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Synthetic mesh in the complications of breast cosmetics surgery

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INTRODUCTION

The work we have done has taken into account two experiences reported by two breast implant manufacturers who, in assessing the quality, reliability and safety of their implants, also examined the complications and reoperations that the patients have subjected themselves to over the years.

The Inamed study on silicone breast implants showed a rate of re-intervention of 28.8% within 6 years of the first breast augmentation procedure and showed that a quarter of the women re-operated upon over the span of six years needed more repeat interventions.

The Mentor study on "Memorygel" breast implants showed a reoperation percentage of 15.4% at 3 years, 19.4% at six years; therefore, breast augmentation represents the procedure associated with the highest reoperation rate of all cosmetic surgery. It follows that these problems constitute a frequent cause of legal controversy and, though generally regarded a routine surgery of modest technical difficulty, breast augmentation should be considered high risk for the surgeon. Nevertheless, 95% of patients say they are satisfied with this kind of surgery and the data correlate poorly with the high rates of complications and repeat surgery commonly described. Patient satisfaction and availability depend largely on their character peculiarities; the selection criteria for these women must not only include physical but (fundamentally) psychological factors as well. Patients with irrational, emotionally fragile or aggressive personality traits should not be treated. Or perhaps it should be made clear that a woman who has undergone breast augmentation cannot consider herself equal to one who has not had implants, so the integrity of anatomic structures stressed by external trauma and the pressure the prosthetic implants exert upon them must always be respected. All this occurs because the breast represents an organ of sexual appeal; therefore, the prosthesis implant requires special attention, protecting and trying to preserve over time the result obtained in the immediate postoperative period. It is therefore no longer possible not to mention or even less to convey the idea of normality in the working, sporting and sexual life of patients who, despite recommendations they fail to comply with, later complain of variations, over time, in the form and position of their prosthetic device.

This thesis aims to create a nexus between the need for women with breast augmentation to maintain their life habits: exercising a right to daily life that justifies structural and aesthetic modifications to the surgical result achieved over time, and the need to clarify that the surgeon acts on an anatomy linked to the quality of its skin, breast thickness and muscle trophism, intervening and cutting anatomical planes that inevitably change tissue quality including prosthetic material.

All this must be understood by women, who perhaps only in an initial emotional phase tend to accept superficially any discomfort without understanding what, over the years, are normal complications naturally attributable to time, local trauma, and genetic factors common to us all.

Therefore, the work not only traces the now well-known path all women undergoing primary breast augmentation travel, but also emphasizes the increasingly frequent complications they face, offering a state-of-the-art solution that not only resolves the more feared and difficult complications of this surgery, but lays the foundation to improve protocols and allows many patients to avoid being forced to undergo numerous reoperations without obtaining stable results over time.

CHAPTER 1. Breast Augmentation Techniques and Historical Background

Surgeons have been dedicated to breast volume augmentation for more than a century and the techniques for increasing breast volume have been different and can be described historically in the following way:

1) Injection techniques
2) Prosthetic implants
3) Lipostructuring

1.1 Injection techniques

In the early 1900s, a comparison of descriptions of intramammary paraffin oil injections began in the literature with their related complications. Similar descriptions were found up until the 50s and 60s. The severe complications secondary to the use of paraffin are hardening of the breasts with chronic inflammation which could be resolved by total mastectomy. Between the 1950s and 1960s, the novelty of silicone oil was widespread, then considered an inert material, always to be used for intramammary injection. In reality, silicone has drawbacks similar to paraffin, albeit in a less acute way but causes hardening of the glandular tissue, granulomas and massive calcifications. Most of these procedures were performed by unskilled doctors, who used not only silicone oil for clinical use, but also industrial products not adequately sterilized and containing additives and impurities. Even in these patients the only way to resolve the infiltration and eliminate the silicone was mastectomy. More recently, for a certain period of time and in particular in Eastern Europe, non-absorbable injectable substances (acrylates) had been used for breast augmentation: the same injected into the subcutaneous space for the treatment of wrinkles; this practice has been abandoned and is prohibited by law due to the rise of serious complications such as granulomas, hardening of the parenchyma and fistulas with persistent secretions.

A filler intended for body remodeling has been available for some years. It is an injectable gel based on stabilized hyaluronic acid of non-animal derivation (NASHA) similar to the fillers already in use for facial corrections but with a significantly higher density. It is used for body remodeling: breast calf and buttock enlargement, correction of irregularities due to liposuction, male pectoral remodeling. The use of hyaluronic acid-based fillers of higher density with respect to products previously used, are for the first time not limited to the correction of wrinkles, but to bring about true and proper body remodeling operations. The advantages of the filler include the possibility of being used in the outpatient setting with local anesthesia or in cases involving sedation where recovery occurs in a few hours. The procedural technique is simple, it is injected using a 16- or 17-guage needle with subglandular boluses. The area is pre-drawn with the patient in the upright position and is performed by placing multiple injections at various access points. It is a temporary

filler, the effects of which last 12-18 months. It is preferable to do several sessions to achieve the desired result. (1)

In reality, even this technique is not often used because of its complications, patient dissatisfaction, limitations related to the indications and interference that limits radiological diagnostic procedures in the study of tumors.

1.2 Prosthetic implants

In the 1950s prostheses made of synthetic material with a spongy structure were used. The products in use were called Ivalon and Etheron. Shortly after implantation the breast hardened; the incidence of infection was high and these prostheses were all withdrawn from the market. In 1963 Cronin and Gerow described a prosthesis consisting of a solid silicone shell filled with the same material in the form of a gel; it was made by Dow Corning. From this point on begins the modern era of silicone breast implants, or polydimethylsiloxane, which had been used for some time in industry, already since the Second World War. It can be produced in the form of oil, elastomer or gel, depending on the length of the polymer chains and the chemical bonds that bind them together. The oil is made of very short chains and actually has the characteristics of a liquid. It is widely used as a lubricant in a large number of pharmaceutical products and in the food industry. It has been used for years, and sometimes still is, as an injectable substance to increase subcutaneous volume, in cosmetic medicine. After a series of clinical investigations carried out in the United States, its use was prohibited by health authorities in most countries. A very viscous gel allows the prosthesis to maintain its original shape unchanged. In 1965 Arion in France made a prosthesis with a silicone elastomer shell and a valve that allowed it to be filled with saline. These prostheses frequently lost their original volume, both due to the rupture of the shell and malfunction of the valve. In the following years, implants equipped with a diaphragm valve and a thicker shell were built in the United States: in this way the rate of rupture was significantly reduced. The use of other than physiological substances to fill the prosthesis (soybean oil, polyvinylpyrolidone, hydrogel, etc.) was not successful and all the implants filled with these materials were removed and withdrawn from the market. The first-generation prostheses made by Dow Corning since 1963 were made from a thick and soft shell, filled with a silicone gel. The second generation was launched on the market in the 1970s: the changes implemented aimed to reduce the retraction of the periprosthetic capsule. The implant had a thinner envelope and the gel contained within was less viscous. This resulted in a high percentage of failures and oozing of the gel. The drops of silicone gel oozed through the shell and accumulated in the periprosthetic space, and although a causal relationship between the oozed gel and systemic diseases has never been shown, this is likely one of the factors that determines retraction of the periprosthetic capsule. Liquid silicone can migrate into the axillary lymph nodes: over time it can spread to the surrounding glandular tissue and muscles. In the most egregious cases, the complete removal of these silicone granulomas can require a long, exploratory intervention. The high percentage of cases of shell breakage and gel exudation led to the development of third generation prostheses in the 1980s. These were

characterized by a multilayer casing, which did not allow any minimal gel exudation. These safeguards have proven safe and effective.

Polyurethane implants were marketed in the early 1970s. They are associated with a lower incidence of capsular retraction (2). The reason for this positive performance is unclear. The real cause of the phenomenon seems to be the chronic inflammatory foreign body reaction against polyurethane, which tends to result in a completely random fibrosis, rather than the more orderly fiber array induced by other types of surfaces. After many years this inflammatory reaction resolves; the polyurethane coating deteriorates, disappearing within 8-10 years. At this point the prosthesis behaves like a normal silicone prosthesis and returns to the usual incidence of capsular retraction. The possibility of a relationship between a prosthesis with polyurethane coating and carcinogenesis was then investigated. Inside the body, polyurethane undergoes biodegradation with metabolite production. One of these is 2-4 toluenediamine, which was carcinogenic in rodents at high doses. On the other hand, it has also been asserted that toluenediamine is found in imperceptible and immeasurable traces within women carrying these prostheses. Furthermore, it seems that this substance is produced only during the laboratory extraction process and not in vivo. Studies conducted in 1990 have come to the conclusion that both for women who have had a prosthetic implant and staff exposed to polyurethane processing, the risk is negligible. Outside the United States, these implants are used extensively and successfully. It is possible to apply the same stresses on the implant surface as common rough prostheses are subjected to without risking damage to the polyurethane coating.

In 1986, McGhan, attempting to reduce the incidence of capsular retraction, introduced a prosthesis whose casing was made of braided silicone fibers, which make the surface of the prosthesis "wrinkled, granular" (textured prosthesis), in imitation of the structure of polyurethane. In 1992, in the United States, the Food and Drug Administration (FDA) asked prosthesis manufacturers for more scientific and clinical data on the safety and efficacy of gel-containing prostheses. The result was the ban on the use of these implants in this country allowing their use only in patients who were part of an approved controlled clinical trial and mainly for reconstructive purposes. Some European countries complied with these directives for a certain amount of time. No relationship was observed between silicone implants and the onset of autoimmune diseases, collagenopathies or tumors.

In the early 90s and immediately before the FDA moratorium, the prostheses went towards their fourth generation, characterized by new standards in quality controls, casings with a braided structure to reduce the severity of capsular retraction and new teardrop shapes to better adapt to the female anatomy.

To face the problem of dimension (introduced by Tebbetts in the 90s), and the subsequent evolution of this concept, a variety of manufacturers have created anatomical prostheses of various shapes. For each basic size, a range of different projections and heights is offered. Initially, a very thick gel was used, which gave an unnatural consistency, corresponding to level 2-3 of the Baker classification; today anatomical prostheses contain a softer gel with a more natural consistency, which however does not risk losing its original shape. These type of pre-formed, anatomically-shaped prostheses maintain their shape even in the

event of capsular retraction, unlike what happens to prostheses with a low-viscosity gel content, which easily deform and tend to become spherical (3)

1.3. Lipostructuring

The increase in breast volume in cosmetic surgery today is not only done using prosthetic implants, in fact for some years several authors have published excellent results obtained with autologous adipose tissue transplants. To be successful, this technique requires the simultaneous presence of localized adiposity, in a quantity sufficient for replanting (4-5).

Lipofilling consists of the transfer of adipose tissue which is aspirated from some regions, such as the abdomen or thighs and which, after preparation, is reimplanted in others. For a long time this surgical procedure yielded disappointing results, as the injected fat underwent an inevitable reabsorption. The techniques evolved over time until 1997 when Coleman developed a procedure called "lipostructure" that gave a new twist and new impetus to its use. It consists in removing the fat with a cannula equipped with a particular kind of blunt tip that limits damage to the adipocytes during their removal. To aspirate, the cannula is connected to a 10 cc syringe, which is held manually in moderate suction. The aspirated fat is made to settle in the syringe and then centrifuged, removing the aqueous part and oil, in order to obtain pure fat. This is then transferred to 1 cc syringes and injected into the areas to be treated using cannulas of a lower caliber than that for the collection. In this way the adipose tissue is deposited in a precise manner into the receiving area, creating small tunnels that favor maximum engraftment. (6-7). Coleman's technique solves and overcomes two major limits previously encountered. The first refers to the damage the tissue undergoes during the aspiration phase. Previously, the adipocyte was so altered that it took root with difficulty, while in this way the cells survive. The second refers to the need to deposit the cells in contact with well-vascularized tissues in order to favor their chances of survival: thus the idea of infiltrating fat through multiple small channels, where a small amount of adipose tissue is deposited in each. This dense network of channels creates a true and proper "structure" arranged on various levels: hence the name of the lipostructure. The technique used by Carraways differs from the previous one in the way the collected adipose tissue is processed. It is more practical and faster as it is mainly washed with lactated or physiological ringers in a special mesh strainer without centrifugation. This system allows the preparation of larger quantities of fat to be transferred to the syringes in less time.

The advantages of breast lipostructure are essentially the perfectly natural aspect, the absence of scars and the ease with which it is possible to modify breast shape. Precisely for this reason this technique has an elective indication in the correction of tuberous breasts. This congenital malformation is created in the development phase when the mammary gland increases in size while the skin envelope instead does not correctly follow the growth. As a result, an alteration in physiological form occurs with the base of the breast reduced in diameter and an abnormal projection of the CAC. (8)

While tuberous breasts have a variety of clinical presentations, the principles of surgical technique for many surgeons have remained unchanged and common for years. They consisted of correcting the

malposition and size of the areola-nipple complex, reshaping the malformed mammary gland and compensating for the volume defect with the insertion of a prosthesis. The results were not always satisfactory and it was often necessary to intervene one or more times. Lipostructuring, however, when indicated, significantly increases the quality of results and integrates with the positioning of the prostheses. (9)

1.4. Surgical anatomy

The mammary gland is positioned above the pectoralis major muscle beside of the serratus anterior, between the second and seventh ribs. It should be noted that the lower rib insertions of the pectoralis major are placed 1 cm above the sulcus below the breast. Placing the prosthesis in the submuscular site lowers the sulcus below the breast and the lower insertions of the pectoralis major must be completely resected. The gland is wrapped in the superficial fascia which is made up of a superficial and deep layer. Vascularization is mainly supplied by the external mammary artery, located in the upper-outer quadrant by the thoracoacromial artery through its perforating branches and the perforating intercostal branches coming from the internal mammary artery. The vascularization is very rich and therefore the incisions and detachment necessary for breast augmentation never compromise the vitality of the tissues. Surgical preparation of the implant site can temporarily, or rarely, permanently compromise the sensitivity of the gland, especially of the nipple. The innervation has wide margins of overlap and for this reason sensitivity is recovered even after preparing very large pockets. The sensory innervation for most of the breast comes from the anteromedial and anterolateral branches of the intercostal nerves, formed in the subclavicular region from nerve fibers of the cervical plexus. It is fundamental to preserve the integrity, during the dissection, of the anterolateral branch of the fourth intercostal nerve, which runs above the serratus anterior laterally to the edge of the pectoralis major, crosses the deep mammary fascia and heads first medially and then anteriorly towards the areola and the nipple. The preparation of the external side of the pocket must be done in a blunt way to save these branches. To the woman who asks for a large volumetric increase, it must be explained that the use of bulky implants can be associated with a compromised nipple sensitivity. (10)

1.5. Planning of the intervention

Having to proceed with breast augmentation, before making any decision both on the operating technique and on the type of prosthesis to be used, it is necessary to carefully evaluate two aspects of fundamental importance:

- the anatomy of the patient's chest wall and glandular structure;
- the results the patient hopes for and the surgeon can deliver.

The patient must be carefully evaluated: in this type of surgery we are faced with many different situations, from the nulliparous patient, lean with skin and breast fascia well stretched, to the elderly overweight with ptosis of the breasts and loose tissues. Obviously, the final results depend to a large extent not only on the prosthesis, but also on existing preoperative conditions. For this reason, at the first visit we

must proceed immediately with a complete evaluation of the patient's anatomical status; and/or after having completed this stage, we can continue with the visit, trying to best understand what the patient wants. It is therefore necessary to evaluate the woman's general physical profile: her weight, pelvis shape, subcutaneous tissue thickness at chest level, any asymmetries of the breasts, nipple position, ribs and sulci under the breasts. The elasticity of the skin, the dispensability of the tissues at the level of the sulcus below the breast and at the lower pole of the gland must also be assessed, as well as the thickness, volume and ampleness of the gland itself. It is essential to cover the prosthesis with tissue of adequate thickness, and the measurement of this thickness therefore becomes important in deciding the most suitable position for the prosthetic implant. The thickness of the tissues at the upper pole of the gland, at the inframammary sulcus and medially, at the sternal margin, can be assessed with a pinching maneuver: performed by pinching with two fingers, skin and subcutaneous tissue from above the deep fascia beyond the projected site of the gland (at these points there is no parenchyma so by measuring the thickness of the tissues pinched in this manner with a gauge, one can determine the choice of anatomical plane where the prosthesis can be inserted). It is believed that the minimum thickness needed to prevent the implant border from being visible, as well as any implant surface undulation, is at least 1 cm, which naturally corresponds to 2 cm evaluated at the time of pinching. In reality, over time (also due to the prosthesis weight itself) it is possible that the skin may relax and the adipose tissue atrophy, with consequent tissue thinning. For this reason, the implants placed in the subglandular site may surface after a few years, requiring reoperation. This risk must be prevented with a mindful attitude present already at the first intervention, thereby placing the prosthesis in a deeper plane. In lean patients with inadequate tissue coverage, subpectoral positioning is always used. At this point we have an idea of our starting point, what results can be achieved and what we are able to discuss more realistically with the patient about her wishes. The results the patient wants to obtain are not easily understood. It is up to the surgeon to explain what can and cannot be obtained, it is necessary to resort to any means useful toward achieving a mutual understanding of the final result. (11)

1.6. Preoperative measurements and choice of implant

Over the years, since the concept of size replaced that of volume, very complicated algorithms have been developed to arrive at the choice of implant. If it is true these complex formulas have greatly helped us to understand the concept of dimensions and take into consideration previously neglected details, it is equally true such algorithms can be deceptive. We present here the criteria for essential preoperative measurements we deem necessary in order to choose the characteristics that define the size of a breast implant:

1. Width of the base;
2. Height;
3. Form;
4. Projection.

With the patient standing, the medial and lateral margins of the breast parenchyma are drawn, slightly pushing the breast inward and outward so that the parenchymal borders are more visible. The submammary

sulcus is drawn by pulling on the nipple and simultaneously pushing the breast down. This line is considered temporarily as the possible new sulcus: with a slight pressure on the lower pole of the breast, the upper limit that one intends to fill is marked; with the help of a caliper the width of the breast is measured; the thickness of the parenchyma is subtracted from this, from one to two centimeters depending on the patient's characteristics. This measure defines the width of the implant to be used in most patients, as the prosthesis must be covered by breast tissue. In selected cases, in which the subcutaneous tissue is of considerable thickness, a wider implant can be chosen, for which it is important to ensure the edges of the prosthesis are not visible medially and laterally through tissue that is too thin. With the help of a caliper, the distance between the submammary sulcus and the upper limit is measured. Nipple distance at rest and under tension: this measurement appears on the implant's packaging.
The measurement under tension corresponds roughly to the post-operative situation when the tissues are stretched from the new volume and gives an indication on the implant projection. Sulcus-nipple distance with a raised arm: this measurement is taken at the body's midline; abducing the arm at 90 °, the nipple is more or less at the height where it will be after the introduction of the implant. The measure corresponds, always provisionally, to the radius of the base of the implant, to be compared with the already calculated transverse diameter. We then check the level of the newly traced sulcus. The distance between the sulcus and the nipple shown on the midline must correspond to the implant radius plus the thickness of the tissues, approximately 1-1.5 cm. The position of the sulcus can eventually be corrected downwards; of course, one must ensure the sulcus is not forced, and can be moved downwards without creating double contour deformities. In thin patients, lowering the sulcus often results in poor coverage of the lower border of the prosthesis, with inevitable border palpability. In the event of a forced sulcus and modest ptosis of the gland, the sulcus must not be lowered, and the choice of anatomical implants with a short upper pole must be considered to avoid excessive and unnatural convexity at the level of the upper half of the breast. Implant projection depends on the ability of the tissues to accommodate the new volume and therefore on their extensibility. An extensibility of 1 cm under tension of the nipple-sulcus distance indicates a poor compliance, while an extensibility of 3 cm indicates the possibility and opportunity to choose an implant with greater projection. A distance of more than 8 cm between the nipple and sulcus with stretched tissue means the presence of ptosis that is difficult to correct with an implant. (12)

1.7. Location of the system

The dissection to create the pocket for housing the prosthesis can be carried out in four different planes: submammary, subfascial, subpectoral and completely submuscular. The latter positioning, which implies the detachment of all soft tissues from the rib cage, including the serratus anterior, is now obsolete and is mainly used for post-mastectomy reconstruction. Submammary implant positioning between the body of the gland and the fasciae of the pectoralis major and serratus anterior muscles should be the first choice whenever tissue thickness allows it. For this reason it is necessary to check its adequacy both with palpation and the "pinch test," which must confirm at least 2 cm. It is considered the most "natural" site because the new

volume is introduced exactly where it should be physiologically, that is, in the glandular plane. A more natural form of the breast is also obtained. The postoperative pain is much less than what occurs with subpectoral implant positioning and the limitation of the patient's physical activity is shorter. In addition, submammary positioning avoids the problem of glandular displacement during the period of pectoral contraction, a problem which must be explained to the patient in great detail. Over the years, posterior fascial positioning has become widespread. The results are very good and natural perhaps because, together with the deep layer of the superficial fascia, a thin layer of fascia of the pectoral muscle is also detached, including the perimysium at the QSS (quadrante superiore sinistro = upper left quadrant). This is believed to be important for optimal vascularization of the tissues surrounding the prosthesis; it would lower the tendency toward capsular contraction and of lower margin visibility of the prosthesis itself at the upper pole. Subpectoral positioning guarantees a better coverage of the prosthesis, particularly in areas of greater visibility, such as the upper and medial areas of the breast. It must be presumed each time that the tissue thickness above the implant seems inadequate, always keeping in mind that with age the problem of tissue thinning intensifies. This decision must also take into consideration the negative aspects of this positioning, such as breast deformity due to physical movement and a longer, more painful postoperative course. The advantages of better prosthesis coverage are incalculable, especially when compared to cases where the implant is seen and felt. The change in breast shape due to pectoralis major contracture can be annoying for the patient, particularly when the muscle has not been manipulated or detached in any way from its medial and inferior insertions. In this case, muscle contraction exerts traction on the prosthesis in the upper and lateral direction which can lead to definitive movement of the implant over time. In addition, the inferomedial insertions of the pectoral muscle and muscle fascia limit the possibility of expansion of the lower half of the breast, with a flattening effect that will tend to decrease with age in an unpredictable way. It is always recommended to completely interrupt the insertions of the pectoralis major at the level of the sulcus under the breast and partially detach the middle ones close to the sternum: in this way the extent of the dynamic deformity is reduced and a better expansion of the lower edge of the breast is gained. In effect, by completely detaching the lower insertions of the pectoral muscle, it is possible to reach the level of the sulcus below the breast, which is generally placed at a lower level than the insertions themselves. Optimal expansion of the lower breast margin may require additional radial and circumferential incisions of both the pectoral fascia and soft tissues. The classic technique requires that the insertions of the pectoral muscle to the glandular tissue above remain intact to avoid an uncontrolled high retraction of the muscle itself with a visible "curtain" effect. More recently, a technique has been introduced and disseminated widely that involves selective disinsertion of the pectoral muscle, which is tailored to the anatomy of each individual patient. This technique of dual plane disinsertion of the pectoralis minimizes dynamic action due to pectoralis contraction while at the same time guaranteeing the best possible coverage for prostheses in the most diverse situations.

The term "double plane" indicates the dissection that takes place is partly sub pectoral and partly subglandular. Isolation is conducted not only behind the pectoralis major, but also above it, detaching the

muscle from the gland for a variable length, based on the need for expansion of the lower pole of the breast and the extent of the ptosis. The technique also involves customized disinsertion of the pectoral muscle, with complete interruption of the lower insertions and partial interruption of the medial ones. The pectoral muscle retracts cranially at various levels and covers only the upper part of the prosthesis. The dissection above the pectoralis is pursued until the upper edge of the areola is reached in order to correct the ptosis, thus allowing the prosthesis to fill in the lower area of the breast and obtain the maximum possible advantage. If the breast is flat, the dissection should be less extensive. The retracted flap of the pectoral muscle is sutured again to the glandular parenchyma: this procedure must be done with the prosthesis in position and the patient seated, to better check the level of repositioning.

1.8 Operating techniques

The surgery executes what has been previously decided and planned, from a technical point of view we distinguish the following phases: patient drawing, access, setting up the implant site or "pocket," positioning of the same; the positioning of a drain, the washing of the pocket leaving an antibiotic in place and the placement (or not) of a compressive or "modeling" dressing. It is indispensable that in the operating room there be an operating bed that allows the backrest to be lifted to put the patient in a sitting position during surgery to evaluate the symmetry and positioning of the implants.

Drawing

With the patient standing or sitting and using a dermographic pen, the landmarks are marked, i.e. the jugular, the midline, the sulci below the breasts, and sometimes the external, medial and upper mammary borders. These landmarks are useful during dissection of the prosthetic pocket, when the patient is on the operating table in the horizontal decubitus position, because in this position the relationship between the gland and the underlying planes can be altered.

Access

The access routes currently most practiced are the axillary, periareolar and submammary sulcus. The axillary access finds supporters because the position of the scars is hidden in the axillary cable posterior to the anterior pillar and is difficult to associate to the intervention that follows. In reality, despite the remoteness of the access point from the breast region, with adequate instrumentation, it is possible to create a subglandular pocket with sufficient ease but, when needed to place the prosthesis under the pectoral muscle, good control of the inferomedial angle of the pocket is not possible without the aid of endoscopic instruments. Finally, it does not allow a free choice of prosthesis type: in fact, while it is easy to introduce saline prostheses, which can be filled when they are already positioned within the pocket or round prostheses, the positioning of anatomical prostheses, of cohesive gel or large dimension, is very complex. Lastly, if reintervention is needed, it is the decidedly less easy access point and requires a new access. The periareolar access being located in the center of the mammary region, allows a good command of the operative field while defining the implant site and during the placement of the anatomical prostheses. If the scar does not develop any pathology, it truly becomes only slightly visible because it is located between the

areolar margin and the breast skin. In rare cases, if the size of the areola is extremely small (less than two centimeters in diameter), it may be difficult or impossible to introduce prostheses larger than 150 cc. Access from the submammary sulcus does not oblige one to cross the gland. The skin incision is placed exactly 7-10 mm caudally to the line where we intend to recreate the submammary sulcus and precisely from the projection of the nipple on the neosulcus proceeding laterally for a length of 4-5 cm. Both the subglandular plane and free edge of the pectoral muscle are easily accessible. It is not as easy to define the upper quadrants and to place prostheses with a polyurethane surface. (13)

Preparation of the prosthetic pocket

Once the access route has been chosen, the prosthetic pocket is created, which will be conducted either on the subglandular, subfascial or subpectoral plane, or with a dual plane. The dissection must be as precise as possible and not exceed the limits of the preoperative plan in relation to the size of the prosthesis to be implanted. This is necessary above all if you have chosen to implant an anatomical prosthesis with a textured surface, to facilitate the adhesion of the prosthesis to the tissues and limit the possibility of dislocation and/or rotation with an evident change in breast shape. To create a retroglandular space, the dissection is fairly simple because the plane chosen is easily detachable from the pectoral muscle fascia and is poorly vascularized. Dissection is carefully limited within demarcated limits. In case of subfascial dissection, a periareolar or sulcus access below the breast is preferable. Dissection in the lower pole can be subglandular initially then progress to subfascial from the level of the nipple and proceed on this plane for the entire upper pole. In this way the visibility of the upper border of the prosthesis is limited, in patients with limited tissue thickness at this site. The dissection is carried out with electrocautery leaving the muscle fibers uncovered, also lifting the perimysium. The contraction of the muscle fibers makes the maneuver rather difficult and can be facilitated by a chest retractor. To create a subpectoral space from the access route chosen, look for the free edge of the pectoralis major and detach it from the costal plane, resecting all the lower rib interarticulations and for the length of 2-3 centimeters and inferosternally, to allow better expansion of the distal pole. Finally, the most articulated of the dissections and currently the most used: the dual plane. It includes the subpectoral dissection as described and a subglandular dissection limited to the lower pole and extended up to the areolar level or a little further, in relation to the mammary ptosis, the prosthesis to be used and the degree of expansion and repositioning of the lower pole desired. If the pectoralis retracts upwards excessively it is possible to control its level of rise with an absorbable suture that reattaches it to the gland. This is done for better evaluation with the prosthesis inserted and the patient in a sitting position.

Implant placement

With round prostheses, positioning is quite simple if the surgically created site is well shaped. Attention is only paid to avoid over/under rotation during insertion, a situation that could create a worsening of the final shape. It is easily avoided by verifying that the small landmarks visible on the base of the prosthesis are in contact with the chest wall. With anatomical prostheses, care must be taken from the moment of

introduction, trying to make the prosthesis penetrate as much as possible with the proper orientation because it is difficult to make large displacements since the surface, being textured or covered with polyurethane, does not slide easily. Before suturing the pocket planes, it is essential to visually verify the landmarks on the prostheses and put the patient in a sitting position to check the shape and symmetry of the breasts, making all the necessary corrections. (14)

Drains and dressings

There is discussion as to whether drainage is really useful. Our choice is to use a drain whenever fluid is anticipated, even if modest bloody secretions. In a surgery made of detail and attention, why risk raising the percentage of likelihood of seromas and hematomas that influence the final result in an unpredictable way? We believe drainage with aspiration reduces the incidence of serosanguinous fluid collections and their complications. Compression or modeling dressings, on the other hand, are equally useful both for hemostatic purposes and for fixing the position of the implant so patients can avoid large arm movements.

CHAPTER 2. Complications of breast augmentation and surgical revision techniques

Complications of a breast implant can be due to changes in breast tissue, implants or the interaction between the implant surface and parenchyma. In addition, some are inherent to any surgery but with peculiar consequences in the presence of breast implants, while others are specific to these interventions. Among the general complications that in the presence of breast implants must have a more timely and specific approach than in other types of surgery, hematoma, seroma, infection and wound dehiscence must be remembered.

2.1 Immediate complications

Hematoma can create an increase in the volume of the prosthetic pocket which can cause dislocation or rotation of the prosthesis. The physiological interaction between the prosthetic surface and the surrounding tissues is altered, creating the conditions for periprosthetic capsular contracture. The progression of the hematoma is assessed both clinically and, if necessary, by ultrasound to measure the extent of the collection. Treatment in clinically manifest cases is almost always operative reintervention to evacuate blood collection, remove the prosthesis, revise hemostasis and re-implant the same prosthesis if it has not been damaged during the intervention.

Seroma: first choice of treatment is with ultrasound-guided aspiration, re-intervention being necessary in case of repeat relapse, putting an aspiration drain and revising the cavity. (15)

Pocket **infection** is an acute event that needs to be treated quickly with antibiotics. In the event of non-resolution, the implant must be removed and the pocket cleaned after which healing is rapid. Failure to remove the prosthesis can lead to severe breast distortions due to tissue liquefaction and consequent fibrosis. A new prosthesis can be reimplanted about a month after healing has taken place. Suture dehiscence can be caused by ischemic necrosis of the wound margins promoted by the complications previously noted, smoking, excessively thin tissues, or the presence of excessively large implants in relation to the space permitted by the patient's anatomy. Without exposure of the prosthesis, a surgical revision of the wound, possibly associated with lipofilling of the periwound area, is sufficient; otherwise, a revision and cleansing of the prosthetic pocket is necessary after cultures are done, followed possibly by selected antibiotic therapy.

2.2. Late complications

The reasons that most frequently lead to reoperation are: fibrous retraction of the capsule (27.5%), patient desire to change breast size or shape (20.6%), malposition of the prosthesis (14%) and ptosis (12%). However, other complications, including the appearance of wrinkles or folds, prosthesis expulsion and its rupture are other reasons for reoperation. Excluding requests for modification of the shape or volume of the prostheses, which justify one out of five reoperations, the causes of a follow-up procedure can be analyzed in the following way:

Fibrous retraction of the capsule

The common aspects of these conditions are represented by prosthetic dislocation and cdiiapsular distortion, events that make it necessary to treat periprosthetic tissues. The correct management of the capsule through total, partial or localized capsulectomies or capsulotomies is of fundamental importance to obtain an aesthetically pleasing final result, even if some improvement can be obtained with drug therapy (leukotriene antagonists, in particular Zafirlukast, administered for three months). The actual severity of the capsular retraction and the subjective reaction to this complication justify the need for possible intervention: the Baker II retractions are generally well tolerated and do not need surgical treatment, while patients with Baker III retractions usually have the need to replace prostheses. Baker's classification represents a useful clinical tool to evaluate capsular retraction, but it is possible to obtain a more objective evaluation by measuring "breast distensibility." Complete removal of the capsular tissue is not always necessary, unless it is calcified or contains silicone nodules.

On the contrary, the rigidity of the capsular tissue can be suitably used to obtain a definitively more natural breast shape or an added thickness to render the prostheses less palpable in the lower quadrants. If there is a need to augment breast volume and protrusion, the capsule tissue must be interrupted, while maintaining its structure in certain areas; (e.g. at the upper pole) thus avoiding the undesired effect of an upper pole which is too full. The Tissue expansion can be achieved through capsulotomies, keeping in mind that the mobilization of structures is always in the direction perpendicular to that of the incisions. Consequently, if the horizontal size of the breast must be increased (which is retracted in a vertical direction), vertical incisions are essentially made; while if a more rounded lower pole is desired, mainly horizontal incisions are made. If these incisions do not adequately free the parenchyma, it is necessary to act on the periprosthetic tissues more vigorously: capsulotomies oriented perpendicularly to the desired direction of tissue expansion must be performed. In the upper part of the pocket no incisions are made or the capsule is removed, so that the upper pole of the gland remains flattened. On the other hand, a complete circular capsulotomy is always practiced, detaching the parietal envelope from the apex of the prosthetic dome, so that the new implant settles more freely and the surrounding tissues can better adapt to the new tension lines. Throughout the extension of this capsulotomy incision, the pocket is enlarged as needed, more often downwards below the existing inframammary fold. This treatment of capsular tissues permits resolution of a variety of problematic situations and allows the surgeon to:

-Change the shape and size of the pocket;

-Create areas where the stiffness of the capsule prevents the expansion and protrusion of the gland;

-Expand the tissues exactly in the desired direction.

It is therefore a more creative and effective measure for the treatment of prosthesis dislocation compared to traditional total capsulectomy. In case of capsular retraction that causes downward movement of the

prosthesis, the capsular tissue provides a robust structure to use to support the lower border of the new pocket and to define the new inframammary sulcus through capsulorrhaphy. Capsular tissue can be suitably used in case of imminent prosthesis extrusion. The thinned area can be reinforced with flaps from the capsule, which provide a reliable tissue layer. (16)

Ripples, wrinkles and dips

The term "folds" or "wrinkles" indicates visible alterations of the breast integument morphology secondary to the formation of undulations at the level of the shell of the underlying prosthetic implant. They become more evident if the patient contracts the pectoral muscles or bends forward. The ban put into effect by the United States Food and Drug Administration (FDA) for fifteen years (1992-2006) on the use of silicone breast implants for cosmetic breast surgery has helped to increase the incidence of these alterations. There are many factors for which an etiological role in the appearance of folds on the surface of the prosthesis are hypothesized. They are more frequently observed in implants containing physiological solution and that have been filled with a quantity of liquid less than the minimum prescribed by the manufacturer. Rough-surface implants can accentuate visible wrinkles, because their surfaces adhere more to the capsule above and are therefore able to transmit traction to the skin that covers them. The depth of the folds is inversely proportional to the viscosity of the material used for filling. Furthermore, the degree of visibility of these wrinkles is inversely proportional to the thickness of the soft tissue layer that covers the prosthesis in the patient. For example, a rough-surface prosthesis insufficiently filled with physiological solution and positioned in the subglandular position, under a thin layer of parenchyma, has the greatest probability of giving rise to folds. One way to improve this situation can be to remove the prostheses and replace them with other soft silicone ones, positioned at the submuscular site. On the other hand, what can be done in the patient to mitigate the persistent folds at the upper pole of soft silicone prostheses positioned at the submuscular site? If this high-folds type became visible, some authors have described the use of a dermal matrix (ADM Acellular Dermal Matrix) inserted between the prosthesis and the capsule. ADM is thought to attenuate wrinkle depth because it provides an additional layer of soft tissue covering the prosthesis. The injection of autologous adipose tissue between skin and capsule can be effective in reducing the evidence of the folds that are seen at the level of the upper pole of the prosthesis. Injections of adipose tissue as a technique for correcting morphological irregularities has been exhaustively described in breast reconstructive surgery and is increasingly widespread as a now standardized form of treatment. However, the use of autologous adipose tissue injections as an adjunctive therapeutic measure in cosmetic breast surgery remains controversial to this day.

Sampaio Goes reports an incidence of prostheses rotation of 0%, a reduced percentage of capsular retraction and better aesthetic results from breast augmentation by using silicone gel prostheses of pre-established anatomical shape with a highly cohesive gel, positioned in the subfascial site. These prostheses seem to facilitate the management of complex problems, such as the resolution of breast cases with "difficult implants." Clinical investigations have shown that the silicone gel prostheses of pre-established anatomical shape are characterized by the high percentage of satisfied patients, the safety at a distance of use and

validity of the results. All patients who undergo augmentation are made aware that over the years their prostheses will become palpable through the skin, generally at the inferolateral site, where the soft-tissue coating is thinner.

Wrong position of the prosthesis

After breast augmentation, it is not uncommon to find implants placed in the wrong position. The event may be secondary to a technical error, resulting from an incorrect planning of the intervention, followed by an inappropriate choice of prosthesis, the appearance of capsular retraction, the inability of the patient's soft tissues to support the implant or any combination of these reasons. Theoretically, the position error of the prosthesis should be recognized intraoperatively then immediately corrected; in reality, however, this drawback is appreciable and recognizable only after the implant pocket has had time to mature. (17)

Types of Malposition

Inferior

Low-lying prostheses are the most common type of dislocation. The prosthesis takes a lower position than the inframammary fold (IMF). This may be due to the patient's anatomical factors (for example, patients with too high an IMF), or to iatrogenic causes due to an excessive lowering of the sulcus. The lower dislocation can have a *bottomed out* or "*double bubble*" deformity. These two terms are not synonymous. Bottomed out refers to an excessive sulcus-nipple distance, while double bubble refers to an alteration of the breast profile due to the presence of a double sulcus, often due to a persistence of the previous IMF. (18)

Medial

It is important to distinguish a medial dislocation, which is nothing more than the confluence of the breasts due to an excessive dissection of the medial margin, from *symmastia*, which is specifically defined as a compromise of the mediosternal fascia, with consequent skin elevation. To facilitate a lasting repair, the removal of the prosthesis may be necessary for a period of time, and it is often advisable to reduce the implant size in order to reduce the risk of recurrence. Several approaches have been described for the treatment of symmastia such as: capsulorrhaphy, capsular flaps, transcutaneous fixation, subglandular pocket change, creation of a neosubpectoral pocket and the combined use of acellular dermal matrices (19). The lack of a uniform approach to this complication underlines its problematic nature.

Lateral dislocation, also known as telemastia, is an abnormal separation between the breasts, usually resulting from excessive lateral dissection.

Lateral displacement should be verified by examining the patient both in the supine and standing position, with the shoulders abducted more than 90 degrees. These positions make the lateral displacement of the prostheses more evident. This problem is generally due to a technical error during the first augmentation surgery; it can be avoided both by choosing an implant of the right size, and carefully preparing the pocket that holds it, so that it does not extend beyond the lateral margin of the breast. Once the implant is positioned, a delicate digital dissection beside it can normalize the surface of the lateral margin of the gland, interrupting the overlying branches of glandular tissue still able to exert a containing effect in that area. In general, lateral displacement is solved by many authors thanks to a corrective intervention, which

aims to obliterate the lateral recess of an excessively large periprosthetic capsular space at that point. In fact, a capsulorrhaphy is performed, restricting herniation of the pocket and lateralization of the prosthesis by placing non-absorbable sutures. This procedure does not take into account the possibility of capsular reabsorption and its relapse due to the laxity of the capsular tissue, as well as obviously that lateral displacement can also be the consequence of using an excessively large prosthesis whose mass exceeds the capacity of soft tissue support over time. It should be pointed out that it is not true that the subpectoral pockets allow the muscle to keep the implant in position indefinitely. Even the systematic contraction of the pectoralis can actually facilitate implant movement downwards and outwards in the long run (20)

Higher

Upper malposition (sometimes referred to as "high riding implant") results in superior prosthesis extension. Historically, capsulotomy and capsulectomy have been the most used techniques to correct this complication, but in reality the frequent finding of lower dislocation after these procedures is a clear indication of their incomplete efficacy.

Causes of prosthetic dislocation

-Factors related to the patient

The patient's anatomy plays a role in dislocation and must be considered before the placement of the prosthesis, at the time of the first breast augmentation. Patients with tuberous breasts or a small nipple-IMF distance (<4 cm) are predisposed to develop double bubble deformity.

Patients with pectus excavatum may be more susceptible to lateral dislocation of the prosthesis. In these patients the use of prostheses with a larger base diameter is recommended, as well as a more conservative lateral dissection.

The anatomical structure of the IMF and its role in prosthetic dislocation remains controversial. Some authors identify the IMF as a distinct ligament and speculate that its injury is responsible for lower dislocation. (22) Others argue it is the confluence of the superficial fascia with the prepectoral fascia. (23) According to this latter explanation, the double bubble deformity is caused by the persistence of the relationship between the superficial fascia and the upper dermis of the new sulcus.

-Surgical factors

Iatrogenic factors are the main cause of prosthetic dislocation. Prior to surgery, inaccurate assessment of anatomical dimensions or inadequate selection of prosthesis size may predispose the patient to dislocation. During surgery, an inadequate dissection of the pocket can cause superior dislocation while excessive dissection can cause inferior, medial, or lateral dislocation. Additionally, postoperative complications such as hematoma, seroma, and capsular contracture can alter the position of the prosthesis.

-Prosthetic factors

The properties of the prostheses can contribute to dislocation. A review of Natrelle silicone prosthesis studies revealed a significantly lower rate of dislocation with the use of textured / anatomically shaped / highly cohesive silicone implants, compared to those with smooth / round / poorly cohesive surfaces. [RR: 0.29 (95% CI: 0.15, 0.56), P <.001], (24)

Dislocation treatment techniques and results

Historically, revision techniques to repair a prosthetic dislocation have produced unreliable results. The literature is unclear as to the procedures for obtaining the best correction. The approaches generally fall into two categories. One aims to repair or overhaul the implant pocket, while the other involves creating a new pocket in which to place the prosthesis. More recently, the use of additional materials has become widespread, such as acellular dermal matrix (ADM), to support weakened anatomical structures.

The following techniques are currently available in planning for dislocation correction.

Capsulorrhaphy

Spear and Little first described the use of capsulorrhaphy to correct prosthetic dislocation in 1988. This initial study of 40 patients showed promising results, with only one reported failure and minimal complications. (25) In 2008, Chasan and Francis reviewed a sample of 75 patients who underwent capsulorrhaphy due to malposition of the prosthesis or reduction of implant size. (26). Capsulotomy has been performed in many cases to relieve tension on the suture line. No complications were reported in the 21-month follow-up period. According to the authors, the patients were "generally satisfied" (26). In the treatment of symmastia, medial capsulorrhaphy with non-absorbable stitches that bind soft tissues to the sternum is commonly performed.

Capsulorraphy is considered a simple, reproducible and convenient technique. However, long-term results are sometimes unsatisfactory. Recurrence can occur when the forces that give rise to dislocation are not treated. In these cases, corrective measures may include support redimensioning, or reinforcement of soft tissues with an acellular dermal matrix.

Capsular flaps

Several authors have proposed the use of capsular flaps to reinforce capsulorrhaphy. This simple and effective technique creates a capsular flap of vascularized tissue and allows the suture line to not coincide with the point of greatest pressure of the prosthesis. Wessels et al used this technique in 12 patients with inferior malposition, who underwent IMF reconstruction and repositioning of the prosthesis with capsular flaps. All patients maintained a stable IMF at 40.4 months of follow-up. (27)

The main limitation of the capsular flaps concerns the quantity of tissue which can often be inadequate for reliable repair. Indeed, Voce and Carlsen suggest that the capsular flaps are not optimal in patients with thin capsules or history of steroid drug use. (28)

Creation of a new prosthetic pocket

- Subglandular site change

Moving the prosthesis to a new plane, such as the subglandular space if not previously used, offers the surgeon the possibility of obtaining results similar to those of a primary breast augmentation. This also frees the prosthesis from the deforming forces of the muscle, thus eliminating a possible cause of dislocation. This can be done alone or in addition to other techniques. Lesavoy reported great patient satisfaction after changing the plan in 36 patients at an average follow-up of 20.2 months (29). This technique is a simple and

reliable alternative to capsulorrhaphy, capsular flaps, and other methods that attempt to maintain the submuscular pocket, even at the price of losing soft tissue coverage.

In patients with double bubble deformity caused by an excessively low sulcus, for an excessive dissection, Handel recommends changing the subglandular site with preservation of connective tissue between the dermis and fascia at the level of the old IMF (30).

-New subpectoral pocket

Maxwell and Gabriel were the first to publish their technique for creating a new submuscular plane in 2008 in patients who had previously placed prostheses in the subpectoral site. This technique uses the creation of a pocket under the pectoralis major, though superficial compared to the anterior capsule. The existing capsule is incorporated into the new pocket after obliteration of the capsular space. Maxwell et al reviewed their results at one year in 15 patients with prosthetic dislocation, 26 with bottoming out and 21 with symmastia. All patients maintained corrections at an average follow-up of 26.2 months (19) Also in 2009, Spear et al reported results of a similar technique called the "neosubpectoral pocket" for correcting symmastia in 23 patients. All symmastia corrections were successful at an average follow-up of 22 months. (20)

There are many advantages in setting up a neosubpectoral pocket compared to the previously described methods and which have been widely used in revision breast surgery. It is often less traumatic than capsulectomy and easily allows for more precise dissection. However, if the capsular tissue is thin, creating a neosubpectoral pocket can be challenging without producing solutions to the existing defect.

- The "dual plane" technique

The "dual plane" technique can be useful to correct the bottoming out of subglandular prostheses, or in patients with submuscular prostheses who do not have adequate tissue for the subglandular plane change or in cases with important deformities. This type of surgery provides muscle coverage for the upper part of the prosthesis, while the lower part is covered by the lower pole of the glandular tissue. As described by Tebbetts, the dual plane technique involves the separation of the parenchyma-pectoral muscle interface to a different extent based on the pre-operative shape of the breasts and their glandular distribution. Incidentally, the medial insertions of the pectoral muscle are often not sectioned to avoid possible symmastia. This position allows upper pole coverage with less displacement of the prosthesis during the contraction of the pectorals, compared to submuscular positioning.

Furthermore, dual plane coverage seems to be useful in case of breast ptosis compared to submuscular positioning, for an increase in the prosthesis-parenchyma interface that helps prevent its descent. Capsulorrhaphy is often used in combination with this technique to support implantation, although these techniques can cause recurrence due to capsulorrhaphy failure.

Additional materials

- Acellular dermal matrix

Baxter first reported the use of ADM in revision breast surgery in 2003. (31). Since that time, other authors have also shown interest in the use of ADM in revision breast surgery. ADM is frequently used in synergy with traditional dislocation repair techniques, such as changes to the capsule (capsular flaps or capsulorrhaphy) and changes in plan (from subglandular to subpectoral or from submuscular to neosubpectoral). Stabilization can also be useful in patients with a chest wall that predisposes to prosthesis migration. ADM is particularly important in patients with inadequate soft tissue, where the capsule can fail over time and lead to recurrence if not effectively strengthened. Finally, ever increasing evidence indicates that ADM plays a role in the prevention of capsular contracture, a complication that can lead to the recurrence of prosthetic dislocation. The excessive cost of biomaterials is the main disadvantage of ADM. Although long-term studies are not available, current data suggest a significantly lower rate of dislocation recurrence with ADM compared to traditional techniques (32). The additional cost may be justifiable if the risk of a new revision is reduced.

- Synthetic net

Absorbable synthetic meshes represent a potential alternative to ADM at a lower cost. The TIGR absorbable surgical network (Novus Scientific, Singapore) has been reported in breast cosmetic surgery, including breast augmentation and breast lift (33). Like ADMs, this network acts as a support for scarce soft tissue. Absorbable synthetic meshes are not widely used in breast surgery so their effectiveness remains uncertain.

SPECIAL SECTION

CHAPTER 3

3.1 Purpose of the thesis

Breast augmentation is currently one of the most common cosmetic surgery procedures performed in Italy with around 33,532 procedures performed in 2014 as emerged from the Aicpe survey of the same year. (34)

The continuous progress by the manufacturers of breast implants aimed at improving biocompatibility, the quality in terms of elastomer, the shapes and silicone content, combined with the choice of surgical techniques increasingly careful to safeguard the anatomical planes has made this procedure relatively safe; however, given the high numbers of applications and the subjectivity linked to both the surgeon's hand and the patient's anatomical and functional conditions, this procedure is not without complications.

In fact, it is observed that a percentage of patients ranging from 15% to 30% of the patients undergo primary breast augmentation revision from 3 to 6 years after the first surgery, (3-15) and approximately from 30% to 40% of the patients who perform breast revision undergo further revision within 6 years. (3.15). The common complications highlighted in the literature are capsular contracture (CC), prosthetic dislocation, ptosis, asymmetry, and rippling. (3-15)

The high revision rate underlines the need for reliable methods to minimize complications in patients who undergo primary breast augmentation, as well as limit the risk of recurrence in patients who have already undergone breast augmentation revision.

Revision surgery traditionally includes various techniques such as: changing the pocket (from subglandular to subpectoral or from subpectoral to neosubpectoral), in combination with capsulorrhaphy, capsulotomy or capsulectomy, replacement of prostheses (passage from prostheses with smooth surface to textured prostheses to the use of polyurethane-coated prostheses) and the use of capsular flaps for the creation and pocket reinforcement.

In truth, it must be accepted that the breasts are inevitably subjected to physical traumas (work, sexual activity, sports) that exert a friction on the muscular or fat-glandular level, as well as chronoaging also linked to weight loss, weight gain and pregnancies.

Therefore, in patients undergoing breast augmentation surgery, even a limited thickness of these anatomical host structures may be present, due to their constitutional or acquired thinness, with muscle and

glandular hypotrophy and laxity of the skin tissue, therefore the possible traumas described can be the cause of dislocation, rotation, surfacing, with capsular contraction of the implants.

It is therefore evident that even if effective, the various techniques developed to remedy or solve these problems and used without the positioning of meshes that reinforce the anatomical structures weakened over time, produce a high recurrence rate for daily endurance and realistically inevitable friction or pressure on the areas of least resistance.

Over the years biotechnology has produced on the basis of clinical research supports that tend to provide reinforcement of weakened anatomical structures by asking two main questions: the complete reabsorption of the host tissue in order not to "pollute" the host tissue or non-absorbable aids that become permanent reinforcement.

More recently, the regenerative acellular dermal matrices (ADM) have been adopted, as well as in reconstructive breast surgery, also in cosmetic surgery to provide soft tissue reinforcement in the revision of breast augmentation and/or mastopexy.

ADM advocates claim that it effectively strengthens capsulorrhaphy, reduces excessive tension on the suture line, helps define the IMF, and maintains the correct position of the prosthesis in the new pocket. Maxwell and Gabriel define ADMs as "prosthesis stabilizers". (19)

Despite having many advantages, ADM has been shown to have a higher probability of seroma, infections, and failure of ADM-assisted reconstructions. (35)

Furthermore, a prospective, randomized, controlled and multicenter pilot study that compared the use of acellular meshes and dermal matrices in immediate breast reconstruction showed high levels of satisfaction of the aesthetic result by patients for both materials, but the group who used ADM has shown to have a higher rate of serious complications in terms of failure of the reconstruction with loss of the implant. (36)

Although these corrective techniques can help improve starting conditions, the high rate of reoperation in patients who have undergone breast augmentation revision is a clear indication that the procedures are not completely effective in correcting or reducing the risk of recurrence.

Given the growing evidence that the use of ADM is associated with greater complications, there has been the need to also experiment in cosmetic surgery with an option that already has obtained excellent results in reconstructive surgery (37): the use of a Tiloop mesh. The objective of the study was not to compare this product with ADM, but to report the results obtained by us using this device for tissue reinforcement in the same range of complications and recurrences as in breast augmentation.

3.2 Methods

A retrospective study was conducted on 123 patients who underwent breast augmentation revision surgery and/or mastopexy and treated with Tiloop mesh, from March 2012 to May 2019 during a period of just over 7 years.

We collected data on the original position of the implant (subpectoral or subglandular), the date of the first surgery, the previous access route used, volume of implant used and date of the revision surgery. Age, lifestyle habits linked to direct trauma, pregnancies and/or weight loss and weight gain, type of implant and access routes used by us, duration of follow-up, and any complications were also reported.

3.2.1 Description of the material

Tiloop is a light titanized polypropylene mesh with a monofilament structure. Compared to common non-titanium coated meshes, such as heavy and light polypropylene (PP) meshes, or PP meshes with polyglactic acid, Tiloop is characterized by greater biocompatibility. In a study by Scheidbach et al, the observed cellular reaction, in terms of proliferation and apoptosis, was lower when using Tiloop (38). Histopathological, immunohistochemical and biological-molecular investigations have shown significant benefits in favor of Tiloop compared to other PP networks. (39)

In particular, significantly lower inflammatory reactions and shrinkage have been demonstrated when using Tiloop compared to the identical amount of heavy PP non-coated titanium mesh. (40)

3.2.2 Surgical procedures

The surgical procedure was chosen based on the clinical presentation.

The main indications for revision surgery were essentially 3: reinforcement of the pocket for the correction of prosthetic dislocation (bottomed-out, symmastia, and lateral dislocation), soft-tissue reinforcement for the correction of rippling, and post-capsulectomy reinforcement for the treatment of capsular contracture for integration and defense of both poor residual connective tissue and loose and stretched skin.

The surgical procedure we carried out involved the replacement of the prostheses in all cases with a change or reinforcement of the pocket.

In any case, non-reabsorbable sutures were placed in the lateral aspect and in the sulcus where muscle laxity or poorly elastic skin and fatty tissue below 1 cm thick were observed. We know very well this reinforcement improves and reduces the capacity and volume of the pocket but does not achieve a lasting reinforcement over time. On the contrary, it increases the force of pressure quickly causing a fracture of the reshaped pocket. That's why after reshaping the pocket, a mesh is positioned on the stitches that protects the muscle and distributes the forces on the entire axillary line, taking into account that the mesh also wraps the prosthesis and that it is fixed above the chest wall at about 4-6 cm from the submammary sulcus in order to stabilize and support the prosthesis in the infero-lateral site, which is the point subjected to the greatest pressure. In practice, a method similar to that carried out for hernia plastics is used, which for its use is still, after decades, the most reliable in terms of biocompatibility, infections, and prevention of complications.

In some cases, pre or post insertion of lipofilling meshes were carried out, to implement or prepare the fat thickness in some quadrants where it was found to be scarcer to improve the shape and limit the palpability

3.2.3. Indications and clinical cases

For the correction of the prosthetic dislocation, in cases where the prosthesis was previously positioned in the subglandular position, and the change of the anatomical plane was not sufficient to resolve the complication (in this case the cases of lower dislocation) the Tiloop was positioned in the lower quadrants, after reshaping the pocket with non-absorbable points to recreate the inframammary sulcus.

In cases where the prosthesis was already positioned in the submuscular seat, the pocket was reshaped and the Tiloop was placed at the lateral, lower, or medial edge of the prosthesis (depending on the type of dislocation). An example is the case of a 43-year-old patient who underwent breast augmentation surgery in 1995 with the placement of submuscular PIP prostheses, after 10 years underwent II replacement surgery for prosthetic rupture and intracapsular silicone spreading. In 2012, III intervention for capsular contracture on the right, prosthesis replacement without silicone removal. He presented himself to our observation for asymmetry of shape and prosthetic position. E.O. showed axillary dislocation of the submuscular prostheses, left slipping of the prosthesis onto the sulcus and asymmetry of shape; access incisions to the sulcus in an anomalous site and dislocated upwards, bilaterally (Fig 1). MRI showed the presence of residual intracapsular and axillary siliconomas bilaterally (Fig. 2). The patient's requests were to be able to have larger prostheses, an improved scar result, medial placement of the prostheses, removal of axillary and intracapsular siliconomas bilaterally, and shape symmetry. The operative planning of this patient provided for: total capsulectomy and removal of the siliconomas incorporated in the axillary lymph nodes (Fig. 3e 4); suturing of the pocket at the axillary site and submammary sulcus bilaterally; positioning of the support mesh from the axillary pillar and to the sulcus (Fig. 5). The results are shown in Fig. 6

Another example, a 26-year-old patient, undergoing vigorous local trauma, underwent I surgery in 2013 for breast augmentation in Dual Banding. After three months, she underwent surgery for prosthetic rotation and lower prosthetic dislocation on the right during which 10 x 15 cm mesh was placed at the submammary sulcus (Fig. 7-8-9). After 5 months she returned to us due to prosthetic rotation and lateralization with an increase in the intermammary distance. (Fig.10) The revision in this case involved positioning the mesh in the axillary region and in the sulcus region, after reshaping the pocket (Fig.11-12-13). The results are illustrated in Fig. 14.

Another case is of a 31-year-old patient who came to our attention for post-additive capsular contracture, severe ptosis, prosthetic lateralization, with a large intermammary space. The surgical strategy in this case included Round Block mastopexy, reshaping of the pocket and positioning of a mesh in the axillary site 10x15. The results are shown in Figure 15.

The cases of rippling and prosthesis surfacing were treated by placing the Tiloop over the areas with thinner tissue to provide further reinforcement of the soft tissues.

An interesting case is a 45-year-old patient who underwent primary breast augmentation surgery plus T-mastopexy with submuscular prosthesis positioning, a secondary prosthetic repositioning intervention and

reshaping of the submammary sulcus on the right. She presented to us for recurrence of prosthesis slipping to the sulcus below the breast on the right, re-ascent of pectoralis major QSI (quadrante supero interno = upper inner quadrant) and loss of profile depth (Fig. 16-17). After reshaping the pocket, we anchored the pectoralis major muscle to the mesh. (Fig 18-19-20). The results are visible in Fig. 21.

Again the case of a patient, 45 years old, who underwent seven revision operations of breast augmentation and mastopexy with prosthesis. The clinical presentation was thinning of the QQII skin flaps, prosthesis surfacing, prosthetic dislocation to the lateral folds. We performed a first surgical procedure of prosthetic replacement and QQII and lateral network positioning to reduce the friction between prosthesis and subcutaneous tissue, followed by a second round of subcutaneous lipofilling to increase the thickness between prosthesis and overlying skin (Fig. 22-23)

For capsular contracture corrections (Baker III/IV), a total capsulectomy was performed in cases where the previous prosthesis was placed at the subglandular site and a total or partial capsulectomy in cases where the previous prosthesis was submuscular. The Tiloop was positioned to protect the submammary sulcus and lateral pillar after capsulectomy or capsulotomy, as these procedures result in an increase in diameter in three dimensions.

In some cases, the polyurethane prosthesis was used.

To minimize contamination during surgery, the pockets were irrigated with a triple antibiotic solution, and all new prostheses were immersed in the same solution before insertion into the new pocket. In addition, all patients were prescribed perioperative antibiotics.

3.3 Results

123 patients were identified who met all inclusion criteria for this study. We excluded patients who did not have at least one year of follow-up. The average age of the patients was 37.4 years, and of these 65% had had at least one child at the time of the first surgery. The clinical signs of presentation are listed in Table 1. Almost half of the patients requiring revision surgery showed CC Baker III/IV. More than a third, on the other hand, came to our attention for prosthetic dislocation. Other indications for the surgical revision surgery were symmastia, implant surfacing, rippling and one case of bottoming out.

85 patients had their original implant in the subpectoral position and 38 in the subglandular position. The average time between primary surgery and revision surgery was 5 years, 5 months (originally subpectoral: 4 years, 9 months; originally subglandular: 6 years, 1 months). The mean follow-up after revision surgery was 5 years (originally subpectoral: 2 years, 1 month, originally, subglandular: 1 year, 11 months). (Table 2)

Among the patients who previously had subpectoral implantation we found 11 (20%) cases of prosthetic rupture at the time of revision; among those who had the previous implant in the subglandular region there were five cases of prosthetic rupture (23%). During the revision surgery 50 patients received silicone implants and 6 polyurethane implants (Table 3).

We followed our patients from a minimum of 12 months to a maximum of 36.

There were 4 complications we encountered requiring surgical intervention (Table 4):

-a hematoma

-a seroma

-the case of a patient operated by us for lower prosthetic dislocation returning to the operating room after 5 months for prosthetic dislocation—this time lateral, due to a shift of the network from the lateral to the submammary margin, linked in our opinion to early mobilization of the patient and to positioning a network of inadequate size.

-We like, then, to highlight a very interesting case in which, about a year after the correction of a prosthetic dislocation in the lateral site, capsular contracture and corrected breast ptosis with round block mastopexy and positioning of the network in the lateral site and at the submammary sulcus, an ultrasound check, followed up with an MRI, was diagnosed with swelling with a risk of neoplasm. This swelling appeared on ultrasound as hyperechoic and located at the lateral and lower margins of the QSE (quadrante supero esterno = upper outer quadrant). Therefore, considering her positive family history, the decision was made to surgically remove this swelling.

Well, pathology findings showed the suspicious swelling was only the end of the network folded over itself and wrapped in connective tissue.

This highlights two aspects: the first is that the network, once integrated into the host tissue, receives a rich vascularization, and can mislead an inexperienced radiologist. The second is that the mesh must be adequately stretched when the implant is removed, eliminating the surplus between the prosthesis and the glandular body, to avoid folds that can give rise to false radiological images of a lesion.

No case of recurrence of the complication or of capsular contracture was found at an average follow-up of 7 years.

Of the 123 patients, 121 (98.4%) showed a soft implant with a Baker I level of CC at final follow-up; two patients (1.6%) had a CC Baker II. No patient showed Baker III or Baker IV at postoperative follow-up. (Table 5).

From June 2019 to today, 21 additional cases of surgical revision have been carried out with the use of Tiloop, increasing the total number of patients undergoing this surgical technique to 144, but having established a minimum follow-up period of one year, they were not included in this series.

However, it is worth noting that all these patients showed no complications and maintained a Baker I classification at an average follow-up of 6.2 months.

3.4 Discussion and conclusions

Polypropylene meshes have been used for decades in various surgical contexts, including abdominal wall repair, inguinal hernia treatment, cystoceles, and, not least of all, in breast reconstruction. (41-42-43)

Immediate breast reconstruction using definitive prostheses has become one of the most common surgical techniques performed after a mastectomy, which has inevitably led to an increase in the number of complications such as rippling and deformity of the breast profile.

Therefore, the introduction of a device that gives support and improves the friction between prostheses and extremely thin soft tissues after mastectomy has increased the indications for the use of absorbable or non-absorbable meshes to reduce the incidence of these complications.

In particular, attention was focused on the use of acellular dermal matrices, which, if proven to have an excellent outcome in terms of reducing the onset of capsular contracture, have also been associated with a greater probability of seroma, infections, and failure of ADM-assisted reconstructions (35). Based on the limits reported by the use of these absorbable meshes, the focus has subsequently shifted to the possibility of using non-absorbable synthetic meshes, and in particular to the use of titanium-coated polypropylene meshes which have demonstrated a number of complications significantly lower than those reported by the ADM (36).

After initial skepticism by the scientific world on the use of a non-absorbable device in patients with breast cancer who are often forced to undergo radiotherapy (RT) cycles, due to the fear of a possible impact of the aforementioned prosthesis with the RT itself or any artifacts that the Tiloop could introduce on radiological images, Camacho et al. showed that the difference in the dose absorbed with or without the mesh was less than 1%. They also found that no metallic artifacts appeared on CT images around the covered surface. (44)

Another study then asked the question of Tiloop tolerance in patients already undergoing RT. Indeed, there is considerable evidence that prostheses after RT are very often hesitant with a high rate of capsular fibrosis.

This study has shown that this titanium-coated mesh, through tissue integration, can develop a "neofascia" in the breast, which allows it to keep the prosthesis stable in its position. (45)

The rapid increase in demand, accompanied by the growing satisfaction in terms of outcomes of immediate breast reconstruction, has also stimulated a strong interest in the use of reinforcement meshes in cosmetic breast surgery, in particular to cope with those complications of breast augmentation where classically recognized techniques of surgical revision, increasingly, unfortunately, lead to long-term failures. In fact, data from current literature indicate approximately twice the higher rate of revision surgery in patients who have already undergone repeat surgery compared to primary breast augmentation.

The multifactorial etiology and presentation of the various kinds of complications that often overlap in the same patient, pose unique challenges for the plastic surgeon who seeks to perform a repeat breast augmentation. In fact, it is not uncommon to find desperate women, because they have already undergone numerous interventions by several surgeons, who, mistakenly placing responsibility in the operator's subjectivity, insist in re-proposing superimposing techniques, inevitably obtaining the same failures over time, even further weakening vascularization and thus the vitality of anatomical structures.

However, there are still no precise indications on reliable methods to help avoid the risk of recurrence of the complications of this surgery. The thinning of the breast parenchyma and the overlying soft tissues have often been observed in patients who undergo breast augmentation as a consequence of the implantation of

bulky implants and the inevitable physical and mechanical stress the mammary bodies are subjected to daily. Thin tissues, in turn, can contribute to prosthesis palpability, rippling, ptosis, dislocation (bottomed out, symmastia, lateral dislocation), and extrusion.

In our study, more than a third of patients overall had dislocation, rippling, or prosthesis exposure as a presenting sign. In all these patients, the Tiloop has been used to strengthen the recreated pockets, as well as to protect soft tissues from prosthetic pressure in cases of rippling. At an average follow-up of two years, the success we obtained with the aid of the aforementioned prosthetic device provides a series of important conclusions.

First of all, the use of a Tiloop mesh gives a supporting structure to the soft tissues, helping to reduce unwanted prosthetic visibility and palpability.

Secondly, the use of this product enhances the ability to successfully manage prosthetic dislocations but above all to prevent their recurrence.

Furthermore, a fundamental aspect, recognized in the literature, is the pressure and friction that the prosthetic body exerts by gravity to the lower mammary quadrants, causing an impoverishment of the vascular network with consequent hypotrophy of the mammary body. A mesh, useful to support prostheses and mediate ischemic and lipolytic pressure, allows sustainment not only of fat thickness but also skin tissue support over time, thus reducing the development of ptosis.

Finally, it is of considerable interest that 58 patients with CC Baker Grade III and IV have been successfully treated. In this regard, we must remember that although the precise etiology of CC is still to be established, it is known that inflammation at the cellular level can lead to the pathological formation of CC. (46) Histopathological analysis has shown significantly lower inflammatory reactions when using Tiloop compared to common non-titanium coated meshes, which would provide an empirical explanation for the low CC rate observed after its use.

We note that no recurrence was found in these patients treated with the use of meshes, at an average follow-up of 7 years. All patients were recommended to have a period of rest from sports stress, or physical trauma of about 40 days, a period useful for the coalescence of the mesh with host tissues and to avoid dislocations and seromas.

The complications we encountered were:

-the formation of a seroma in a patient who had undergone revision surgery for CC;

-a hematoma in a patient who has had revision surgery for lateral dislocation;

-the very suggestive case of a patient who underwent a first revision with positioning of the network for lower prosthetic dislocation who after about 5 months came back to us for lateral dislocation and prosthetic rotation. Not to be underestimated is early mobilization in the patient's post-operative period. The same, in fact, reported the resumption of normal work and sports activities after only one week after the surgery we performed. From this case it can be deduced that the reinforcement of the lower pole was preserved only because the mesh, though placed to protect the lower pole while modestly extending to the lateral margin

due to its length (Tiloop mesh 15x10 cm), due to early mobilization and probably direct trauma that the patient did not admit to openly but easily intuited, the net dislocated, rolled up and retracted, positioning itself at the edge of the submammary sulcus. This was found intraoperatively at visual inspection and gave rise to two considerations: the first is that if a patient experiences a weakening of the submammary sulcus, it must always be taken into account that the pressure exerted on the pocket will weaken or has also already weakened the lateral pillar; this evaluation found on clinical experience poses the need to always correct and reinforce the lateral and submammary pole simultaneously with a mesh that has a diameter and length useful to cover and protect both areas.

The second consideration one is obliged to make is that traumatic movement from local trauma can not only produce prosthetic dislocation but also seromas that increase the risk of dislocation of the implanted mesh. After the second revision, the patient does not show complications after 7 years of follow-up, despite admitting to having an intense sporting activity that forces the prosthetic bodies to undergo continuous trauma.

Ultimately, the use of Tiloop non-absorbable meshes in the management of complications of breast augmentation offers us, according to our data, a new and reliable surgical option.

However, important results have been obtained using this device also in selected cases of primary breast augmentation. In fact, the requests from patients to receive prostheses of ever larger volume are growing even when the anatomical conditions are not very favorable. In these cases, where there is constitutional thinness, with thin and flaccid skin, and/or scarce muscle thickness, even a prosthesis of moderate size would risk being unpleasantly visible. The use of a mesh that reduces the friction between prosthesis and overlying tissues, safeguarding the scarce thickness both breast and muscle, we believe can offer valuable help by sheltering and preventing a cascade of complications ranging from prosthesis palpability to dislocation .

The only obstacle this product unfortunately still encounters in routine use in cosmetic surgery is the cost-benefit ratio, given the relatively high expense it represents for the patient. Further prospective and multicenter studies would be useful to evaluate the effective impact of this cost in the primary setting, the documented improvement in outcomes these devices provide in our surgical specialty and the continuous relapses and relative costs the patient bears over a lifetime using this protection in advance. Currently there are no findings in the literature that highlight an increase in tumor rates due to the presence of both absorbable and non-absorbable meshes; all that remains is to pay attention to diagnostic tests such as breast ultrasound and MRI, though operators have not yet highlighted the possibility of negatively interfering in the diagnosis of tumor lesion. (46) Our specific reported case is evidence of this, which in a numerically more significant use will also focus for non-absorbable meshes, as it had for breast prosthetic devices, new attention, new experiences, and new frontiers for radiological specialists who deal with the prevention of tumors and the integrity of prosthetic bodies.

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Tab 1. Clinical Signs

	Patients
Capsular contracture	67
Implant Dislocation	32
Implant rotation	4
Rippling	12
Bottoming out	5
Symmastia	3
Tot.	123

Tab. 2. Timing of second surgery and Follow-up.

	Patients	Time second surgery, months	Follow-up, months
Previously sub-muscular Implant	85	57	25
Previously sub-glandular Implant	38	73	23
Tot.	123	65	24

Tab. 3. Type of Implant

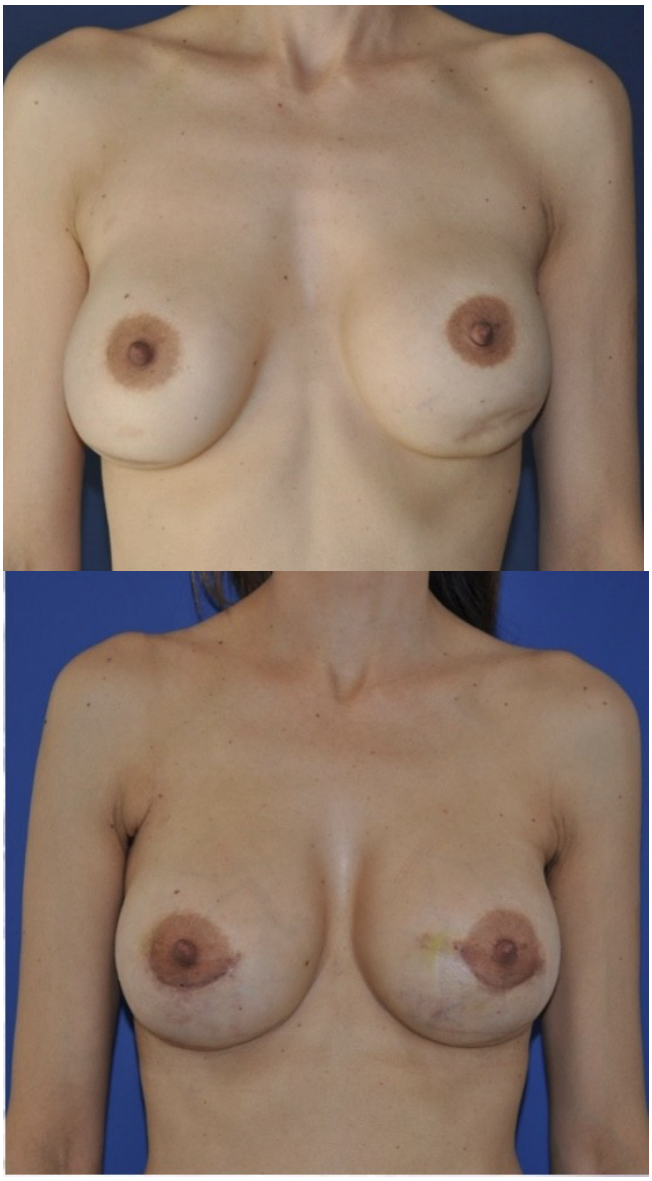
Type of Implant	Patients
Silicon implants	100
Polyuretane implants	23
Tot.	123

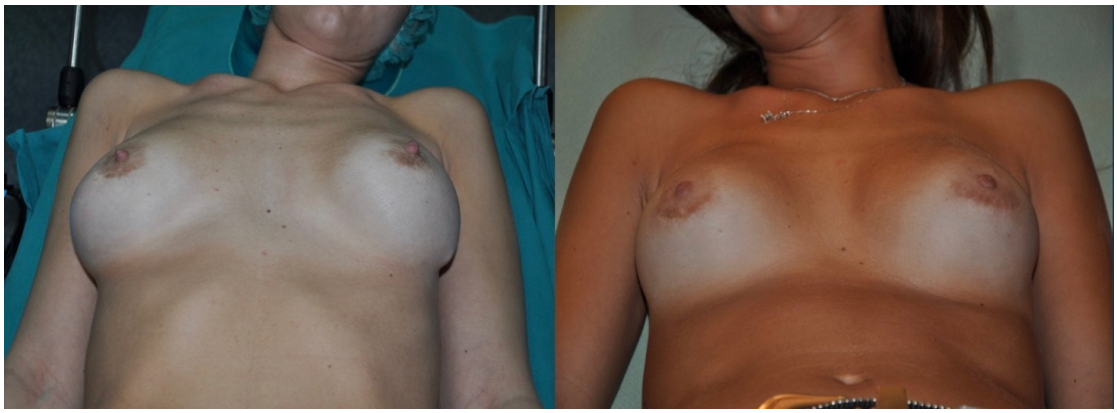
Tab. 4. Complications

Complicantions	Patients
Hematoma	1
Seroma	1
Implant dislocation	1
False radiological images of Neoplastic lesion	1
Infection	0
Rippling	0
Implant damage	0
Capsular Contracture	0

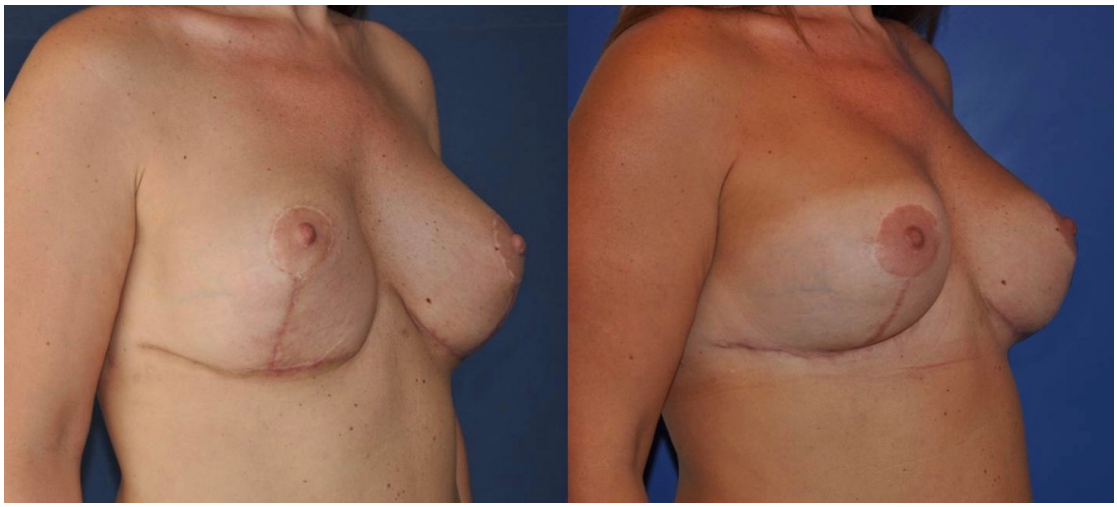
Tab.5 Capsular contracture classification (sec Baker)

Capsular contracture (Baker)	Pre op, %	Post op, %
I	17,9	98,2
II	35,7	1,8
III	14,3	0
IV	32,1	0





Pic 3. Pre e post op lateral dislocation



Pic 4. Pre e post op medial dislocation.