



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Reports of health problems related to breast implants

Dutch Reporting and Expertise Centre for Adverse Effects of Medical Implants (MEBI)

Introduction

The Dutch Reporting and Expertise Centre for Adverse Effects of Medical Implants (MEBI) was established to facilitate early detection of adverse effects related to medical implants. Both citizens, patients and healthcare professionals can report health complaints which might have been caused by medical implants. MEBI then carefully assesses all reports. When necessary, MEBI informs patients, health professionals, the government and/or manufacturers of medical implants about its findings by publishing relevant information. All types of health problems can be reported associated with all types of medical implants, such as those about hip implants, breast implants, copper intrauterine devices, fillers and pelvic mesh implants.

In 2020, MEBI released its [first factsheet](#) on reported health problems related to breast implants. It listed 476 reports received between July 2017 (when MEBI became operational) and December 2019. Since then, MEBI has gathered another 501 reports about breast implants. This new factsheet covers information about all reports related to breast implants collected between July 2017 and December 2022.

To identify potential issues with medical implants at an early stage, it is vital to report as many possible health problems early on, when these might have been caused by medical implants. It is equally important for the information in these reports to be as comprehensive as possible, including details on the brand and type of medical implant, as well as the timing and duration of health problems. This data will allow MEBI to conduct a better analysis of the reported health problems and help identify potential issues with a given medical implant at an earlier stage.

Results

From July 2017 up to and including December 2022, MEBI received a total of 977 reports of health problems suspected to be related to medical implants. The average age¹ of patients² to whom the reports related to was 46 years old (ages ranged from 21 to 84 years old). Of all the reported health problems, 56.9% emerged before the patient was 40 years old and 40.6% thereafter. In 2.5% of the cases, the patient's age was unknown.

The 977 reports comprised a total of 7,645 health problems. 835 different types of health problems were reported³.

In most cases, a single report included several health problems. Some health problems (such as localised capsular contracture) had already been identified in scientific literature as potential adverse effects from breast implants. In addition, MEBI received many reports about more wide-ranging physical health problems, such as fatigue, memory impairment, joint and muscle pain. More knowledge is needed to ascertain whether such health problems may be caused by medical implants. This remains the subject of intensive research, also in the Netherlands⁴.

In the online questionnaire, reporters are invited to reflect about the impact of the reported health problems on the patients' daily lives. This allows those who report to specify whether they are, for instance, still able to work, to look after their children or practise sports or hobbies. A significant percentage (70%) indicated that the reported health problems had either a high or very high impact on their daily lives.

Around one-third of those reporting a health problem had their breast implants removed. In some cases, this had taken place soon after the implants were inserted – within the same year – but in others, only after a longer period. On average, 10 years passed between the insertion and removal of breast implants. One-fourth of patients who had had their breast implants removed did replace them with new implants.

MEBI is a reporting centre where patients and health professionals can voluntarily report health problems which they suspect to be related to medical implants. As a consequence, the number of reports of suspected adverse effects is not indicative neither of the risk nor of the frequency of an adverse effect attributed to a given medical implant. Likewise, the total number of reports of health problems does not provide a comprehensive overview of all potential adverse effects from medical implants. It is just an illustration of the number of suspected adverse effects reported to MEBI.

¹ This refers to the patient's age at the time of reporting.

² In this overview, the term 'patients' refers to users with breast implants who experienced health problems.

³ MEBI uses the 'MedDRA' system for the systematic categorisation of health problems. This is an internationally recognised coding system to 'translate' health problems into medical terminology, as used in this fact sheet.




⁴ Some of the research taking place in the Netherlands is being conducted within [a research programme](#) coordinated by RIVM and funded by the Ministry of Health, Welfare and Sport.

Reports of health problems

Who made the report, and how many reports were made?

| | |
|---|------------|
| Number of reports made by patients | 965 |
| Number of reports made by healthcare professionals | 12 |
| Total number of reports made between July 2017 up to and including December 2022 | 977 |
| Average age of the patients | 46 |

Why did reporters get breast implants?

| | | |
|---|-----|---|
| Cosmetic | 78% |  |
| Breast reconstruction after cancer and/or preventive to mitigate breast cancer risk | 17% |  |
| Other/unknown | 5% |  |

Which types of health problems were reported?

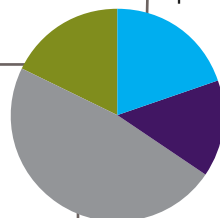
1,506 Wide-ranging health problems, mainly:

| | |
|--|-----|
| Fatigue | 703 |
| Capsular contracture ⁵ | 123 |
| General pain (non-localised) ⁶ | 92 |
| Fuzzy (head) / Foggy feeling in head (brain fog) | 77 |
| Malaise | 48 |



1,342 Health problems related to muscles and/or joints, mainly:

| | |
|-------------------------|-----|
| Joint pain | 313 |
| Muscle pain | 222 |
| Joint/muscle discomfort | 142 |
| Fibromyalgia | 80 |
| Back pain | 60 |
| Limb pain | 60 |



1,118 Health problems related to the nervous system, mainly:

| | |
|--|-----|
| Memory impairment, including word finding difficulty | 292 |
| Disturbance in attention | 248 |
| Headache | 148 |
| Dizziness | 77 |
| Sensations (such as tingling) | 71 |

3,679 Other reported health problems

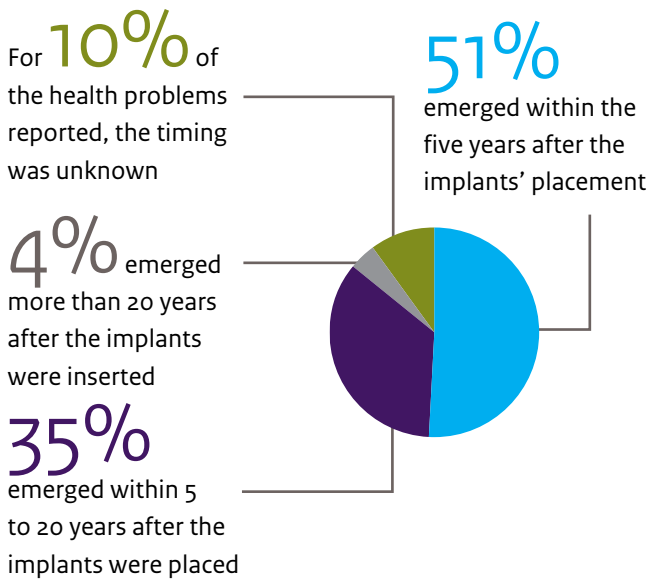
These health problems covered 24 different main categories⁷, such as problems related to the skin, reproductive system and breasts, gastrointestinal system, mental illness or issues with the product, etc. Alongside those mentioned previously, frequently referred problems included breast pain (n=286), implant rupture/breakage (n=111) and hair loss (n=114).

⁵ This included all reports of capsular contracture irrespective of severity, including a hardening of or change in the shape of the breasts. A certain amount of capsular contracture is a frequent and normal response of the body to the insertion of a medical implant.

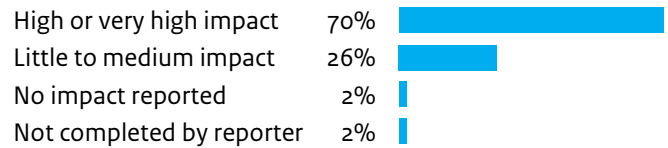
⁶ General pain was categorised under General health problems due to the use of the MedDRA system for the encoding and categorisation of health problems. Specific pain was categorised as a specific health problem.

⁷ Main categories within the MedDRA system.

How long did it take for the reported health problems to emerge?



What was the reported impact of the health problems?



How old were the patients when the reported health problems emerged?

| Age category | Percentage of reporters |
|--------------|-------------------------|
| Under 20 | 2.4% |
| 20 - 30 | 21.7% |
| 30 - 40 | 32.9% |
| 40 - 50 | 25.0% |
| 50 - 60 | 11.7% |
| 60 - 70 | 3.4% |
| 70 - 80 | 0.4% |
| Unknown | 2.5% |

Differences between 2017-2019 and 2020-2022

In 2020, MEBI released its first fact sheet on breast implants. It listed 476 reports breast implants received between July 2017 and December 2019. From January 2020 up to and including December 2022, MEBI received another 501 reports about breast implants.

When we compare the reports made in both periods, we can see that the average number of reports per month fell slightly, from 16 to 14 reports. Yet, the average number of health problems per report increased from 6 in the first period to 8 in the second period.

The experienced impact on daily life and the time between the insertion of the medical implant and the emergence of health problems remained roughly the same across both periods. Yet the average age of patients at time of reporting decreased somewhat recently, from 48 to 44 years old.

Shifts in the overall picture

MEBI identified some minor shifts in the overall picture. These mainly concerned the types of reported health problems and the reasons for having medical implants placed. Below is a comparison of the summary of the first 476 reports with that of the overall 977 reports (i.e. the total including the first 476).

While the most frequently reported health problems largely overlapped, there were some minor changes. For the total 977 reports, 'Confusion or sense of being hazy/woolly' entered the top five 'General health problems' – replacing 'Infections' – and the ranking thereof was also slightly different. In the 'Health problems with the muscles and/or joints' category, 'Back pain' emerged alongside 'Limb pain' in the top five. The ranking in that category was also slightly different. In the 'Health problems with the nervous system' category, 'Dizziness' and 'Sensations' swapped places.

| Most frequently reported health problems | First 476 reports (from the first fact sheet, between July 2017 and December 2019) | Current 977 reports (total number of reports until December 2022) |
|--|--|--|
| Top five reported general health problems | <ol style="list-style-type: none"> 1. Fatigue 2. General pain 3. Capsular contracture 4. Malaise 5. Infections | <ol style="list-style-type: none"> 1. Fatigue 2. Capsular contracture 3. General pain 4. Fuzzy (head) / Foggy feeling in head 5. Malaise |
| Top five reported health problems with the muscles and/or joints | <ol style="list-style-type: none"> 1. Joint pain 2. Muscle pain 3. Joint/muscle discomfort 4. Limb pain 5. Fibromyalgia | <ol style="list-style-type: none"> 1. Joint pain 2. Muscle pain 3. Joint/muscle discomfort in 4. Fibromyalgia 5. Back pain/Limb pain |
| Top five reported health problems with the nervous system | <ol style="list-style-type: none"> 1. Memory impairment, including word finding difficulty 2. Disturbance in attention 3. Headache 4. Sensations 5. Dizziness | <ol style="list-style-type: none"> 1. Memory impairment, including word finding difficulty 2. Disturbance in attention 3. Headache 4. Dizziness 5. Sensations |

The most frequently reported health problem continues to be fatigue.

More patients had their breast implants placed for cosmetic reasons, from 70% to 78%.

The number of reports that specified BIA-ALCL⁸ rose from 1 to 7, and the number of reports that specified ASIA⁹ rose from 21 to 44.

⁸ Breast Implant-Associated Anaplastic Large Cell Lymphoma.

⁹ The emergence of several immune system-related symptoms after the insertion of medical implants is known as Autoimmune Syndrome Induced by Adjuvants (ASIA).

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**National Institute for Public Health
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P.O. Box 1 | 3720 BA Bilthoven
The Netherlands
www.rivm.nl/en

**Dutch Reporting and Expertise Centre for Adverse
Effects of Medical Implants**

Antwoordnummer 3254 | 3720 VB Bilthoven
The Netherlands
www.meldpuntbijwerkingenimplantaten.nl

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