91% to 93% (cosmetic). The use of drains decreased in reconstructive procedures (80% to 78%) but increased in cosmetic augmentations (14% to 16%).

Table 2. Surgery characteristics, presented on breast level (2015-2017)

	Cosmetic		Reconstructive	
	n	%	n	%
Breasts[A]	26,036		4,505	
Incision site				
Inframammary	24,404	93.7	854	19.0
Mastectomy scar	194	0.7	2,391	53.1
Axillary	55	0.2	1	0.0
Areolar	109	0.4	370	8.2
Latissimus Dorsi	0	0.0	218	4.8
Other	1,072	4.1	344	7.6
Unknown	*202*	*0.8*	*327*	*7.3*
Plane				
Subglandular	3,584	13.8	173	3.8
Subfascial	1,823	7.0	34	0.8
Sub flap	13	0.0	360	8.0
Subcutaneous	20	0.1	52	1.2
Full pectoral muscle	6,830	26.2	1,783	39.6
Dual plane	12,343	47.4	1,512	33.6
Unknown	*1,423*	*5.5*	*591*	*13.1*
Mastopexy				
Yes	935	3.6	212	4.7
No	24,567	94.4	3,659	81.2
Unknown	*534*	*2.1*	*634*	*14.1*
Autologous flap cover				
Yes	95	0.4	511	11.4
No	25,386	97.5	3,362	74.6
Unknown	*555*	*2.1*	*632*	*14.0*
Fat grafting				
Yes	14	0.1	87	1.9
No	25,486	97.9	3,791	84.2
Unknown	*536*	*2.1*	*627*	*13.9*
Mesh/ADM use				
Yes	16	0.1	333	7.4
No	25487	97.9	3,776	83.8
Unknown	*533*	*2.0*	*396*	*8.8*

[A] *Breasts per unique surgical procedure, no unique breasts.*
ADM: Acellular Dermal Matrix.

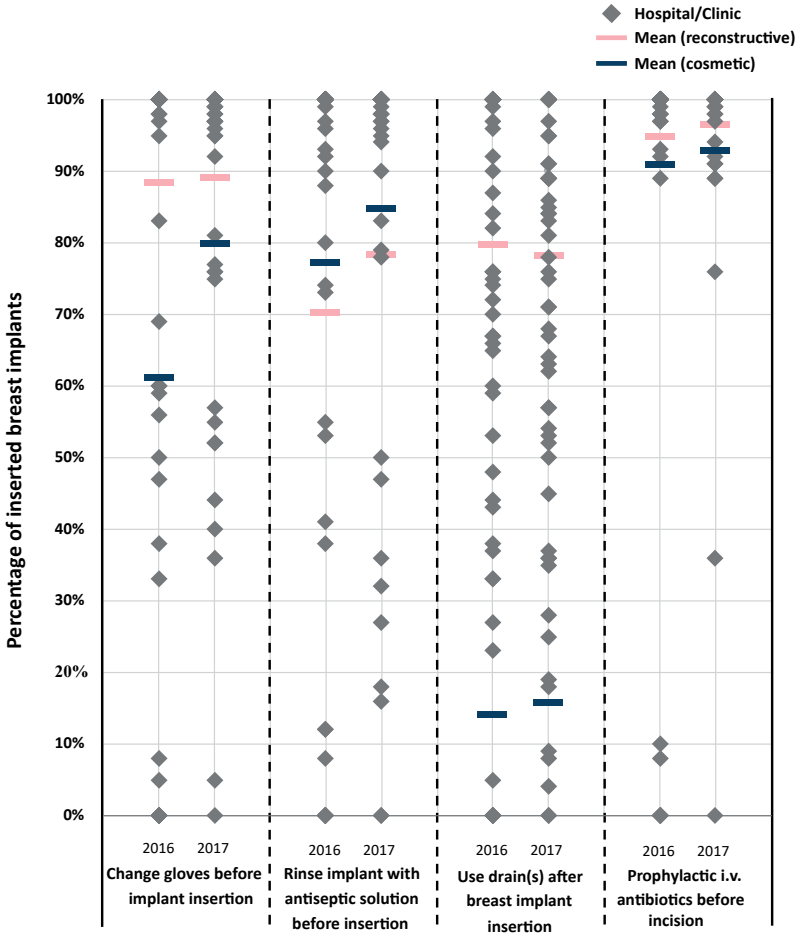


Figure 4. Nationwide variation for a selection of infection control measures (2016-2017), presented on breast level.
* 2015 was not a complete registration year, and is therefore not included in this figure.

DISCUSSION

This study provides an overview of the first outcomes and experiences of the Dutch Breast Implant Registry (DBIR), one of the first opt-out breast implant registries in the world. Since the national rollout in April 2015, information on 41,919 breast implants has been registered, including details of patients, devices, and procedures. The participation rate of hospitals (95%) and private clinics (78%) is high compared to other breast implant registries in the world with a maximum participation rate of 80% (or unknown capture rates).[15,16,17,18] For the first time, we were able to calculate the minimum breast implantation incidence rate in the Netherlands. In 2016 and 2017, at least one woman per 1,649 women, or one per 1,691, respectively, received one or more breast implant(s). However, it must be realized that this incidence rate is an underestimation, considering the current nationwide coverage of procedures.

Essentially, there were two groups of patients undergoing breast implant surgery with significant differences in characteristics: elective patients undergoing augmentation for cosmetic reasons who are generally young, healthy adults versus more complex patients requiring reconstructive surgery (mainly) after breast cancer treatment. Within our population, there was a predominance of textured silicone gel implants used for both indications. However, a significant increase in the use of smooth implants was observed, that appears to coincide with the critical issue of breast implant-associated Anaplastic Large Cell Lymphoma (BIA-ALCL), a rare cancer of the immune system believed to be causally associated with textured breast implants.[26,27] In recent research of Becherer and de Boer et al., data of the DBIR and the Dutch Nationwide Network and Registry of Histo- and Cytopathology (PALGA) was combined, resulting in a dataset with both pathological, clinical and implant related information. This result demonstrated the potential of DBIR as an important tool for health risk assessments of implants.[28]

The DBIR aims to provide a pragmatic source of evidence of potential risks and benefits associated with clinical practice. For example, previous studies have suggested that the risk of capsular contracture is reduced by the use of an inframammary fold incision compared to periareolar incisions.[29] Or implants placed in a subpectoral position appeared to result less often in malposition of the implant or the development of capsular contracture.[30] However, these studies are often biased or unreliable due to

confounding by indication or loss to follow-up. Moreover, other factors such as the use of antiseptic precautions or the type of implants used may influence adverse outcomes as well. Therefore, only epidemiologically sound, longitudinal data such as from the DBIR, will be able to reveal optimal surgical treatment strategies and differences in implant performance by taking risk adjustment factors (casemix) into account.

The main purpose of the DBIR is to improve the quality of breast implant surgery in the Netherlands by providing benchmarked information on a set of process and outcome measures (quality indicators). Several other clinical audits have preceded, leading to substantial improvements in quality of care.[31,32,33] As an example of possible interesting process indicators, the national variation in the use of 4 infection control measures was presented (the use of antibiotics, antiseptic rinse of the implant, glove change prior to implant handling and the use of postoperative drains). A wide variation from 0 to 100% between hospitals and clinics in the use of these measures was seen. Understanding the nature of this variation and the effect of infection prevention on clinically relevant outcomes, such as postoperative surgical site infections, is paramount in decision-making about improvement efforts. Other examples of potential outcome indicators are: the percentage of explanations due to complications within an x number of days or long-term capsular contracture or implant rupture rates.

A balance is required between capturing all valuable information on the one hand and spending an acceptable amount of time needed for data entry on the other hand. To reduce the administrative burden an minimize the chance of typing errors, the GS-1 barcode system was implemented in the online data form of DBIR. With the help of this barcode, relevant implant characteristics, including the unique device identification (UDI) number, is automatically retrieved and registered. This will also help to decrease the amount of missing information on implant characteristics. Fortunately, an increasing amount of implant manufacturers are using a correct GS1 barcode in the Netherlands.

In general, completeness of the DBIR data has increased over the last three years.[23] It can be deduced from our results that missing data is not random; but namely patient records in certain hospitals. The DBIR online system provides already instant feedback on missing records using a 'list of errors'. Also, a data verification project to evaluate the validity of the data will be scheduled shortly. To further increase our nationwide

coverage, linking data from external databases could catalyse completeness of the DBIR data; e.g. external databases from the industry, the Dutch NABON Breast Cancer Audit (NBCA) and the Dutch Pathology Databanking and Biobanking (PALGA).

Internationally, the International Collaboration of Breast Registry Activities (ICOBRA) has defined an internationally agreed minimum core set of data points to be used by all breast device registries globally.[34] This dataset is integrated into the DBIR dataset. A future step is to combine breast implant registries globally to perform implant surveillance and evaluate clinical outcomes on an international level. Long-term data will eventually reveal the actual health effects of breast implants and breast implant surgery.

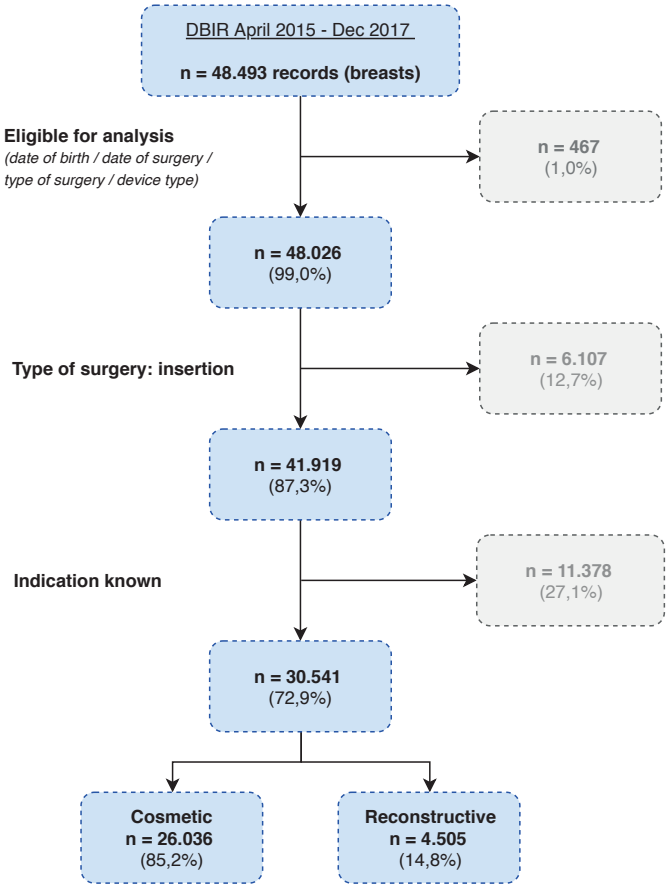
CONCLUSION

The opt-out Dutch Breast Implant Registry (DBIR) is one of the first up-and-running breast implant registries worldwide, which is the result of collaborative and conjoint efforts from clinicians, health care providers, and policymakers. First experiences with DBIR and its preliminary results show that DBIR has the potential to provide answers to clinically relevant questions and to provide quality assurance and outcome research for breast implant surgery.

REFERENCES

1. Rocco N, Rispoli C, Moja L, et al. Different types of implants for reconstructive breast surgery. *Cochrane Database Syst Rev.* 2016;(5):CD010895.
2. Coroneos CJ, Selber JC, Offodile AC, et al. US FDA Breast Implant Postapproval Studies: Long-term Outcomes in 99,993 Patients. *Ann Surg.* 2018;14.
3. Cheng NX, Chen B, Li Q, et al. Late haematoma and seroma in patients with silicone mammary prosthesis: our reports and literature review. *J Plast Reconstr Aesthetic Surg.* 2011;64(7):185–6.
4. Park BY, Lee DH, Lim SY, et al. Is late seroma a phenomenon related to textured implants? A report of rare complications and a literature review. *Aesthetic Plast Surg.* 2014;38(1):139–45.
5. de Boer M, van Leeuwen FE, Hauptmann M, et al. Breast implants and the risk of analplastic large-cell lymphoma in the breast. *JAMA Oncol.* 2018;4(3):335–341.
6. Thompson PA, Prince HM. Breast implant-associated anaplastic large cell lymphoma: a systematic review of the literature and mini-meta analysis. *Curr Hematol Malig Rep.* 2013;8(3):196–210.
7. de Jong D, Vasmel WL, de Boer JP, et al. Anaplastic large-cell lymphoma in women with breast implants. *JAMA.* 2008;300(17):2030–5.
8. Hennekens CH, Lee IM, Cook NR, et al. Self-reported breast implants and connective-tissue diseases in female health professionals. A retrospective cohort study. *JAMA.* 1996;275(8):616–21.
9. Sánchez-Guerrero J, Colditz GA, Karlson EW, et al. Silicone breast implants and the risk of connective-tissue diseases and symptoms. *N Engl J Med.* 1995;332(25):1666–70.
10. Watad A, Rosenberg V, Tiosano S, et al. Silicone breast implants and the risk of autoimmune / rheumatic disorders: a real-world analysis. *Int J Epidermiol.* 2018;Oct 16:1-9.
11. Balk EM, Earley A, Avendano EA et al. Long-Term Health Outcomes in Women With Silicone Gel Breast Implants: a systematic review. *Anne Intern Med.* 2016;164(3):164-75.
12. Coroneos CJ, Selber JC, Offodile AC et al. US FDA Breast implant postapproval studies: long-term outcomes in 99,993 patients. *Ann Surg.* 2018:1–7.
13. Vandenbroucke JP. Observational research, randomised trials, and Two Views of Medical Science. *PLoSMed.* 2008; 5(3):e67.
14. Colwell AS, Mehrara B. Editorial: US FDA Breast Implant Postapproval Studies - Long-term Outcomes in 99,993 Patients. *Ann Surg* 2018;6:11–2.
15. Renner C, Neuhann-Lorenz C. International breast implant registry: A user report. *Aesthetic Plast Surg.* 2006;30(5):616–21.
16. Henriksen TF, Hölmich LR, Friis S, et al. The Danish Registry for Plastic Surgery of the Breast: establishment of a nationwide registry for prospective follow-up, quality assessment, and investigation of breast surgery. *Plast Reconstr Surg.* 2003;111(7):2182–9.
17. Shakespeare PG, Bazire N, Whitworth IH. The UK breast implant registry-ten years on. *Br J Plast Surg.* 2005;58(3):283–5.
18. Wurzer P, Rappl T, Friedl H, et al. The Austrian Breast Implant Register: Recent Trends in Implant-Based Breast Surgery. *Aesthetic Plast Surg.* 2014;38(6):1109–15.

19. Rowell KS, Turrentine FE, Hutter MM, Khuri SF, Henderson WG. Use of National Surgical Quality Improvement Program Data as a Catalyst for Quality Improvement. J Am Coll Surg 2007;204(6):1293–300.
20. Heidekrueger PI, Juran S, Patel A, Tanna N, Broer PN. Plastic Surgery Statistics in the US: Evidence and Implications. Aesthetic Plast Surg 2016;40(2):293–300.
21. Rakhorst H, Mureau MA, 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(10):1354–1360.
22. https://nvpc.nl. Accessed September, 4th, 2018.
23. https://dica.nl/dbir/home Accessed September, 4th, 2018. [annual rapport 2017 online soon]
24. https://mrdm.nl. Accessed September, 4th, 2018.
25. https://opendata.cbs.nl/statline Accessed September, 4th, 2018.
26. Doren EL, Miranda RN, Selber JC, et al. U.S. epidemiology of breast implant-associated anaplastic large cell lymphoma. *Plast Reconstr Surg*. 2017;139(5):1042–1050.
27. Loch-Wilkinson A, Beath KJ, Knight RJW, et al. Breast implant associated anaplastic large cell lymphoma in Australia and New Zealand—high surface area textured implants are associated with increased risk. *Plast Reconstr Surg*. 2017;140(4):645–654
28. Becherer BE, Boer M De, Boer JP De, et al. The Dutch Breast Implant Registry (DBIR): Registration of Breast Implant - Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), a proof of concept. *Accepted for publication in Plast Reconstr Surg*.
29. Namnoum JD, Largent J, Kaplan HM, et al. Primary breast augmentation clinical trial outcomes stratified by surgical incision, anatomical placement and implant device. *J Plast Reconstr Aesthet Surg*. 2013;66(9):1165–72.
30. Stevens WG, Harrington J, Alizadeh K, et al. Eight-Year Follow-Up Data from the U.S. Clinical Trial for Sientra's FDA-Approved Round and Shaped Implants with High-Strength Cohesive Silicone Gel. *Aesthet Surg J*. 2018;35 Suppl 1:S3–10.
31. Leersum NJ Van, Snijders HS, Wouters MWJM, Henneman D, Marijnen CAM. Evaluating national practice of preoperative Leersum NJ Van, Kolfschoten NE, Klinkenbijl JH, et al. 'Clinical Auditing', a novel tool for quality assesment in surgical oncology. *Ned Tijdschr Geneesk*. 2011;155(45):A4136.
32. Bergqvist D, Troëng T, Elfström J, et al. Auditing Surgical Outcome: Ten years with The Swedish Vascular Registry - Swedvasc. The Steering Committee of Swedvasc. *Eur J Surg Suppl*. 1998;(581):3–8.
33. Bommel van ACM, Spronk PER, Peeters MTFDV, et al. Clinical Auditing as an Instrument for Quality Improvement in Breast Cancer Care in the Netherlands: The National NABON Breast Cancer Audit. *J Surg Oncol*. 2017;115(3):243–249.
34. Spronk PER, Husna B, Vishwanath S, et al. From the ICOBRA initiative: A globally agreed core set of minimum data for breast implant surgery. [submitted]



Supplementary Figure 1. Patient selection process.

Supplementary Table 1a. Patient characteristics per surgical procedure in which no indication was specified, presented on patient level (2015-2017)

	Indication not specified	
	n	%
Patients[A]	6,884	
Age		
<30	750	10.9
30-39	1,336	19.4
40-49	1,701	24.7
50-59	1,878	27.3
>60	1,219	17.7
ASA		
I	5,149	74.8
II	1,417	20.6
III-IV	130	1.9
Unknown	*188*	*2.7*
Smoking[B]		
Yes	2	4.8
No	1	2.4
Unknown	*39*	*92.9*
BMI[B] (kg/m^2)		
<18.5	0	0.0
18.5-25	6	14.3
25 - 30	0	0.0
>=30	0	0.0
Unknown	*36*	*85.7*

[A] *Patients per unique surgical procedure, no unique patients.*
[B] *Registered since September 2017. Percentages are calculated for a smaller population: n=42.*
ASA: American Society of Anesthesiologists. BMI: Body Mass Index.

Supplementary Table 1b. Device characteristics per inserted device for the records in which no indication was specified (2015-2017)

	Indication not specified	
	n	n
Inserted devices	11,378	
Texture		
Smooth	164	1.4
Textured	9.353	82.2
Unknown	*1,861*	16.4
Coating		
Silicone	9,517	83.6
Polyurethane	1,130	9.9
Unknown	*731*	6.4
Fill		
Silicone	10,080	88.8
Saline	155	1.4
Hydrogel	106	0.9
Unknown	*1,013*	8.9
Shape		
Round	4,989	43.8
Anatomical	5,529	48.6
Unknown	*860*	*7.6*
Volume[A] (median, in cc with IQR)	N/A	

[A] *Registered since September 2017. Percentages are calculated for a smaller population: n=0.*
IQR: Interquartile Range. N/A: not applicable.

Supplementary Table 1c. Surgery characteristics for the records in which no indication was specified, presented on breast level (2015-2017)

	Indication not specified	
	n	%
Breasts[A]	26,036	
Incision site		
Inframammary	6,228	54.7
Mastectomy scar	2,389	21.0
Axillary	10	0.1
Areolar	150	1.3
Latissimus Dorsi	206	1.8
Other	271	2.4
Unknown	*2,124*	*18.7*
Plane		
Subglandular	1,444	12.7
Subfascial	108	0.9
Sub flap	393	3.5
Subcutaneous	53	0.5
Full pectoral muscle	3,035	26.7
Dual plane	1,654	14.5
Unknown	*4,691*	*41.2*
Mastopexy		
Yes	473	4.2
No	8,534	75.0
Unknown	*2,371*	*20.8*
Autologous flap cover		
Yes	252	2.2
No	8,780	77.2
Unknown	*2,346*	*20.6*
Fat grafting		
Yes	157	1.4
No	8,892	78.2
Unknown	*2,329*	*20.5*
Mesh/ADM use		
Yes	62	0.5
No	9,102	80.0
Unknown	*2,214*	*19.5*

[A] *Breasts per unique surgical procedure, no unique breasts.*
ADM: Acellular Dermal Matrix.