

BRIMP- BREAST IMPLANT REGISTER ANNUAL REPORT 2019



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ANNUAL REPORT 2019

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OBJECTIVE INFORMATION FOR PATIENTS AND THE PROFESSION

The Breast Implant Register was started in May 2014. This was the beginning of the first systematic registration of breast implants in Sweden. At the same time, the web page www.brimp.se was also commenced.

The aim of the BRIMP is to offer patients who, for whatever reason, are to undergo breast implant surgery, adequate and objective information about the types of implants available on the market today.

For those surgeons who perform implant operations, it is also important to have access to objective and impartial information about the different breast implants available.

Registration of information in BRIMP facilitates, not only the prompt detection of possible abnormalities, as in the case of the PIP-implant, but also allows for long-term follow-up of the effects of having breast implants.

The statistics collected in the register enables the profession to have access to ever increasing knowledge about different implants and their performance. This allows surgeons to be better able to more readily adapt the choice of implant to the specific needs of the patient.

Healthcare organizations are expected to experience a gigantic paradigm shift in the coming years. The BRIMP will become an important tool in the evaluation of outcome measures in patient-centred, evidence-based healthcare.

It is of the utmost importance that as many clinics as possible participate in the BRIMP. Those clinics that take part are shown on the register's home page and some statistical analyses are also available on the home page.

The home page will show statistics that will be readily available to the general public, as well as statistics which can only be accessed by the specific clinics that participate in the register.

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aps Plastikkirurgi - Gothenburg
Art Clinic - Gothenburg
Art Clinic - Jönköping
Art Clinic - Stockholm
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Conturkliniken - Stockholm
Dalakliniken - Falun
De VitaNova AB - Stockholm
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Gerlee Plastikkirurgi - Helsingborg
Gävledalakliniken - Gävle
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Kirurgkliniken - Växjö
Kirurgkliniken - Västervik
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INFORMATION FROM THE REGISTRAR

Birgit Stark, Associate Professor, Consultant in Plastic Surgery and Registrar for the BRIMP

History and the Future

The general aim of the BRIMP is to inform patients, members of the caring professions and government authorities about safety regarding implant-based operations performed for breast cancer, as well as, benign conditions of the breast. Using the PROM (Patient Reported Outcome Measurement) questionnaires patients can provide information about how they perceive the level of success of their operation. During 2018 and 2019, a consolidation of the data collected in the BRIMP has occurred. We have worked towards simplifying for participating clinics to allow them to have access to their own results compared to the data on a national level. This is part of the quality and safety work, with the intention of helping to reduce complications and increasing patient safety. The BRIMP annual report 2019 is available on www.brimp.se

Since the BRIMP started in 2014, implant-based operations have undergone major changes. For example, operation techniques have changed with the use of the, so called, hybrid technique, where the body's own fatty tissue is used in combination with the implant. The use of net inserts, in conjunction with breast implants, is another hybrid technique under evaluation. Implant-related problems have been reported widely in the media both nationally and internationally. Worth mentioning in this context is the symptom complex "Breast Implant Illness" (BII) also known as "ASIA disease". The lymphoma disease BIA-ALCL is a subject which is brought up at most national and international meetings of the profession. Therefore, the content of the BRIMP requires continual critical evaluation and needs to be adapted to capture relevant new information to be able to answer important new questions raised on the subject of breast implants.

An extended analysis of the impact of certain variables which are relevant in short- and long-term complications connected with breast implants from different manufacturers and seen both in patients with benign and malignant breast conditions is given in the report. Many colleagues in Sweden have been contacted by patients concerned about their specific breast implants. A popular scientific description of the important outcome data has been compiled and is also presented in the report.

The Swedish and English version of the BRIMP report is published annually on the BRIMP's homepage www.brimp.se and is distributed free of charge to all members of the Swedish Association for Aesthetic Plastic Surgery (SFEP) and the Swedish Plastic Surgeons Association (SPKF). All clinics and units that report in data to the BRIMP receive a special summary of their own results, which is sent via mail twice yearly. The units' data, in relation to the aggregated data in the BRIMP register, can be followed on-line using the units own specific access codes.

To run and maintain a quality register is costly and has, up until today, been funded principally through grants from the Swedish Association of Local Authorities and Regions (SKR), gained in competition with the approximately 100 other quality registers in the country also seeking funding.

In order to provide statistically conclusive answers to relevant questions, a large amount of data is required and therefore it is necessary for the registrar to maintain an intensive co-operation with other international breast implant registers within the International Collaboration of Breast Implant Registries (ICOBRA). This co-operation will potentially provide answers to specific problems with breast implants more quickly given the possibility to compare large data sets of outcome variables. This co-operation has already resulted in the publication of four articles on the subject.

BRIMP 2019

At present, in Sweden, all university clinics performing plastic surgery and 85% of plastic surgeons in private practice participate in the BRIMP. In co-operation with the Registercentrum Västra Götalands region (RC), data from 40,000 breast implants is managed, as of the end of December 2019. At present, there is only one clinic in Stockholm which has actively declined to participate in the work of the BRIMP. During 2019, the continuing work of the register has focused on four main projects:

1. Work with Data Function as a Support for Healthcare

Feedback to the participating units is an important function of the register. In co-operation with the project management at RC, two on-line web modules for participating clinics have been constructed. All participating clinics can access the register and compare the quality of the healthcare provided by their clinics in relation to the aggregated data in the BRIMP. To facilitate the individual clinic's possibility for analysis and critical thinking, a module has been constructed which generates a report summarizing each clinic's half-yearly data. This module was launched in 2018 and two reports have been sent out during 2019. In this way, those clinics participating in the register can more easily follow their own results over time and initiate quality measures as required.

2. Improved Register Content

The BRIMP is still a relatively new register and is still under development. Generally, we must evaluate if the data registered is relevant for our questions, as well as, monitor the response frequency and response quality. The significance of the parameters registered is evaluated continuously. Improvements during 2019 have resulted in an updated data registration form for the collection of statistically valuable data. A critical analysis of the importance of the variables is being constantly monitored and has resulted in an update of relevant data. This is a work in progress and it will probably require several more years of work to create the optimal, complete and comprehensive breast implant register. During the autumn of 2019, the registrar has conducted a new critical analysis of the data quality, particularly in view of the new implant-related problems receiving special attention. Therefore, a new updated set of data variables has been introduced into the register for 2020.

Improved register content is also created by analysis of the level of coverage. During the period from 2015 – 2017, we have noted an increase of 11% in the reporting of primary operations and 25% for re-operations. During 2018 and 2019, reporting has stagnated at a certain level. There has even been an increase in the number of implant removals registered in the BRIMP.

Since the initiation of the BRIMP, there has been a continual increase in the number of clinics reporting to the register. We have also experienced an increased understanding regarding the benefits and importance of the BRIMP quality register. More clinics and units nationally are requesting information about the BRIMP. During the autumn of 2019, the registrar was invited as guest speaker for presentations at meetings in Norway, Austria, as well as, meetings on BIA-ALCL in Rome, Italy and Bruges, Belgium.

The current total level of coverage of the BRIMP is approximately 65%. Reliable sales-data from the industry which the registrar has received, report that the register has information about an estimated 50% of all implants sold in Sweden. It must be remembered, that the BRIMP is a relatively new register, which can explain why the level of coverage is not higher. Also, breast implants are used in special cases where we have not been able to persuade the breast surgeons to participate in the BRIMP. We are hoping for a closer co-operation between the national breast cancer register and the BRIMP, which should lead to a considerable increase in the level of the register's coverage.

To help increase the level of "compliance" and "completeness" in the BRIMP, regular face to face meetings, as well as electronic meetings are required during the coming year. It is also important to maintain contact, with those clinics that, up until now, have not joined the register.

This continued work, together with presentations at scientific conferences will help to improve the position of the BRIMP register in the scientific community. Colleagues are becoming, more and more aware of the benefits of the BRIMP for their own clinics and participation in the BRIMP will become an integral part of the workplace. Specific efforts will be made to contact those colleagues who, at present, do not participate in the BRIMP and who hopefully in the future will join the register and provide data from their respective clinics.

It is primarily the breast surgery units that have not participated in reporting to the register. Therefore, in co-operation with RC and the regional Cancer Centre Stockholm-Gotland, we have constructed a model for information transfer and sharing. In those cases where a primary reconstruction follows treatment for breast cancer and this is registered in the national Breast Cancer Register, in future, specific data will also be transferred to the BRIMP. In other cases where an eventual reconstruction is performed at a later stage, the breast surgeons will be encouraged to register the data directly into the BRIMP. This new model will be tested during 2020.

3. The Management of PROM in BRIMP

The Board of the Breast Implant Register has decided that the PROM questionnaire in its present form would be introduced during 2019. A proposal for PROM data has been worked out, discussed and adopted during the past year, after a successful pilot project was conducted. In consultation with the project management at the RC, suitable forms for sending out questionnaires to patients who have undergone breast operation have been planned, taking into consideration the requirements of GDPR. The PROM-instrument has been used in BRIMP since autumn 2019 and is available for sending to all patients. The PROM data is collected 6 months after the primary operation. All participating clinics are sent a digital reminder from the BRIMP 6-months after the operation date to send out questionnaires to the specific patients. The logistics of PROM management has been planned and prepared during the past year. The outcomes of PROM data in the BRIMP will be evaluated during the second half of 2020.

4. Report to Industry

In co-operation with the RC, the BRIMP has created different report models for the report intended for the implant-manufacturing industry. Data regarding complications and reasons for re-operation of specific manufacturing company's products are compared to the aggregated data in the BRIMP. The manufacturer Allergan has purchased the report from the BRIMP, and it has been delivered twice during 2019. Two other implant-manufacturing companies, Mentor and Motiva, have also expressed interest in receiving similar reports and have contacted the registrar about the desired co-operation for the industry report for 2019-2020. RC has prepared a legally correct contract for co-operation with the two implant-manufacturing companies, Mentor and Motiva, in relation to the industry report for 2019-2020. The fee payable covers the actual cost of creating the report for the industry

The Work of the Board and Registrar in 2019

The work of the register in Sweden

The board has met for a face-to-face meeting and two video-telephone conference meetings during the year. The registrar has participated in two meetings with the project management at RC, as well as, participated in around 20 Skype-meetings and had on-going contact via telephone and mail. There was intensive contact with the project management group and the statisticians during the first six months of 2019, so that the work with the preparation of the annual report for 2018 could be completed. The registrar has also held several separate meetings per term with the register co-ordinator to plan the on-going work of the register and the continuing work with participating clinics. The co-ordinator has had on-going contact with the participating clinics nationally to provide support with the work of the register.

The registrar has shouldered the principal responsibility for the work concerning the compilation of the annual report, the analysis of relevant data, the writing of manuscripts and the arranging an English version of the report. In addition, the registrar has participated in the national and international working groups for BIA-ALCL and ICOBRA.

Co-operation with the Industry

During the past year the compilation of a report for the implant manufacturing industry has demanded several meetings and a significant amount of time, as the registrar has been involved in contact with representatives from the industry and the project management group at RC.

Presentations

The BRIMP has received increased attention internationally and the registrar has held presentations on the outcome variables and data in the BRIMP at national plastic surgery conferences in the Nordic countries, as well as, at the ALCL meetings in Rome and Bruges. The registrar was elected by the European Association of Anaesthetic Plastic Surgery Associations (E(A)SAPS) to "Chair of the Scientific Committee", which has facilitated good marketing on a European level of the BRIMP via the (E(A)SAPS) homepage. The registrar was also elected to the position of "President Elect for (E(A)SAPS) at their 2019 meeting in Bruges. Apart from the different plastic surgery meetings, the registrar has, also held presentations about the results from the BRIMP at her own clinic at Karolinska University Hospital.

International Collaboration

Since the beginning of 2017, the registrar has been involved in a collaboration with the Dutch and Australian Breast Implant Registers, which are part of a larger association of several European breast implant registers, the International Collaboration of Breast Registry Activities (ICOBRA). During 2019, the registrar participated in 12 video meetings, with the goal of creating a register with a common data set of relevant variables. Part of this process involved several rounds of evaluating questionnaires, as a basis for achieving consensus about the importance of

specific variables. The BRIMP's experiences as a register at the cutting edge were very much appreciated. This collaboration has resulted in four scientific publications.

Economy

SKR has reduced the economic support to all quality registers in Sweden, so the question regarding how the economic situation is to be solved is always ever present and is on the agenda and discussed at every board meeting of the BRIMP. The BRIMP is not a profit-making organisation and is independent of the implant-manufacturing industry. During 2019, the registrar has participated in four telephone conferences with the economists from the RC regarding evaluation of the BRIMP's expenses and two telephone conferences with lawyers from the RC to check on contracts with the industry. We have managed to maintain the budget by adhering to a strict work plan.

Coverage

The credibility and reliability of a quality register depends, to a large extent, on the coverage of that which is being measured. For the BRIMP, it is principally, all re-operations that have been performed that are registered, as this allows for the possibility of estimation of risk and provides information about eventual indicators for re-operation. It is also important for the BRIMP to register primary operations, as these are essential for estimating risk and for finding explanations in the data registered concerning the reasons for re-operation.

The challenge for the BRIMP is that information and data concerning primary operations and re-operations is not collected in the National Board of Health and Welfare's Patient Register (Socialstyrelsens patientregister), which makes it difficult to calculate the coverage of the BRIMP register. During 2020, the BRIMP intends to explore the possibility of determining the quality of data registered in the BRIMP primarily for re-operations.

The BRIMP is a relatively new register in Sweden and experience tells us that between 5-10 years are needed for a quality register to consolidate. It must be pointed out, that surgeons in private practice register in the BRIMP voluntarily and it demands a considerable contribution each year to motivate colleagues to continue their participation. Unfortunately, there are no other incentives available to encourage these clinics to continue entering data other than their good will to continue contributing their clinics important data to the BRIMP. In other countries, for example, Great Britain and Australia, participation in quality registers is a legal requirement, which makes it easier to run a quality register. In the public hospitals, colleagues are very hard pressed with work commitments and delivering medical care. A state regulation would ensure a better continuity of participation in the BRIMP. A lack of staff and tough budgetary constraints for saving have not made the work of the register any easier. The best solution would be if the necessary data could be extracted from the existing journal systems automatically, as this would save much work. For this to be possible, it would require a harmonisation in the way patient records are completed and kept in the country.

Approximately 80% of patients have their surgery in private healthcare and pay for the surgery themselves. It is of the utmost importance that the medical care given is safe for the patient and that equality of care can be offered to all women who receive a breast implant, regardless of their diagnosis or healthcare provider.

QUALITY OF DATA AND SAMPLE CONTROLS OF THE ANNUAL REPORT 2019

The general aim is to show the BRIMP data for primary operations and re-operations for implant-based operations, as well as, to be able to present a risk analysis for specific parameters supported by the data reported in the register.

As a preparatory step in the current work, a control of the data quality in the BRIMP was carried out in the actual register, with the aim of clarifying eventual incorrect observations (Figure 1). For example, excluding all patients who had more than one entry per page in the primary operation section of the database, as well as patients with re-operation dates prior to their primary operation date. A flowchart showing the processing of the data is shown below.

Therefore, operations which lack an operation indication will not be reported in the graphs of the annual report. This applies to 991 patients in 2014 and 35 patients in 2015. In the risk analyses, we have excluded patients who lack an entry for their primary operation in the BRIMP.

We have chosen to divide up the outcome data from reported benign breast conditions in indication group A and cancer conditions in indication group B. In accordance with previous annual reports we continue to report data from primary operations and re-operations.

The extraction of data from the register for the annual report was conducted on 24th February 2020. Register entries occurring after this date are not included in any of the analyses. The time difference in registration of data after operation differs widely between the different clinics and for the different time periods. In some cases, the entry of data into the register can take place several months after the actual operation date. After the extraction of data, entry of data for 2019 has occurred and as the cut-off date was 24th February, these are not included in the analyses.

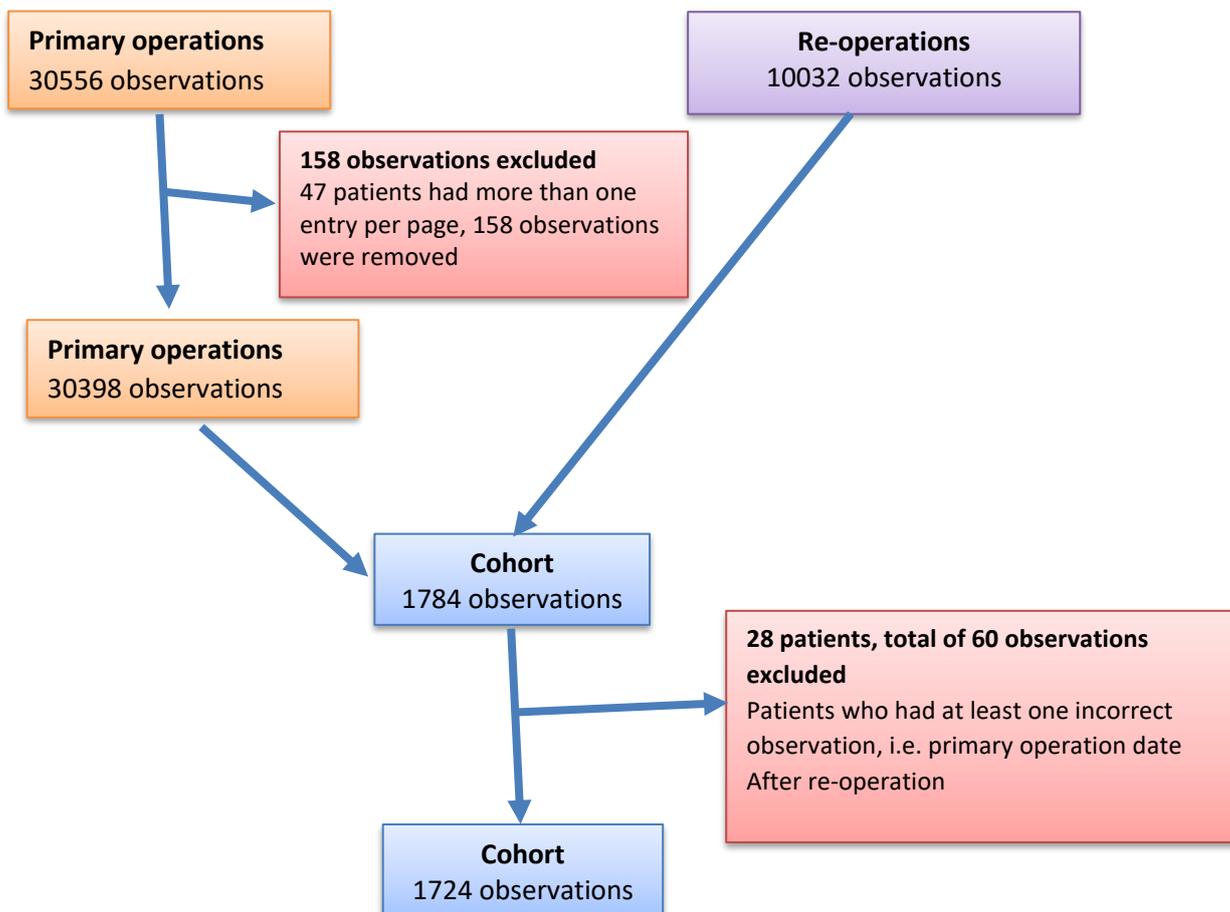


Figure 1. Flowchart showing the preparatory analysis for the 2019 annual report

PRIMARY OPERATIONS

The distribution of indications for operation are shown in Figure 2. In group B, 2124 breast implants are reported and in group A, 25333 breast implants.

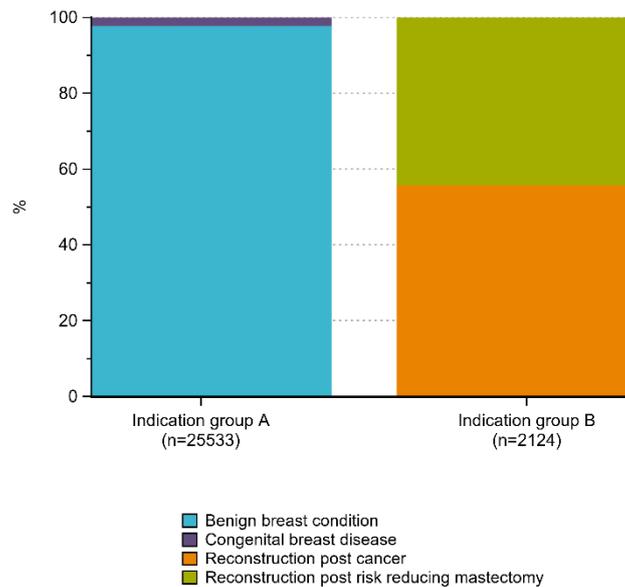


Figure 2. The distribution of indications for operation for primary operation

Indication group B; implant-based primary operations for breast reconstruction

The indication group B reports data from implant-based primary operations for cancer or risk-reducing mastectomies, carried out on the basis of the presence of the BRCA- gene. These patients undergo surgery within the publicly funded healthcare system in Sweden. A general national recommendation or consensus regarding the choice of implant manufacturer or the type of implant has not been reached during the past year. Some health providers have advocated the use of smooth implants for this patient group, in view of the prevalence of BIA-ALCL in connection with textured implants. The number of patients in group B has over the years been relatively stable, as has the number of implants. Grouping this data together with the data in the breast cancer register will increase the amount of reported data.

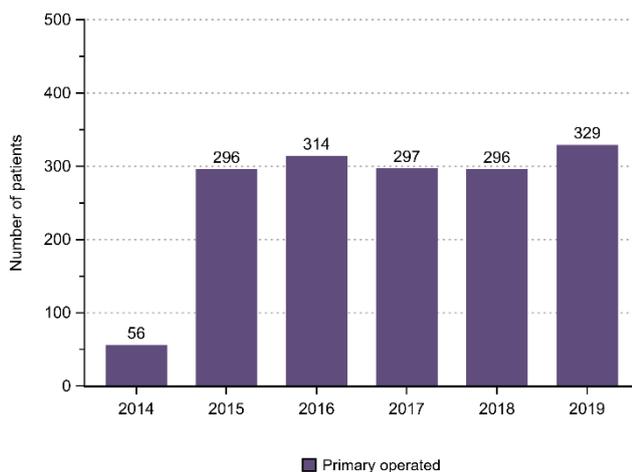


Figure 3a. The number of patients having primary operations due to cancer or BRCA 2014-2019

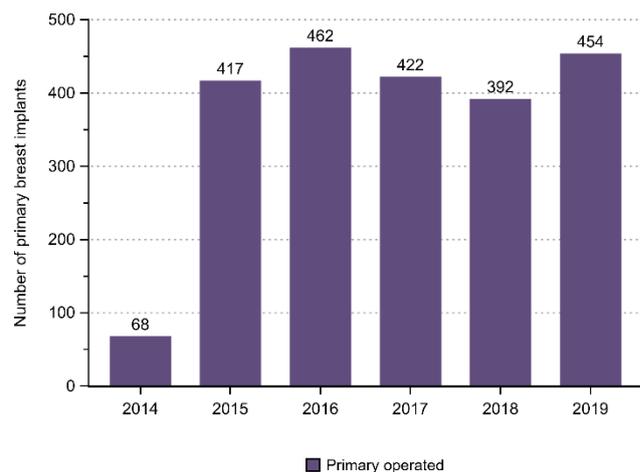


Figure 3b. The number of primary operations of breasts resulting from cancer or BRCA 2014-2019

The reported age distribution in the BRIMP 2019 does not differ from the figures reported in 2018. As expected, a majority of patients are middle-aged (Figure 4). Actual data confirms that patients in the age group >41 years show a larger proportion of overweight patients in group B (Figure 5). Compared to the figures for 2018, the number of permanent expander prostheses inserted has decreased from 50% to 36.5% in 2019 (Figure 6)

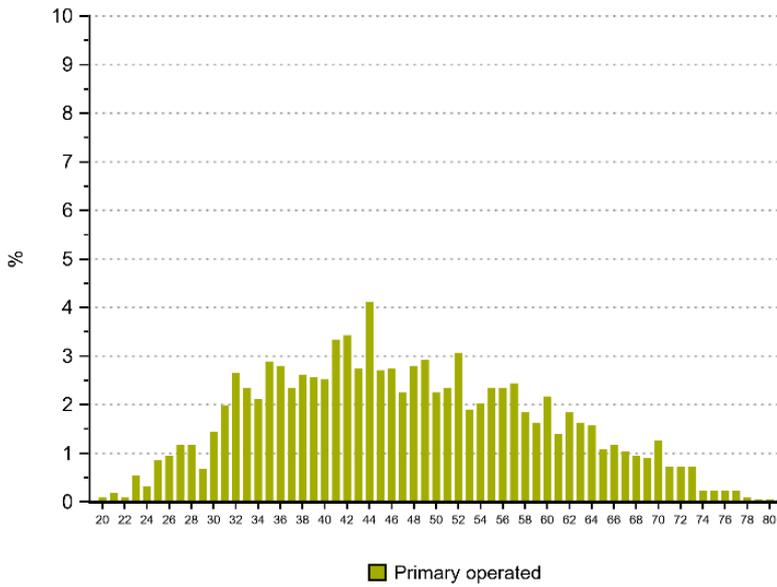


Figure 4. Age distribution of cancer patients in the BRIMP, 2014-2019

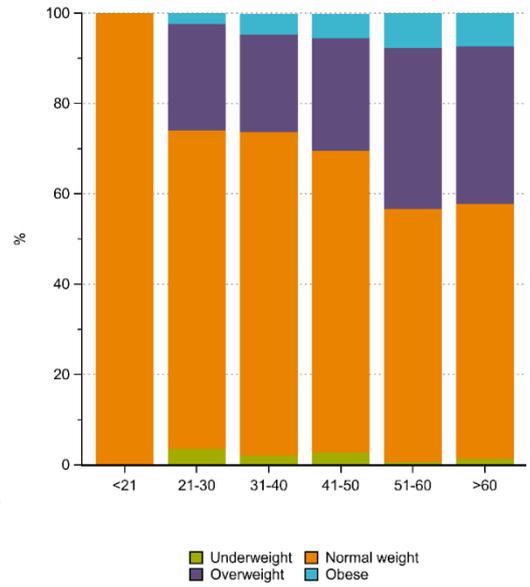


Figure 5. BMI in the different age groups having reconstructions 2014-2019

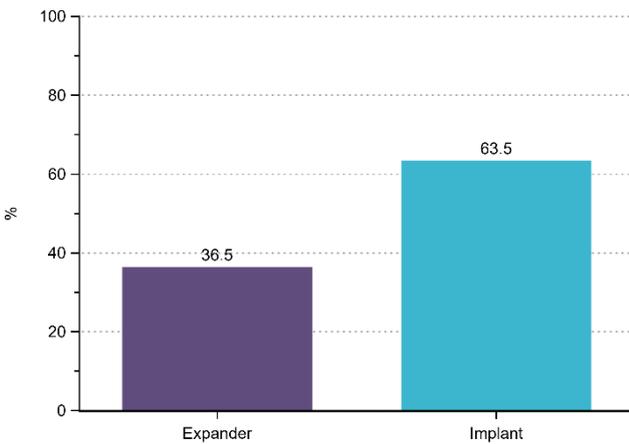


Figure 6 The proportions of expander prostheses and implants used, the BRIMP 2019

In Sweden, the Mentor brand is predominately used for reconstruction surgery. The proportion of smooth implants used in 2019 was 10% lower than textured implants (Figure 7). Anatomical implants from Mentor were preferred to round shapes (Figure 8). Few patients expressed dissatisfaction with breast shape or alternatively the combination of shape and volume, or breast pain in patients who had a cancer diagnosis or genetically increased risk for cancer (Figure 9).

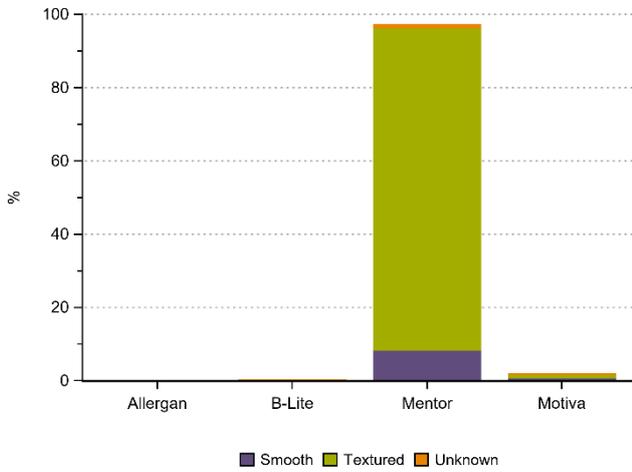


Figure 7. The proportion of smooth vs textured implants 2019

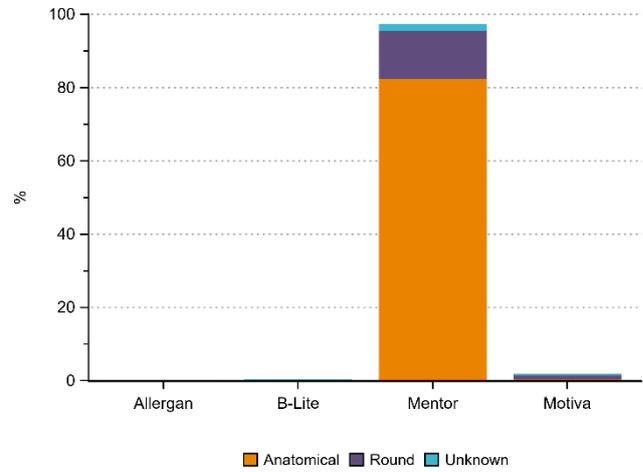


Figure 8. The proportion of round vs anatomical implants 2019

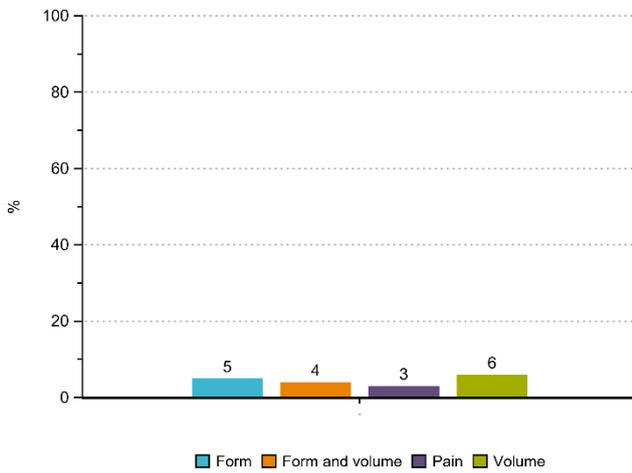


Figure 9. The proportion of dissatisfied patients with pre-operative shape, shape/volume, pain in the breast 2014-2019 (cancer diagnosis)

Implant-based operations in combination with fat transplantation, so called hybrid operations were entered at the primary operation and 118 breasts are registered in the database (Figure 10). Implant volumes up to 399 gr were mainly combined with this technique, although even larger implants volumes > 400 gr were noted in 26 breasts.

The use of net in combination with breast implants has not experienced any large breakthrough in connection with reconstructive surgery, as the data in Figure 11 shows. The proportion of benign breast augmentations combined with net was 14%.

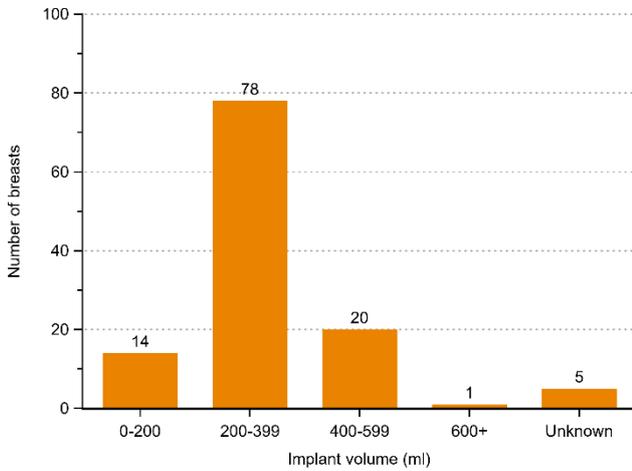


Figure 10. The number of breasts irrespective of indication group undergoing primary operation with hybrid technique 2014-2019

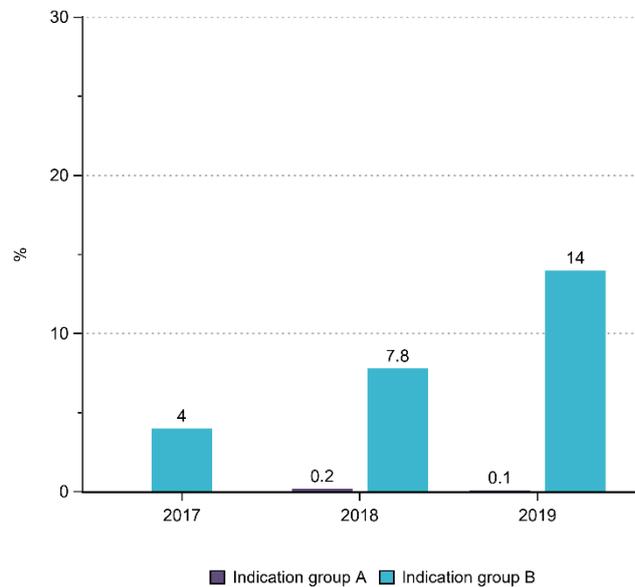


Figure 11. The proportions of net usage in reconstructive operations 2014-2019

Pre-operative antibiotic treatment is routine for reconstructive implant-based breast reconstruction. Data in the BRIMP shows that 70% of these patients are treated per-operatively and 30% pre-operatively. The definitions of “per- and pre-operative” are probably not used totally correctly when reporting data. Information regarding this definition will be sent out again to the users of the BRIMP. Generally, we can say that patients are receiving good antibiotic coverage prior to the insertion of their implant (Figure 12). Data regarding intraoperative antibiotic irrigations of the prosthesis cavity or the prosthesis itself before insertion suggest that providers do not live up to the national treatment recommendations for reconstructive surgery. Antiseptic irrigation is today not permitted within the public healthcare system.

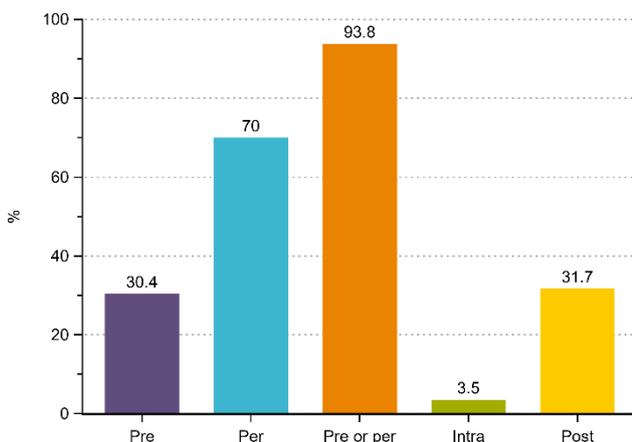


Figure 12. The use of antibiotics in conjunction with reconstructive implant operations 2019

Indication group A; Implant-based primary operations for benign conditions of the breast

The number of primary operations in the BRIMP has decreased during the past year. The figures are probably, to a certain extent, a consequence of the general concern about the implications of implants short- and long-term effects in the human body and reports about BIA-ALCL and “breast implant illness” in social media and the press (Figure 13).

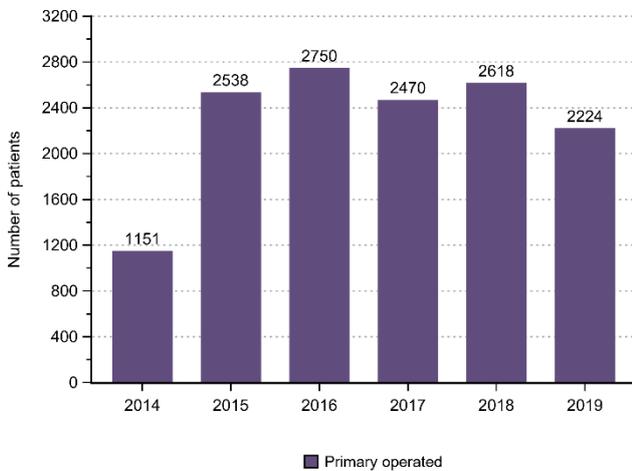


Figure 13a. The number of patients in the BRIMP who received a breast implant 2014-2019

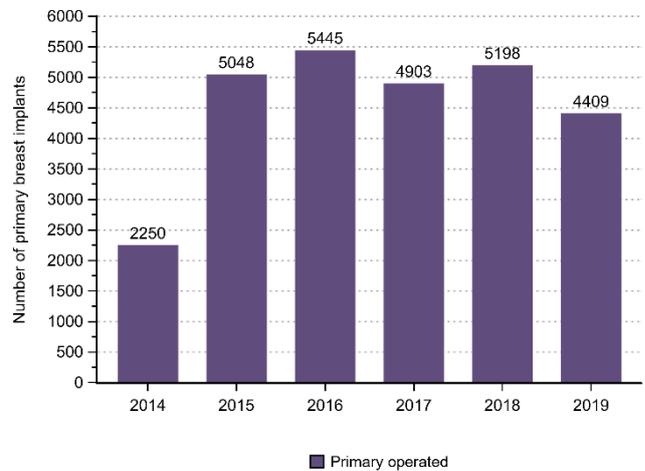


Figure 13b. The number of primary operations for breast implants 2014-2019

The age distribution of patients undergoing primary operation corresponds well to data reported previously (Figure 14). The BMI distribution in the different age categories does not deviate from data reported previously (Figure 15). Patients undergoing primary operation were mainly in the age group 21-40 years with a relatively even distribution in all weight categories according to the WHO. This data has remained constant over the years.

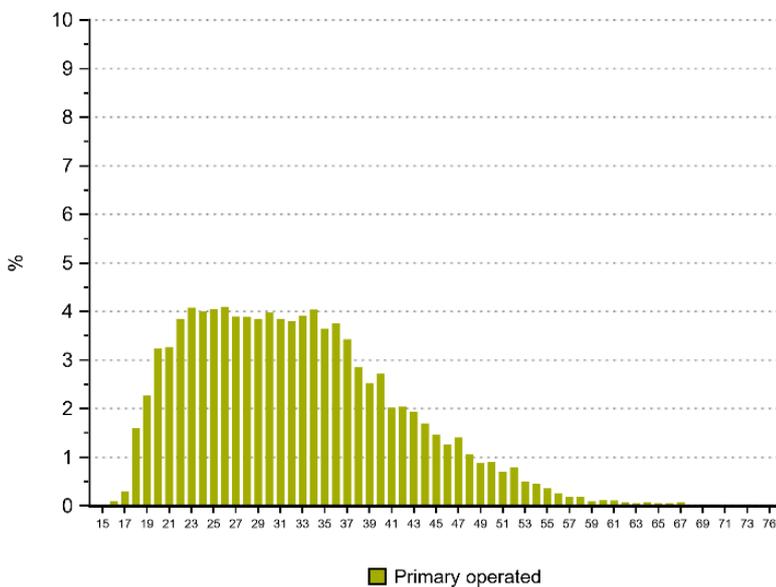


Figure 14. The age distribution at primary operation for patients with benign conditions of the breast

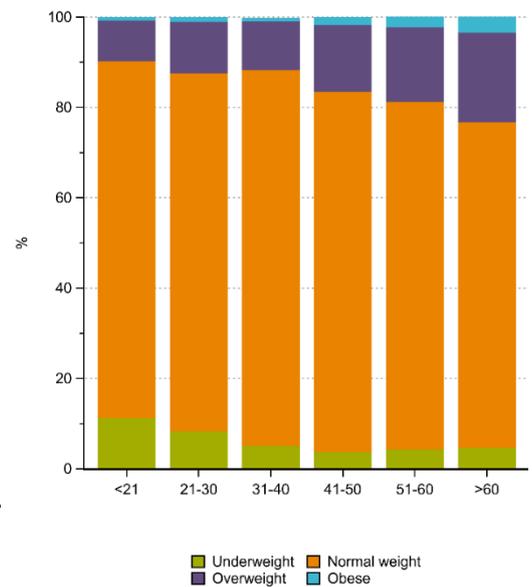


Figure 15. BMI in relation to age at primary operation

Mentor and Motivas brands are well represented in Sweden for benign conditions (Figure 16). A small number of Polytech implants have been registered in the BRIMP in 2019. Motivas market share has increased as a result of Allergans recall of products in 2019 and the general concern regarding textured implants. Anatomical and round implant shapes have been used in equal quantities. Compared to 2018, more smooth implants from Mentor have been used, although the proportion reported in the BRIMP is still below 20% (Figure 17).

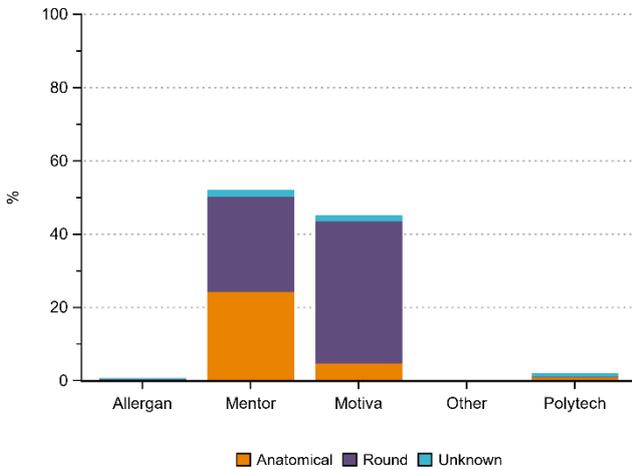


Figure 16. Use of implant type and manufacturer for primary operations in the BRIMP 2019

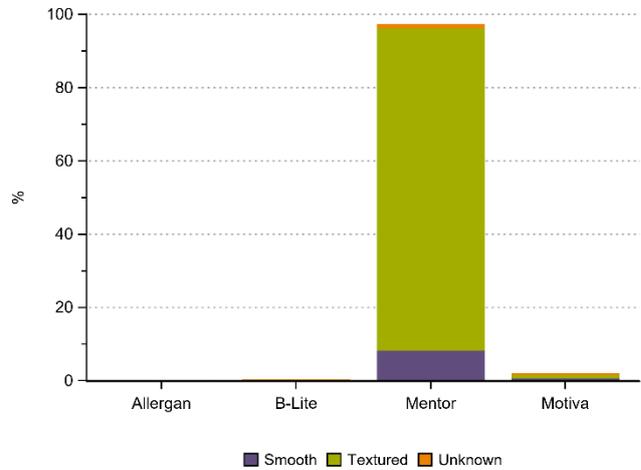


Figure 17. Proportion smooth/ textured implants in the BRIMP 2019

Patients with benign breast conditions reported dissatisfaction with shape and volume to a greater extent than patients who underwent reconstructive surgery. The difference between preoperative patient experience in group B is significant. Only 1% of patients in group A had chest pain prior to surgery (Figure 18).

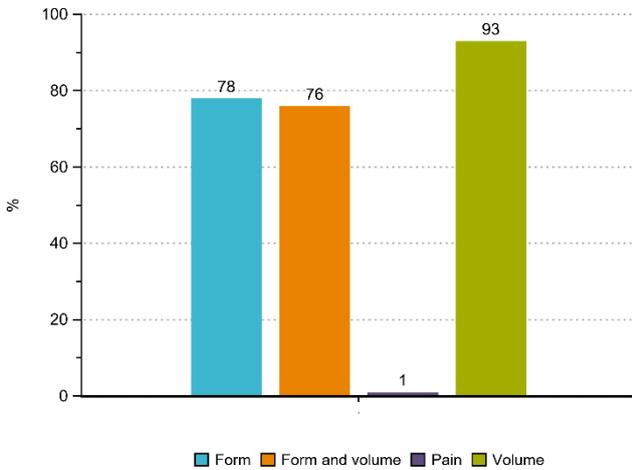


Figure 18. Patient-reported dissatisfaction with breasts before primary operation 2014- 2019

Antibiotic use is standard in conjunction with the primary insertion of implants for benign conditions of the breast. Irrigation of the implant cavity or implant before insertion is, however, not the national standard but occurs in 22% of primary operations in group A (Figure 19). There has been a significant increased tendency toward irrigation compared to 2018.

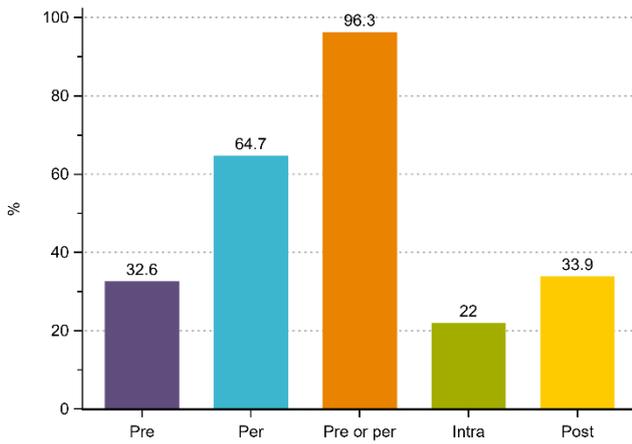


Figure 19. Antibiotic usage in primary operations and benign conditions 2019

RE-OPERATION

BRIMP'S variable "indication" at primary operation and re-operation

The BRIMP contains data from a total of 5,465 admissions where patients have undergone re-operation, irrespective of the date and indication (Figure 20) for the primary operation. Figure 21 shows that between 2014-2019, 9790 implants were revised, irrespective of the date of the primary operation. Patients with a re-operation date prior to the primary operation date were excluded from the cohort containing primary and re-operation data, but not from the re-operation data. Patients with benign indications are presented in the indication group A and cancer patients or risk-reducing mastectomies are presented in group B. Data concerning indication has been taken from the primary operation and has been an obligatory variable in the BRIMP since 2015. During 2014 and 2015, some patients' entries are missing the "indication for operation" in the primary operation data. This occurred prior to the variable becoming obligatory. As well as these patients, there are some patients who are missing the indication data in the re-operation data section, as they did not have a known indication in the primary operation data section of the BRIMP.

It is important to consider that the same individual patient or implant can have undergone revision several times and can appear in the register in the different year columns.

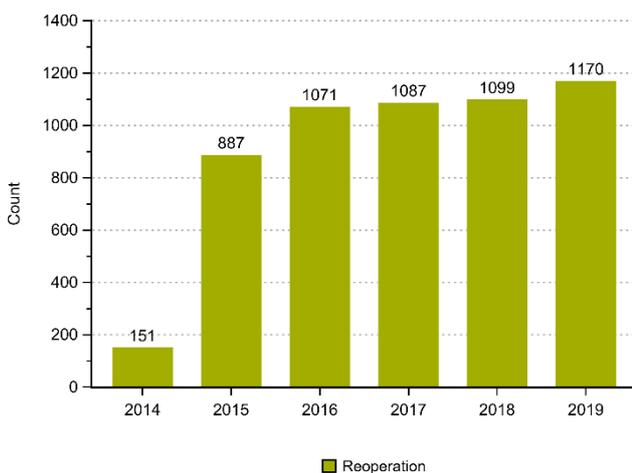


Figure 20. The number of revised patients in the BRIMP 2014- 2019

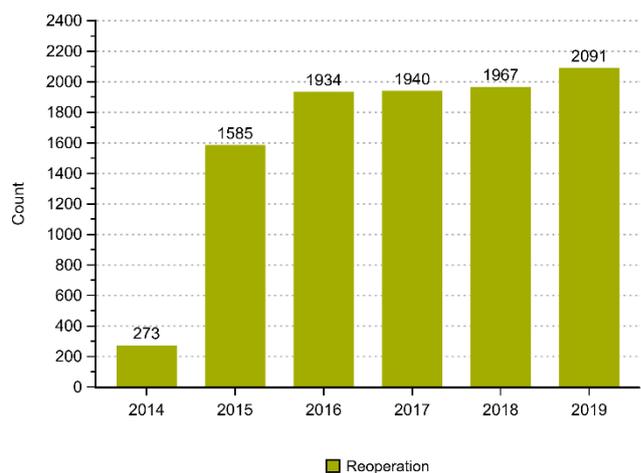


Figure 21. The number of revised implants in the BRIMP 2014- 2019

The patient collective in the BRIMP with both primary operation and re-operation, the cohort 2014-2019

The majority of patients registered in the BRIMP for a primary operation have not undergone revision (Figure 22). Generally, most patients are very satisfied with the choice and the outcome of their operation. It is also important to look at the reasons for re-operation from both the patient’s and the specialist’s perspective.

Over the years, we have seen that the data in the BRIMP is reliable. For example, it has been noted that the proportion of implants that are revised within a specific time frame after the primary operation has remained constant in the BRIMP’s total database (Figure 23). The figure for revisions within 2 years remains constant at 30% and at 36% for revisions within 10 years after the primary surgery. This result is in keeping with previous reports.

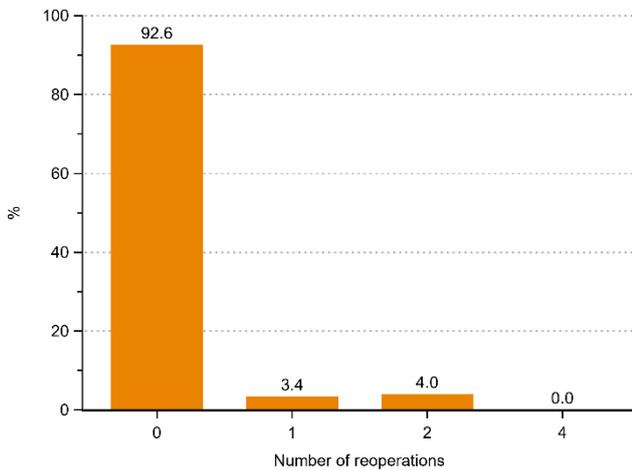


Figure 22. The number of re-operations per patient av all patients registered as a primary operation, shown as the proportion of patients 2014-2019

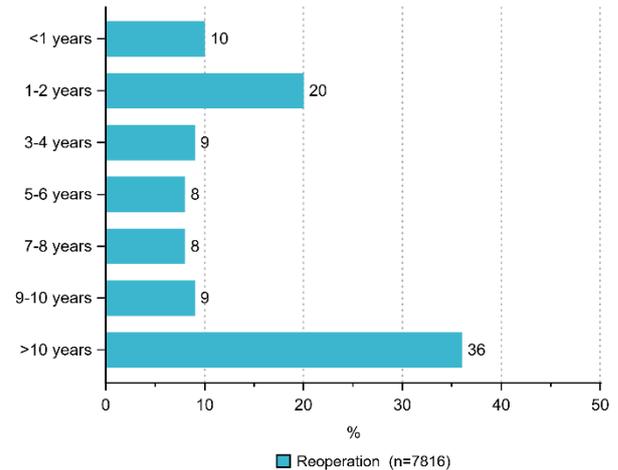


Figure 23. Time to revision of implant, based on re-operations in the BRIMP and information about when actual implant was inserted

Patient-reported problems and the motivation for re-operation

The comparison of patient-reported problems in the cohort 2014-2019, showed that a larger proportion of patients in group B experienced symptoms such as pain, hard breasts and even the desire for a shape change in comparison to the patients in group A. Volume changes as was the most common reason for re-operation in group A (Figure 24a, 24b). Please note that an individual patient may have given several symptoms/problems as reasons for their re-operation. Noticeably, patients in group B have problems with questions about breast symmetry which is mirrored in the desire for changes in form and volume of the reconstructed breast and the breasts consistency which is shown as the proportion of “hard breasts”. Questions regarding breast appearance have not been an important aspect for this patient group, and neither did these patients report painful breasts pre-operatively.

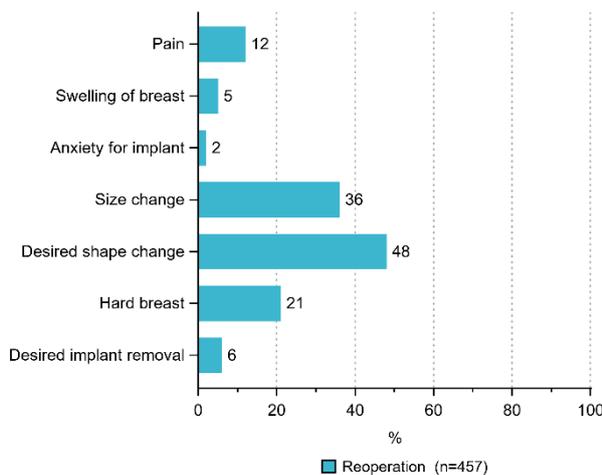


Figure 24a. Patient-reported problems per breast for Group A (benign conditions)

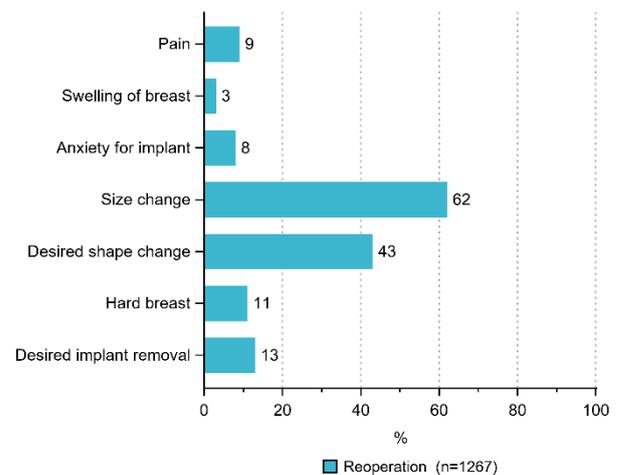


Figure 24b. Patient-reported problems per breast for Group B (cancer diagnosis)

Antibiotic treatment in conjunction with re-operation for the cohort 2014-2019

At re-operation all patients in both groups received antibiotics in conjunction with their operation. Around 20% of patients were even treated with intra-operative antibiotic irrigation in group A and 3.4% in group B. Interesting to note is that even a significant proportion of patients in group A and B received antibiotic treatment post-operatively (Figure 25a, 25b). A comparative study using data from the National Medical Product Agency gives information about the type and length of antibiotic treatment which can be related to the effect of the treatment.

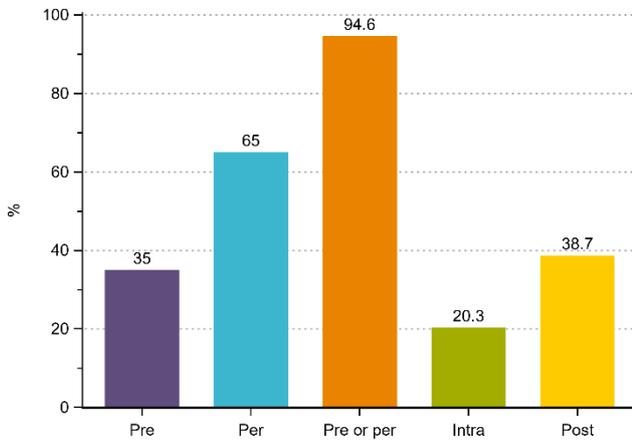


Figure 25a. The proportion of patients treated with antibiotics in conjunction with re-operation in group A 2014-2019

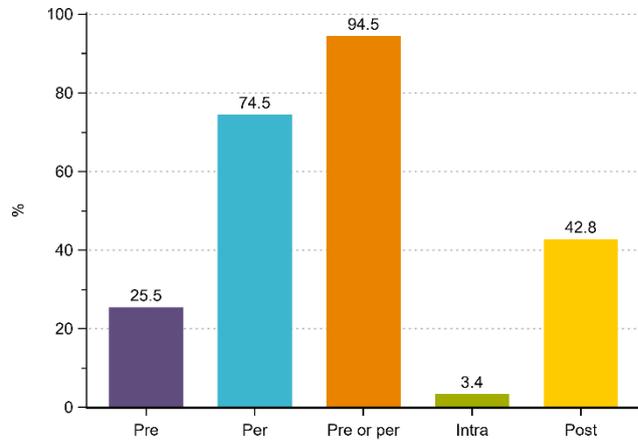


Figure 25b The proportion of patients treated with antibiotics in conjunction with re-operation in group B 2014-2019

Intra-operative findings at re-operation for cohort 2014-2019

All the data, which are production figures as reported in the BRIMP and not a risk analysis. The proportion of intra-operative observations concerning ruptured implants was reported at 3.1% for group A and 0.7% for group B. The proportion of mal-positioned implants was higher in group B, 14.7% versus 10.5% in group A. Capsule-formation requiring treatment was also more commonly observed in group B, whereas double capsules occurred more frequently in group A (Figure 26a, 26b). The proportion reported as “unknown” means that 63.8% in group A and 58.7% in group B did not report findings shown in Figure 26a and 26b (implant rupture, mal positioning of implant, capsule problem, seroma or haematoma).

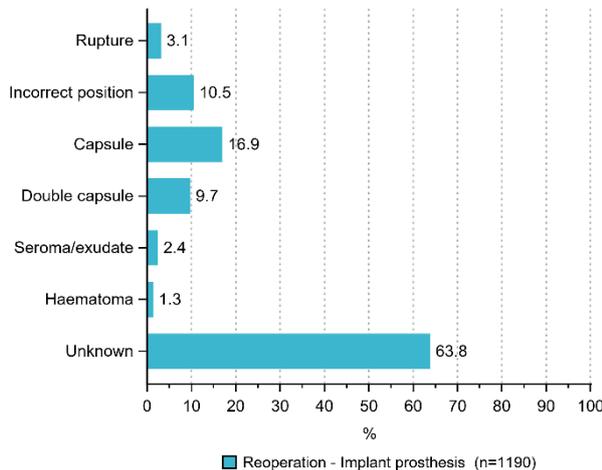


Figure 26a. Intra-operative findings in group A 2014-2019

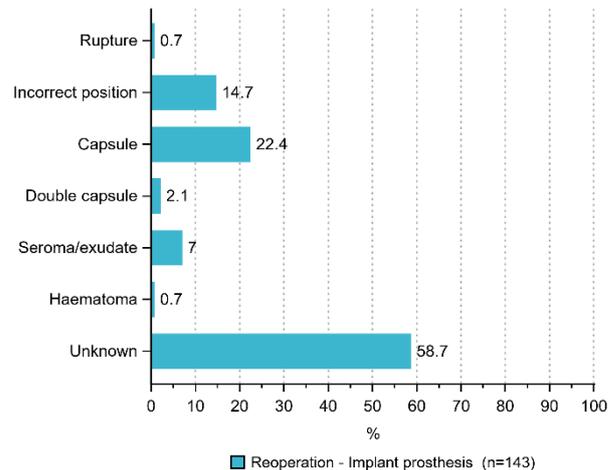


Figure 26b Intra-operative findings in group B 2014-2019

APPENDIX

The occurrence of capsule formation, rupture and rotation in the cohort 2014-2019

The following analyses mirror the proportion of specific implants in relation to the number of revised breasts. It is a given, that if a specific problem with a specific make of implant had occurred during the period of 5.5 years it would have shown up in the data. Thus, the following observations can be regarded as a contribution to “post-market surveillance”. It is important to understand, even in this instance, that it is not a risk analysis but rather a description of a proportion.

The analysis of the proportion of capsule formation, rupture and rotation in relation to the geometry of the implant make showed that the proportion of capsule formation with anatomical shapes differed between revised implants from Mentor and Allergan in group A. Though, please note that the number of cases using anatomical shapes is low for Motiva’s products in group A (Figure 27a). Mentor’s make dominates in group B and the distribution of intraoperative findings is shown in Figure 27b.

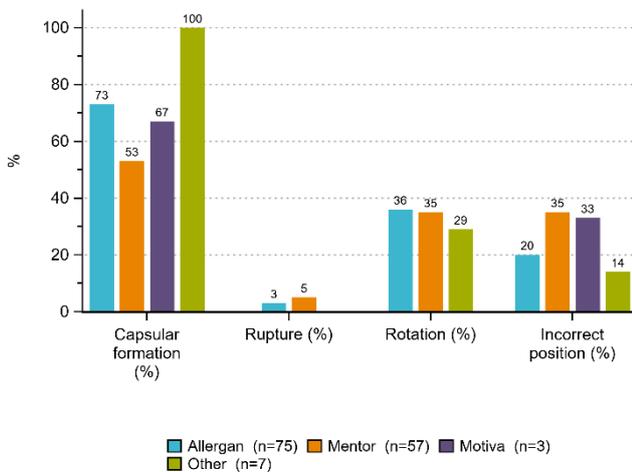


Figure 27a. Intra-operative findings when using an anatomical implant in group A

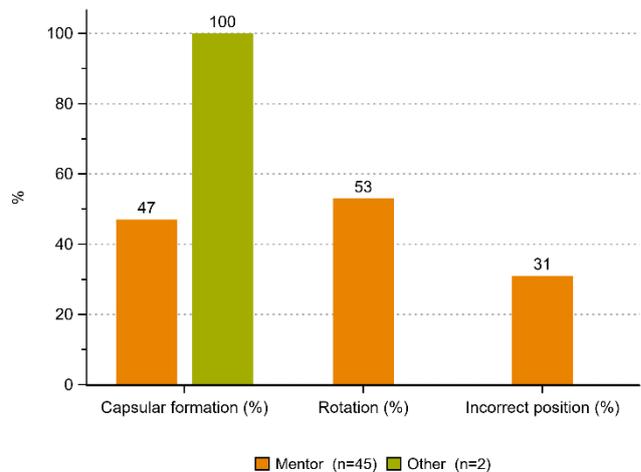


Figure 27b. Intra-operative findings when using an anatomical implant in group B

The proportion of round *Allergan* implants requiring measures to be taken for capsule formation was larger than *Mentor*’s products at revision. In group A, it was shown that 16% of *Motiva* implant ruptured and 9% of *Mentor* implants, while the figure for rupture was 7% for the round *Allergan* implant and 22% where the make was unknown to the surgeon (Figure 28a). Round *Motiva* and *Mentor* implants seem to give rise to re-operation because of “mal-positioning”. These figures will be followed prospectively. Data for group B is shown in Figure 28b and it speaks for itself.

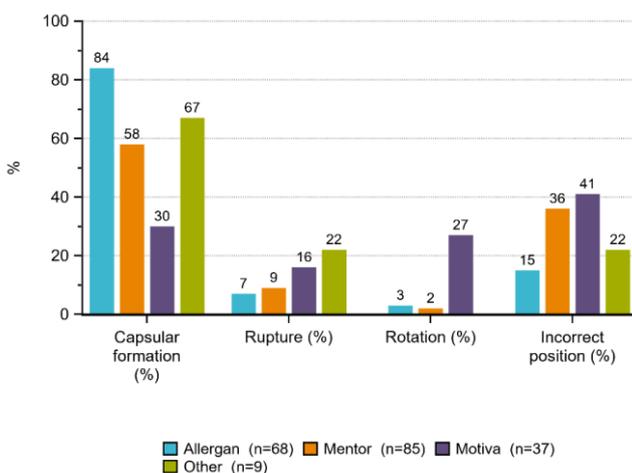


Figure 28a. Intra-operative findings when using round implants in group A, 2014-2019

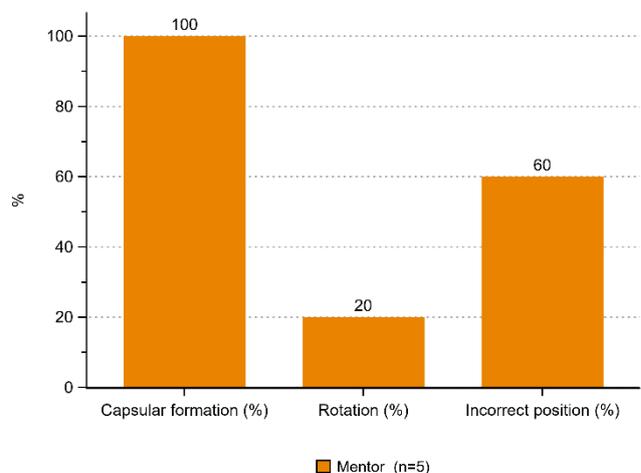


Figure 28b. Intra-operative findings when using round implants in group B, 2014-2019

Data for the permanent removal of implants in the BRIMP and for the cohort 2014-2019

The number of patients who request permanent removal of implants has risen over the years. Figure 29 shows the distribution of voluntary breast implant removal over the years, irrespective of the date of the insertion of the primary implant. In the 2014-2019 cohort, a time span of 5.5 years, it is clear, that the voluntary removal of implant has increased for patients in group A since 2017, while in group B it has remained relatively constant over the years, with the exception of 2017 (Figure 30a, 30b).

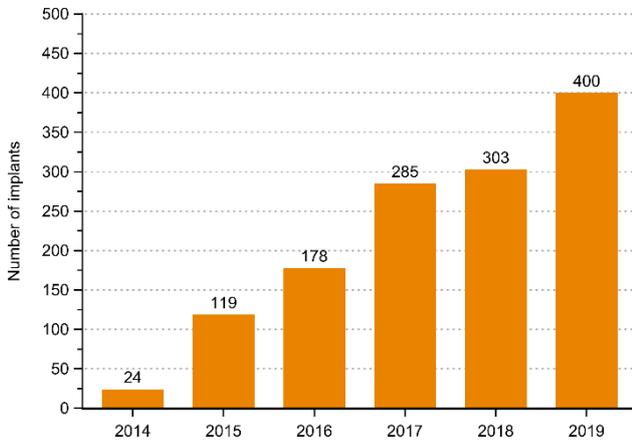


Figure 29. The number of implant removals over the years irrespective of date for index operation and indication, total registration in the BRIMP.

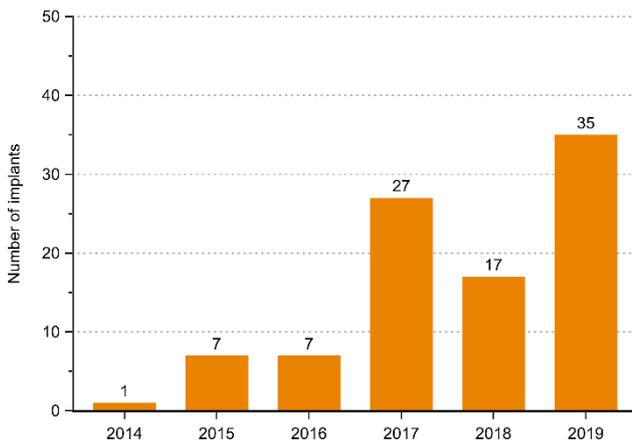


Figure 30a. The number of implant removals in group A, 2014-2019 cohort

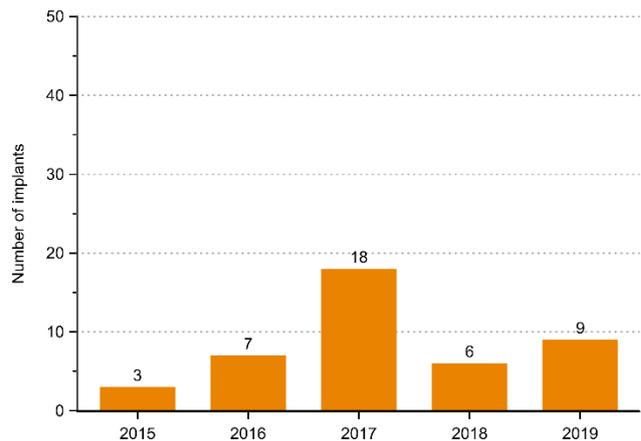


Figure 30b. The number of implant removals in group B, 2014-2019 cohort

The patients’ motivation for removal of implants is multifaceted. Different problems can have arisen and individual patients may have several reasons for wanting the implant removed. Anxiety for the implant has, through the years, been one important reason for requesting removal, together with the experience of the breast becoming hard or painful (Figure 31).

If we look more closely at the age of implants at removal, we have chosen to show the total data in the BRIMP in figure 32a, as well as, selected data concerning group A (Figure 32b) and group B (Figure 32c). The total data is the most interesting to observe. With the exception of “outliers”, the data shows that the implants have been in the womens’ bodies for a considerable length of time, approximately 10 years on average, before the patient decides to have the implant removed. Please note that the y-axis in these figures differ.

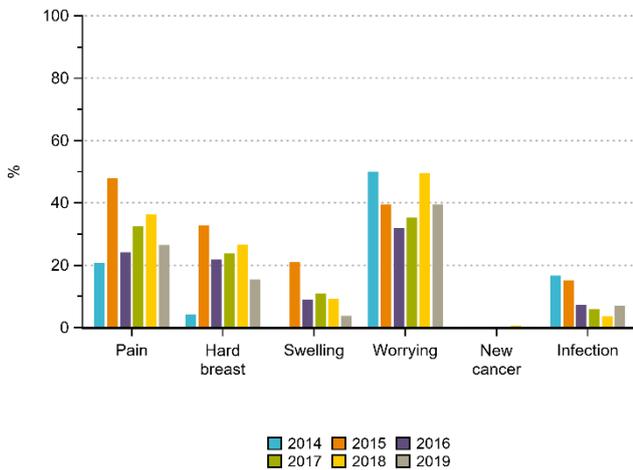


Figure 31. Reasons for voluntary removal of implant regardless of the date of primary operation

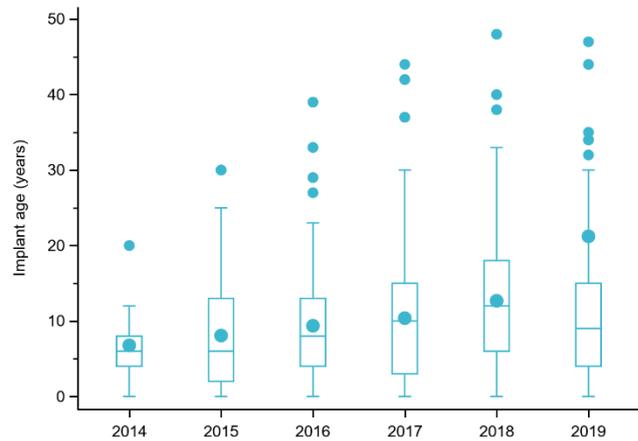


Figure 32a. The age of the implants at voluntary removal, regardless of the date of primary operation

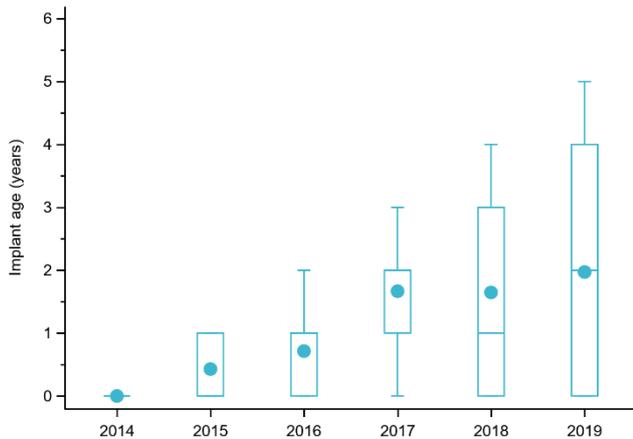


Figure 32b. The age of the implant at voluntary removal in group A, 2014-2019 cohort

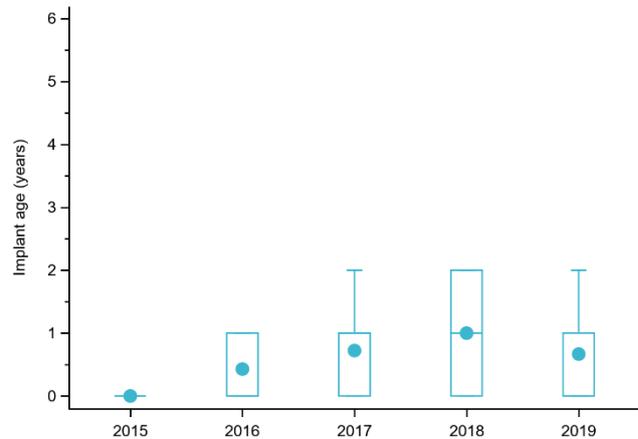


Figure 32c. The age of the implant at voluntary removal in group B, 2014-2019 cohort

THE RISK OF UNDERGOING A NEW OPERATION

The results are comprised of all the data in the BRIMP for patients having undergone primary operation or re-operations during the years 2014-2019, a period of 5.5 years. The risk of the first operation is calculated on the breast level and not on the patient level and is graphically illustrated according to Kaplan-Myer. The statistical analysis was done using logrank tests where $p < 0.05$ was considered statistically significant. Further operations on the same breast are not included in the analysis.

Short-term risk for re-operation

The short-term risk of undergoing re-operation within 60 days is very low, even if a significant difference between the groups was demonstrated. Figure 33 shows that the risk of undergoing re-operation within 60 days due to infection or haematoma is below 1% in both groups. Although group B (0.62%) had a significantly higher risk than group A (0.08%) ($p > 0.05$).

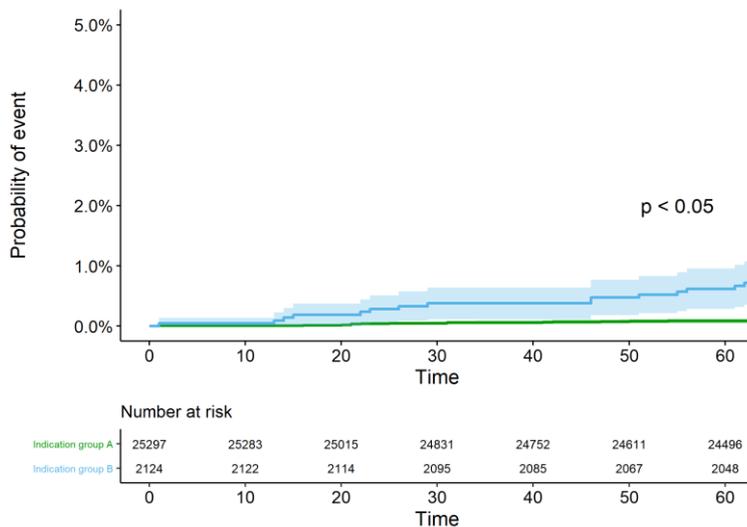


Figure 33. The risk for haematoma or infection within 60 days in the BRIMP, 2014-2019

Long-term general risk for re-operation within 5.5 years

Breast reconstructions done using a permanent expander prosthesis in group B have a significantly higher risk (40.5%) of requiring a re-operation within 5.5 years (=2000 days) compared to those patients with an implant in group B (14%) and A (5.0%) ($p < 0.05$) (Figure 4). Even at the 1, 2- and 3-year follow-up the differences between the groups are statistically significant. These findings, which were evident in the 2018 annual report have now been confirmed.

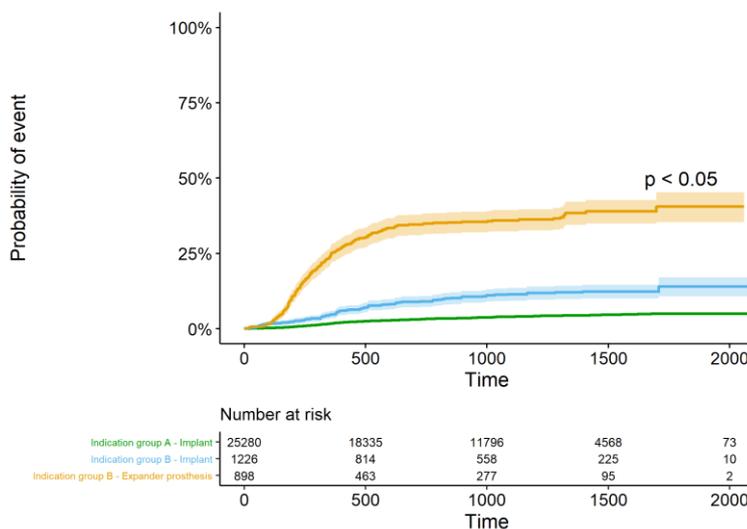


Figure 34. The risk analysis for implant in group A and implant and expander prosthesis in group B, 2014-2019

If we look specifically at what bearing the effect measure “radiation” had on the general risk for re-operation, it was shown to be significant in group B for radiated breasts (29.0%) versus non-radiated breasts (25.0%). The difference between group A (5.0%) and non-radiated breasts in group B was also significant ($p < 0.05$). Significant differences between the groups were also seen at the 1, 2- and 3-year follow-up (Figure 35)

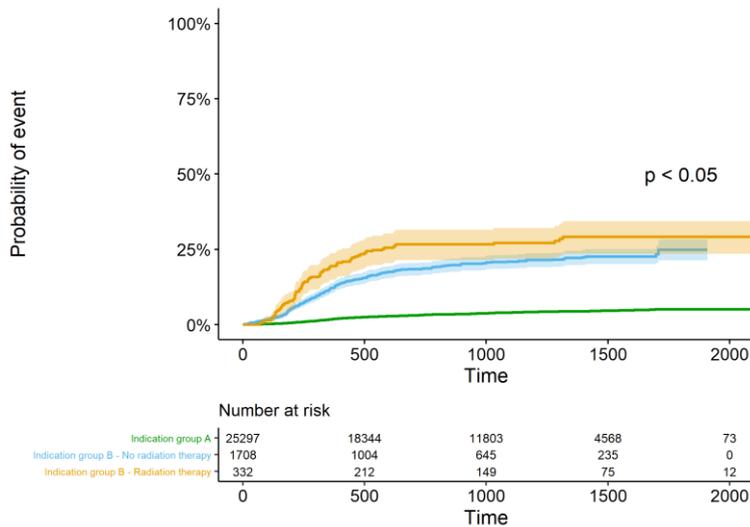


Figure 35. The risk for re-operation in groups A and B for radiation and non-radiation, 2014-2019

Risk analysis for implant-related factors

The evaluation of what effect the variable “implant-shape“ has on the re-operation risk, has shown that 5.5 years after the index operation, there is a higher risk of re-operation with round implants (5.3%) compared to anatomical implants (4.6%) in group A. In group B, the anatomical implants gave a higher risk 16.0% compared to round shapes (6.5%) for the observation time of 5.5 years. The difference between anatomical and round implants is significant ($p < 0.05$) (Figure 36a, 36b). Please note that the calculation has not been done at the manufacturer level.

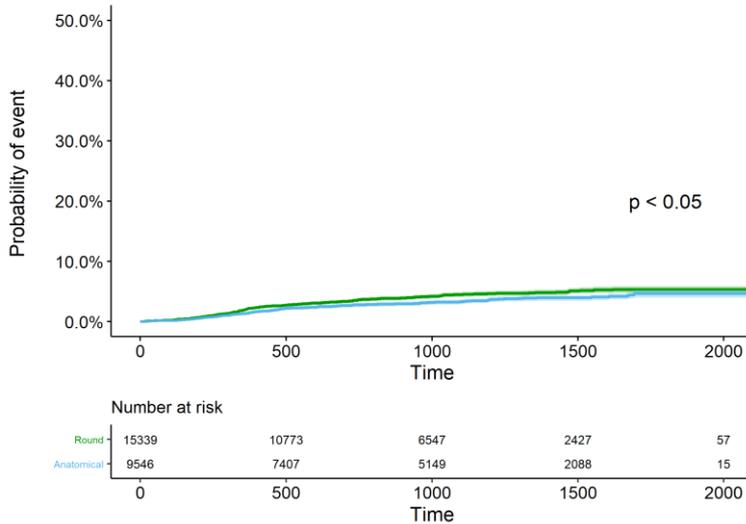


Figure 36a. The risk of re-operation in group A shown in relation to implant shape

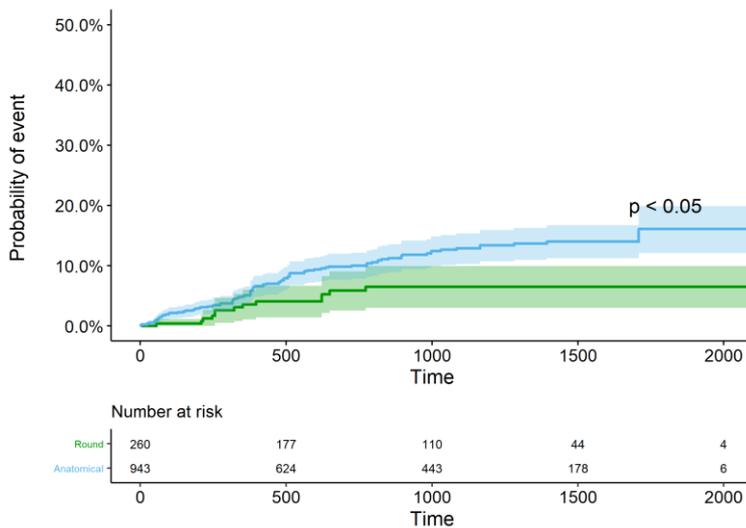


Figure 36b. The risk of re-operation in group B shown in relation to implant shape

The implant surface also has importance for the risk of re-operation. The analysis showed that the risk with polyurethane implants was 9.0%, with textured implants was 5.1% and with smooth implants, the risk was 3.7% after 5.5 years in group A. When considering the same data for group B, it must be remembered that the number of smooth implants is still low in the BRIMP, therefore no definite conclusions can be drawn. Textured implants showed a risk of around 14.5% (Figure 37a, 37b)

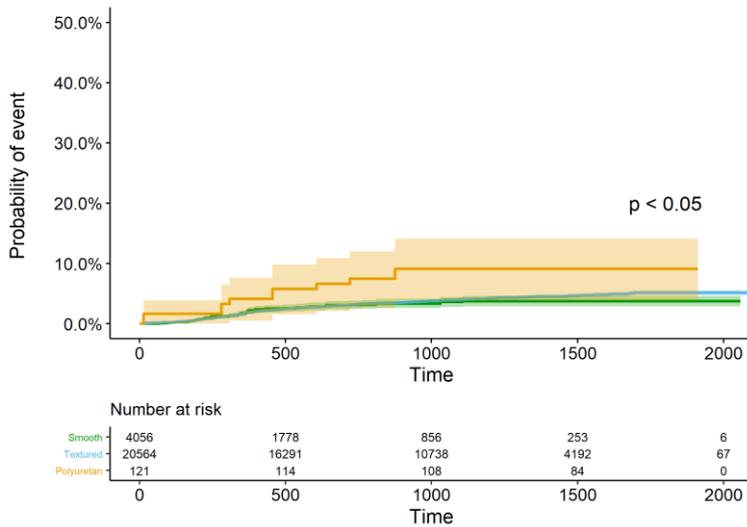


Figure 37a. The risk of re-operation in group A shown in relation to implant surface

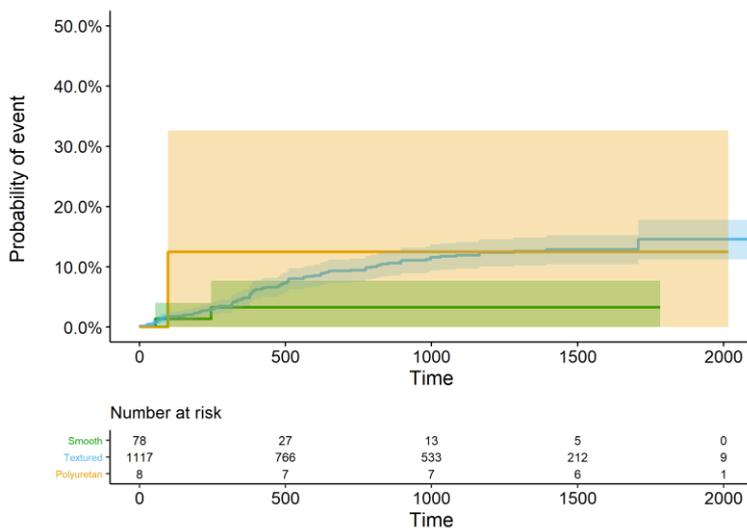


Figure 37b. The risk of re-operation in group B shown in relation to implant surface

During the last few years, we have not been able to see any great differences between the implant manufacturers Allergan, Mentor and Motiva regarding “implant rupture”. The data is graphically represented for groups A and B. Please note that the Motiva products are not used in reconstructive surgery in Sweden. The combined assessment is that the risk for re-operation, due to a ruptured implant is very low within the first 5.5 years after the index operation and was found to be 0.1% for Allergan’s products, 0.13% for Mentor and 0.08% for Motiva (Figure 38)

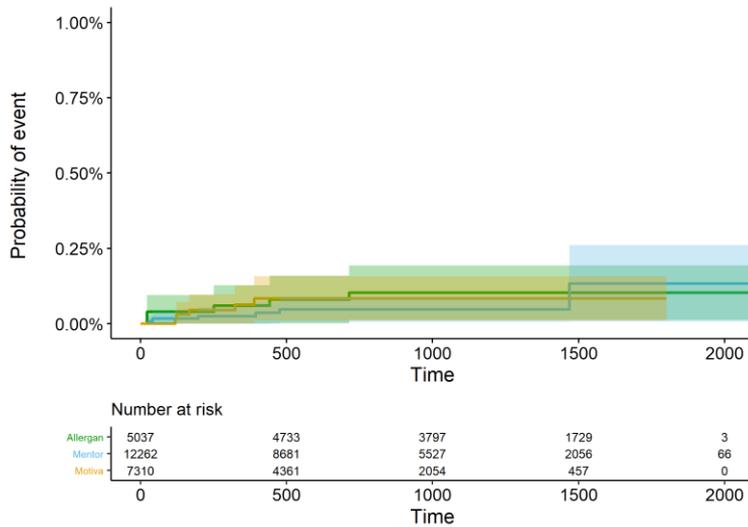


Figure 38. The risk of re-operation due to a ruptured implant shown per implant manufacturer

The risk that a patient requires to undergo a new operation because of capsule formation up to 5.5 years after implant insertion of one of the three most frequently used implant makes in Sweden is assessed to be very low. *Allergan's* risk is 1.95%, *Mentor* has a 0.73% risk and *Motiva* has a 0.34% risk in patient group A. Statistically significant differences occur between manufacturers in group A. In group B, there was a difference between *Allergan's* and *Mentor's* products for radiated contra non-radiated patients, but the difference was not significant. (Figure 39a, 39b,39c).

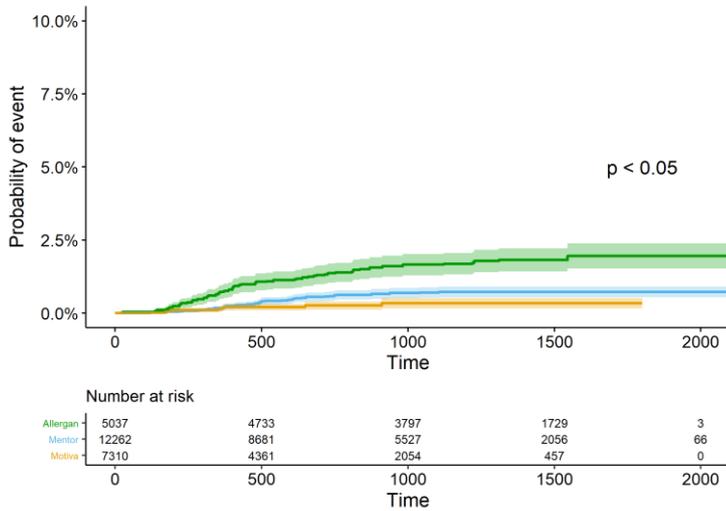


Figure 39a. The risk of re-operation for capsule formation shown per implant manufacturer in group A

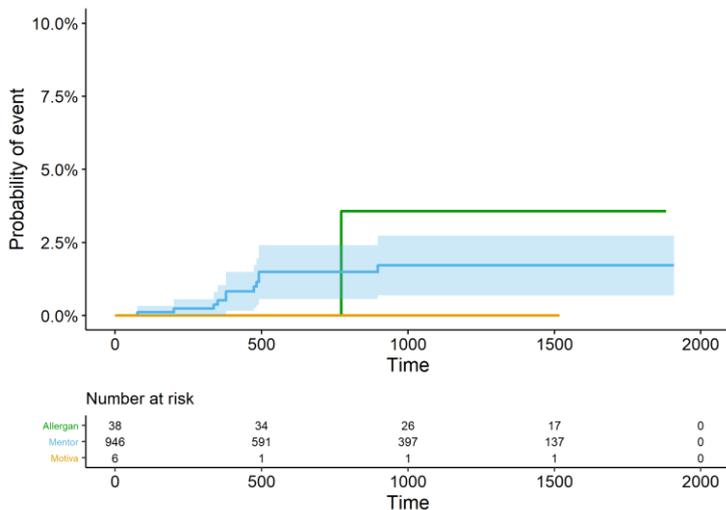


Figure 39b. The risk of re-operation for capsule formation shown per implant manufacturer in group B, non-radiated patients

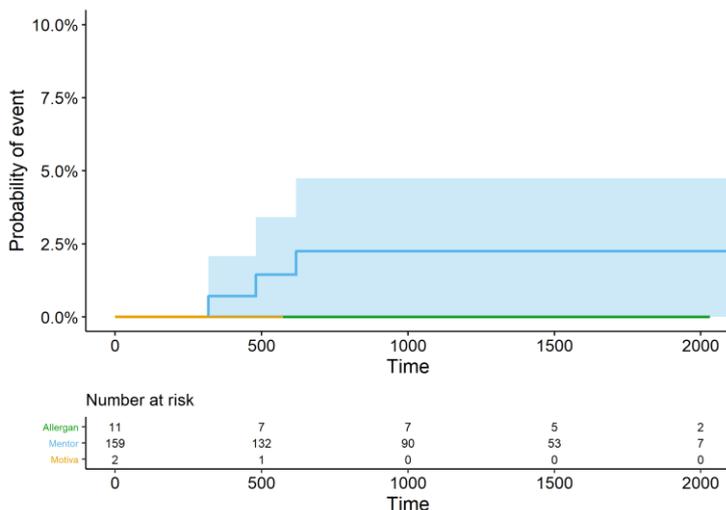


Figure 39c. The risk of re-operation for capsule formation shown per implant manufacturer in group B, radiated patients

Patient-reported symptoms in conjunction with re-operation

Patient-reported problems such as pain were seen more often in patients with reconstructed breasts in group B (2.5%) (Figure 40a). The difference compared to group A (0.26%) was significant, and differences between the groups were seen even at 1, 2- and 3-years after the index operation. The risk for re-operation due to pain and hardness of the breast was significantly higher in group B compared to group A (Figure 40b). It will be interesting to see how these figures compare in an international comparison.

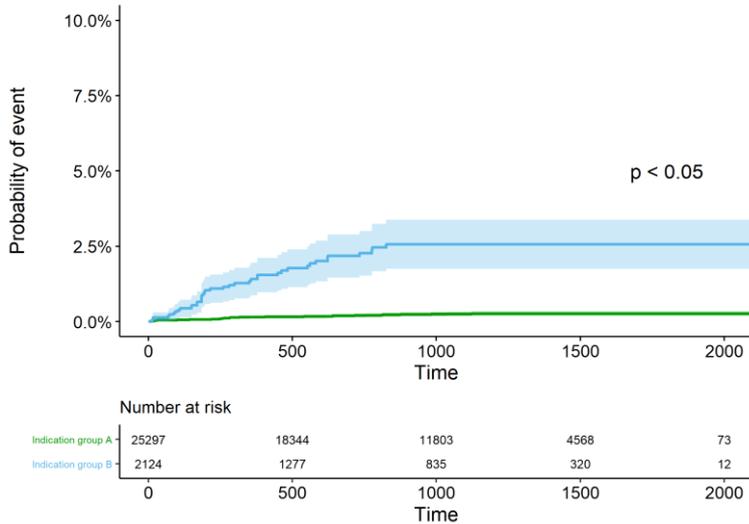


Figure 40a. The risk of re-operation because of pain

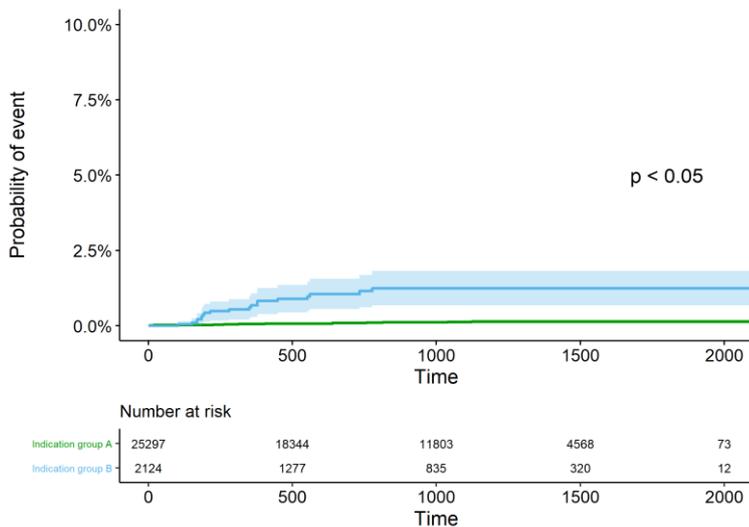


Figure 40b. The risk of re-operation for a combination of hard breast and pain

What impact BMI has on the risk for re-operation has been evaluated and this is shown in figure 41. Vi chose a BMI limit of under and over 25 in accordance with the WHO guidelines. The risk for patients in group B is about 25% irrespective of BMI. The difference between overweight patients and patients of normal weight in group B was not significant. For patients in group A, those who were overweight showed a higher risk for re-operation within 2000 days. There was also a difference between the groups, regarding the proportion of patients undergoing re-operation within 1, 2-and 3-years after their index operation.

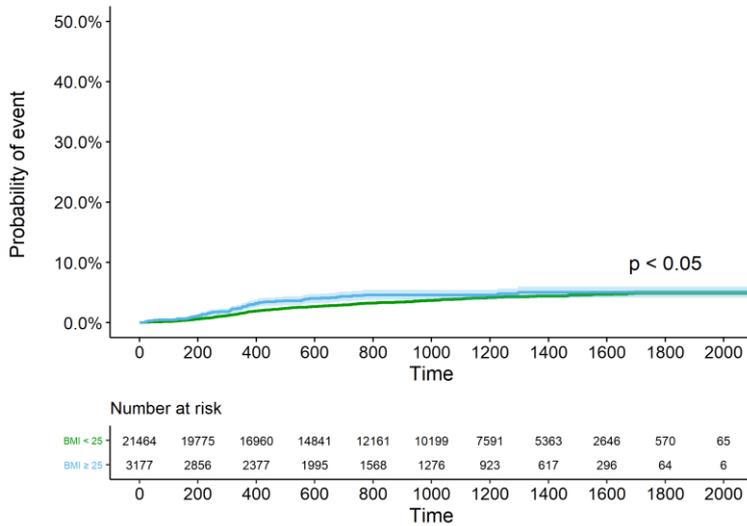


Figure 41a. The risk of re-operation in relation to BMI in group A

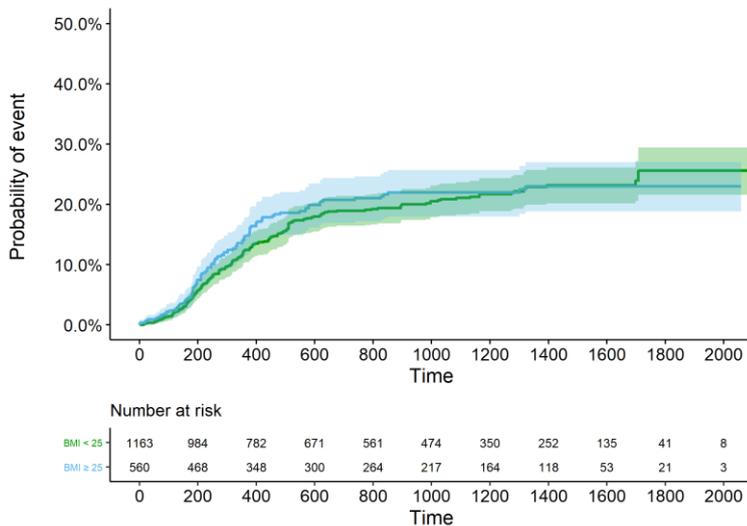


Figure 41b. The risk of re-operation in relation to BMI in group B

SUMMARY

In Sweden, it is predominately implants from the manufacturer Mentor are used for breast cancer operations, while for benign conditions of the breast Mentors' and Motivias' products dominate. The number of primary registered patients with a cancer indication has been stable in 2019. For benign conditions of the breast in group A, the number of registrations in the BRIMP has decreased slightly during 2019. There is a slightly increased tendency to use smooth implants, which has been noted in both groups, although textured anatomical implants still make up the majority in group B. An even distribution between anatomical and round shapes has been noted in group A. Generally, the risk of re-operation within both 60 days and 5.5 years after the primary operation is very low. Radiated patients ran a considerably higher risk of re-operation compared to non-radiated cancer patients. Regarding the choice of implant for this patient group, it has been shown that the use of expander prostheses increases the risk of re-operation. Whether textured implants pose a greater risk compared to smooth implants only future data will answer this question. The actual data indicates that there is a significant difference in the general risk for re-operation with the use of textured implants compared to smooth implants in group A. Patients in group B displayed a higher risk for re-operation due to hardness of the breast and pain in the breast compared to patients in group A. The data in the BRIMP has shown a very low risk of re-operation due to implant rupture within 5.5 years of the initial surgery. No differences could be seen between the different implant manufacturers regarding implant rupture. Future analyses will provide patients with more information about which specific factors can be seen to increase the risk of re-operation. Ultimately, the goal is to be able to identify which special groups run an increased risk for re-operation. An improved register content can hopefully help to illuminate difficult questions regarding the symptom complex "Breast Implant Illness", BII and BIA-ALCL in the future.

In the BRIMP, we process and analyze our data continually and try to improve the register content. The BRIMP is an extremely important tool for our patients, as it makes it possible to inform them about complications with specific implants. We can always improve the statistical relevance of our analyses and help the decision makers in the healthcare system to choose the right implant for the right patient. Our international collaboration with Australia, Holland, Germany, Great Britain, Switzerland and Italy in ICOBRA seeks to define the quality parameters for care on an international scale.

Stockholm 23rd April 2020

Birgit Stark

Associate Professor, Consultant in Plastic Surgery

Registrar for the BRIMP.

QUESTIONNAIRE PRIMARY OPERATION 2019

The Swedish Register for Breast Implants (BRIMP)

Primary Surgery 2019

Personal ID _____
 Date of operation _____ yyyy-mm-dd
 Length _____ cm Weight _____ kg

Use of Antibiotics:
 Pre-operative No Yes ___ Days
 Per-operative No Yes
 Intra-operative No Yes
 (Irrigation implant/ cavity)
 Post-operative No Yes ___ Days

LEFT SIDE

Indication for surgery:
 Patient Perceived hypoplasia Asymmetry
 Primary Micromasty Asymmetry
 Secondary Micromasty Asymmetry
 Tuberos breast Asymmetry
 Prophylactic Mastectomy
 Reconstruction after Mastectomy

Type of permanent implant:
 Implant Expander Prosthesis (ep)
 Manufacturer

Content
 Saline Silicone Saline and Silicone

Serial Number.....
 LOT-number.....
 Ref. number.....
 Volyme ml / cc / g
 Stamped Volume (ep):

Type of surface:
 Smooth Textured Polyurethane

Shape
 Round Anatomical Half moon

Implant- or Expanderprosthesis
 Sub-muscular Sub-glandular
 Sub-fascial Dual plane

Surgical incision
 Sub-mammary Axillary
 Periareolar Mastectomy scar
 Mastopexy with augmentation

Drain after surgery No Yes

Breast surgery prior to present operation
 Tumor No Yes
 Infection No Yes
 Reduction/ mastopexy No Yes

Patient's experience before surgery
 Dissatisfaction with shape No Yes
 Dissatisfaction with volume No Yes
 Pain in breast No Yes

Fat transplantation No Yes

Completed radiation therapy
 before primary operation No Yes

RIGHT SIDE

Indication for surgery:
 Patient Perceived hypoplasia Asymmetry
 Primary Micromasty Asymmetry
 Secondary Micromasty Asymmetry
 Tuberos breast Asymmetry
 Prophylactic Mastectomy
 Reconstruction after Mastectomy

Type of permanent implant:
 Implant Expander Prosthesis (ep)
 Manufacturer

Content
 Saline Silicone Saline and Silicone

Serial Number.....
 LOT-number.....
 Ref. number.....
 Volyme ml / cc / g
 Stamped Volume (ep):

Type of surface:
 Smooth Textured Polyurethane

Shape
 Round Anatomical Half moon

Implant- or Expanderprosthesis
 Sub-muscular Sub-glandular
 Sub-fascial Dual plane

Surgical incision
 Sub-mammary Axillary
 Periareolar Mastectomy scar
 Mastopexy with augmentation

Drain after surgery No Yes

Breast surgery prior to present operation
 Tumor No Yes
 Infection No Yes
 Reduction/ mastopexy No Yes

Patient's experience before surgery
 Dissatisfaction with shape No Yes
 Dissatisfaction with volume No Yes
 Pain in breast No Yes

Fat transplantation No Yes

Completed radiation therapy
 before primary operation No Yes

QUESTIONNAIRE RE-OPERATION 2019

The Swedish Register for Breast Implants (BRIMP) Secondary Surgery 2019

Personal ID _____
 Date of surgery _____ yyyy-mm-dd
 Length _____ cm Weight _____ kg
 Date of primary implant surgery _____ Year
 Date of actual implant surgery _____ Year
 Surgery performed at my clinic No Yes

Use of Antibiotics:

Pre-operative - Y/N
 Per-operative - Y/N
 Intra-operative - Y/N
 (Rinsing of implant/pocket) - Y/N
 Post-operative - Y/N

Indication for operation**Patient reported symptoms**

	LEFT		RIGHT	
Pain	No	Yes	No	Yes
Swelling of breast	No	Yes	No	Yes
Anxiety for implant	No	Yes	No	Yes
if anxiety is it because of				
recent mammography	No	Yes	No	Yes
Change of size	No	Yes	No	Yes
Change of shape desired	No	Yes	No	Yes
Hardness of the breast	No	Yes	No	Yes
Removal of implant desired	No	Yes	No	Yes
Infection (T81.4 t)	No	Yes	No	Yes
Newly diagnosed breast cancer	No	Yes	No	Yes

Pre-operative status

Palpable lymph node in axilla/ armpit	No	Yes	No	Yes
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Implant related

Rupture	No	Yes	No	Yes
Rotation	No	Yes	No	Yes
Confirmed ALCL	No	Yes	No	Yes
Deflation	No	Yes	No	Yes
Incorrect position	No	Yes	No	Yes
Capsular (T85.4)	No	Yes	No	Yes
Double capsule	No	Yes	No	Yes
Seroma/exsudate (T81.8)	No	Yes	No	Yes
Hematoma	No	Yes	No	Yes

Measure

Permanent removal of implantat	No	Yes	No	Yes
Replacement with the existing implant	No	Yes	No	Yes
Replacement with new implant after prosthesis removal	No	Yes	No	Yes
Implant change	No	Yes	No	Yes
Capsule/dissection	No	Yes	No	Yes
Capsular extirpation	No	Yes	No	Yes
Drain	No	Yes	No	Yes
Mesh/ADM in	No	Yes	No	Yes
Mesh/ADM out	No	Yes	No	Yes
Fat transport	No	Yes	No	Yes
Completed radiation before operation	No	Yes	No	Yes

Details of removed implant LEFT**Type of implant:**

Implant	Expander Prosthesis (ep)	Manufacturer	_____
Content	Saline	Silicone	Saline and Silicone
Volyme	_____	Stamped volume (ep)	_____
Surface	Smooth	Textured	Polyurethane
Shape	Round	Anatomical	Half moon
Pocket	Submuscular	Subglandular	
	Subfascial	Dual plane	

Details of inserted implant LEFT**Type of implant:**

Implant	Expander Prosthesis (ep)	Manufacturer	_____
Content	Saline	Silicone	Saline and Silicone
Serial Number	_____	LOT-number	_____
Ref. number	_____	Volyme	_____
Stamped volume (ep)	_____		
Type of surface	Smooth	Textured	Polyurethane
Shape	Round	Anatomical	Half moon
Pocket	Submuscular	Subglandular	
	Subfascial	Dual plane	

Details of removed implant LEFT**Type of implant:**

Implant	Expander Prosthesis (ep)	Manufacturer	_____
Content	Saline	Silicone	Saline and Silicone
Volyme	_____	Stamped volume (ep)	_____
Surface	Smooth	Textured	Polyurethane
Shape	Round	Anatomical	Half moon
Pocket	Submuscular	Subglandular	
	Subfascial	Dual plane	

Details of inserted implant LEFT**Type of implant:**

Implant	Expander Prosthesis (ep)	Manufacturer	_____
Content	Saline	Silicone	Saline and Silicone
Serial Number	_____	LOT-number	_____
Ref. number	_____	Volyme	_____
Stamped volume (ep)	_____		
Type of surface	Smooth	Textured	Polyurethane
Shape	Round	Anatomical	Half moon
Pocket	Submuscular	Subglandular	
	Subfascial	Dual plane	

DEFINITIONS OF VARIABLES FOR PRIMARY OPERATION

Variable	Definition
Civic identity number	Patients date of birth + 4 last digits
Date of Operation	Date of index operation
Height	Patient's self-reported height in cm
Weight	Patient's self-reported weight in kg
Side: Each breast operation per side is registered separately	
Left side	Data registration concerning left breast
Right	Data registration concerning right breast
Indication for surgery	The reason for the implant surgery
Patient-reported hypoplasia	Patient-reported experience that breast volume is too small
Asymmetry	Difference in volume or shape between breasts
Primary Micromastia	Disproportionally small breasts in relation to height and weight in a nulliparous woman
Secondary Micromastia	Disproportionally small breasts in relation to height and weight or loss of breast volume after pregnancy and breast feeding, massive weight loss, trans-sexual surgery, status after breast surgery e.g. reductions, ptosis plastic Breast-saving cancer surgery or other conditions with reduction in breast volume.
Tuberous breasts	Abnormality of breast
Prophylactic mastectomy	Surgical measure where one or both breasts are removed to reduce the risk of breast cancer
Reconstruction after mastectomy	Surgical measure where the breast is reconstructed with implant or expander prosthesis simultaneously or at a later date after removal of breast tissue
Completed radiation before primary operation	Radiation of the breast or thorax before the actual implant surgery
Fat transplantation	Supplement to breast implant surgery using patient's own fat tissue
Type of permanent implant	Specification of the actual implant
Implant	EU-certified medical product intended for augmentation or reconstruction of the breast
Expander prosthesis	EU-certified medical product used for the gradual expansion of the soft tissue of the thorax wall when reconstructing the breast in a "one-stage" operation
The BRIMP does not register "two-stage" procedures, implant change after intermittent expander use is registered as primary insertion of implant and not as a re-operation	
Manufacturer	Name of the company which manufactures the actual implant
Content	Describes the implant's or expander prosthesis' chemical filler material
Silicone, Normal Saline or combination	Type of filler material
Serial number	Serial number of the implant or expander prosthesis
LOT-number	LOT or Batch number of the implant or expander prosthesis
Ref-number	Catalogue reference number of the implant or expander prosthesis
Volume	Measured in ml, cc or g. Printed on the implant or expander prosthesis by the manufacturer or measured inter-operatively using the Archimedes principle

Type of surface	Specification of the implant's or expander prosthesis' surface
Smooth, textured, polyurethane	The nature of implant's or expander prosthesis' surface
Shape	Shape of the implant or expander prosthesis
Round	Implant's shape is round
Anatomical	The implant's or expander prosthesis' shape imitates the drop-shaped form of a mature breast
Implant or expander prosthesis position	Position of the actual of the implant or expander prosthesis
Sub-muscular	Implant or expander prosthesis is placed under the pectoral muscle
Sub-glandular	Implant or expander prosthesis is placed superficial to the pectoral muscle
Sub-fascial	Coverage of the implant with pectoral fascia over the pectoral muscle
Dual plane	Coverage proximally of the areola with pectoral muscle, distally of the areola with breast tissue
Operation incision	Type of incision used for insertion of implant or expander prosthesis
Sub-mammary	Operation incision in the natural fold under the breast or in the scar after a previous mastectomy
Axillary	Operation incision in the armpit
Peri-areolar	Operation incision on the edge of the areola
Mastectomy scar	Operation incision in the scar after a previous mastectomy
Mastopexy with augmentation	Insertion of the implant through a planned skin resection caudally of the areola
Drain	Use of drain in the implant cavity and / or subcutaneously during the actual operation
Net/ADM	Insertion of net or ADM during the actual operation
Previous breast surgery	Document if patient has had any previous breast surgery due to tumour, infection or breast reduction / breast lift prior to the actual operation
Patient's experience before surgery	Description of patient's self-reported dissatisfaction with breast volume or shape and any pain in breast tissue
Antibiotics	Describe if and when patient received antibiotics in connection with the actual operation
Pre-operatively	Antibiotics given intravenously or orally on the day before surgery
Per-operatively	Antibiotics given intravenously or orally on the day of surgery
Intra-operatively	Irrigation of the implant in sterile package or of the prosthesis cavity with antibiotics (antiseptics do not apply)
Post-operatively	Antibiotics given intravenously or orally after the day of surgery

DEFINITIONS OF VARIABLES FOR RE-OPERATION

Variable	Definition
Civic identity number	Patients date of birth + 4 last digits
Date of re-operation / revision	Date of re-operation
Height	Patient's self-reported height in cm
Weight	Patient's self-reported weight in kg
Year for initial implant insertion	The year when breast implant was initially inserted
When was the current implant inserted	When was the current implant, that concerns this entry in the register, inserted
Was the surgery for the current implant performed at this department	Was the initial operation for the current implant performed at this department
Indication for operation right and left side	Reasons for re-operation
Pain	Patient-reported pain in breast
Swelling of the breast	Patient-reported swelling of breast
Anxiety about the implant	Patient-reported anxiety for existing implant
If anxiety exists is it due to the result of recent mammography	Patient-reported anxiety due to mammography within the last 3 months
Change of size	Patient experienced that breast volume is too small or large
Desired shape change	Patient's desire for change in breast shape
Hardness of the breast	Patient's experience that breast is hard
Desired implant removal	Patient's desire for implant removal
Infection (T81.4)	Infection after breast surgery
Recently diagnosed breast cancer	Diagnosis breast cancer is reason for the actual operation
Pre-operative status	Patient's medical status prior to operation
Palpable lymph nodes in axilla	Lymph nodes in the axilla which can be palpated
Per-operative status	Patient's medical status/condition and implant status during operation
Rupture	Defect/injury in the implant's exterior casing (from hole in the casing to total degeneration of the implants shape)
Rotation	Implant has rotated in the prosthesis cavity
Confirmed ALCL	Breast implant-associated Anaplastic Large Cell Lymphoma, confirmed with CD30 and ALK
Deflation	Volume and/or shape change of implant / expander prosthesis due to normal saline loss
Incorrect position	Implant is in incorrect position in the breast
Capsule (T85.4)	Hard connective tissue capsule formation around the implant which requires surgical correction (Baker III,IV)
Double Capsule	A capsule in contact with the exterior of the implant and a capsule in contact with breast tissue. Between the capsules, seroma fluid may be present
Seroma/ Exudate (T81.8)	Collection of wound fluid in implant cavity
Haematoma	Collection of blood in or outside implant cavity
Measure	Treatment
Permanent removal of implant	Breast implant is removed and not replaced
Return of existing implant	Breast implant is removed and after treatment the same implant is re-used in the patient
Insertion of new implant after removal of existing implant	A new implant is inserted after removal of an existing implant e.g. after an infection or other conditions where breast tissue requires several months to heal without the presence of an implant
Change of implant	New implant is inserted during operation after removal of existing implant
Capsule dissection	Incision of capsule in one or more quadrants

Capsule exstirpation	Removal of capsule tissue except the thoracic section
Drain	Use of drain in the implant cavity and / or breast tissue
Net/ADM inserted	Insertion of net/ADM during the actual operation
Net/ADM removed	Removal of net/ADM during the actual operation
Fat transplantation	Supplementation of implant-based surgery with the patient's own fat tissue
Completed radiation before operation	Radiation of the breast or thorax before the actual implant surgery
Information about implant which is removed from Right or Left side	Registration of data concerning Right or Left side
Implant	EU-certified medical product intended for augmentation or reconstruction of the breast
Expander prosthesis	EU-certified medical product used for the gradual expansion of the tissue of the thorax wall when reconstructing the breast in a "one-stage" operation
Manufacturer	Name of the company which manufactures the actual implant
Content	Describes the implant's or expander prosthesis' chemical filler material
Silicone, Normal Saline or combination	Type of filler material
Serial number	Serial number of the implant or expander prosthesis
LOT-number	LOT / Batch number of the implant or expander prosthesis
Ref-number	Catalogue reference number of the implant or expander prosthesis
Volume	Measured in ml, cc or g. Printed on the implant or expander prosthesis by the manufacturer or measured inter-operatively using the Archimedes principle
Type of surface	Specification of the implant's or expander prosthesis' surface
Smooth, textured, polyurethane	The nature of implant's or expander prosthesis' surface
Shape	Shape of the implant or expander prosthesis
Round	Implant's shape is round
Anatomical	The implant's or expander prosthesis' shape imitates the drop-shaped form of a mature breast
Half-moon /Crescent shaped	The implant is shaped like a half-moon
Position	The placement of the actual implant or prosthesis expander
Sub-muscular	Implant or expander prosthesis placed under the pectoral muscle
Sub-glandular	Implant or expander prosthesis placed superficial to the pectoral muscle
Sub-fascial	Coverage of the implant with pectoral fascia over the pectoral muscle
Dual plane	Coverage proximally of the areola with pectoral muscle, distally of the areola with breast tissue implant with pectoral fascia over the pectoral muscle