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ORIGINAL ARTICLE BREAST SURGERY

Removal of Polyurethane Implants

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Abstract Polyurethane (PU) implants are associated with great difficulties in extraction if secondary surgery is needed. The published data are contradictory, often misleading, making the decision for the secondary surgery complicated, the time period and the procedure itself not optimal, thus negatively influencing the final result.
Materials and Methods Typical videos of PU implant removal in different periods after primary surgeries with polyurethane implants were selected for the study. The videos show the strength and extent of the tissue ingrowth and the manipulations needed for implant extraction in different periods from the initial procedure. Classifications of the types of adhesion and adhesion patterns are introduced.
Conclusions The data provided in this article facilitate the decision-making process if secondary surgery is indicated. Secondary surgery should be performed in the first 30 days after the initial surgery or in the period after 6 months. The optimal layer for removal of the PU implant depends on the time after the primary surgery. The polyurethane implant should be exchanged after 1 month if the properties of the polyurethane foam are expected to be used.

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Keywords Removal of polyurethane implants · Breast augmentation · Secondary breast surgery · Capsulectomy

Introduction

The use of polyurethane (PU) implants is the subject to many rumors: the difficulties in inserting the implant [1, 2], risk of cancer [3–5], delamination of the foam [6], late breast pain [7, 8], late hematomas [9, 10], infection [11–15], skin rash, wrinkling [14], late capsular contractures [8, 16], etc. But one that prevents many surgeons from using PU implants is the difficulty of removing the implant in case a secondary surgery is needed. PU foam stabilizes the implant immediately after placement. This stabilization renders any further movement of the implant impossible. So, the surgeon must position the implant precisely where needed and cannot count on any postoperative changes. This necessitates a thorough understanding of the 3D changes that occur after the implant is in place, the influence of gravity and body position, and the precise symmetry.

Failure in the correct positioning of the implant is an indication for revision. The question that arises and is still not solved in the literature is about the proper time for the revision. This article aims at sharing our experience in and establishing guidelines for extracting the PU implants at different periods after the initial surgery.

Materials and Methods

We present typical videos of PU implant removal in different periods after the initial breast augmentation or augmentation-mastopexy with PU implants. The indications for reoperations are asymmetry of the inframammary fold and other malpositions, size change, secondary ptosis, hematoma, high riding implants and wound dehiscence. All the surgeries were performed under local anesthesia with intravenous sedation. Sub-mammary or peri-areolar incisions were used. All patients received drains for 3 to 4 days.

The time of reoperation depended on the diagnosis. The absolute indications for reoperation were asymmetry of the inframammary fold that disturbed the patient and was caused by the implant, implant malpositions including high riding implants, hematoma and wound dehiscence. As all these complications occur during the surgery or in the first 2 to 3 weeks thereafter, a reoperation should be performed at the nearest reasonable time if diagnosed, according to the authors' experience. The main reasons for this are ease of implant repositioning and preservation of the benefits of PU foam. Size change, secondary ptosis and any implant malposition diagnosed later than 1 month from the initial surgery were considered indications for elective surgery. The main questions that arise in such cases are how to perform the removal of the implant safely and atraumatically and when is the proper time for the revision in conjunction with the postoperative changes.

Results

We found four major intraoperative situations that can occur when the surgeon removes the PU implant.

Video 1 shows complete bio-integration of the implant. Intraoperative situations at 9 years, 13, 9.5 and 6 months are similar: The anterior surface of the implant is usually but not always connected to the surrounding capsule. The implant is in a perfect position with regard to rotation. It is textured and has a typical whitish color. The PU foam has remained in the capsule. The implant can be detached bluntly from the surrounding capsule. Subjectively, the strength of attachment is inversely proportional to the time that the implant remains in the body. Ease of detachment of the base of the implant depends on the plane of dissection (Video 5).

Video 2 shows the process of bio-integration of the PU implant (3 months after the primary surgery). Very strong connections exist between the implant and the surrounding tissues, making it virtually impossible to detach the implant from the tissues without destroying the shell. No definite plane of dissection can be located. Sharp dissection is needed. The foam may remain attached to the implant or be in the capsule. The implant can be removed safely only with the capsule. It is not possible to remove the implant bluntly.

Video 3 shows the border-line situation (33 and 36 days after primary surgery). The process of bio-integration is progressing. Moderate connections of the implant with the surrounding tissues alternate with strong connections that are difficult to destroy. Some tissue after blunt separation stays attached to the implant. The foam remains on the implant. There also are some very strong connections of the implant with the surrounding tissues, which are difficult to destroy. The traction applied to the capsule moves the whole implant.

Video 4 covers the situation when the bio-integration process has just begun (21 and 6 days after primary surgery). It is still possible to relocate the implant, but the connections of the tissues to the implant are sufficient to hold the implant in place. The implant is easily and bluntly detachable from the tissues. Objectively, the strength of the connection increases with the passage of time. The foam remains on the implant.

Because of the manufacturing process, there exists a second sheeting of PU foam on the base of the implant (Fig. 1). It overlaps with the main sheeting of the PU foam that comes from the anterior surface by a few millimeters and is connected strongly to the implant. The connection between these two sheetings of PU is only as strong as the PU foam itself (Fig. 2), and the connection is gradually lost when the implant is in the body (Fig. 3). If the dissection proceeds under this second PU sheeting (easy plane of dissection), the base of the implant is detached from the capsule without any difficulties (like the anterior surface). If the dissection appears possible between those two PU sheetings, the surgeon needs to tear the second sheeting to

Fig. 1 Intact PU implant. Note the overlapping sheeting of PU that is connected to the main sheeting

Fig. 2 New PU implant. The overlapping sheeting of PU was manually detached from the main PU sheeting that is strongly connected to the implant

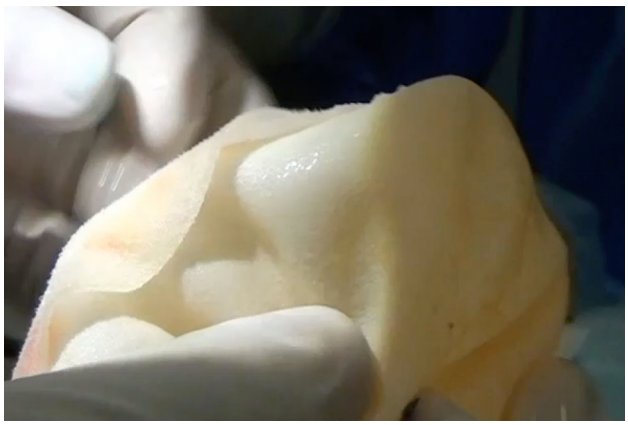

Fig. 3 Thirteen-month-old PU implant after removal. Note the unattached sheeting of PU

proceed with dissection toward the center of the implant (difficult plane of dissection). After that, the implant separates from the capsule as easily as it does on the anterior surface. Video 5 clearly demonstrates this difference.

Discussion

PU implants have a long history. The first PU implant used was designed by Ashley to decrease the rate of the capsular contracture associated with smooth implants [17].

Before they were banned in the USA in the 1990s, PU implants had about 40% of the implant market. This meant that thousands of these implants were used for breast augmentation. These implants have also been available for decades in many countries.

Two main changes have occurred with PU implants after their introduction by Ashley. The PU coating has been vulcanized on the silicone since 1989, which has probably reduced the risk of detachment of the PU foam and the risk of rashes associated with the adhesive. Another change is the sterilization process that may have also reduced rashes. The PU foam itself has remained the same [16, 18, 19].

There is plentiful clinical evidence of the advantages of the PU implants in the prevention of capsular contracture and malposition. These data are consistent in the publications and should persuade surgeons to implement these implants in daily practice [6, 16, 18, 20–30].

However, the data about PU implant removal are scarce and contradictory. The majority of the articles omit any mention of the time of the removal of the implants, the level of difficulty, whether capsulectomy was performed and whether it was performed with the implant or separately, after what time after the initial surgery, how the removal of the PU implants should be done and should the implant be exchanged or not.

Many authors note that PU implants can be removed *easily* after the primary surgery. Flemming states that within 3 weeks, the implant can be removed as a smooth or textured implant, and the same implant may be used. After 6 months, the implant should be detached from the capsule prior to its removal and the foam remains in the capsule [16]—Gasperoni talks about "few months" [31], Frame about 1 year [32], O'Connell about 14 months [33] and Mossaad about 2 years [34]—when the removal of the PU implants was easy.

Some of the authors do not mention at what period an easy removal was possible. But according to the descriptions, secondary surgeries were performed after full biointegration of the implant [28, 30, 35–37].

There are publications that state that the extraction of the PU implant was *difficult* in the "immediate postoperative period" [38], "soon" [28], at 1 week [39], at 4 months [40], between 3 weeks, and 6 months [16] and even after more than 10 years [41].

According to the publications, the fear of using PU implants in daily practice is based not only on the more complicated extraction if needed but also on the possible damage to the surrounding tissues. Thus, Berrino mentions that the removal of PU implants after more than 1 week requires general anesthesia and may lead to the sacrifice of large amounts of muscular, subcutaneous or glandular tissue [39]. Prado notes that PU implant removal may lead to partial mastectomy and necessitate blood transfusions [41].

Many authors do not mention the period at which the extraction was difficult [36, 39, 40, 42–46].

The presence of the second overlapping sheeting of PU described in the methods section and explained in Video 5 might be misleading for the surgeon as to the real strength of the tissue ingrowth and the complexity of PU implant removal.

According to Frame, the maturated capsule surrounding PU implants consists of five layers: pseudo-synovial layer,

circumferentially arranged lamellar collagen, the layer of PU bio-integration, circumferentially arranged lamellar collagen and native tissues [32]. The extraction of the PU implant inevitably damages at least one of these layers.

Although Frame and others state that the simple and bloodless separation of the silicone elastomer implant from the pseudo-synovial layer of the PU foam integration is possible 1 year after the initial surgery [32], we found that it is possible after as early as 6 months after (Video 1), when the bio-integration process has occurred. In all these cases, the PU stays in the capsule. This layer of separation is exactly the layer of vulcanization because the attachment of the PU foam to the shell becomes weak and the foam becomes part of the capsule, so it cannot be separated without the tissues.

At 3 months, the bio-integration process is in progress (Video 2), and layers 1, 2 and 4 are not yet well defined. Thus, the separation is possible only below or in layer 5 and inside or under layer 3. The attachment of the PU foam to the shell is stronger than the foam itself, and the connection of the foam to the tissues is even stronger, which is why the attempt to develop the plane on the PU foam will inevitably ruin it.

The first month after the surgery (Video 4), these layers (except layer 5, native tissues and layer 3, PU itself) do not exist. Thus, the implant is separated from the surrounding tissues below layer 5 with the PU remaining on the implant. The attachment of the PU foam is stronger to the shell than to the tissues. However, tissue ingrowth progresses and, by the end of the first month, becomes significant (Video 3). This is the border-line period for revision. We also found that the degree of ingrowth 33 days after the surgery was considerably greater than 36 days after. We assume that wound healing problems that were the indication for the revision at 33 days influenced the tissue ingrowth in this case.

The summary representing differences in PU implant removal is presented in Table 1.

According to our experience in the long term (after 6 months), the PU implant may totally, partly or not at all adhere to the surrounding capsule. Nonadherence may occur in two different situations. No initial tissue ingrowth into the PU foam may occur. Then, PU foam remains on the implant and gradually degrades. This is called *primary nonadherence*. The main reasons for this are nonvirgin tissues (scar, capsule), infection and the nonstable contact between the implant and surrounding tissues (fluid collection, movements).

Apparently, Parsa described exactly this nonintegrated PU that he found during the first 5 years after the surgery, which he stated as beginning to disappear about 2 years after the surgery [26]. Pompei also found this nonintegrated PU on the implant several years after the surgery [28].

There is another situation in which the initial tissue ingrowth is successful but secondary delamination occurs after the bio-integration process is completed. This is called *secondary nonadherence*. It may happen because of the tissue properties and mechanical stress exerted on tissues and implant during the late postoperative period. Figure 4 clearly shows the difference between primary and secondary nonadherences.

The PU implant may be connected to the capsule differently. Major final patterns of PU implant integration after 6 months are summarized in Table 2.

Independent of the period after the initial surgery, removal of the PU implants and capsulectomies was possible under local anesthesia with intravenous sedation. When performed correctly, this is practically bloodless and not traumatic.

This study has a few limitations. PU foam exerts its influence only if the bio-integration process occurs. In cases of primary or secondary nonadherence, the surgery does not differ from that with non-PU implants. All the surgeries were performed for definite indications. However, taking into account the process of bio-integration, we consider the period between 1 and 6 months after the initial procedure to be a contraindication for the secondary surgery. The reason for that is also the universal wound healing process that takes from 6 to 12 months. We observe substantial postoperative changes in our patients during this period. The planning of the secondary procedure is thus complicated and less predictable. So, it may happen that the removal of PU implants without the

Table 1 PU implant removal in different periods after primary surgery

	Plane of separation	Ease of detachment	PU foam localization
6 days	Below layer 5	Very easy	On the implant
21 days	Below layer 5	Easy	On the implant
33 days	Layer 5	Moderately difficult	On the implant
36 days	Layer 5	Difficult	On the implant
3 months	Layer 5, layer 3	Extremely difficult*	On the implant, in the capsule
6 months–9 years	Layer 1	Easy	In the capsule

*If trying to perform implant removal without the capsule

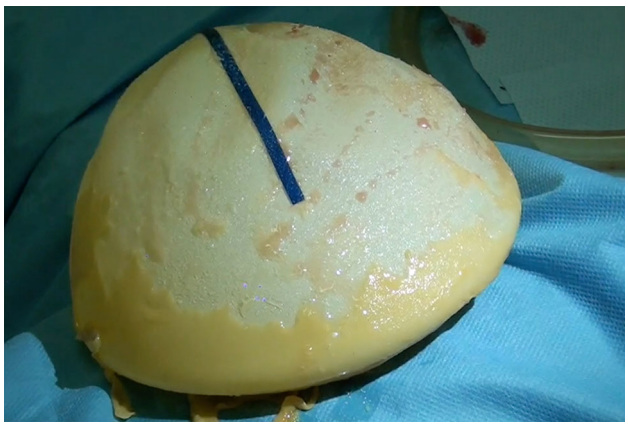

Fig. 4 PU implant after removal, 2 years after primary surgery. The implant was not attached to the surrounding tissues. The anterior surface of the implant is mostly whitish and textured. There is no PU foam on this part of the implant because it is integrated into the capsule (secondary nonadherence). The border where the color of the surface changes to yellow indicates the beginning of the PU foam that remains attached to the implant and continues to the periphery and on the base of the implant (primary nonadherence)

Table 2 Patterns of PU implant integration

Anterior surface	Posterior surface
Adherence	Adherence
Secondary nonadherence	Adherence
Adherence*	Secondary nonadherence*
Secondary nonadherence	Secondary nonadherence
Primary nonadherence*	Primary nonadherence*
Secondary nonadherence	Primary nonadherence
Primary nonadherence*	Secondary nonadherence*

*Not seen in the authors' patients

capsule at 5 months is as easy as it is at six, but revisions before 6 months may negatively influence the result.

Meanwhile, independent of the time after primary surgery, the surgeon should just understand that if the PU implant does not detach from the capsule with the PU remaining in the capsule (in case of bio-integration) or on the implant (in case of primary nonadherence) the implant should be removed with the capsule—like the procedure adopted, if possible, in capsular contracture cases with non-PU implants.

Awareness of the details of PU implant bio-integration and its patterns permits the surgeon to choose the optimal technique regardless of the time from the initial surgery.

Conclusion

The process of PU foam integration occurs in the first 6 months after the surgery. Secondary surgery should be performed in the first 30 days after the initial surgery when the integration process is beginning or in the period after 6 months when it has already occurred. Removal of PU implants between 1 and 6 months should be performed with the capsule, may be an excessively aggressive elective procedure and may lead to traumatization of the tissues or destruction of the implant shell due to the absence of any other layer of separation. The PU implant should be exchanged after 1 month if the properties of the PU foam are expected to be used.

Compliance with Ethical Standards

Conflict of interest D. Batiukov received a speaker honorarium from POLYTECH Health & Aesthetics. V. Podgaiski and D. Ladutko declare that they have no conflict of interest.

Human and Animal Rights This article does not contain any studies with human participants or animals performed by any of the authors

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