

BRIMP

THE BREAST IMPLANT REGISTRY
ANNUAL REPORT 2016



THE REGISTRY MANAGER'S REPORT

In 2016, BRIMP saw further consolidation



Birgit Stark, Associate Professor in Plastic Surgery and Registry Manager for BRIMP

Over the past year, consolidation of data in BRIMP has continued. The Registry coordinator, Heléne Fägerblad, and I have contacted and visited several clinics to encourage their cooperation with BRIMP and to support its work. At present, all University Clinics and a total of 75 of 84 Private Surgeons (members of SFEP) report to BRIMP.

Web modules for index surgery and reoperation

Together with the Management Committee and statisticians at the Registry Centre in Västra Götaland, we have now completed a graphical report of various data that BRIMP has collected for index surgery and reoperation. In collaboration with the project management and statisticians at the Registry Centre, Västra Götaland we have completed a graphical report of various data that BRIMP has collected for index- and reoperation.

Each affiliated Clinical Unit now has the ability to follow up its own data and compare them with nationwide data accumulated in BRIMP. BRIMP reports will now provide descriptive statistics that each Unit has access to by logging in. The module for index surgery was launched in 2016, and the module for reoperation was launched in January 2017.

Patient-reported outcome measure data (PROM) for validation

In 2016, the BRIMP Steering Committee decided to launch a 3-month pilot validation project using a PROM questionnaire, where the form's design and user-friendliness was tested and evaluated.

Three units participated in this pilot project: the Department of Reconstructive Plastic Surgery, Karolinska University Hospital, Solna; Aleris Plastic Surgery, Stockholm; and ArtClinic, Gothenburg. The pilot project was completed in October 2016 resulting in structure evaluation of the questionnaire and an analysis of the practical process involved. Together with the Management Committee we have decided to extend the pilot project to become an established validation survey process accessible to all units in the future. The stability and reliability of this validation tool will be further explored during 2017. We expect to be able to introduce the use of PROM at the national level when final analysis of the validation process is complete. All legal, technical and practical requirements for registering and analysis of PROM data in the Registry are now fulfilled.

Quality of data in the BRIMP are continually monitored

An analysis of registry data in 2016 showed a steady stream of registrations per month. There was some "delay" between operation and registration by the units reporting. However, that delay appears to be constant suggesting that units have built up a satisfactory practical routine for recording their data. In the spring of 2016, analysis of random data samples was performed to confirm completeness of capture. Data from the Department of Reconstructive Plastic Surgery, Karolinska University Hospital, Solna and Aleris Plastic Surgery, Stockholm, showed very good "compliance, where the number of breast implants registered in BRIMP corresponded to the actual number of implants at both clinics.

During the spring of 2017, we will perform the first analysis of data lost to BRIMP. Some data, including implant identification at reoperation, are missing in BRIMP and this requires investigation. If the majority of data lost involves certain variables, then the significance of these variables for BRIMP must be questioned. We must also investigate how data recorded in BRIMP complies with reality. Comparison of a random sample of registered data with entries in patient notes will be performed at both of the above-mentioned departments.

Research has begun

A research project is under way exploring the use of antibiotics associated with breast implantation, in which BRIMP data will be compared with data from the Swedish Medical Product Agency, MPA.

The Ethics Examination Board and the Steering Committee have approved the application.

Furthermore, we have embarked on deeper statistical analyses of BRIMP's existing data to see if such analyses are feasible in future annual reports. The questions today are: "How far can we go in the interpretation of BRIMP data?" and "What conclusions can we draw in terms of completeness and compliance?"

A research project has also been started to validate the PROM survey.

Firm establishment of collaboration with the Breast Cancer Registry

A meeting between the BRIMP Registry Manager, and the Management Committee, and colleagues from the Breast Cancer Registry was held in October 2016. There was full agreement that data need to be reported once only. Specific data important to BRIMP are not registered in the current Breast Cancer Registry. At our consensus meeting, we agreed upon a minimum data set essential to BRIMP that need to be registered in the new Breast Cancer Registry. Unfortunately, establishment of this collaboration will take some time, and our colleagues in the public healthcare system must continue to register in both BRIMP and Breast Cancer Registry (INCA) for some years to come. This is due to reconstruction of the Breast Cancer Registry. Our future goal is that each year data will be transmitted from the Breast Cancer Registry BRIMP, making it easier for colleagues in the public healthcare system to use one quality registry only. We at BRIMP have seen to it that all legal and technical requirements for this process have been fulfilled.

Industrial cooperation has begun – Allergan is our first partner

A huge advantage of BRIMP's existence for the implant industry is undoubtedly access to data for post-market surveillance. The introduction of new EU rules, 2018, will make the legal work necessary for cooperation between BRIMP and the implant industry less of a hinder. The industry will have access to non-individualised pooled registry data on complications, patient-related inconvenience and actions taken at reoperation. Furthermore, companies will have access to information on their own product at reoperation; for example, was their implant replaced with the same type or was a product from another company chosen instead? The cost of this information for the individual company will be based on the number of their implants registered in BRIMP.

In September 2016, the Registry Manager together with the Management Committee and representatives of the implant industry took part in a workshop in conjunction with the Annual Meeting of the Swedish Society of Aesthetic Plastic Surgery SFEP. The goal of the workshop was to increase the industry's cooperation with BRIMP hopefully providing us with access to industrial data such as the number of each sort of implant sold in Sweden.

International cooperation with ICOBRA has begun

BRIMP has been invited to participate in international cooperation with other countries where a breast implant registry is kept. Hinne Råghorst, Chairman of the Dutch Plastic Surgical Association, and I have had several telephone conversations regarding this. We have also made contact with the manager of the Australian Breast Implant Registry, Prof Rodney Cooter, Monash University, Australia, at an international meeting in Japan. Our goal is to improve the use of our data in the long run by developing a common data set that is both limited and practical. A joint ICOBRA meeting is scheduled to take place in Prato, Italy, April 2017.

Running a quality Registry is expensive but BRIMP is economically independent

Approved grant applications from the Association of Swedish Municipalities and County Councils (SKL) and from the Allergan 2016 Industry Report have provided a good economic foundation on which BRIMP can build. The Registry Manager also applied for external funding for BRIMP in 2016. Running a quality registry is expensive, so even in the future a good and stable economy will always be necessary if we are to work completely independently.

Business Meetings 2016

In order to be able to run BRIMP's activities, the Registry Manager, Heléne Fägerblad and the Management Committee at the Registry Centre in Västra Götaland have held regular meetings both physically and over the Net. I have been able to spend 3 working days a month doing BRIMP business as well as a number of weekends and evenings. BRIMP's Steering Group met in the spring and autumn of 2016. A meeting with the industry was held in conjunction with the Annual Meeting of the SFEP. I held a lecture on BRIMP's current database at ISAPS international meeting in Japan. A widening of BRIMP's horizon, however, requires greater efforts by the Registry Manager and members of the Steering Group.

BRIMP – A national quality registry



Jonas Lekander, Senior Adviser and Development Manager, Registry Centre, Västra Götaland

A healthcare quality assurance registry contains individual-based data on problems, measures and outcomes. These data may only be used to develop and secure the quality of care in the healthcare system and to produce statistics for research!

After testing for confidentiality, information may also be disclosed to persons using the data on any of these three variables. When data from BRIMP is being used for research purposes, approval of an Ethics Examination Board (EPN) is always required. This follows formal application, examination and approval which must be obtained before research projects specifically involving breast implant surgery, are begun.

Privacy and Security

All data in BRIMP are confidential and handled in accordance with current legislation in the PUL (Personal Data Act 1998: 204) and according to the PDL (Patient Data Act 2008: 355). Information in BRIMP is therefore treated with the same confidentiality as data in all official records, meaning, that data of a patient cannot be accessed by anyone other than the patient's actual healthcare provider. An exception to this is that elected representatives on the board of a registry have the right to handle and process the data in that registry. The Registry Centre in Västra Götaland has responsibility for the personal data collected in BRIMP and for ensuring that all handling of the data is correct and complies with the laws applicable.

Patient rights

Patient participation in the BRIMP registry is always voluntary and in no way affects the care the patient receives. The care provider must always inform the patient that his/her treatment will be reported to a quality registry. This may be made simpler by having an explanatory poster in the waiting room or information in the letter calling the patient to their operation. Having received information, the patient must inform their healthcare provider if he/she does not wish data to be registered. The patient is entitled at any time to have his or her data removed from the registry, in which case all information regarding the patient is removed. If a patient wishes to know what data are registered, then once a year they have access to their personal data in the registry.

The BRIMP national quality registry - the future

Between 2012 and 2016, the SKL and the Government pledged commitment to the support of national quality registries. Their efforts included increased funding of 1.5 billion SEK with the aim of consolidating quality records and their operation. That period of investment is now over and the structure and financing of quality registries is currently not clear.

BRIMP was established during this investment period and has had great success as a registry. The registry has received on-line data from mid-2014, and modules for registering data are in use at affiliated clinics. The majority of clinics are taking part in a PROM pilot project with very promising results. Collaboration with the Breast Cancer Registry has begun, and there is good support from the professional associations. Close contact with implant suppliers and distributors has been established, and the registry has received approval for this from the local Ethics Committee.

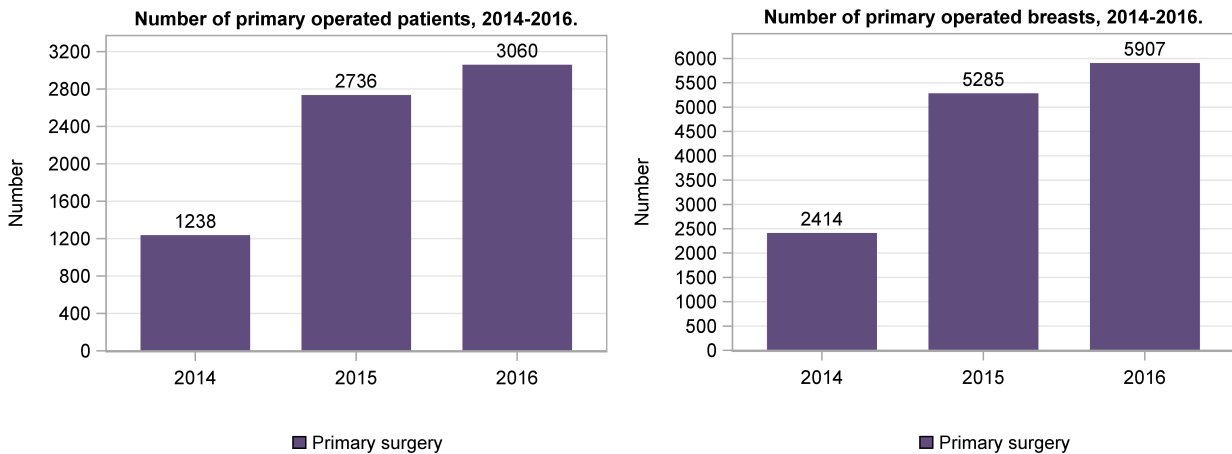
In other words, BRIMP continues to thrive despite completion of the national investment campaign.

PRIMARY OPERATIONS

The number of patients and breast implants registered has increased continuously since 2014. By 31.12.2016 there were 3060 new patients in the Registry; an increase of 11.8% compared to 2015 (Fig.1a). These figures should not be interpreted as more patients being operated in Sweden, but that more clinics or colleagues reported their data compared to 2015.

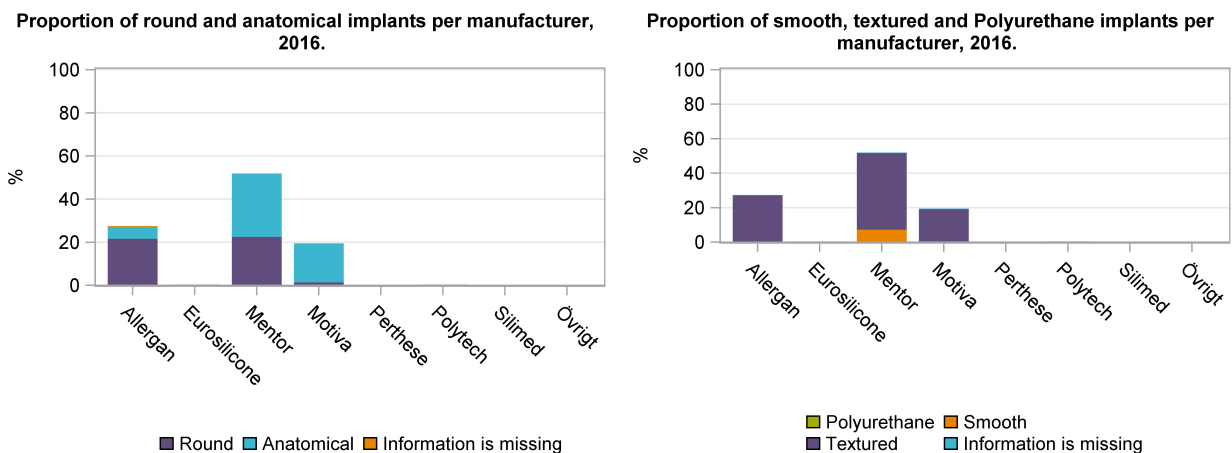
The number of primary operated breasts registered increased from 5285 in 2015 to 5907 in 2016. Again, an increase of 11.8% (Fig.1b).

This mean that we have the opportunity to follow up a total of 13,606 primary breast implants since BRIMP went online.



FIGURES 1a and b Number of primary operated patients and number of primary operated breasts, 2014-2016

The majority of implants registered in BRIMP, 2016, were textured types from the companies Mentor, Allergan and Motiva. Smooth implants were reported in 8.5% of cases. The number of smooth implants registered in 2016 was twice that in 2015, with Motiva's implants representing approximately 19.3% (1138 implants) of reported manufacturers in 2016. Mentor accounted for 52% (3055 implants) and Allergan for 27% (1601 implants). Eurosilicone has a share of 0.4%. Only 18 polyurethane implants have been registered. A tendency towards a change in of share of the market can be seen. Compared to data reported in the Annual Report 2015, we see no major differences in the proportions of round and anatomical implants. Those using Allergan implants tend to choose anatomical shapes whereas those using Mentor's products more often choose round shapes (Fig.2a).



FIGURES 2a and b: Distribution of shape and surface

Indications for surgery have previously been divided between those in the National Health Service (A) and those in private surgery (B). Accumulated data from 13,606 breast implants in BRIMP show that the majority of breast implants are for benign disease. Under the Indication Group A, indications such as aplasia, primary and secondary hypoplasia, transsexual surgery and esthetical breast enlargement are summarised below. Less than 7% of all registered primary operations in BRIMP follow surgery for cancer or prophylactic mastectomy (899 patients) (Fig.3). The proportion of "missing data" has been reduced to less than 20%, reflecting the fact that clinics have received better information on the definition of registry variables through BRIMP's actions to continuously improve the quality of data. Unfortunately, 14% of registrations still lack indication for surgery.

Distribution per indication at primary surgery, 2014-2016.

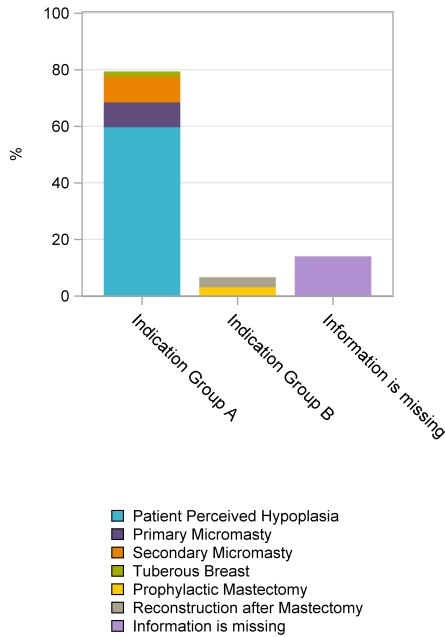
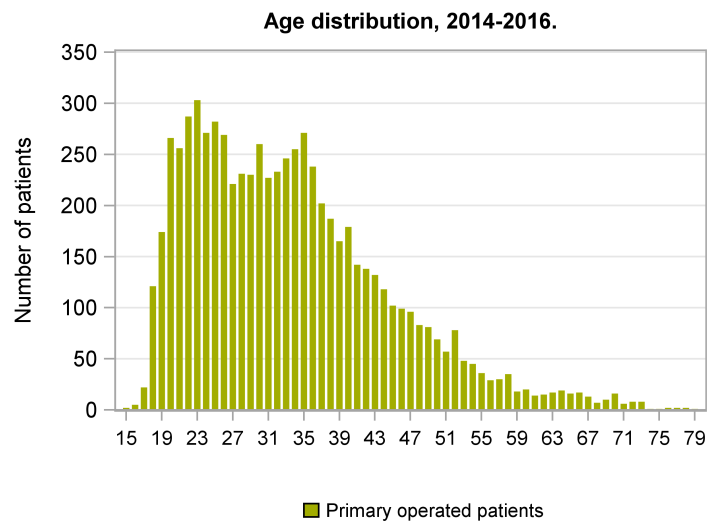
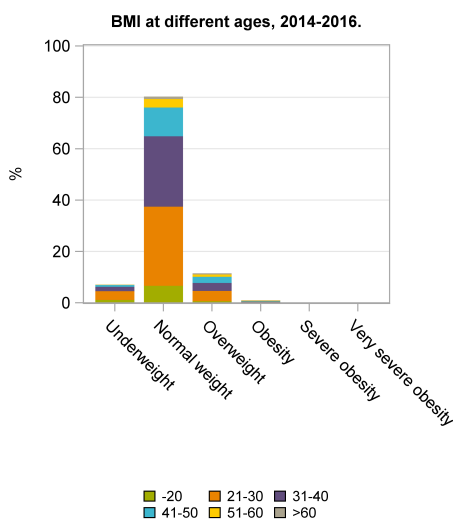


FIGURE 3: Distribution of indications for primary operation, 2014-2016

Accumulated data in BRIMP (n = 6715) show that 80% of our patients are healthy at the time of primary implantation (Figure 4a). In the distribution plot against age at primary surgery below, it can be seen that 47% of BRIMP patients are operated before the age of 31 and 79% before the age of 41 years. A point to note is that 14 patients had severe obesity and 1 patient had very severe obesity (Figure 4b).



FIGURES 4a and b: BMI according to age and age distribution at registered primary operation 2014-2016

Data in BRIMP indicate that the majority of patients (65%) had surgery due to dissatisfaction with both form and volume of their breasts. These patients belonged to Indication Group A. Patients with a diagnosis of cancer or undergoing prophylactic mastectomy were dissatisfied with form and volume in only 2% (16/899 patients). Only 18% of patients found that dissatisfaction with volume was the most important indication for surgery (Figure 5).

A total of 72 patients experienced pain prior to surgery during the period 2014-2016, of which 20 were cancer-treated patients (3%). Twenty-six per cent (N = 104/695) registered in BRIMP had had radiation therapy for cancer prior to primary surgery (these data are not graphically reported).

Proportion of patients experiencing both form and volume dissatisfaction versus only dissatisfaction with volume, 2014-2016.

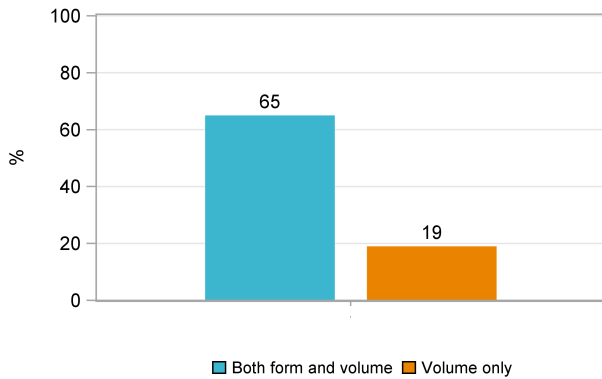
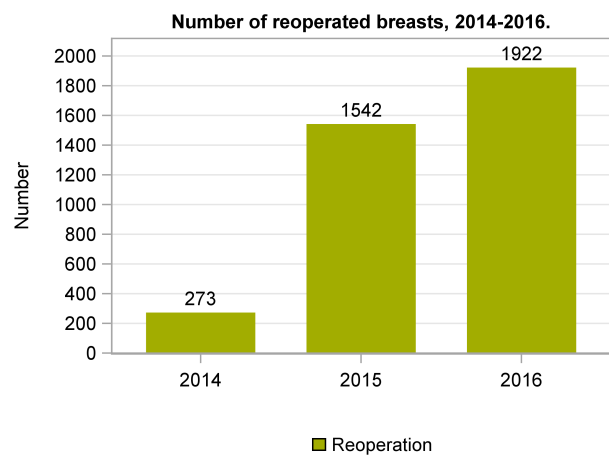
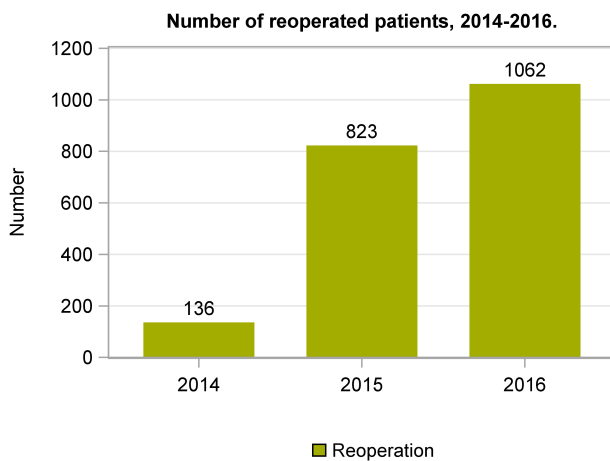


FIGURE 5: Proportion of patients experiencing dissatisfaction with both form and volume versus volume only 2014-2016

REOPERATIONS

In parallel with the increase in number of registrations of primary operated patients, an increased revision breast surgery rate (1922) was reported in BRIMP in 2016 compared to 2015, when the number reoperations increased by 25%. Figures 6a and b show the number of reoperated patients (1062) and reoperated breasts (1922) in 2016 compared to 2014 and 2015.



FIGURES 6a and b: Number of reoperated patients and reoperated breasts, 2014-2016

Figure 7 shows that 32% (994) of implant revisions registered took place within two years of primary surgery. In the near future when we have enough data on both index operation and reoperation in BRIMP to enable deeper analyses, we will be in a position to investigate the reoperation group more closely. At the time of this report there were 401 such cases registered. BMI at reoperation did not differ significantly from last year's data. Overweight was noted in 16% of patients and obesity in 2% (Figure 8). Future analyses will provide information on the impact of age-related comorbidity and BMI on the incidence of reoperation.

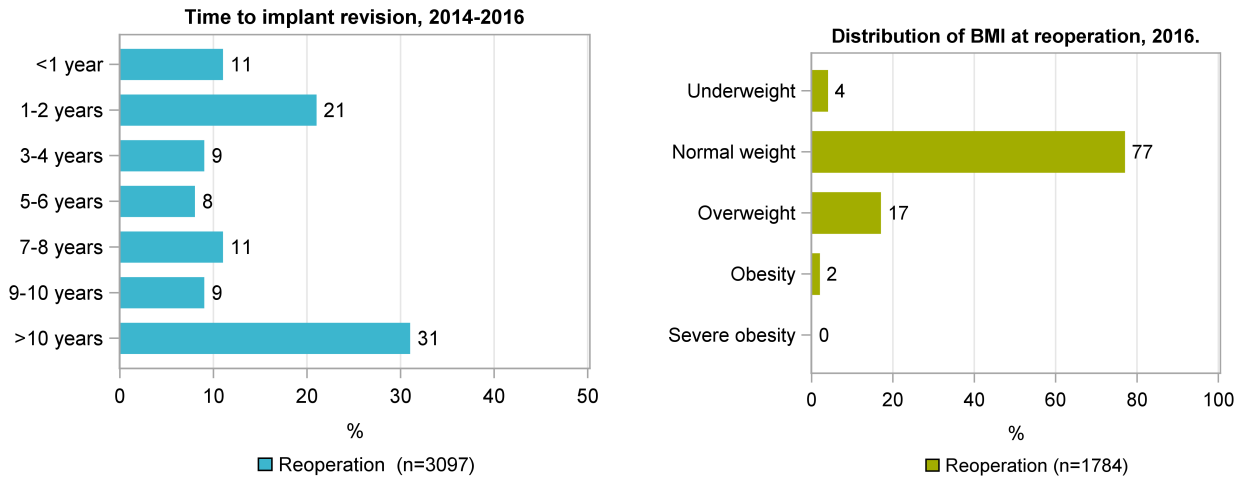


FIGURE 7: time between index and reoperation, 2014-2016
FIGURE 8: Distribution of BMI at reoperation, 2016.

Patient-reported symptoms

Accumulated data in BRIMP showed that, from the patient's point of view, 2 or more symptoms motivated revision surgery. Data from 2016 (Figure 9) showed the same trend as the corresponding figures in 2015.

Patient-reported dissatisfaction with size and form was the indication for reoperation in the majority of cases, followed by worry about having an implant and desire to remove the implant (Figs. 10a, b, c).

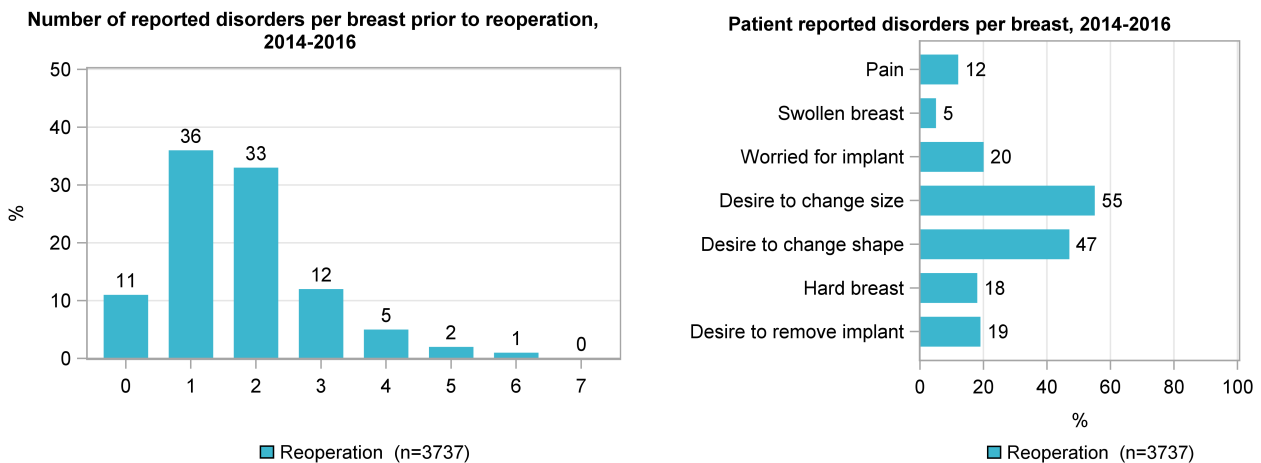
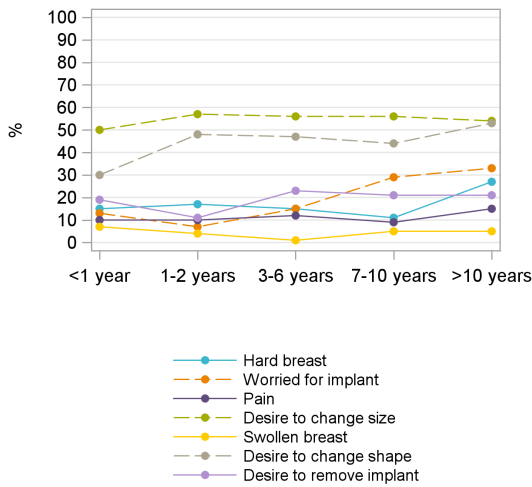


FIGURE 9: No. of reported complaints per breast prior to reoperation, 2014-2016. **FIGURE 10a:** Patient-reported disorders per breast, 2014-2016.

Patient reported disorders prior to reoperation and time to implant revision, 2014-2016



	<1 Year (n=335)	1-2 Years (n=659)	3-6 Years (n=505)	7-10 Years (n=624)	>10 Years (n=974)
Hard breast	15% (50)	17% (110)	15% (74)	11% (66)	27% (264)
Worried about the implant	13% (44)	7% (44)	15% (77)	29% (181)	33% (322)
Pain	10% (32)	10% (63)	12% (59)	9% (58)	15% (149)
Size change	50% (167)	57% (375)	56% (283)	56% (350)	54% (523)
Swollen breast	7% (25)	4% (26)	1% (7)	5% (33)	5% (50)
Desire to change form	30% (100)	48% (317)	47% (239)	44% (274)	53% (514)
Desire to remove implant	19% (65)	11% (71)	23% (116)	21% (131)	21% (205)

FIGURES 10b and c: Patient-reported complaints per breast, 2014-2016.

With respect to time until revision and dissatisfaction with size, 542 out of 994 (55%) of women returned within a period of 2 years after the index operation, due to dissatisfaction with the breast volume achieved (Fig.11). Change in size and secondly, change in shape were important end-points for the patient. When looking at how dissatisfaction with shape affects the rate of reoperation, it is mostly the patient's own perception of poor shape achieved that was the reason for revision, especially of breast implants that had been in place a long time. This observation is in line with observations from the profession in general. Furthermore, it can be seen that hardness of the breast and anxiety about the implant increases significantly with time.

Data in BRIMP on dissatisfaction with shape and volume as the reason for revision do not appear to have changed during the period 2014-2016. These data need further investigation as regards indication and its subgroups. Each affiliated clinic has the ability to follow its own data against accumulated data in BRIMP. Improved patient information could possibly contribute to a reduction in reoperation rate due to dissatisfaction with volume and form. Future data will show whether or not information on the geometry of the implant planned meets the patient's requirements and affects the revision frequency.

Pain registered in BRIMP occurred in 361/3097 reoperated breasts and usually developed within 10 years after surgery. It is notable that 10% of reoperations within 2 years after the index operation were due to the patient complaining of pain.

Of the registered 3090 reoperated breasts, symptoms such as swelling of the breasts were evenly distributed 10 years after the index operation. The proportion of patients complaining of swelling amounted to 5% of all reoperated breasts.

Hardness of the breast appeared to increase markedly after 10 years after index surgery. Data suggest that the above named symptoms developed parallel to this, and this was the cause of the patient seeking medical advice.

Data in BRIMP showed that 668 patients experience increasing concern about their implants and 588 patients ask for removal of their implants without insertion of new ones. We observed that 1% of all revised breasts (n = 3737) were due to a combination of serology, hardness and swelling. The BRIMP has introduced a special warning for BIA-ALCL upon registration of seroma. Late developing seroma may be an indicator of BIA-ALCL. It is of utmost importance to follow up these patients clinically in accordance with current guidelines for the diagnosis of BIA-ALCL.

Intraoperative findings

Accumulated data from the 2814 revised implants registered on implant failure, capsule formation and rotation have been evaluated regardless of indication and preoperative radiotherapy. BRIMP is a young registry and data must be consolidated before any significant conclusions regarding the implant type or manufacturer can be drawn.

In more than 6% of revised breast with round implants, free silicone was found in the prosthetic cavity with or without a combination of silicone in surrounding tissues or the local lymph nodes. The 812 anatomical implants undergoing revision showed more than 3% free silicone in the prosthetic cavity or in surrounding tissues. We will soon have a clearer view of how these issues are developing, considering that in the future most of the PIP implants in Sweden will presumably have been replaced.

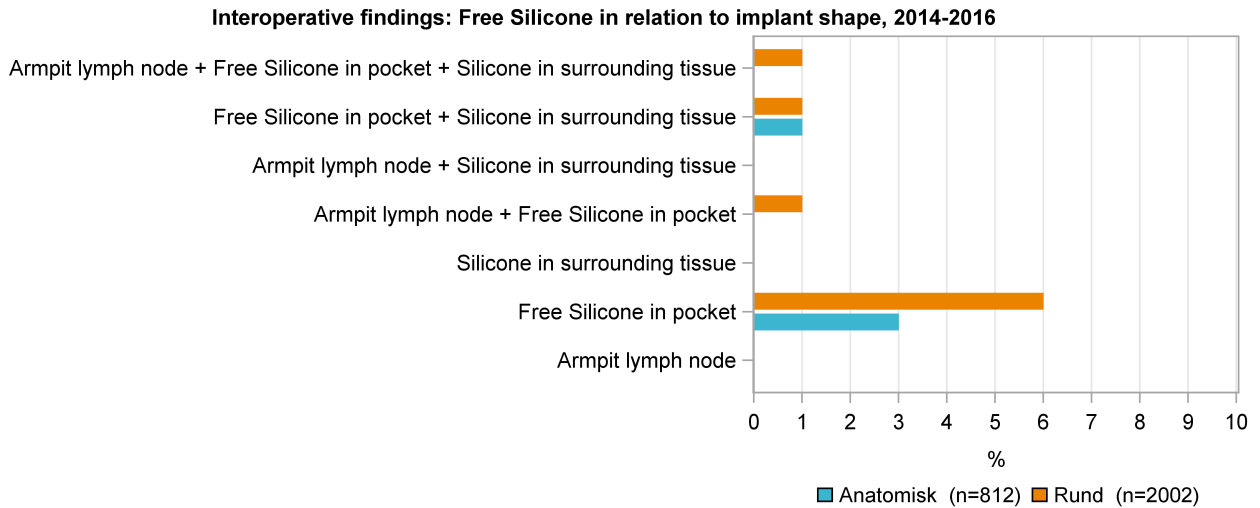


FIGURE 11: Intraoperative findings, free silicone in relation to implant form, 2014-2016
 “Anatomical” “Round” “Intraoperative”

Figure 12 shows the proportions of capsule formation, rupture and rotation observed in 2814 of 3737 revised implants registered in BRIMP. We found 20% ruptured implants, 14% rotated anatomical implants, and a significant proportion of capsular formations where anatomical implants represented the majority. We will study these variables over the next few years when consolidation of data in BRIMP has progressed.

When analysing accumulated data from 3737 implants (Fig.13) regardless of the geometric implant design, 11% of implants were ruptured during the time of reoperation; in 10% correction of the implant position was needed, and 27% had capsule formation requiring attention. Furthermore, we found 6% double capsules with seroma, and 1% of acute revisions were due to hematoma formation.

Capsular contracture, rupture, rotation in relation to implant shape, 2014-2016

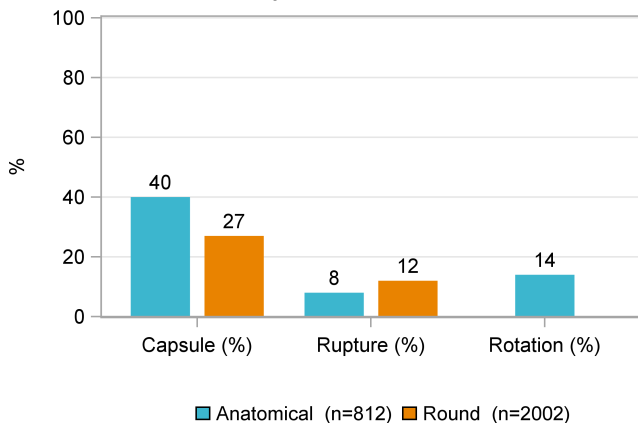


FIGURE 12: Capsule, rupture, rotation in relation to implant form, 2014-2016
 “Rupture” “Intraoperative findings at implant revision”

Interoperative findings for implants, 2014-2016

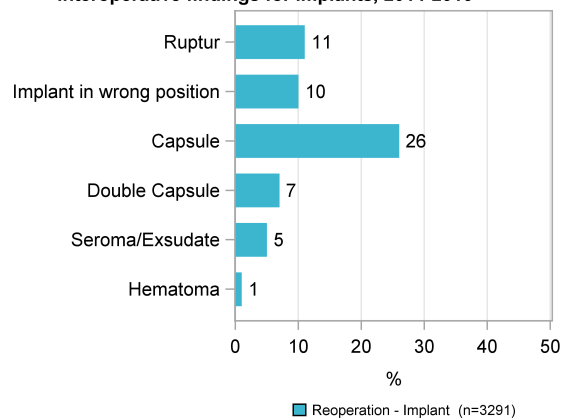


FIGURE 13: Intraoperative findings, implant status, 2014-2016

Expander prostheses are mainly used for breast reconstruction after cancer or after surgery for prophylactic reasons. The database reports results from 239 revised expander prostheses that were initially aimed to be a permanent implant without the need for replacement.

Deflation occurred in 9% of expander prostheses, and valve leakage in 3% (Fig. 14). Other complications such as capsule formation, rupture and rotation were not specifically reported for this group but are included in Figure 14

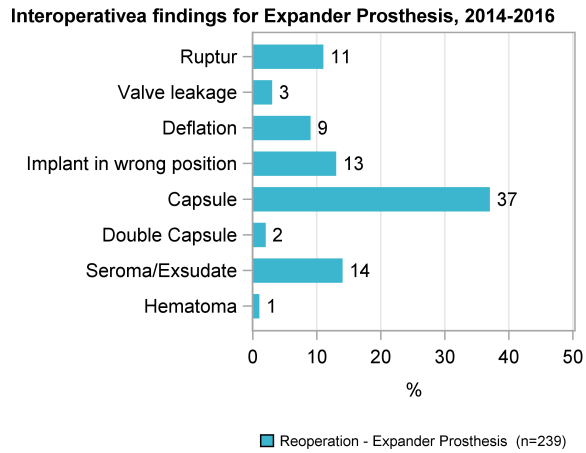


FIGURE 14: Intraoperative findings, expander prosthesis, 2014-2016
 “Intraoperative findings at expander prosthesis revision” “Rupture” “Hematoma”

SUMMARY

By December 2016 BRIMP had followed up 7034 primary surgery patients and 13,606 breast implants. An 11.8% increase in registrations had taken place, which is encouraging but further efforts are required to persuade private breast surgery clinics not currently affiliated to BRIMP to register their data. Desire to change the form and volume of the breasts accounted for the majority of indications for surgery in normal weight young patients with benign disease. In Sweden, products from well-established implant companies were used but new manufacturers are coming into the market. Here BRIMP is an important independent partner for post-market surveillance of products newly introduced into the country. A total of 2021 patients had been reoperated for the revision of 3737 breast implants by December 2016. Thirty-three per cent of these implant revisions were performed within 2 years of primary surgery because of dissatisfaction with shape and volume. Other disorders such as hardness, seroma, pain, swelling and implant rupture occurred more often the longer time had passed since primary surgery.

Data quality

The Breast Implant Registry is relatively new and when first performing registration, newly affiliated clinics may have difficulty in the interpretation of certain registry variables. This can result in inaccurate or incomplete registration. This is evident from various figures in the report where the n-digit changes as a result of failed registration. We are continuously working to improve the quality of the registry and clarification of definitions of variables will take place in 2017. An example of this is ambiguity in the interpretation of various indications for surgery as well as the meaning of capsule formation. As well as continuous improvement in the quality of data, data in BRIMP need further consolidation. Difficulties in identifying implant-specific details at reoperation are also seen when the index operation was performed far back in time or when the implants are no longer in use. A meaningful Registry requires continuous critical analysis and validation of data.

The Management Committee of BRIMP would like to express their particular thanks for the cooperation of the manufacturers and distributors of breast implants in Sweden. This cooperation helps us in the estimation of compliance and completeness of registration.

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