

RISKS CONNECTED WITH MAMMARY IMPLANTS AND SURGICAL INTERVENTION COMPLICATIONS

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Abstract

In this work several complications related to mammary implants have been analyzed. These complications can be divided into different groups: local, systemic, immediate and long term. Particular attention has to be directed to the most important complications which are capsular contracture and implant rupture, with consequent new surgical intervention.

Keywords: Mammary implants, capsular contracture, implant rupture

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Introduction

Valid scientific studies able of demonstrating the real efficacy and safety of mammary implants started only after their complications and side effects became evident in the last ten years. One of the problems faced is the heterogeneity related both to the variety of the implants materials and to the differences peculiar to each manufacturer. A further obstacle in the research of the risk from implants concerns the size of the samples analyzed, samples which are typically not wide enough as to exclude without any doubt the possible risk of uncommon pathologies such as - for example - some forms of connective tissue disease.

Up-today, according to the studies reported in the literature, the only actual and certain complication is the capsular contracture followed by the rupture of the implant and by a consequent new surgical intervention.

Local immediate risks

There are short-time side effects which are considered post-surgical complications. For example haematoma is an infrequent complication which in most cases occurs within the first 24 hours with increasing pain. Hematoma is a collection of blood within the space around the implant, and a seroma is a build-up of fluid around the implant. In the case of either being remarkably extended, it must be removed in order to reduce the possible occurrence of capsular contracture. Infection and/or capsular contracture are possible consequences of hematoma and seroma. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, these can also occur at any time after injury to the breast. While the body usually absorbs small hematomas and seromas, larger ones will require surgery, typically involving draining. Draining potentially requires the

temporary insertion of a surgical drain in the wound to facilitate and expedite healing. A small scar can result from surgical draining. Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure. Seroma is a more frequent complication and, if notably extended, it may cause capsular contracture and dislocation of the implant. Its extent can be largely reduced by placing drainage. In the case of infection the implant must be substituted. Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain, and fever. In rare instances, as with other invasive surgeries, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery. This is a life-threatening condition. Symptoms of TSS occur suddenly. These include a high fever $>38.8^{\circ}\text{C}$, vomiting, diarrhoea, a sunburn-like rash, red eyes, dizziness, light-headedness, muscle aches and drops in blood pressure which may cause fainting. Infection can result from any surgery or implant. Most infections tend to appear within a few days to weeks after the operation, but may occur at any time after surgery. The likelihood of infection is further increased by breast and nipple piercing. In the presence of an implant infections are usually harder to treat, to the extent that the implant may need to be removed if the antibiotics fail to deal with the infection and another implant may be placed after the infection is resolved. As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhoea, fainting, dizziness, and/or sunburn-like rash. Failure of the wound to close and weakening of the tissue surrounding the implant may cause extrusion. Extrusion requires additional surgery and possible removal of the implant, which may result in additional scarring and/or loss of breast tissue. Finally, it is necessary also to point out the particularly infrequent occurring of pneumothorax.

Local and systemic risks from silicone gel implants

Studies conducted by two scientific teams, an Anglo-Saxon team and an American

team have excluded any statistically significant data on eventual short-time occurring of carcinogenesis (1,2). However from a diagnostic point of view, the data have evidenced an actual capability of interfering with mammography only for the prostheses implanted at a sub-glandular level, making it more difficult to notice characteristics of the neoplastic type such as micro-calcifications and glandular distortions. Nowadays thanks to the creation of more and more accurate structures, allowing a multi-disciplinary approach, it is possible to effect good differentiated diagnosis. The risk of association between silicone implants and connective pathologies of immunological nature has been excluded by several studies (3-5).

A still open question concerns the occurrence of atypical symptoms, in women, some years after silicone infiltrations or after the implant of a prosthesis. The whole of these symptoms has induced to coin the aspecific definition of "human disease from alloplastic materials", but, as previously reported, it is to be tested and possibly demonstrated by future studies.

Some studies have excluded risks connected with breast nursing, however the U.S. F.D.A. has reported the possibility of altering the nursing capability after addictive mammoplasty. Necrosis may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of breast tissue. Implant removal may also be necessary. Known determinants of necrosis include infection, use of steroids, smoking, chemotherapy, radiation, and excessive heat or cold therapy.

Local and long-term risks

Capsular contracture

Capsular contracture consist of the reaction of our organism to the introduction of a foreign body, such as the mammary prosthesis. The scar tissue that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in patients undergoing revision surgery than in patients undergoing primary im-

plantation surgery. The severity of capsular contracture is classified according to a subjective scale by Baker into four different categories corresponding to different levels of severity (6). Based on the level of contracture pain may be experienced and dislocation of the prosthesis may occur (tab. 1). In these cases, it is necessary to surgically intervene in order to break and remove the capsule and then substitute the prosthesis. Recent studies have demonstrated a higher percentage of capsular contracture when silicon prostheses or smooth prostheses had been used, while the percentage was lower when textured prostheses had been used (7). Moreover, evidence was found of a higher percentage of capsular contractures with implants placed in retro glandular location (7).

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability, capsular contracture is graded into 4 levels depending on its severity. Baker Grades III or IV are considered severe and often additional surgery is needed to correct these effects. Implant rupture, often a consequence of capsular contracture, typically requires a new operation in most augmentation and reconstruction patients.

Rupture

In the past, the study of the rupture of prosthesis implants did not permit to obtain quantitative data about the actual frequency of the phenomenon in the long run. The difficulties faced by the researchers were the fact that existing studies only collected data relative to patients who had undergone the explants of a prosthesis because they were symptomatic. From the patients sampled were excluded those with asymptomatic breast or with still safe

Baker's Classification	
1	Breast increased in size, as soft as if there were no implant
2	Palpable but not visible implant
3	Breast with scarce mobility, visible and palpable implant
4	Hand consistency, painful, cold. Evident distortion

Tab. 1: Baker's subjective scale classifies four different categories corresponding to levels of severity of capsular contracture.

implants, which made it impossible to conduct a complete study of the population. Moreover, it is to be remembered that, studies on explanted prostheses, do not allow for the collection of data on the natural history of the phenomenon, because the real date of the rupture is unknown and can be estimated only indirectly after the explants. Yet, the data collected in the past have allowed for the estimation of the life of the implant (8,9). An increasing frequency of the rupture, related to the age of the implants implanted, has been observed; moreover, the generation of implants has been evaluated, in this case, with a decreasing rupture frequency in the following generation (10).

Silicone gel-filled implant ruptures are usually silent. In most cases neither the doctor, nor the patient, realize that the implant may be torn or present a hole in the shell. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

Possible causes of implant rupture include: surgical damage e.g. surgical instruments interfering with the prosthesis during implantation; folding or twisting of the implant shell: excessive pressure to the chest e.g. during closed capsulotomy, which is contraindicated: trauma; compression during mammographic imaging: and severe capsular contracture. Breast implants may also simply wear out over time. The existing literature often relates rupture to complications which are also typical of capsular contracture. These include: breast pain, hardness or possible changes in shape or size of the breast. These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture.

Conclusions

Nowadays, thanks to the creation of more and more accurate structures, allowing a multidisciplinary approach, it is possible to effect good differentiated diagnosis. Up to today, according to the studies reported in the literature, the only actual and certain complication is the capsular contracture followed by the rupture of the implant and by a consequent new surgical intervention.

Rupture and duration of an implant	
Prevailing rupture	63% in 77% of the women
Average duration of an implant	10,8 years

Tab. 2: Statistic data report percentage of implant rupture and average duration of implant life.

A new approach, which will certainly permit to overcome the statistic limitations of previous studies on prosthesis explant, is now possible thanks to nuclear magnetic resonance. A study of this type has been conducted by Brown et al. and it has allowed for the assessment of the prevalence and average life of a prosthesis (Tab. 2) (11,12). Moreover, the study of implants still in loco has supplied data about the possible migration of silicon through the capsule.

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RISCHI LEGATI A PROTESI MAMMARIE E COMPLICANZE DELL'INTERVENTO CHIRURGICO.

In questo lavoro, vengono analizzate diverse complicanze legate all'utilizzo di protesi mammarie. Queste complicanze possono essere divisi in quattro gruppi: locali, sistemiche, immediate ed a lungo termine. Particolare attenzione deve essere rivolta alle sole e certe complicanze che sono la contrattura capsulare e la rottura della protesi con conseguente re-intervento chirurgico.

Parole chiave: Protesi mammarie, contrattura capsulare, rottura di protesi.

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