

THE DANISH REGISTRY FOR  
PLASTIC SURGERY OF THE BREAST

STATUS REPORT 2003





Patient reasons for seeking breast implants are multiple, and the outcome is associated with the indication for operation. Reconstructive breast implantation after mastectomy constitute 15% of the implantations performed in Denmark. Other medical indications for breast implantation include aplasia of breast tissue and thoracic malformation, which constitute the indications for implantations among the youngest patients. Still, the majority of implantations are performed at cosmetic indication. By February 2003 breast implants were reclassified from CE-class IIb to III, which is the highest class and thereby the strictest requirements imposed on the manufacturers for achieving the CE-mark prior to marketing in Europe. Further, clinical follow-up and registration is required for understanding long term clinical performance of implant devices and in patient follow-up in the event of unforeseen device malfunction. Political and medical fields agree on the need for central registration. There are major tasks in establishment and financing central registrations, which also strongly depends on the will and efforts of the clinics of plastic surgery. Internationally, activities are implemented to establish national and international registries. The Danish Registry for Plastic Surgery of the Breast, DPB, comprises data systematically collected on an unselected, nationwide cohort of women, with clinical follow-up data up to 4 years after breast implantation or reduction surgery. The registration has continuously been improved, thus medical facility data are maintained in such a way as to allow continuous survey of implant performance and expeditious traceability of a set of patients who have been implanted with a specific device type should it be required. This will allow for timely evaluation of devices for which safety is questioned and allow for uniform, scientifically based information of benefits and risks to women considering mammoplasty for cosmetic or reconstructive purpose.

We are pleased to present the second status report with aggregated data based on collaboration with plastic surgeons in both the private and the public sector. For internal quality assessment each participating clinic receives clinic specific data for comparison with the aggregated data. The current report presents registration activities and descriptive statistics of surgical and follow-up data about implantations for cosmetic and reconstructive purposes as well as reduction surgery and mastopexy, respectively. The report is freely available as pdf-format or as a hardcopy by contact to the Registry.

November 2003



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## REGISTRATION

### Introduction

After thorough evaluation of the long-term safety of silicone breast implants, local complications remains the primary safety issue with silicone breast implants. In February 2003 The European Parliament demanded implementation of specific measures to improve information for patients, tracking and surveillance of the implants. A request for national and international active central registration activities and thorough follow-up of breast implantations has been raised from several parties from the medical field, interest groups and regulation authorities.

The Danish Registry for Plastic Surgery of the Breast (DPB) was implemented in May 1999. It is based on a collaborative initiative between surgeons and epidemiologists, dedicated to provide valid, scientific data on the outcomes of plastic surgery of the breast, including the safety of breast implants, and to establishing quality care to patients. The initiative was taken by the Danish Society of Plastic and Reconstructive Surgery, the Danish Society for Aesthetic Surgery, the Institute of Cancer Epidemiology at the Danish Cancer Society, and the International Epidemiology Institute, Rockville, Maryland, USA. Establishment of the Registry and prospective follow-up has been approved by the Danish Ethical Committee system and Danish Data Protection Agency.

#### Purpose

The specific purpose of the DPB is to systematically collect baseline and follow-up data on women undergoing cosmetic or reconstructive breast surgery, allowing for prospective examination of local complications and potential short- or long-term health effects, as well as evaluation of surgical results and surveillance of breast implants.

#### Perspectives

The DPB provides plastic surgeons with the first nationwide system for data collection of both pre-, peri- and post-operative data on women receiving mammoplasties. With these data potential risk factors and hypotheses related to breast implantation and reduction surgery may be investigated. Description and analysis of potential short- and long-term effects following cosmetic and reconstructive surgery are published regularly. For internal quality assessment each clinic receives analyses of their own data for comparison with the aggregated data. Further, frequent surveys of complication rates stratified on implant variables, including manufacturer and lot/batch number, may add to the continuous evaluation of the devices.

DPBs central registration will contribute to active post-marketing surveillance of breast implants used in Denmark, and thereby monitor and document their safety. Additionally, it will provide uniform, scientifically based information on risks and benefits to the patients.

### Registry Data

#### Criteria for inclusion

The DPB includes women undergoing breast implantation for augmentation, correction of malformation and reconstruction following mastectomy. If a woman undergoes implantation in one breast and contralateral reduction surgery, she is exclusively enrolled in the implantation cohort. In case of reconstruction with breast implant and

contralateral implantation in order to establish symmetry, both implantations are registered, and the contralateral implantation is coded as a sub-group. Breast reconstruction with a combination of implant and use of autologous tissue are included in the implantation cohort. Reconstructions without use of implants are not included.



## REGISTRATION

### ...Registry Data

Women who undergo breast reduction or mastopexia are invited to join the DPB to serve as a comparison group in outcome studies as well as for quality assessment of the reduction procedures themselves. Prior breast cancer is an exclusion criterion for the reduction cohort.

#### Source of data

For both clinics and patients participation is voluntary. Participating clinics are listed on page 10.

Using DPB-generated operation and follow-up sheets, notifications are forwarded to the DPB from public hospital departments and private clinics of plastic surgery. The surgeons register date of operation, indication and type of operation, surgical technique and implant characteristics. Additionally, the surgeons provide reports on objective findings and any adjuvant treatment when the patients are seen at follow-up visits. Any registered woman, who wish-

es to be removed from the DPB, can submit a written request and her data will be deleted from the DPB.

#### Clinical registration

At the first consultation prior to surgery, the women are informed about the surgery and risk of complications and about the central registration procedures of the DPB, and asked to consider participation. Written information on the goals and methods of the registration, including a consent form, is given to the patient. Further information is available by phone from the administrator of the DPB. For each woman, data are obtained using the pre-operative questionnaire, an operation sheet and a post-operative follow-up sheet (Table 1). At each clinic, the registration procedure has been planned in cooperation with the staff to ensure that it fits into the daily routines of the clinic and minimizes time expenditure. The clinics are reimbursed for costs at 14 Euro for each registered woman.

**Table 1. Clinical registration procedure**

Preoperatively	<ol style="list-style-type: none"> <li>1. Information about registration is provided by surgeon at the first consultation</li> <li>2. Women who accept registration fill in a self-administered <i>questionnaire</i></li> </ol>	The woman mails the questionnaire directly to the Danish Registry for Plastic Surgery of the Breast, DPB
Perioperatively	<ol style="list-style-type: none"> <li>1. A blood sample is drawn prior to implantation/other breast surgery</li> <li>2. The <i>operation sheet</i> is completed by the surgeon</li> </ol>	The clinical staff mails the blood sample to the State Serum Institute and the operation sheet to the DPB
Postoperatively	<ol style="list-style-type: none"> <li>1. The follow-up sheet is kept in the medical file and updated at clinical consultations. The surgeon registers date, objective findings and, if relevant, additional treatment.</li> </ol>	The clinical staff mails the follow-up sheet to the DPB when patient follow-up terminates at the clinic

#### Blood collection procedure

Women accepting registration are asked to provide a blood sample. Immediately following anaesthesia but prior to breast surgery, blood samples are obtained from an extremity not used for anaesthesia. Silicone-free hypodermic needles, two vacutainers of 7 ml (with no additive) with glycerin plugs, and powder-free/silicone-free gloves

are used for the blood sampling. The blood samples are sent to the State Serum Institute where they are centrifuged at 3000 rpm and the supernatant is stored in multiples of 2-ml aliquots at -20 degrees Celsius. Any use of the blood samples must be approved by the DPB Oversight Board and the Danish Ethical Committee System.



## REGISTRATION

### ...Registry Data

#### Central registration and coding

The DPB functions as a clearing house and information is registered in accordance with the rules for the administration of registers laid down by the Danish Data Protection Agency. DPB utilizes an Access database for the registration of key data and a SAS-library for analyses. When the sheets are returned from the clinics, they are reviewed, and key data (i.e., a clinic-specific number, operation- and follow-up dates) and the patient's name and personal identification number (PIN) are checked during data entry in the registration database. Hereafter the identification data are replaced by a unique, random patient sequence number, before the notified information is coded and transferred to the computerized system (Details in appendix B). After computer-assisted checking of the data has been completed, the datasets are updated at regular intervals.

#### Validation of data

The clinical data are validated by comparison with notes in the medical files for consecutively included patients and for random samples. Validity of key data is checked during data entry by built-in functions in the registration database. Errors of structure and content of data from the various sources are checked manually and by automatic checking/merging of DPB databases. Special programs have been written in Visual Basic for Applications (VBA) used in Access, which enable verification of input, automatic generation of codebooks and SAS set-ups for error checking and correction.

#### Data access

Permission to use data from the DPB is based on scientific criteria. Personally identifiable information is available for the purpose of specific research projects only. Prior to access, a protocol for the research project must be approved by the Oversight Board of the DPB and the Ethical Committee. In addition, the requested data must be clearly specified. Authorship of scientific papers based on data from the DPB must follow the requirements of

the Vancouver Group. The Oversight Board supervises that the rules concerning data access and processing are observed.

Clinics reporting to the DPB have access to their own data in statistical form. Furthermore, for the purpose of internal quality assessment, they are also granted access to overall data in aggregate form, which are published regularly.

In case of extraordinary, adverse effects of specific surgical procedures or types of surgical implants, the reporting clinics can be granted access to their own patients' relevant person-specific data for the purpose of appropriate control and/or follow-up treatment.

#### Organisation

DPB is located in Copenhagen, at the Department of Medicine and Genetics within the Institute of Epidemiology, Strandboulevarden 49, DK-2100 Copenhagen. Scientific oversight is performed by the Oversight Board of the DPB, which is composed of: *Vibeke Breiting*, MD, Plastic surgeon, Holte Clinic for Plastic Surgery and *Benedikte Thuesen*, MD, Plastic surgeon, the Erichsen Clinic, who were both appointed by the Danish Society of Aesthetic Plastic Surgery; The Danish Society of Plastic & Reconstructive Surgery appointed *Annette Pernille Hoyer*, MD, Plastic surgeon, Department of Plastic Surgery, Copenhagen University Hospital, Herlev, and *Morten Bischoff-Mikkelsen*, MD, Plastic surgeon, Department of Plastic Surgery, Odense University Hospital. In addition, Dr Bischoff-Mikkelsen was also appointed by the plastic surgery societies' joint committee on quality control. The chair of the Oversight Board is *Jørgen H Olsen*, Professor, MD, DMSc, Head of Institute of Epidemiology, and the secretary of the Oversight Board is *Trine F Henriksen*, MD, Institute of Epidemiology, Danish Cancer Society.

Professionals with special expertise may be invited by the Oversight Board to serve on a Scientific Advisory Panel for the DPB. At present the Scientific Advisory Panel is



## REGISTRATION

### ...Registry Data

comprised of specialists within the fields of rheumatology, immunology and plastic surgery: *Allan Wiik*, MD, DMSc, Head of Department of Autoimmunology, the State Serum Institute, *Paul Halberg*, MD, DMSC, Department of Rheumatology, Copenhagen University Hospital, H:S Hvidovre, *Christen Krag*, MD, DMSc, Plastic surgeon, Department of Plastic Surgery, Copenhagen University Hospital, Herlev, *Jens Jørgen Elberg*, MD, Plastic surgeon, Clinic of Plastic Surgery, Copenhagen University Hospital, H:S Rigshospitalet and Frederiksborg Clinic for Plastic Surgery and, *Kim D Kjoller*, MD, former employee at Institute of Cancer Epidemiology, now Medical Director at Lundbeck, and *Lisbet Hölmich*, MD, Institute of Epidemiology, Danish Cancer Society and Department of Plastic Surgery, Copenhagen University Hospital, Herlev. The Panel is summoned twice a year by the Oversight Board, and may participate in decisions concerning research projects and special issues concerning the Registry.

Daily administration is maintained by the full-time Registry administrator, *Trine F Henriksen*, MD, who is responsible for the organisation of the DPB, including the establishment of contacts with plastic surgeons, nurses and researchers and a project nurse, *Randi Karlsen*, who assists in the registration and correspondence with the clinics. The data manager, senior programmer *Henrik Gregersen*, is responsible for the continuous maintenance and updates of the databases kept in the DPB. (Rules and regulations for the Registry in Appendix A).

International Epidemiology Institute, Rockville, Maryland, and the Dow Corning Corporation, Midland, Michigan, USA funded the establishment and preservation of the DPB through the year 2003. For the coming year, another implant manufacturer Inamed Corporation, Santa Barbera, California will sponsor the DPB.



## REGISTRATION

### Status of registration

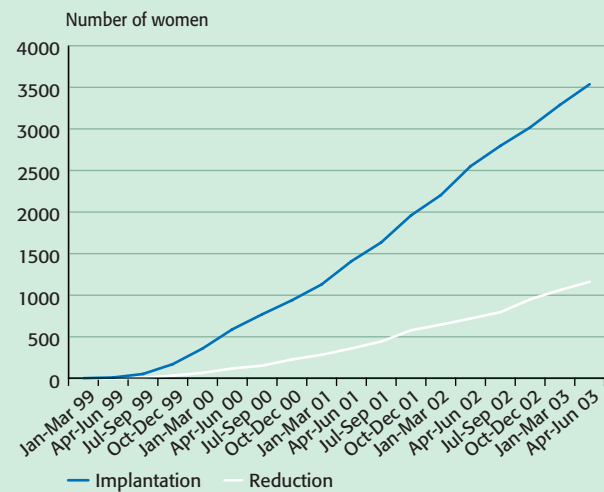
The participating clinics and departments have been enrolled successively since implementation of the registration. Currently, all public clinics of plastic surgery and the majority of private clinics performing mammoplasties contribute to the registration. An additional four clinics have agreed to participate in the registration.

Clinics contribute both clinical and biological data, however, four clinics do not provide blood samples.

From June 1999 to 25 April 2003, a total of 3,537 women, seeking breast implants were included in the DPB. Of these, surgical information and questionnaire data were received for 2,951 women, for the remaining 586 patients questionnaire data were recorded. Usually, a latency period from 1 week to 1 month was observed between times where questionnaires were mailed by the patient until surgical data were registered in the DPB. Additionally, 1,161 women, seeking breast reduction or mastopexy were included in the DPB. As shown in Figure 2, the total number of operations registered in DPB has increased steadily over time.

From most surgeons we are informed that the patients are willing to participate, and when the registration procedure has become a routine, the time-consumption is minor. Patients may participate with or without questionnaire data or blood-samples, although the majority provides both.

**Figure 2**  
Accumulated number of women registered in DPB



The registration appears to provide a feeling of security for both women who are enrolled in the DPB as well as for women, who are considering implantation. Many patients have contacted the DPB-administrator with questions and comments. Several of these have emphasized that they approve of surgeons who actively contribute to quality assessment and care about the postoperative course.



## REGISTRATION

...Status of registration

Figure 1 Participating private and public clinics

THE DANISH REGISTRY FOR PLASTIC SURGERY OF THE BREAST



**Implantation mammoplasty • Registered in the DPB****Analysis strategy**

All women undergoing implant related operations were grouped in cohorts according to pre-operative health status. Healthy women undergoing augmentation or correction of the breast were included in the cosmetic cohort. Women receiving implantation with or without autologue tissue reconstruction of the breast after mastectomy were included in the reconstructive cohort.

Analyses were conducted separately for the cosmetic and reconstructive implantations; initial cosmetic implantation and subsequent implantation were analysed separately on both patient and implant levels. If a woman had her primary implant registered in the DPB, and also had an implant exchange, she would be included in both the analyses of the primary implant group and the revision group. Further, if a woman initially registered in the cosmetic cohort subsequently underwent post-mastectomy breast reconstruction, she changed status and contributed follow-up time in the reconstruction cohort from the date of reconstruction surgery. Women, who had undergone implant reconstruction and a contralateral augmentation to enhance symmetry, are exclusively included in the reconstructive cohort and in this report only the reconstructive implantation is included in the analysis.

Simple descriptive statistics were calculated to describe the study population and various surgical and implant characteristics. For all but immediate post-operative events, incidence rates were calculated as numbers of events per 1000 person-months for the first two years after implantation. The follow-up period for clinical outcome started on the date of first implantation procedure and ended on the date of last residence in Denmark, exchange of implant (censoring was only performed at implant level; follow-up on patient level continued), or the end of study (April 25, 2003), whichever came first. Similarly, in the analyses of subsequent implantations, follow-up started on the date of implant exchange or implant insertion after earlier removal and ended on the date of last residence in Denmark, re-exchange of implant, or April 25, 2003, whichever came first.

**Summary of implantation statistics from June 1999 to April 2003:****Operations included in the DPB:**

In total 5,933 implant related operations were registered: 4,595 were first implantations (4,043 for cosmetic purpose, 552 for reconstructive purpose), and 1,016 were re-implantations (implant exchanged (930) or implant placed after earlier removal (86)). Another 186 revisions were performed without inserting a new implant (explantation or implant left in situ). Finally, four revisions with unknown implant status and 132 contra lateral breast operations were recorded Table 3 lists all operations registered in DPB. Due to inconsistent data 154 initial implantations (30 cosmetic, 124 reconstructive) and 110 re-implantations (21 cosmetic, 89 reconstructive) were excluded from analysis, thus the report is based on the remaining 4,439 initial implantations (4,013 cosmetic and 426 reconstructive) and 906 re-implantations (535 cosmetic and 371 reconstructive), respectively.

**Women included in the DPB:**

Through April 2003, a total of 2,793 women undergoing breast implantation constituted the implantation cohort in DPB: 2,277 women who underwent breast augmentation or correction due to aplasia or developmental malformation (cosmetic cohort), and 516 women who underwent post-mastectomy reconstruction of the

**Table 2.**

	<b>Cosmetic cohort</b> Women undergoing augmentation or correction	<b>Reconstructive cohort</b> Women undergoing reconstruction after mastectomy	<b>Total</b>
First implantation	2,027	357	2,384
Re-implantation	276	275	551
Total	2,303	632	2,935*

\* A woman may be registered with both first implantation and re-implantation(s) and hereby contribute with follow-up time in both subgroups. Thus, in the cosmetic cohort 26 women were included in both groups. In the reconstructive cohort 116 women were included in both groups.



**Implantation mammoplasty • Registered in the DPB**

breast (reconstructive cohort).

For 2,384 women, the index implantation was a first implantation. 85% of these women underwent a cosmetic implantation, whereas 15% underwent a reconstruction following mastectomy, as shown in Table 2 and Table 4. Among patients undergoing breast augmentation or correction the mean age at the time of initial implantation was 32 years (range, 15 to 66 years). All patients younger than 18 years (n=10) received implants for medical indications (severe asymmetry, aplasia of breast tissue or congenital malformation), thus the youngest patients received unilateral prostheses. In the reconstructive cohort, age at first implantation ranged from 21 to 78 years, with a mean of 50 years.

**Implant characteristics :**

Indication for surgery at implant level is shown in Table 5 and 6. Mode of implantation and implant characteristics stratified for cosmetic and reconstructive, as well as primary and subsequent implantations, is shown in Tables 7-10. Of the implants used for initial augmentation or correction of developmental anomalies, 99% were silicone-gel filled (76% standard silicone-gel, 23% cohesive gel), and 93% had textured surface. Implant size ranged from 80-775 cc, with 300 cc as the most common size (Table 9-10). Most surgical approaches were through the inframammary fold (77%) and most implants were placed in the submuscular position (70%). Systemic antibiotics were frequently used, either alone (51%) or combined with local antibiotics (30%). Virtually the same implant characteristics and surgical

procedures were current for subsequent implantations. Reconstructive breast implantation after mastectomy, were generally performed through the mastectomy scar. Forty-seven percent of the initial implants were expanders, which subsequently were exchanged to permanent prostheses. Implants used for subsequent implantation included silicone-gel filled (84%), saline-filled (6%), double-lumen implants (4%), while 6% were expanders. Size of implants was slightly higher in the reconstructive cohort, with 330 cc being the most common size. For most reconstructions both prophylactic antibiotics (>65%) and drainage of the cavity were used. Exchange of the temporary expanders to permanent prostheses was the most common indication for re-implantation in the reconstructive cohort.

At explantation after cosmetic implantation 61% of the implants were intact; 7% were intact but oily while 21% had ruptured (17% before explantation, 3% during explantation). Silicone was observed at the outside of the implant in 18%, and calcification recorded in 7%. In 24% of explantations the brand of the implant was unknown. During reconstructive courses, 53% of the removed implants were expanders, the majority (78%) intact, while rupture was recorded among 11%.



## ...Implantation • Tabela

Table 3. Implant-related operations registered in the DPB

Characteristic	Cosmetic		Reconstruction		Total	
	n	(%)	n	(%)	n	(%)
<b>1. Primary implantation</b>	4043	(100)	552	(100)	4595	(100)
1.1 Implantation exclusively	3860	(97)	481	(99)	4341	(97)
1.2 Implantation + mastopexia	146	(3)	9	(1)	155	(3)
1.3 Implantation + other surgery	37	(0)	62	(0)	99	(0)
<b>2. Revision</b>	668	(100)	538	(100)	1206	(100)
2.1 Revision without capsulotomy/-ectomy	368	(55)	265	(49)	633	(52)
2.11 Implant removed	28	(4)	21	(4)	49	(4)
2.12 Implant in situ	40	(6)	17	(3)	57	(85)
2.13 Implant exchanged	299	(45)	227	(42)	526	(44)
2.14 Missing/ Unknown	1	(0)	0	(0)	1	(0)
2.2 Capsulotomy	122	(18)	146	(27)	268	(22)
2.21 Implant removed	4	(1)	2	(0)	6	(0)
2.22 Implant in situ	14	(2)	15	(3)	29	(2)
2.23 Implant exchanged	104	(16)	129	(24)	233	(19)
2.24 Missing/ Unknown	0	(0)	0	(0)	0	(0)
2.3 Capsulectomy	72	(11)	26	(5)	98	(8)
2.31 Implant removed	6	(1)	3	(1)	9	(1)
2.32 Implant in situ	4	(1)	0	(0)	4	(0)
2.33 Implant exchanged	62	(9)	23	(4)	85	(7)
2.34 Missing/ Unknown	0	(0)	0	(0)	0	(0)
2.4 Revision + mastopexia	24	(4)	6	(1)	30	(2)
2.41 Implant removed	0	(0)	0	(0)	0	(0)
2.42 Implant in situ	1	(0)	0	(0)	1	(0)
2.43 Implant exchanged	23	(3)	6	(1)	29	(2)
2.44 Missing/ Unknown	0	(0)	0	(0)	0	(0)
2.5 Revision + other surgery	40	(6)	51	(9)	91	(8)
2.51 Implant removed	2	(0)	2	(0)	4	(0)
2.52 Implant in situ	10	(1)	17	(3)	27	(2)
2.53 Implant exchanged	26	(4)	31	(6)	57	(5)
2.54 Missing/ Unknown	2	(0)	1	(0)	3	(0)
2.6 Implant placed after earlier removal	42	(6)	44	(8)	86	(7)
<b>3. Contralateral mastopexy/reduction surgery</b>	23	(100)	109	(100)	132	(100)
<b>Total</b>	4734	(80)	1199	(20)	5933	(100)

Distribution of operations registered in DPB June '99-April '03 by first implantation and revisions. A patient may have more than one operation, e.g. a first implantation of each breast and subsequent revision(s). Of the 4043 initial cosmetic implantations recorded to the DPB, 30 were flawed by inconsistent data, leaving 4013 implants among 2027 women for analysis. Of the 552 initial reconstructive implantations, 126 were flawed by inconsistent data, leaving 426 implants among 357 women for analysis. First implantations and reimplantations are the focus of this report.

**Characteristics of women registered in the DPB at their first implantation**

**Table 4. Indication for first implantation**  
(n=2384 women)

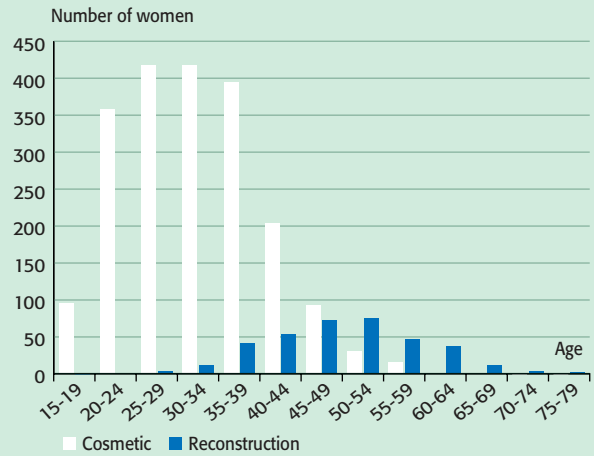
	Cosmetic cohort <sup>1</sup> Aesthetic or corrective implantation	Reconstructive cohort <sup>2</sup> Post-mastectomy implantation
Number of women (Number of implants)	2,027 4,013	357 426
<b>Indication for first implantation</b>		
• Augmentation	1,939	0
• Correction for malformation	88	0
• Reconstruction	0	357
<b>Age at first implantation</b>		
Mean age	32	50
Range	15-66	21-78
Standard deviation	8	9

Proportional distribution of indication for first implantation.

<sup>1</sup>The cosmetic cohort comprises healthy women receiving augmentation or correction due to aplasia of breast tissue uni- or bilaterally, or other developmental anomalies.

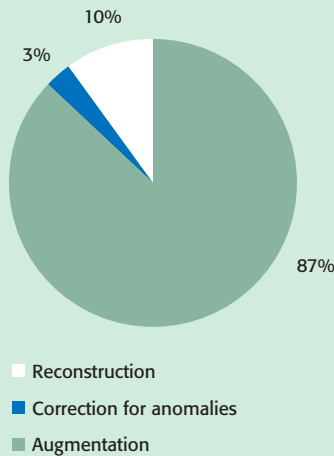
<sup>2</sup>The reconstructive cohort comprises women receiving an implant following mastectomy (after breast cancer or prophylactically because of genetic predisposition to breast cancer).

**Figur 3. Age distribution**  
(n=2384 women)



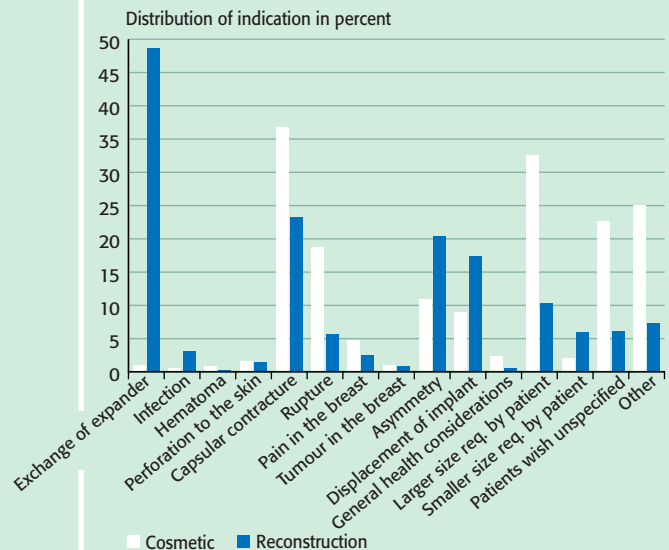
**Indication for breast surgery – implant level**

**Figur 4. Indication for first implantation**  
(n=4441 implants)



Proportional distribution of indication for first implantation on breast level.

**Figur 5. Indication for explantation**  
(revision with removal or exchange of implant (n=871))



Proportional distribution of indication for removal or exchange of implants. Multiple indications are possible at one revision. Revisions with implant in situ are not included in this figure.



## Indication for breast surgery – implant level

Table 5. Indication for first implantation – implant level

Characteristic Indication for primary implantation	Cosmetic		Reconstruction		Total	
	N=4,013	(%)	N=426	(%)	N=4,439	(%)
Augmentation	3870	(96)	0	(0)	3870	(87)
Reconstruction	0	(0)	426	(100)	426	(10)
Correction of malformation	143	(4)	0	(0)	143	(3)

Table 6. Indication for explantation – implant level

Characteristic Indication for revision with removal or exchange of implant	Cosmetic		Reconstruction		Total	
	N=513*	(%)	N=358**	(%)	N=871	(%)
Exchange of expander	5	(1)	174	(49)	179	(21)
Infection	3	(1)	11	(3)	14	(2)
Hematoma	4	(1)	1	(0)	5	(1)
Perforation to the skin	8	(2)	5	(1)	13	(2)
Capsular contraction***	189	(37)	83	(23)	272	(31)
- Baker II	45	(9)	24	(7)	69	(8)
- Baker III	86	(17)	40	(11)	126	(15)
- Baker IV	57	(11)	17	(5)	74	(9)
Rupture (suspicion of)	96	(19)	20	(6)	116	(13)
Pain	24	(5)	9	(3)	33	(4)
Tumor in the breast	5	(1)	3	(1)	8	(1)
Asymmetry	56	(11)	73	(20)	129	(15)
Displacement of implant	46	(9)	62	(17)	108	(12)
General health considerations	12	(2)	2	(1)	14	(2)
Larger size req. by patient	167	(33)	37	(10)	204	(23)
Smaller size req. by patient	11	(2)	21	(6)	32	(4)
Patient's wish unspecified	116	(23)	22	(6)	138	(16)
Other indication	128	(25)	26	(7)	154	(18)

At each revision multiple indications were possible, thus, total percentage exceeds 100%

\* Re-implantations were registered in DPB for 276 women with cosmetic implants (augmentation or correction): 513 explantations were registered, while the remaining women got re-implantations after earlier removal of an implant.

\*\* Re-implantations were registered in DPB for 275 women after implantation for the purpose of reconstruction of the breast (including exchange of expander to permanent prosthesis) corresponding to 358 explantations.

\*\*\* Some surgeons reported both overall capsular contracture and a specific subgroup, while others only reported overall contracture.

**Mode of implantation****Table 7. Mode of implantation at first implantation – implant level**

Characteristic	First implantation					
	Cosmetic N=4,013 (%)		Reconstruction N=426 (%)		Total N=4,439 (%)	
<b>Surgical Route</b>						
Inframammary	3,115	(77)	18	(4)	3,133	(71)
Axillary	6	(0)	10	(2)	16	(0)
Areolar	95	(2)	13	(3)	108	(2)
Mastectomy scar	0	(0)	237	(56)	237	(5)
Other	116	(3)	39	(9)	157	(4)
Missing	681	(17)	107	(25)	788	(18)
<b>Location of Implant</b>						
Subglandular	1,165	(29)	0	(0)	1,165	(26)
Submuscular	2,797	(70)	411	(96)	3,208	(72)
Other/Missing	51	(1)	15	(3)	66	(1)
<b>Use of Antibiotics</b>						
Local	11	(0)	1	(0)	12	(0)
Systemic	2,056	(51)	288	(68)	2,344	(53)
Local and systemic	1,213	(30)	17	(4)	1,230	(6)
None	250	(6)	5	(1)	255	(27)
Missing	483	(13)	115	(27)	598	(13)
<b>Use of other prophylactic medical treatment</b>						
Yes	513	(13)	28	(7)	541	(12)
No	3,500	(87)	398	(93)	3,898	(88)
<b>Drainage implant cavity</b>						
Yes	1,315	(33)	360	(85)	1,675	(38)
No	2,430	(60)	26	(6)	2,456	(55)
Missing	268	(7)	40	(9)	308	(7)
<b>Anesthesia</b>						
General	2,893	(72)	293	(68)	3,186	(72)
Local	2	(0)	1	(0)	3	(0)
General and local	644	(16)	14	(3)	658	(15)
Missing	474	(12)	118	(28)	592	(13)

Table 7 shows surgical information for women receiving first implantation. 2027 women received first implantation for cosmetic purpose (augmentation or correction) corresponding to 4013 implants. 357 women underwent post-mastectomy reconstruction, corresponding to 426 implants



## ...Mode of implantation

Table 8. Mode of implantation at re-implantation – implant level

Characteristic	Re-implantation					
	Cosmetic N=535 (%)		Reconstruction N=371 (%)		Total N=906 (%)	
<b>Surgical Route</b>						
Inframammary	381	(71)	28	(8)	409	(45)
Axillary	0	(0)	8	(2)	8	(1)
Areolar	15	(3)	0	(0)	15	(2)
Mastectomy scar	0	(0)	242	(65)	242	(27)
Other	21	(4)	21	(6)	42	(45)
Missing	118	(22)	72	(19)	190	(21)
<b>Location of Implant</b>						
Subglandular	186	(35)	0	(0)	186	(21)
Submuscular	336	(63)	352	(95)	688	(76)
Other/Missing	13	(2)	19	(5)	32	(4)
<b>Use of Antibiotics</b>						
Local	4	(1)	1	(0)	5	(1)
Systemic	273	(51)	256	(69)	529	(58)
Local and Systemic	138	(26)	15	(4)	153	(17)
None	32	(6)	8	(2)	40	(4)
Missing	88	(16)	91	(25)	179	(20)
<b>Use of other prophylactic medical treatment</b>						
Yes	43	(8)	27	(7)	70	(8)
No	492	(92)	344	(93)	836	(92)
<b>Drainage implant cavity</b>						
Yes	282	(53)	182	(49)	464	(51)
No	206	(39)	130	(35)	336	(37)
Missing	47	(9)	59	(16)	106	(12)
<b>Anaesthesia</b>						
General	373	(70)	271	(73)	644	(71)
Local	2	(0)	0	(0)	2	(0)
General and local	74	(14)	11	(3)	85	(9)
Missing	86	(16)	89	(24)	175	(19)

Table 8 shows surgical data for women undergoing re-implantation (exchange of implant or implantation after earlier removal of an implant). 276 women with implants for cosmetic purpose (augmentation or correction) received re-implantation (corresponding to 535 implants), and 275 women received re-implantation as part of the reconstructive course (corresponding to 371 implants)



**Implant characteristics****Table 9. Implant characteristics at first implantation – implant level**

Characteristic	First implantation					
	Cosmetic		Reconstruction		Total	
	N=4013	(%)	N=426	(%)	N=4439	(%)
<b>Filler type</b>						
Silicone gel	3050	(76)	23	(5)	3073	(69)
Cohesive silicone	912	(23)	31	(7)	943	(21)
Saline	31	(1)	62	(15)	93	(2)
Saline and silicone (combined prosthesis)	7	(0)	105	(25)	112	(3)
Hydrogel	8	(0)	0	(0)	8	(0)
Expander	0	(0)	201	(47)	201	(5)
Missing	5	(0)	4	(1)	9	(0)
<b>Surface</b>						
Silicone, smooth	252	(6)	3	(1)	255	(6)
Silicone, textured	3720	(93)	409	(96)	4129	(93)
Other/Missing	41	(1)	14	(3)	55	(1)
<b>Size* (ml)</b>						
80-259	934	(23)	45	(11)	979	(22)
260-299	838	(21)	12	(3)	850	(19)
300-349	1126	(28)	11	(3)	1137	(26)
350-775	1051	(26)	27	(6)	1078	(24)
Missing	64	(2)	331	(78)	395	(9)
Mean	304		283		303	
Mode	300		200		300	
Range	80-775		80-600		80-775	

Table 9 shows characteristics for implants used for first implantation. 2,027 women received first implantation for cosmetic purpose (augmentation or correction) corresponding to 4,013 implants. 358 women underwent reconstruction following mastectomy, corresponding to 426 implants.

\* Size is not recorded for expanders.



## ...Implant characteristics

Table 10. Implant characteristics at re-implantation – implant level

Characteristic	Re-implantation					
	Cosmetic N=535 (%)		Reconstruction N=371 (%)		Total N=906 (%)	
<b>Filler type</b>						
Silicone gel	415	(78)	69	(19)	484	(53)
Cohesive gel	108	(20)	241	(65)	349	(39)
Saline	6	(1)	21	(6)	27	(3)
Saline and silicone (combined prosthesis)	1	(0)	15	(4)	16	(2)
Hydrogel	0	(0)	0	(0)	0	(0)
Expander	2	(0)	22	(6)	24	(3)
Missing	3	(1)	3	(1)	6	(1)
<b>Surface</b>						
Silicone, smooth	34	(6)	0	(0)	34	(4)
Silicone, textured	493	(92)	355	(96)	848	(94)
Other/Missing	8	(2)	16	(4)	24	(3)
<b>Size* (ml)</b>						
80-259	113	(21)	75	(20)	188	(21)
260-299	69	(13)	31	(8)	100	(11)
300-349	115	(22)	52	(14)	167	(18)
350-775	222	(42)	153	(41)	375	(41)
Missing	16	(3)	60	(16)	76	(8)
Mean	334		340		336	
Mode	300		330		300	
Range	125-775		100-650		100-775	

Table 10 shows implant characteristics for implants used for re-implantation. 276 women with implants for cosmetic purpose (augmentation or correction) received re-implantation (corresponding to 535 implants), and 275 women received re-implantation as part of the reconstructive course (corresponding to 371 implants).

\* Size is not recorded for expanders.



## ...Implant characteristics

Table 11. Implant characteristics at explantation – implant level

Characteristic	Explantation					
	Cosmetic		Reconstruction		Total	
	N=513	(%)	N=358	(%)	N=871	(%)
<b>Status of explanted implant</b>						
Intact implant	314	(61)	280	(78)	594	(68)
Intact but oily implant	37	(7)	8	(2)	45	(5)
Ruptured implant	110	(21)	39	(11)	149	(17)
Ruptured prior to explantation	87	(17)	31	(9)	118	(14)
Ruptured during explantation	15	(3)	5	(1)	20	(2)
<b>Silicone-gel outside the implant*</b>						
Intracapsular	90	(18)	24	(7)	114	(13)
Extracapsular	82	(16)	21	(6)	103	(12)
Missing	4	(1)	0	(0)	4	(0)
Calcification	4	(1)	0	(0)	4	(0)
Other findings	37	(7)	2	(1)	39	(4)
	34	(7)	16	(4)	50	(6)
<b>Filler type of removed implant</b>						
Expander	5	(1)	190	(53)	195	(11)
Silicone	369	(72)	94	(26)	463	(53)
Saline	22	(4)	20	(6)	42	(5)
Saline + Silicone	6	(1)	29	(8)	35	(4)
Hydrogel	20	(4)	1	(0)	21	(2)
PVP	17	(3)	0	(0)	17	(2)
Other	10	(2)	6	(2)	16	(2)
Missing	64	(13)	18	(5)	82	(9)
<b>Brand unknown</b>						
Yes	123	(24)	22	(6)	145	(17)
No	390	(76)	336	(94)	726	(83)
<b>Size</b>						
Mean	252		386		293	
Median	240		355		260	
Mode	200		600		200	
Range	0-650		75-900		0-900	
Missing (N)	188		215		403	

Table 11 shows implant characteristics at explantation.

\* Several categories are possible. Some surgeons reported both overall category "silicone-gel outside the implant" and a specific subgroup, while others only reported the overall category.

**Follow-up course • Implantation surgery****Analysis strategy.**

Stratified analyses were conducted for the four groups: (i) first implantation for cosmetic purpose, (ii) first implantation for reconstructive purpose, (iii) cosmetic re-implantation, and (iv) reconstructive re-implantation, including exchange of expander. If a woman had her first implant registered in the DPB, and also had an implant exchange, she contributes with follow-up time from the primary implantation until revision in the "first implantation-group" and at the date of exchange of implant she changes status and contributes with follow-up time in the "re-implantation group". Women who underwent implant reconstruction and a contralateral augmentation to enhance symmetry are exclusively included in the reconstructive cohort. The reconstructive implantation is analyzed, whereas the contralateral breast, which is coded as a sub-group, is not included in the presented follow-up data. Follow-up analyses were conducted on both the implant and woman level. For the implant-level analysis, follow-up is calculated from the date of operation until the date of the outcome of interest. For the woman-level analysis, follow-up is calculated from the date of operation until the earliest date of the outcome of interest regardless of implant side. Incidence rates of complications based on the entire cohort were compared with incidence rates based on women from clinics that reported follow-up data on more than at least 90% of their patients. Higher complication rates were found in the cohort based on the clinics with at least 90% follow-up. Therefore, to reduce the risk of selection bias the analyses reported below are based on the clinics where 90% of the women were followed-up. This left 2030 women with 3553 implants for analysis.

**Summary on follow-up statistics**

for those women who had an implantation in a clinic with at least 90% follow-up of patients after surgery. DPB June 1999-April 2003.

**Clinical follow-up:**

In total, 2030 women were followed for an average of 22 months (range 0 to 49) at clinics that reported follow-up data for more than 90% of their patients.

1,247 women (2,458 implantations) were followed clinically after primary cosmetic implantation (Table 12.1). 265 of the 1,247 women (21%) developed some degree of adverse effect/complication, ranging from minor adverse effect (such as temporary change of tactile sense or minor asymmetry of the breasts) to complications requiring medical and surgical interventions (Baker 3-4 capsular contracture, peri-prosthetic infection or perforation to the skin). Six percent of primary implantations were followed by complications requiring surgical intervention. However, the majority of adverse effects was insignificant and required no treatment. Overview of the degree of adverse effects following primary cosmetic implantation is given in Table 14.

During reconstructive courses after mastectomy, 33% of the women developed adverse effects after primary implantation. Infection was the most frequent immediate complication (8%), while asymmetry/displacement of the implant was the most frequent delayed adverse effect (9%) In total, 22% of the women in the reconstructive cohort received further surgical intervention, while 3.2% received other treatment. The degree of the most common adverse effects is shown in Table 15.



## ...Follow-up course

Table 12.1 Incidence of complications following first cosmetic implantation

	Initial implantation					
	Adverse effects				Incidence rate per 1000 person-months	
	Implant level N=2,458		Woman level N=1,247		Implant level	Woman level
	N	(%)	N	(%)	IR*	IR*
<b>Immediate adverse effects</b>						
Wound infection	14	(0.6)	13	(1.0)		
Peri-prosthetic infection	2	(0.1)	2	(0.2)		
Wound rupture	3	(0.1)	2	(0.2)		
Perforation to the skin	2	(0.1)	2	(0.2)		
Hematoma	16	(0.7)	15	(1.2)		
Seroma	1	(0.0)	1	(0.1)		
Change of tactile sense	178	(7.2)	113	(9.1)		
<b>Delayed short-term adverse effects</b>						
Capsular contracture, Baker grade II	46	(1.9)	41	(3.3)	0.98	1.74
Capsular contracture, Baker grade III-IV	26	(1.1)	21	(1.7)	0.55	0.87
Implant rupture	0	(0.0)	0	(0.0)	0.00	0.00
Visible skin wrinkles	19	(0.8)	15	(1.2)	0.40	0.62
Palpable implant folds	22	(0.9)	16	(1.3)	0.46	0.67
Asymmetry/displacement of the implant	63	(2.6)	44	(3.5)	1.34	1.86
Prolonged pain in the breast (> 3 months)	17	(0.7)	13	(1.0)	0.36	0.54
Necrosis	1	(0.0)	1	(0.1)	0.02	0.04
Ptoxis	14	(0.6)	8	(0.6)	0.29	0.33
Asymmetry of mamillae	4	(0.2)	2	(0.2)	0.08	0.08
<b>Other</b> (E.g. bruising or swelling)	33	(1.3)	20	(1.6)		

A patient may have developed more than one adverse effect after an implantation.

\* Incidence rates at implant level are calculated as numbers of events per 1000 implant-months. Incidence rates at patient level are calculated per 1000 person-months.



## ...Follow-up course

Table 12.2 Incidence of complications following subsequent cosmetic implantation

	Subsequent implantation					
	Adverse effects				Incidence rate per 1000 person-months	
	Implant level N=312		Woman level N=163		Implant level	Woman level
	N	(%)	N	(%)	IR*	IR*
<b>Immediate adverse effects</b>						
Wound infection	8	(2.6)	7	(4.3)		
Peri-prosthetic infection	0	(0.0)	0	(0.0)		
Wound rupture	1	(0.3)	1	(0.6)		
Perforation to the skin	2	(0.6)	2	(1.2)		
Hematoma	5	(1.6)	4	(2.5)		
Seroma	0	(0.0)	0	(0.0)		
Change of tactile sense	3	(1.0)	3	(1.8)		
<b>Delayed short-term adverse effects</b>						
Capsular contracture, Baker grade II	6	(1.9)	5	(3.1)	0.96	1.58
Capsular contracture, Baker grade III-IV	6	(1.9)	4	(2.5)	0.97	1.26
Implant rupture	0	(0.0)	0	(0.0)	0.00	0.00
Visible skin wrinkles	2	(0.6)	2	(1.2)	0.31	0.61
Palpable implant folds	10	(3.2)	7	(4.3)	1.64	2.25
Asymmetry/displacement of the implant	9	(2.9)	8	(4.9)	1.46	2.60
Prolonged pain in the breast	4	(1.3)	3	(1.8)	0.64	0.94
Necrosis	0	(0.0)	0	(0.0)	0.00	0.00
Ptosis	1	(0.3)	1	(0.6)	0.16	0.31
Asymmetry of mammillae	1	(0.3)	1	(0.6)	0.16	0.31
<b>Other</b>	12	(3.8)	9	(5.5)		

A patient may have developed more than one adverse effect after an implantation.

\* Incidence rates at implant level are calculated as numbers of events per 1000 implant-months. Incidence rates at patient level are calculated per 1000 person-months.



## ...Follow-up course

Table 13.1 Incidence of complications following initial reconstructive implantation

	Initial implantation					
	Adverse effects				Incidence rate per 1000 person-months	
	Implant level N=417		Woman level N=349		Implant level	Woman level
	N	(%)	N	(%)	IR*	IR*
<b>Immediate adverse effects</b>						
Wound infection	28	(6.7)	27	(7.7)		
Peri-prosthetic infection	15	(3.6)	13	(3.7)		
Wound rupture	6	(1.4)	5	(1.4)		
Perforation to the skin	11	(2.6)	10	(2.9)		
Hematoma	12	(2.9)	11	(3.2)		
Seroma	14	(3.4)	14	(4.0)		
<b>Delayed short-term adverse effects</b>						
Capsular contracture, Baker grade II	35	(8.4)	30	(8.6)	6.01	6.20
Capsular contracture, Baker grade III-IV	18	(4.3)	16	(4.6)	3.12	3.33
Implant rupture	2	(0.5)	2	(0.6)	0.34	0.41
Visible skin wrinkles	6	(1.4)	5	(1.4)	1.03	1.03
Palpable implant folds	7	(1.7)	6	(1.7)	1.22	1.25
Asymmetry/displacement of the implant	36	(8.6)	31	(8.9)	6.42	6.69
Prolonged pain in the breast (>3 months)	5	(1.2)	4	(1.1)	0.86	0.82
Necrosis	5	(1.2)	4	(1.1)	0.86	1.04
Ptosis	2	(0.5)	1	(0.3)	0.34	0.20
Asymmetry of mamillae	1	(0.2)	1	(0.3)	0.17	0.21
Skin excess	2	(0.5)	2	(0.6)	0.34	0.41
Scar indentation	0	(0.0)	0	(0.0)	0.00	0.00
<b>Other</b>						
	31	(7.4)	28	(8.0)		

A patient may have developed more than one adverse effect after an implantation.

\* Incidence rates at implant level are calculated as numbers of events per 1000 implant-months, Incidence rates at patient level are calculated per 1000 person-months.



## ...Follow-up course

Table 13.2 Incidence of complications following subsequent reconstructive implantation

	Subsequent implantation					
	Adverse effects				Incidence rate per 1000 person-months	
	Implant level N=366		Woman level N=271		Implant level	Woman level
	N	(%)	N	(%)	IR*	IR*
<b>Immediate adverse effects</b>						
Wound infection	12	(3.2)	12	(4.4)		
Peri-prosthetic infection	3	(0.8)	3	(1.1)		
Wound rupture	1	(0.3)	1	(0.4)		
Perforation to the skin	2	(0.5)	2	(0.7)		
Hematoma	12	(3.2)	12	(4.4)		
Seroma	10	(2.7)	10	(3.7)		
<b>Delayed short-term adverse effects</b>						
Capsular contracture, Baker grade II	16	(4.4)	14	(5.2)	2.56	3.04
Capsular contracture, Baker grade III-IV	19	(5.2)	16	(5.9)	3.05	3.46
Implant rupture	2	(0.5)	2	(0.7)	0.31	0.43
Visible skin wrinkles	8	(2.2)	6	(2.2)	1.27	1.30
Palpable implant folds	2	(0.5)	2	(0.7)	0.31	0.42
Asymmetry/displacement of the implant	60	(16.4)	52	(19.2)	10.95	13.20
Prolonged pain in the breast	9	(2.5)	7	(2.6)	1.44	1.52
Necrosis	2	(0.5)	2	(0.7)	0.32	0.43
Ptosis	0	(0.0)	0	(0.0)	0.00	0.00
Asymmetry of mamillae	1	(0.3)	1	(0.4)	0.16	0.21
Skin excess	4	(1.1)	4	(1.5)	0.64	0.87
Scar indentation	7	(1.9)	7	(2.6)	1.12	1.51
<b>Other</b>						
	39	(10.7)	35	(12.9)		

A patient may have developed more than one adverse effect after an implantation.

\* Incidence rates at implant level are calculated as numbers of events per 1000 implant-months. Incidence rates at patient level are calculated per 1000 person-months.



## ...Follow-up course

Table 14. Degree of adverse effects after first cosmetic implantation

Treatment for the most common adverse effects after first cosmetic implantation - woman level

	N	% of adverse effect	% of women
<b>Wound infection</b>			
Requiring surgery	4	31	0.3
Requiring other treatment	7	54	0.6
Requiring no treatment	2	15	0.2
Treatment uninformed	0	0	0.0
Total number	13	100	1.00
<b>Hematoma</b>			
Requiring surgery	10	67	0.9
Requiring other treatment	0	0	0.0
Requiring no treatment	5	33	0.4
Treatment uninformed	0	0	0.0
Total number	15	100	1.2
<b>Capsule Baker grade III-IV</b>			
Requiring surgery	14	67	1.1
Requiring other treatment	1	5	0.1
Requiring no treatment	0	0	0.0
Treatment uninformed	6	29	0.5
Total number	21	100	1.7
<b>Palpable implant folds</b>			
Requiring surgery	3	19	0.2
Requiring other treatment	0	0	0.0
Requiring no treatment	11	69	0.9
Treatment uninformed	2	13	0.2
Total number	16	100	1.3
<b>Asymmetry/displacement</b>			
Requiring surgery	28	64	2.2
Requiring other treatment	0	0	0.0
Requiring no treatment	14	32	1.1
Treatment uninformed	2	5	0.2
Total number	44	100	3.5
<b>Prolonged pain in the breast</b>			
Requiring surgery	3	21	0.2
Requiring other treatment	0	0	0.0
Requiring no treatment	3	21	0.2
Treatment uninformed	8	57	0.6
Total number	14	100	1.1

Severe complications were rare after first implantation for cosmetic purpose. In total, 6% of the 1,247 women received surgical intervention or correction for adverse effects.



## ...Follow-up course

Table 15 Degree of adverse effect after first reconstructive implantation

Treatment for the most common adverse effects after reconstructive implantation - woman level

	N	% of adverse effect	% of women
<b>Wound infection</b>			
Requiring surgery	9	33	2.6
Requiring other treatment	15	56	4.3
Requiring no treatment	3	11	0.9
Treatment uninformed	0	0	0.0
Total number	27	100	7.7
<b>Periprosthetic infection</b>			
Requiring surgery	12	92	3.4
Requiring other treatment	1	8	0.3
Total number	13	100	3.7
<b>Hematoma</b>			
Requiring surgery	5	45	1.4
Requiring other treatment	2	18	0.6
Requiring no treatment	4	36	1.1
Treatment uninformed	0	0	0.0
Total number	11	100	3.2
<b>Seroma</b>			
Requiring surgery	7	50	2.0
Requiring other treatment	0	0	0.0
Requiring no treatment	7	50	2.0
Treatment uninformed	0	0	0.0
Total number	14	100	4.0
<b>Capsule Baker grade III-IV</b>			
Requiring surgery	14	89	4.0
Requiring other treatment	0	0	0.0
Requiring no treatment	0	0	0.0
Treatment uninformed	2	13	0.6
Total number	16	100	4.6
<b>Asymmetry/displacement</b>			
Requiring surgery	26	84	7.4
Requiring other treatment	0	0	0.0
Requiring no treatment	5	16	4.6
Treatment uninformed	0	0	0.0
Total number	31	100	8.9

Severe complications were more common after post-mastectomy reconstruction than after cosmetic implantation. In total, 22% of the 349 women received surgical intervention or correction for adverse effects.



**Reduction surgery • Registered in the DPB**

**Analysis strategy.**

All women included in the reduction cohort were stratified according to type of surgery required, (i) reduction surgery, defined in this report as removal of at least 75 gram of breast tissue, (ii) mastopexy, defined as removal of less than 75 gram of breast tissue. Woman who underwent reduction surgery of one breast and contralateral mastopexy to enhance symmetry are exclusively included in the reduction-group. Reduction surgeries were performed at cosmetic or medical indication. Women with a previous diagnosis of breast cancer were excluded from this cohort. Operations were performed and registered in DPB in the period June 1999 through April 2003. Clinical follow-up information on these women was collected through July 2003.

Analyses were conducted separately for the stratified groups, i.e. the reduction-group and the mastopexy-group, respectively, on both patient and breast levels. Descriptive statistics were calculated to describe the study population and various surgical procedures. Incidence rates were calculated as numbers of events per 1000 person-months after surgery.

**Summary of reduction surgery statistics from June 1999 to April 2003:**

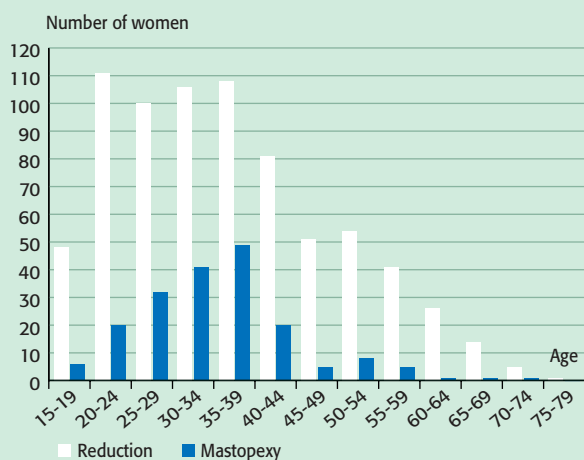
**Women included in the DPB:**

Through April 2003, 2199 breast reducing surgeries were registered among 1107 women: 81% of these (897 women, 1782 breasts) underwent breast reduction of at least one breast (reduction cohort). Another 210 women underwent breast lift with removal of less than 75 gram breast tissue (mastopexy cohort), as shown in Table 16. The mean age at the time of breast reduction was 36 years (range, 15 to 77 years). Women who underwent mastopexy had a mean age of 35 years (range, 16 to 70 years). 408 (37%) of these women were operated at public clinics, 700 (63%) at private clinics.

**Reduction surgeries included in the DPB:**

Breast Reduction surgery may be performed by different surgical techniques, both concerning the orientation of the pedicle for the mamillary complex and concerning the skin incisions. Table 18 shows surgical characteristics for the reduction and mastopexy cohorts. Amount of tissue removed at reduction surgery ranged between 75 and 2800 gram per breast, with a mean of 454 gram.

**Figure 6 Age distribution At reduction or mastopexy (N=1107 women)**



**Woman characteristics at reduction surgery****Table 16 Woman characteristics**

	<b>Reduction<sup>1</sup></b>	<b>Mastopexy</b>
Number of women	897	210
Number of breasts	1782	417
<b>Age at surgery</b>		
Mean age	36	35
Range	15-77	16-70
Standard deviation	13.28	9.84

<sup>1</sup>if a woman underwent breast surgery with removal of at least 75 gram of breast tissue of at least one breast, she was included in the reduction cohort

**Table 17a Presurgical measures**

<b>Characteristic</b>	<b>Reduction</b>		<b>Mastopexy</b>	
	Mean	(Range)	Mean	(Range)
Height, cm	167	(144-192)	169	(153-182)
Weight, kg	69	(36-130)	65	(47-100)
BMI, kg/m <sup>2</sup>	25	(15-41)	23	(18-32)
<b>Breast variables, cm</b>				
Papilla-jugulum difference	29.3	(12.0-46.0)	26.3	(12.0-37.0)
Lower pole-sulcus difference	9.2	(0-27.0)	6.7	(2.0-17.0)
Areola diameter	6.7	(1.0-16.0)	6.2	(3.0-14.0)

**Table 17b Paraclinical examination**

<b>Characteristic</b>	<b>Reduction</b>		<b>Mastopexy</b>	
	N=1782	(%)	N=417	(%)
<b>Pre-operative ultra-scanning performed</b>				
Yes	197	(11)	109	(26)
No	1450	(81)	274	(66)
Missing information	135	(8)	34	(8)
<b>Pre-operative mammography</b>				
Yes	208	(12)	33	(8)
No	1273	(71)	293	(70)
Missing information	301	(17)	91	(22)

**Surgical procedures****Table 18 Mode of breast reduction or mastopexy (breast level)**

Characteristic	Reduction		Mastopexy		Total	
	N=1782	(%)	N=417	(%)	N=2199	(%)
<b>Indication for surgery*</b>						
Ptosis	62	4	417	100	479	22
Hypertrophy or asymmetry	1697	95	0	0	1697	77
Other	26	2	0	0	26	1
<b>Surgical technique</b>						
Orlando	1210	68	130	31	1340	61
McKissock	60	3	14	3	74	3
Roundblock	9	1	13	3	22	1
Regnault	4	0	8	2	12	1
Lejour	197	11	150	36	347	16
Other	288	16	85	20	373	17
Missing information	14	1	17	4	31	1
<b>Amount of tissue removed unilaterally (gram)</b>						
Mean	455		17			
Median	400		0			
Range	75-2800		0-73			
<b>Use of antibiotics</b>						
Local	0	0	2	0	2	0
Systemic	679	38	194	47	873	40
None	667	37	115	28	782	36
Missing information**	436	24	106	25	542	25
<b>Use of trombolysis prophylaxis</b>						
Yes	457	26	81	19	538	24
No	553	31	110	26	663	30
Missing information**	772	43	226	54	998	45
<b>Other prophylactic medication</b>						
Yes	50	3	4	1	54	2
No	1250	70	299	72	1549	70
Missing information**	482	27	114	27	596	27
<b>Use of drainage</b>						
Yes	726	41	66	16	792	36
No	288	16	121	29	409	19
Missing information**	768	43	230	55	998	45
<b>Histological examination of excised tissue</b>						
Yes	880	49	24	6	904	41
No	385	22	204	49	589	27
Missing information	517	29	189	45	706	32

Table 18 shows surgical information for women receiving breast reduction or mastopexy. 897 women got breast reduction corresponding to 1782 breasts. Another 210 women, corresponding to 417 breasts, underwent mastopexy.

\* Multiple indications may be notified. Stratification in reduction or mastopexy cohort was performed at patient level. If a patient underwent reduction surgery at at least one breast, she was included in the reduction cohort. In case of asymmetry, a woman may receive reduction surgery at one breast and only mastopexy of the contralateral breast.

\*\*Use of prophylactics is not consistently notified at the operation sheets, so information on these variables was missing for 25-45% of the surgeries.

## Follow-up course • Reduction mammoplasty

**Analysis strategy**

Stratified analyses were conducted for the two groups: (i) reduction surgery, defined in this report as removal of at least 75 gram of breast tissue (ii) mastopexy, defined as removal of less than 75 gram of breast tissue. Woman who underwent reduction surgery at one breast and contralateral mastopexy to enhance symmetry are exclusively included in the reduction-group.

Follow-up analyses were conducted on both the implant and woman level. For the breast-level analysis, follow-up is calculated from the date of operation until the date of the outcome of interest. For the woman-level analysis, follow-up is calculated from the date of operation until the earliest date of the outcome of interest regardless of laterality.

Follow-up analyses were based on the clinics where 90% of the women were followed-up corresponding to the analyses in the implantation cohort. This left 805 women with 1601 breasts for analyses. Incidence rates were calculated as numbers of events per 1000 person-months after surgery.

**Summary on follow-up statistics**

for those women who underwent breast reduction or mastopexy in a clinic with at least 90% follow-up of patients after surgery.

**Clinical follow-up:**

Women were followed for an average of 3.5 months (range, 0 to 20 months) after reduction surgery and 5.2 months (range, 0 to 26 months) following mastopexy at clinics that reported follow-up data for more than 90% of their patients.

595 women (1184 breasts) were followed clinically after breast reduction. In total, 145 of the 595 women (24%) undergoing breast reduction developed at least one of the adverse effects listed in Table 20. Wound infection (8.7%; IR 5.22 per 1000 person-months) was the most frequent finding followed by hematoma, wound rupture and necrosis. Overview of the degree of adverse effects following breast reduction is shown in Table 22.

Lower rates of adverse effects were seen following mastopexy: 15% of the women developed at least one of the adverse effects listed in Table 21. Wound infection was the most common complication at woman level as well as breast level, followed by wound rupture and hematoma. Surgical and medical treatment for the most common adverse effects are shown in Table 23.

**Table 19**  
Clinical results after breast reduction or mastopexy

Characteristic	Reduction		Mastopexy	
	N=1184	(%)	N=258	(%)
<b>Form/contour</b>				
Symmetry	576	(48.6)	123	(47.7)
Minor asymmetry	75	(6.3)	8	(3.1)
Surgery-requiring asymmetry	2	(0.2)	0	(0.0)
Missing information	531	(44.8)	127	(9.2)
<b>Measures, cm</b>				
Papilla-jugulum difference				
Mean	20.8		20.9	
Range	13.0		17.0-25.0	
Areola-diameter				
Mean	4.2		4.2	
Range	2.3-6.0		3.0-6.0	
Lower pole-sulcus difference				
Mean	1.6		2.0	
Range	0.0-10.0		0.0-9.0	



## ...Follow-up course

**Table 20 Incidence of complications following reduction surgery**

The table shows adverse effects (including temporary post-operative conditions and complications) registered at clinics with follow-up data for more than 90% of their patients (in total 595 women). The degree of complications varies as shown in Table 22.

	Reduction					
	Adverse effects				Incidence rate per 1000 person-months	
	Breast level N=1184		Patient level N=595		Breast level	Patient level
	N	%	N	%	IR*	IR*
<b>Immediate short-term adverse effects</b>						
Wound infection	67	5.7	52	8.7		
Wound rupture	36	3.0	28	4.7		
Hematoma	51	4.3	41	6.9		
<b>Delayed short-term adverse effect</b>						
Prolonged pain in the breast (>3 months)	21	1.8	15	2.5	0.99	1.41
Necrosis	28	2.4	23	3.9	1.33	2.20
Delayed wound healing	16	1.4	13	2.2	0.76	1.24
Scar indentation	7	0.6	4	0.7	0.33	0.37
Contour deficits	2	0.2	1	0.2	0.09	0.09
Asymmetry of mamillae	5	0.4	3	0.5	0.23	0.28
Bruising	8	0.7	5	0.80	0.37	0.47
Skin excess	28	2.4	19	3.2	1.33	1.82
Other	53	4.5	37	6.2		

\* incidence rates are calculated as numbers of events per 1000 person-months for the first two years after reduction surgery



## ...Follow-up course

**Table 21 Incidence of complications following mastopexy**

The table shows incident and incidence rate of complications registered at clinics with follow-up data for more than 90% of their patients (in total 130 women). The degree of complications varies as shown in Table 23.

	Mastopexy					
	Adverse effects				Incidence rate per 1000 person-months	
	Breast level N=258		Patient level N=130		Breast level	Patient level
	N	%	N	%	IR*	IR*
<b>Immediate short-term adverse effects</b>						
Wound infection	11	4.3	8	6.2		
Wound rupture	6	2.3	5	3.8		
Hematoma	5	1.9	5	3.8		
<b>Delayed short-term adverse effects</b>						
Prolonged pain in the breast (> 3 months)	-	-	-	-	-	-
Necrosis	2	0.8	1	0.8	0.38	0.38
Delayed wound healing	2	0.8	1	0.8	0.38	0.38
Scar indentation	-	-	-	-	-	-
Contour deficits	-	-	-	-	-	-
Asymmetry of mamillae	-	-	-	-	-	-
Bruising	4	1.6	3	2.3	0.78	1.17
Skin excess	2	0.8	2	1.5	0.38	0.77
Other	12	4.6	8	6.1		

\* incidence rates are calculated as numbers of events per 1000 person-months for the first two years after mastopexy



## ...Follow-up course

Table 22 Degree of adverse effects after reduction surgery

Treatment for the most common adverse effects after reduction surgery - woman level

	N	% of adverse effect	% of women
<b>Wound infection</b>			
Requiring surgery	1	2	0.2
Requiring other treatment	38	73	6.4
Requiring no treatment	12	23	2.0
Treatment uninformed	1	2	0.3
Total number	52	100	8.7
<b>Hematoma</b>			
Requiring surgery	15	37	2.5
Requiring other treatment	7	17	1.2
Requiring no treatment	19	46	3.2
Treatment uninformed	0	0	0.0
Total number	41	100	6.9
<b>Wound rupture</b>			
Requiring surgery	2	7	0.3
Requiring other treatment	0	0	0.0
Requiring no treatment	24	86	4.0
Treatment uninformed	2	7	0.3
Total number	28	100	4.7
<b>Necrosis</b>			
Requiring surgery	2	9	0.3
Requiring other treatment	0	0	0.0
Requiring no treatment	4	17	0.7
Treatment uninformed	18	74	2.9
Total number	24	100	3.9
<b>Skin excess</b>			
Requiring surgery	11	58	1.8
Requiring other treatment	0	0	0.0
Requiring no treatment	5	26	0.8
Treatment uninformed	3	16	0.5
Total number	19	100	3.2
<b>Delayed wound healing</b>			
Requiring surgery	0	0	0.0
Requiring other treatment	3	23	0.5
Requiring no treatment	9	69	1.5
Treatment uninformed	1	8	0.2
Total number	13	100	2.2

Severe complications were rare after breast reduction surgery. In total, 6% of the 595 women received surgical intervention or correction for adverse effects after reduction surgery.



## ...Follow-up course

Table 23 Degree of adverse effects after mastopexy

Treatment for the most common adverse effects- woman level

	N	% of adverse effect	% of women
<b>Wound infection</b>			
Requiring surgery	0	0	0
Requiring other treatment	8	100	6.2
Requiring no treatment	0	0	0.0
Treatment uninformed	0	0	0.0
Total number	8	100	6.2
<b>Wound rupture</b>			
Requiring surgery	1	20	0.8
Requiring other treatment	0	0	0.0
Requiring no treatment	3	60	2.3
Treatment uninformed	1	20	0.8
Total number	5	100	3.8
<b>Hematoma</b>			
Requiring surgery	2	40	1.5
Requiring other treatment	1	20	0.8
Requiring no treatment	2	40	1.5
Treatment uninformed	0	0	0.0
Total number	5	100	3.8

Severe complications were uncommon after mastopexy. . In total, 2% of the 130 women received surgical intervention or correction for adverse effects.





## Registry rules and regulations for DPB • May 2001

**1. Purpose**

To collect baseline and follow-up data on all persons receiving breast implants, breast reduction or mastopexia allowing for a prospective examination of short- and long-term local complications, and potential health effects as well as to contribute to the evaluation of surgical results and surveillance of the products.

**2. Location**

Danish Registry for Plastic Surgery of the Breast  
Postbox 838  
Strandboulevarden 49  
DK - 2100 Copenhagen

**3. Organisation****3.1. Oversight board**

The oversight board for the DPB is composed of:

- two members appointed by the Institute of Cancer Epidemiology,
- two members appointed by The Danish Society of Aesthetic Plastic Surgery and
- two members appointed by The Danish Society for Plastic- and Reconstructive Surgery, of the last-mentioned one represents the Committee on quality control.

*The chairman of the DPB/the chairman of the oversight board:* is the Head of Department, Institute of Cancer Epidemiology, Danish Cancer Society, Strandboulevarden 49, DK-2100 Copenhagen.

*The secretary of the oversight board* is responsible for the day-to-day activities of the DPB and is employed full-time at the Institute of Cancer Epidemiology.

All members of the oversight board are appointed for two years with possibility of extension.

**3.2. Advisory panel**

People with professional competence and special interest in the DPB may be invited by the oversight board to join the advisory panel. The advisory panel is convened at biannual meetings of the oversight board, and may participate in decisions concerning research projects and in case of significant problems concerning the DPB. Members of the advisory panel have no right of voting at the meetings of the oversight board. Members of the advisory panel receive agenda and report of all meetings of the oversight board.

**3.3. Meeting activity**

The oversight board meets at least four times annually. Additional meetings are held on an as needed basis.

**3.4. Responsibilities of the oversight board**

*The chairman* is formally responsible for all activities of the DPB, serving as contact person for the Danish Board of Data Protection and the Ethical Committee, and having overall responsibility for research assignments and registry finance. The chairman is the controller, who exerts the necessary oversight to ensure that incorrect or misleading information is purged from the computer registry. The chairman is responsible of enforcement of the rules on the administration of registers laid down by the Danish Data Protection Agency.

*The secretary of the oversight board* is responsible for the Registry organisation, including the development and maintenance of contacts with the plastic surgeons, nurses, and researchers. After the establishment of the DPB, the secretary will coordinate all initiatives between the oversight board, plastic surgeons, and researchers. She will initiate and assist in research projects. Finally, she will be responsible for the daily administration of the DPB and the preparation of meetings of the oversight



## ...Registry rules and regulations for DPB • May 2001

board. A clerical secretary, and part-time DPB personnel will assist her in these activities.

*The oversight board* is responsible for the scientific oversight of DPB activities. All research projects using data or specimens of blood have to apply and receive approval of the oversight board, and the oversight board will supervise that regulations concerning data access and processing are observed, and advise on uses of DPB data and on future studies of the population of registered women.

### 3.5. Voting

The following matters can only be adopted unanimously by the Oversight Board:

- amendments to the DPB Rules, and
- approval of project protocols and access to data held by the DPB.

Other matters can be put to a vote by the Oversight Board and be decided by ordinary resolution. In the case of a tie vote the chairman has a double vote. Any member may veto such decision, whereupon the matter must be transacted again at the next Oversight Board meeting, within the next seven work days. A veto can be exercised once in a given case. The Oversight Board forms a quorum when at least two thirds of the members are present.

### 4. Registration

Information is registered in accordance with the rules on the administration of registers laid down by the Danish Data Protection Agency, cf. section 2(3) of the Danish Private Registers Act (lov om private registre).

All identifying information must be erased or anonymised at conclusion of the project at the latest, rendering it impossible subsequently to identify individual persons participating in the survey.

Identification data must be encrypted or separated from the other registered data by means of a special code number. The encryption key/input data material and other project material containing identifying information, including blood samples, etc., and the key file with information on the correlation between code number and civil registration number must be kept under lock.

At any given time one controller will perform the necessary control to ensure that no incorrect or misleading data are entered in the computer register. Any data which turn out to be incorrect or misleading must promptly be erased or rectified. All necessary precautions must be taken to prevent any misuse or disclosure of the data in the register to any unauthorised person.

Women recorded in the register can be deleted from it following a written request to that effect. Both the civil registration number and data registered under a code number will be erased.

### 5. Security measures

Security measures and erasing procedures for the Registry will follow the standard rules for computer registers and special rules for questionnaire-based surveys laid down by the Danish Data Protection Agency.

#### Standard rules for computer registers:

1. The chairman of DPB is responsible for compliance with the rules.
2. Computer processing of the data must only be performed by or at the request of the DPB chairman or the DPB administrator.
3. Identification data must be encrypted or separated from the other registered data by means of a special code number.



## APPENDIX A

### ...Registry rules and regulations for DPB • May 2001

- |  |  |
|--|--|
| <p>4. The encryption key/input data material and other DPB material containing identifying information and the key file with information on the correlation between code number and civil registration number must be kept under lock.</p> <p>5. Extracts from the DPB must only be in the form of statistical information and error or check lists. The error and check lists must be kept under lock when not in use and destroyed within one month of the printout date.</p> <p>6. Identifying information must not be released from the DPB. In special cases, patient data may, with the patient's consent, be released to the treating physician for follow-up control and/or treatment of the patient (see rule 6, Data Access)</p> | <p>The register must not be combined or merged with other privat research registers. Any publication of the survey results must observe the confidentiality of the individual persons.</p> <p>7. All identifying information must be erased or anonymised at conclusion of the project at the latest, rendering it impossible subsequently to identify individual persons participating in the survey.</p> <p>8. The DPB administrator must notify the Danish Data Protection Agency at conclusion of the project and when the data have been erased or anonymised. Furthermore, the DPB administrator must notify the Agency of any material changes made to the project.</p> |
|--|--|



## ...Registry rules and regulations for DPB • May 2001

The key file must be kept in a safe-deposit box to prevent any misuse of the data or destruction of the file.

#### Special rules for questionnaire-based surveys, etc.:

If a project is to include an interview-based or questionnaire-based survey or clinical examination or treatment of a defined group of persons, the persons in question must be informed of the sources and nature of the information to be collected. They should also be informed that the information will be stored in a register and that the register will be erased or anonymised at conclusion of the project. Finally, it must be mentioned explicitly that participation in the survey is voluntary.

#### 6. Data access

All data are stored in anonymised form at the DPB.

Prior to data access, a protocol for the research project must be presented and approved by the Oversight Board. In addition, the requested data must be specified.

Any follow-up survey involving renewed contact with DPB participants is subject to full briefing of and a written approval from the clinic/department where the participants received surgery. All communications to data subjects will be written on the stationery of the relevant clinic/department, unless otherwise agreed to in writing with the clinic/department.

#### The following output data may be released from the Registry:

- Output data extracted for the purpose of safeguarding the objectives of the database.
- Statistics: The public departments or private clinics who report to the DPB have access to their own data in the form they appear in the register, i.e., data that do not identify individual persons but are solely in statistical form, cf. rule 7 of the Agency. Furthermore, for the purpose of internal quality assessment, they will have access to national mean values in aggregate and anonymised form. Once a year, statistical data on implantation and debulking procedures will be published in a statistical yearbook.
- In the event that special surgical procedures or types of surgical implants involve an extraordinary high incidence of undesirable complications, the reporting clinics/departments can retrieve the relevant person-specific data on their own patients for the purpose of appropriate control and/or follow-up treatment, cf. Security Measures, rule 6.
- Error lists and check lists.
- Printouts and machine-readable media with data on specified persons for the purpose of concrete research projects.

Authorship of scientific publications based on DPB data is subject to compliance with the requirements of the Vancouver Group.



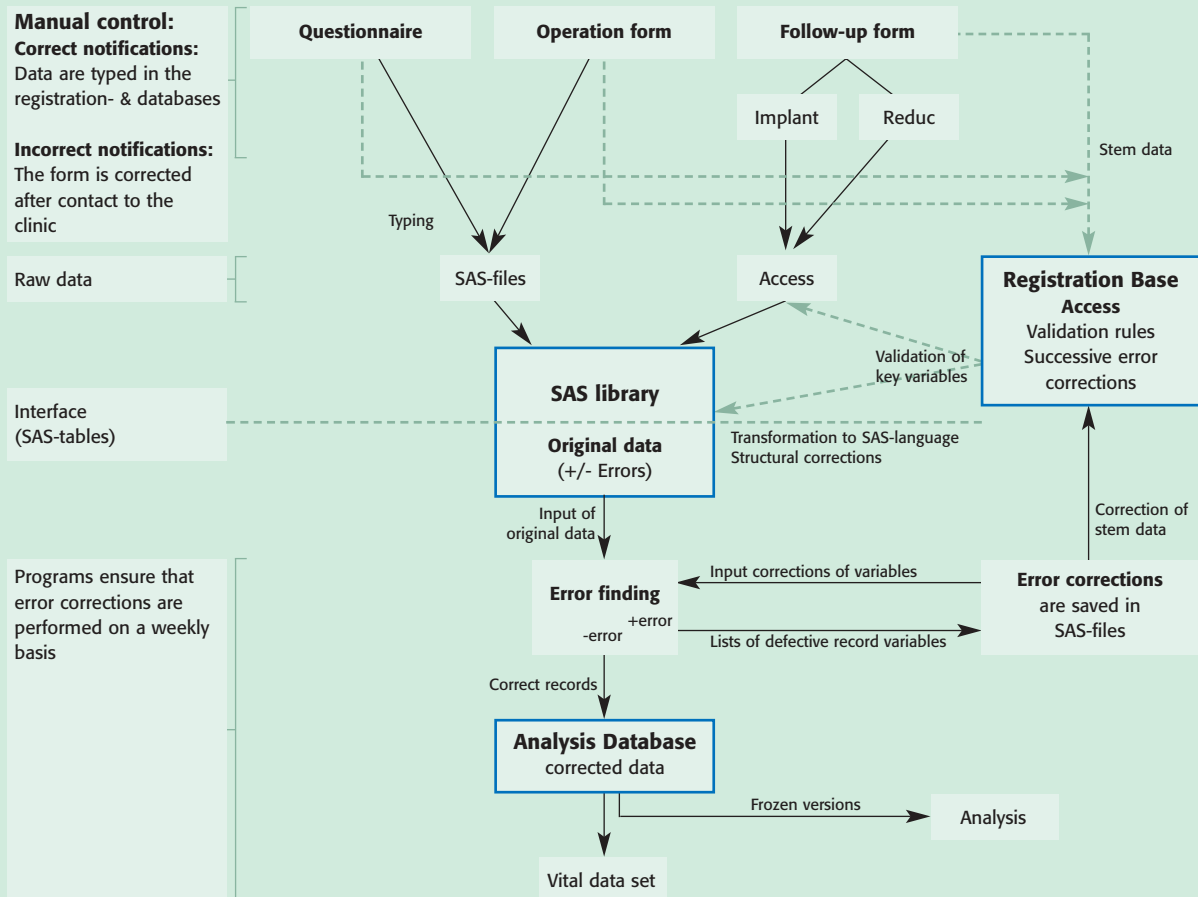
**Overview of the DPB databases**

Before analyses for the yearbook became possible, major efforts were undertaken to enhance the quality of the in the DPB. The DPB registry consists of an Access registration database, three distinct Access databases for the questionnaire, operation- and follow-up sheets for implantations (and three corresponding distinct databases for the breast reductions), respectively, and the final SAS-library for analyses. The architecture of the computerised system is shown in figure 2.

Currently, the registration process is designed to allow computer-based error correction and documentation of both operation and follow-up data (figure): The information collected by the registry is classified by person and by indication of surgery.

When operation sheets are returned from the clinicians, the form is checked for completeness and legibility. Hereafter the study id, operation date, and clinic number are

**Figure xx: Overview of the data bases comprised in DPB**



**...Overview of the DPB databases**

entered into the Registration Database. The Registration Database is an Access database which checks that the new operation sheet contains unique information for study id, operation date, and clinic. The new form cannot be entered unless the study id, operation data, and clinic are unique. If these have been previously entered into the Registration Database, the user is prompted by the Access Registration database that the data already exists in the database. As another check for patients who already have one operation in the Registration Database, the Access program only allow data entry for operations after the date of the last operation registered. After entering identifying data and a DPB unique ID number into the Registration base, the operation sheets are stripped of all identify information and labeled with the DPB ID and mailed to the typing agency (Ap Data), where data are double-typed.

ApData returns the raw data as a flat file with an input statement so that it can readily be read into SAS. When data files are returned from AP Data, frequency and range checks are performed on all variables to identify outliers and unusual data entry errors, such as miskeys. A SAS file is constructed to document any changes to the raw data. All changes are dated, the name of the person making the changes noted, and a brief explanation of the changes is included. These documented changes are kept in a separate log notebook of the SAS session.

When follow-up sheets are received from the clinics, they are entered into an access database. The follow-up database is linked to the Registration database. Only those patients with an operation date already entered in the Registration database are allowed entry into the follow-up database. The follow-up database will check the registration database for valid patient identification and for duplicates. As in the OP database, all data errors and logic checks are recorded in a SAS file which hereafter is run against the raw data in order to get the clean datasets in the Analyse-database. Extraction of registry data is herafter possible in order to produce statistical surveys and specific research projects.

Data handling, cleaning and editing has been more complex and time consuming than anticipated, due to different variations of operation sheets, structural errors (default or missing personal identification number or operation date) as well as errors of content of returned sheets. The overall design of the operation and follow-up databases and input of data did not cause obstacles, however cleaning of data and programming to enable merging of the databases comprised in the registry has drawn unexpected resources.

**Security measures**

Security measures and erasing procedures for the Registry follow the standard rules for computer registers and special rules for questionnaire-based surveys laid down by the Danish Data Protection Agency. The chair of DPB is responsible for compliance with the rules. Both input data material and the key file with information on the correlation between the unique patient sequence number and the PIN is kept under lock. No-one but the data responsible staff of DPB has access to any data recorded in the DPB. The data security is kept at a high level by physical control of access to the registry as well as by electronic control of access to data with more levels of passwords protected access control, ensuring that no breach of the confidentiality of personal data occur unnoticed.





