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Information for reconstructive and aesthetic plastic surgeons

Issue 03/2013

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Frequency of seromas and possible causes

A review of available scientific literature

by Dr. Oliver Bögershausen

POLYTECHinformed® is a service offered by:

POLYTECH Health & Aesthetics GmbH
Altheimer Str. 32 | 64807 Dieburg | Germany

Tel. +49 (0)6071 98 63 0
Fax +49 (0)6071 98 63 30

eMail: info@polytechhealth.com
www.polytech-health-aesthetics.com

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If you are going through medical scientific literature based on the keywords „breast implant“ and „seroma“, you will get a lot of hits. It is however hardly possible to find a really informative report. Below you will find some publications giving information on the frequency of seromas:

Managing Late Periprosthetic Fluid Collections (Seroma) in Patients with Breast Implants: A Consensus Panel Recommendation and Review of the Literature. Bengtson et al., 2011, Plastic & Reconstructive Surgery 128 (1) 1-7
The group concluded that late periprosthetic fluid collection (arbitrarily defined as occurring 1 year after implant) is an infrequently reported occurrence (0.1 percent) after breast implant surgery …

Seroma as a late complication after breast augmentation. Pinchuk & Tymofii, 2011, Aesthetic Plastic Surgery, 35 (3) 303-314
This report deals with late seromas occurring in the periprosthetic cavity. This complication is a rare development after breast augmentation. From 1996 to 2009, the authors performed 568 initial breast augmentation procedures. During this period, they observed late seromas in six cases. … Late seromas occurred at various intervals 2 to 10 years after the initial breast augmentation. In five of the six reported cases, revision surgery was required. In one case, conservative treatment was applied. An implant rupture was observed in only one case. In the remaining five cases, the implants were intact. In the authors‘ opinion, seromas may occur when any sliding surfaces are present and as a result of micromotion of implants in cavities. The inner surface of a capsule with a synovial metaplasia becomes a target for chronic infections.
Six observations with 568 augmentations correspond to a rate of a little bit more than 1%.

The so-called core studies of Allergan and Mentor are considered as additional sources.

Allergan Core Study (2006) – results after 4 years

- Primary augmentation patients: 455
  Smooth implants 59%, textured implants 41% (the number of textured implants results from mathematics)
  Seroma/Fluid Accumulation: 1.3%
- Revision-augmentation patients: 147
  Smooth implants 57%, textured implants 43% (the number of textured implants results from mathematics)
  Seroma/Fluid Accumulation: 5.0%

Mentor Core Study (2006) – results after 3 years
Revision-augmentation patients: 146
No information on the percentage of smooth and textured implants.
Seroma/Fluid Accumulation: 2.1%

In summary, the available data is rather heterogeneous, giving seroma rates between 0.1% and 5.0%. The only thing that this review shows is the fact that a revision of an initial augmentation bears a significantly higher risk for a seroma. Corresponding studies on mammary reconstruction show an even higher risk for seromas. One thing is definitely obvious: seromas are usual complications. As far as augmentations are concerned seromas might occur in a minimum of 0.1% to 1% of cases.

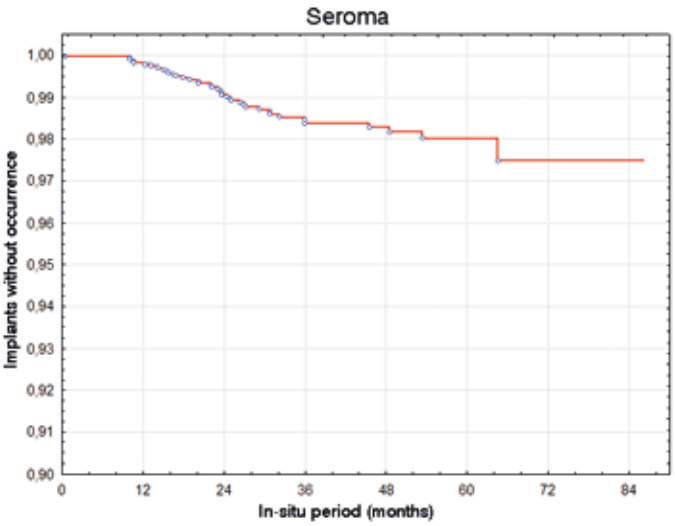
Results from our own sources

For proprietary data to make a statistical analysis pertaining to the occurrence of seroma, POLYTECH Health & Aesthetics can rely on two sources: our year by year complaint analyses covering all implants returned by customers, and our Implants of Excellence extended warranty program for breast implants.

In the POLYTECH Health & Aesthetics complaint analyses, the causes of returns / explantations indicated by our customers, if available, are statistically documented and evaluated. To this effect, the number of returns is related to the products sold during the period under observation. The evaluated period covers 11 years, 2001 to 2011, and the average percentage of seromas during this time was 0.016%.

The data derived from the Implants of Excellence program are based on the annual surveys of the patients participating in the program. The evaluation of the occurrence of seroma in this context is based on 2,704

implants. With 38 implants, seromas were recorded, which corresponds to 1.4%. For the evaluation of the time-related probability for seroma occurrence, we relied on the canonical Kaplan-Meier analysis. With this method and our data we were able to calculate a risk of 2.5% for the in-situ occurrence of seromas after 7 years or 0.36% per year.



Possible causes for delayed periprosthetic seromas

Although seromas and delayed periprosthetic seromas are regularly mentioned as a typical complication in the medical scientific literature in connection with mammary reconstructions and augmentations, there are only few sustainable data available. The following possible causes are mentioned:

1. Infections (clinical and subclinical)
2. Postoperative implant mobility
3. Mechanical stress / traumatic events, working on the tissue surrounding the implant.

As to (1): Different types of infections have to be considered:

a) Infections, directly related to the surgery. Based on the delayed occurrence of the problems (at least 1 month between surgery and occurrence of seromas), they can be ruled out as possible causes.

b) Infections concerning another part of the body. It is well known that such infections can “spill over” to an augmented breast. As an example, we refer to a case documented by POLYTECH Health & Aesthetics. Several years after a breast augmentation, a patient had to undergo a jaw surgery because of a massive infection. A few days later, the patient observed typical signs for the occurrence of a seroma in one breast. During revision surgery, an infection as cause of the late seroma and a connection with the jaw infection was detected.

c) In scientific literature, so-called subclinical infections are taken into consideration for different types of complications. Such infections are called subclinical, if no systemic symptoms (e. g. fever) are caused. Typically, non-locally used antibiotics do not show any effect. Often, the proof of a subclinical infection is not possible with standard methods.

As to (2): A postoperative implant mobility is usually caused by a non-match between implant and tissue pocket.

As to (3): POLYTECH Health & Aesthetics considers traumatic events provoking mechanical forces to work on the contact area of the capsular tissue and implant surface as the most likely causes for late seromas. The surface texture invites a certain adhesion of the capsular tissue to the implant surface. The disconnection of such an adhesion by mechanical forces results (apart from minor tissue damages) in a “cavity”, which will be filled by interstitial fluids. Depending on the extent and individual patient factors, such an event can cause late seromas. It is entirely conceivable that the active forces are not considered as a special event by the patients.

Based on the published and our own data, the claim that certain design characteristics of breast implants do influence the frequency of the formation of seromas is untenable. The data however show a tendency that the surface texture might have a certain influence in this case. The better the surface texturing, which avoids a disconnection of the capsular tissue from the implant surface by mechanical forces, the smaller the risk for a delayed seroma will be. In a reverse conclusion this approach would imply that seromas do significantly more often occur with smooth implants. This is however not backed by either the published or our own data. Both, the lack of this simple relation and the heterogeneous situation in the medical scientific literature, show that this phenomenon cannot be explained by a simple cause and impact principle.

The current discussion of seromas seems to indicate that this is something new, which has occurred during the last months, maybe for 1 to 2 years. The suggestion is that

something must have changed with the implants that would explain this trend.

If such a trend really exists and is connected to the implants, it can only be caused by an interaction of the body with the implant. Such an interaction is determined by the following factors:

- The structure of the surface: To our knowledge, none of the main suppliers (Allergan, Mentor, Eurosilicone, POLYTECH, Silimed, etc.) has changed anything concerning the surface structure for many years (decades), which means that this cause can be ruled out.

- The chemical properties of the implant surface: For decades, all main manufacturers (as listed above) have been using the same raw silicones for shell manufacturing, which means that the chemical properties of the silicone shells have remained unchanged. This means that this cannot be the cause either.

As the principal design characteristics of breast implants have not been altered for many years (this applies to all manufacturers), the occurrence rates of seromas should also remain unchanged. This is backed by the data available with POLYTECH Health & Aesthetics and is in contrast to the current discussion.

In case that there is a trend, which is not reflected in our statistics, the other side needs to be examined too: What changed in the operation theatre? Are there new / other drugs, suture material, techniques, instruments, etc. being used? The complaining surgeons should be asked to check carefully everything that might have an influence: Have there been any modifications, i. e. was there anything changed that gets in contact with the implant or the wound and might have a systemic effect?

We do not believe in a new development but that the number of seromas has remained unchanged for years. However, for one reason or the other this subject moved to the centre of attention. Reasons for this hype may be:

- the ALCL discussion,
- an exploitation of the issue by marketing staff, in order to present their products in a better light and to disparage competitive products.

We know that with some users, this presently increased interest resulted in a subjective overrating of the current seroma cases. However, this overrating does not withstand a statistical evaluation of the actual numbers.