Bioethics and Medicolegal Aspects in Breast Cancer Reconstruction

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49.1 Introduction

The integration of bioethics in reconstructive breast cancer surgery is essential, because few diseases represent such complexity from the scientific, psychological, therapeutic, ethical, and social points of view as breast cancer. Surgeons who are dedicated to this delicate field of work face daily situations that demand great sensitivity and deep bioethical and medicolegal analysis.

Bioethics is one of the most dynamic emerging fields of philosophy applied to professional praxis and research in biotechnology and in medical practice. Although bioethics was born in the USA in 1970, in Brazil and in Latin America it appeared only in the mid-1980s, and is considered now as late bioethics within the global scenario. Yet, it has been assuming increasing importance among the main specialized medical societies and medical associations. That is because of its relationship with both individual and professional dilemmas that affect health professionals, legislators, and citizens. This chapter considers the most relevant bioethical issues and medicolegal aspects concerning breast cancer treatment, with a special focus on breast reconstruction.

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49.2 Current Concept

The concept that has come the closest to the ideal that bioethics proposes was elaborated by Reich in 1995 in his *Encyclopedia of Bioethics*: "A systematic study of the moral dimensions—including moral visions, decisions, conduct, and policies—of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting" [1].

Bioethics must be considered a tool for medical decision-making, although being interdisciplinary is its most important characteristic. This is what makes it different from classical medical ethics, which is traditionally marked by an almost exclusive emphasis on the physician–patient relationship. This deontological approach has proven to not be enough to encompass the emerging situations that have arisen in the past few decades [2]. Thus, the domains of medical ethics and today's deontology interact with bioethics for the resolution of conflicts in research, public health, and internal medicine.

49.3 Bioethics and Research in Breast Cancer

Breast cancer is one of the most currently researched diseases involving human subjects. The ethical regulations that govern such research were developed from events that raised great concern among the academic community because of history, such as the research performed by Nazi physicians and by the American postwar physicians, especially those in the study of Tuskegee, in the state of Alabama [1, 3].

One of the main bioethical elements found in the regulations for research involving humans is the expectation that the knowledge and advances produced will ideally lead to the well-being of all humanity. Therefore, a moral principle in research with humans is respect for human dignity. Two components must be highlighted here. The first one is the choice of subjects for research, aiming to provide the subjects

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themselves and other groups with benefits, and also for the advance of science. The second one is the use of morally acceptable means to reach the same ends. The key point in moral objections to research is using another human as a means to legitimate ends. It is unacceptable to treat people as a means or an object. Such an attitude harms the dignity that is innate to humans, as it also downgrades the medical professionals, researchers, and humanity as a whole [3–5].

Risks in research must be interpreted from the bioethical principle of no harm, that is, the duty of forecasting or avoiding harm to the subjects involved in research. They must not be involved in unnecessary risks. Research with humans must be beneficial to society as a whole, but also to the subjects themselves. That means that all patients with breast cancer involved in research need to benefit as well [3–5]. Umberto Veronesi stated that "*si cura meglio dove si fà ricerca*," which means "we can treat patients better where we can perform research." It is necessary that this principle be respected and advocated by members of the institutional review board and also by the sponsors involved and by the researchers themselves.

The ethical approach to this research needs to center on the patient with cancer. Sometimes the expectations, interests, and hopes of the patient in research are not proportional to the real benefits. In order for their free and clear consent to be established in its full potential, the transmission of information must be technically adequate, individualized, and in clear language. Therefore, a positive and collaborative relationship between the researcher and the research subject is established. Considering patients with breast cancer, it is important to highlight the vulnerability existing among patients diagnosed with a serious, chronic, and potentially mutilating disease. These patients demand special attention as to free and clear consent in order to respect their autonomy.

Research in breast surgery that involves patients either directly or indirectly (e.g., those researches who use health records or test results) must follow the principles specified in international recommendations such as the Helsinki Declaration, the Norms for Good Clinical Practice, and the Human Rights Declaration. Research protocols must go through the approval of an institutional review board, in agreement with each country's standards. Research involving areas such as genetics, human reproduction, and research with new drugs with the cooperation of industry need special attention in order to protect patients, and prevent them from being the subject of exploitation in research that involves significant conflict of interest, especially in developing countries and vulnerable populations [5]. Particularly, in breast reconstruction research, patients should be respected in regard to their privacy, with special care taken with photographs.

49.4 Breast Cancer and Public Health Care

The remarkable American bioethicist Daniel Callahan has severely criticized the ways of Western medicine. He argues that one of Western medicine's main problems is setting unlimited horizons for its range of work. This lack of limits and the uncontrolled expansion (even disregarding the health–disease relationship) end up resulting in an increase of medical care costs that does not always corresponds to an improvement in most people's health. Therefore, the use of sophisticated resources with high costs and benefits that are not always proportional to such costs has turned modern medicine into an impossible project to accomplish [6].

One examples concerns the USA, a country that spends over two trillion dollars on health, which corresponds almost to the amount spent by all other countries together, or the Chinese economy [7, 8]; yet, over 46 million Americans are not covered by the health system. Suffice to say that one of the key points of Barak Obama's past presidential campaign was health reform in the USA. This is something that will become even more difficult to complete in a period of global economic crisis.

Breast cancer, as a health problem all over the world, may have important consequences if erroneous decisions in health policies are made. In Brazil, breast cancer is the main cause of death from cancer among females. The use of only 2–3 % of gross domestic product on health (in the USA, more than 15 % is used) results in an ethical dilemma of considerable proportions within the public health system, which is known by all Brazilian health professionals. The public health system in Brazil is a Universalist one, and it is similar to most European models (guaranteed by article 196 of the Brazilian Federal Constitution of 1988—"health is the right of all people and the duty of the state…."). However, as happens in many European countries, the state cannot limit its costs, so it risks becoming bankrupt. That is why in the specific case of breast cancer, mammographic screening and timely access to updated treatments are inadequate given the distribution of existing resources. So the Universalist model does not manage to reach everybody equally. The unequal conditions in diagnosing and treating breast cancer in the Brazilian environment have not been properly studied yet. The damage in terms of life expectancy and years of work lost are noticeable and may increase in the coming years.

The aim of health policies on cancer in developed countries is focused on prevention and early diagnosis. The mammographic screening test and the routine clinical examination may reduce mortality caused by breast cancer by 25–30 % among women over 50 years of age. Such measures aim to find small tumors, which implies treatments will have more effective results and at lower costs. An example of how

this can work is ductal carcinoma in situ, which is the sort of breast tumor with the highest incidence in developed countries. Over 90 % of cases are not palpable, and diagnosis is only possible through mammography. There is no need for chemotherapy or sentinel node biopsy or for axillary dissection. The rate of cure is approximately 100 %, and for most of patients with breast preservation techniques.

Considering that the number of years wasted with breast cancer is second only to cardiovascular diseases, the economic and social importance of breast cancer are evident. The reduction in breast cancer mortality, first noticed in the USA then in Sweden and England, and now reaching most countries of the European Union, is a result of investments in detection and access of most of the population to better diagnostic and therapeutic modalities. It is clear that early diagnosis not only benefits women in terms of survival and less mutilating surgical procedures, but also reduces treatment costs and keeps an important portion of society with breast cancer economically active.

On the other hand, in developing countries in reproductive age groups, breast cancer is considered a substantial problem with importance similar to that of major global priorities such as maternal mortality [8, 9]. Advanced tumors demand therapeutic resources at higher costs. Results in terms of disease-free survival, however, are less satisfactory than at the early breast cancer stages. Local recurrences and distant metastasis require the use of chemotherapy schemes, hormone therapy, radiotherapy, and monoclonal antibodies of growing complexity in relation to those applied to more precocious tumors. Besides, they diminish the labor capacity of these patients and require longer rehabilitation periods. A patient with metastatic breast cancer currently undergoing the recommended treatment will cost the state and health insurance companies more than the transplant of organs and a few mammography and ultrasonography devices.

In developing countries, an increase in both the incidence of cases and the mortality caused by this disease is expected [8, 9]. Therefore, it is imperative that the population has access to early diagnosis and proper treatment at the right time. These are some of the challenges in breast cancer that public health systems all over the world have to face. In this situation, bioethics may work as an element of facilitation in the formation of governmental decisions, following the example of other countries such as the USA and Italy, which have national committees of bioethics involved in public health matters.

49.5 Genetics and Breast Cancer

Although a positive family history is reported in between 15 and 20 % of women with breast cancer, congenital breast cancer occurs only in 5–6 % of all cases [10], and mutations of genes *BRCA1* or *BRCA2* are found in most of these cases [11]. Today genetic tests to identify such mutations are commercially available. The frequency of these mutations is rare; however, they occur in approximately 0.1 % of the population in general [12]. The prevalence of BRCA mutations is higher among Ashkenazi Jewish women, reaching 2 % [13]. These genes are considered tumor-suppression genes, and they work on repairing DNA. When there is a mutation, this function is not performed properly, which allows a tumor to form. Transmission is autosomal dominant, but penetration is incomplete; therefore, genetic mutation points to a higher susceptibility of developing breast cancer, but that does not occur in all cases. It is estimated that a person with a mutation of gene *BRCA1* or *BRCA2* has a risk of developing breast cancer of around 50–87 % throughout life, and a risk of developing ovary cancer of between 15 and 44 % [14, 15].

Genetic advice and a genetic test should be proposed when (a) the patient has a personal or family history that points to a genetic condition susceptible to cancer, (b) the genetic test may be adequately interpreted, and (c) the test results contribute to the diagnosis or influence the clinical or surgical treatment of patients or their families with risk of congenital cancer. It is recommended that the genetic test be performed only together with genetic advice before and after the test, which must include a discussion of the possible risks and benefits of early detection of cancer and the modalities for prevention [16].

It is critical to interpret the results adequately. There are three types of results:

1. *Positive result* The mutation with deleterious effects in *BRCA1* or *BRCA2* was found, and it puts the person at risk by increasing the risk of development of breast cancer and ovarian cancer.
2. *Negative result* A mutation is known in the family, but the person tested does not carry such a mutation.
3. *Inconclusive or undetermined result* No mutation is identified in the person tested and there is no case of mutation known in the family, or otherwise, a mutation was found in the test but its meaning is unknown.

The decision to undergo the diagnostic test must be made exclusively by the patients. They must be aware of their decision to either accept or refuse the genetic test. In the pretest advice session, all of the important and necessary information must be given to the patient. This must cover the advantages and limitations of the test, the possible types of results, and the measures to minimize risk that can be taken. Informed consent is, therefore, a mandatory prerequisite for any type of genetic test. The principle of autonomy is the basis of informed consent, and it is essential for preserving the individual's freedom and her right to make choices [17].

When an inherited breast cancer syndrome is suspected in a family, the first person that has to be tested is the relative with the disease. If the test identifies the mutation, a genetic test for this specific mutation can be performed in the other family members. Each relative has a 50 % chance of being a mutation carrier [18].

If the genetic test is positive for a mutation, one of the most effective methods that can be considered to reduce the breast cancer risk is prophylactic surgery. Prophylactic surgery includes prophylactic bilateral mastectomy and/or prophylactic bilateral salpingo-oophorectomy. If the patient does not want to undergo prophylactic surgery, chemoprevention (tamoxifen) and surveillance (clinical breast examination, self breast examination, mammography, and magnetic resonance imaging) can be considered [18].

Although there are no randomized prospective trials that evaluated the efficacy of prophylactic bilateral mastectomy, and not many studies have considered this issue, the literature shows that bilateral prophylactic mastectomy reduces the risk of breast cancer by approximately 90 % in *BRCA1*/*BRCA2* mutation carriers and high-risk breast cancer patients [19–23]. Even though the accomplishment of a prospective randomized trial would be the best way to evaluate the efficacy of prophylactic surgery, it probably would be not possible because not many patients would accept being randomized for prophylactic surgery or no treatment.

In terms of surgery, there are four kinds of prophylactic mastectomy: total mastectomy, skin-sparing total mastectomy, nipple-sparing mastectomy, and areola-sparing mastectomy. The lack of prospective randomized studies comparing these different techniques makes it more difficult to establish which one is the ideal approach. Total mastectomy initially appears to be the safest procedure because it removes the breast tissue, skin, and nipple–areola complex; on the other hand the aesthetic outcome is poor. Skin-sparing mastectomy emerged as an alternative to total mastectomy, with better aesthetic outcome because it preserves the skin, and when it is associated with a reconstruction procedure, it can achieve a better outcome. Recently, subcutaneous mastectomy (nipple-sparing mastectomy) has appeared as a surgical variation that consists in preservation of the skin and the nipple–areola complex, ensuring an even better aesthetic result, with a more natural appearance of the breast. There is a serious concern with this technique, however, because a greater amount of tissue is preserved along with the nipple–areola complex and this could be associated with a higher incidence of cancer. Although this fear came from pathology studies that showed the presence of cancer cells in the nipple ducts, there are insufficient data to support this argument, and some studies have already demonstrated good results with this technique [18, 24]. Finally, areola-sparing mastectomy consists in the preservation of the skin and the areola, and the removal of the breast and the nipple. There are insufficient data with this kind of surgery in terms of aesthetic–functional outcomes and/or long-term oncologic results.

Respect of the privacy of the patient's genetic information demands that the result of the test not be revealed to anyone without the consent of the individual tested. When family mutations are identified, individuals should be strongly encouraged to share the results with other family members who are also at risk, especially when risk reduction measures can be taken [25]. However, some people may not feel like revealing genetic information to other members of the family. The physician may face an ethical dilemma if the patient refuses to reveal genetic information to relatives who are at risk. In such situations, the subject of confidentiality conflicts with the ethical principle of preventing damage to others [26]. Most authors do not support the revealing of family genetic information without the patient's consent, unless the possibility of serious damage exists and is very high [25, 27].

Another important aspect to be considered is genetic discrimination. This refers to less favorable or adverse treatment that an individual without traces or symptoms of the disease gets on the basis of the genetic or genotypic characteristics [25]. The affected individual may experience discrimination from insurance companies and job agencies. The fear of discrimination is one of the most commonly identified reasons among women who are not willing to take a BRCA genetic test [28–30]. Considering that, preserving the confidentiality of the individual's genetic information is very important.

Finally, the psychosocial influences that the result of the genetic test will have on the life of the patient must be considered. Knowing that a genetic mutation is present and the consequences of the personal risk of breast cancer may affect a person in various ways. Women with positive test results might experience a wide variety of emotions, such as anxiety, depression, fear, and anger. Women who have already had breast cancer may feel disturbed when learning that they have the risk of developing other types of cancer. Also, individuals might have a feeling of guilt, despite the existence of a possible mutation. Carriers of a BRCA mutation may experience "transmission sense of guilt" because they can transfer an increased genetic risk of cancer to their children, whereas noncarriers may experience the "survivor's sense of guilt" for being among the members of the family who did not inherit the mutation. Therefore, proper psychological preparation of the patient before performing the genetic test is important.

49.6 Clinical Bioethics

Clinical case study: 37 year-old, white, homemaker, Catholic, diagnosed with breast cancer, T2N0, estrogen receptor/progesterone receptor positive and human epidermal growth factor receptor 2 (HER2) negative. She is in the seventh week of

pregnancy and wants to have an immediate breast reconstruction. The breast surgeon was asked to give an opinion on the case.

Regardful medical virtues such as integrity, compassion, and altruism are determinant for the exercise of medicine [31]. Albert Jonsen [2] created a practical method to aid in the resolution of complex clinical cases, like the one presented above. It is based on four fundamental points: medical indications, patients' preferences, quality of life, and contextual aspects. A favorable point of this method is that it allows a shared bioethical sense that is easy to understand.

49.6.1 Medical Indications

It is the relationship between pathophysiology and therapeutic/diagnostic interventions that is indicated to solve the case properly. This refers to the application of medical and scientific knowledge. Whenever possible (and when such conditions are available), decisions must be based on clear scientific evidence. In breast oncology, around 60–80 % of all decisions can use data from evidence-based medicine, in contrast with general medicine, in which a little more than 15 % of the clinical decisions are based on consistent scientific evidence, and around 40 % are based solely on professional expertise. Important points to be considered and those with bioethical implications are:

- What is the patient's health problem?
- Is it a severe or a chronic problem? A critical one? An emergency? Is it reversible?
- What are the targets of the treatment?
- What are the probabilities of success?
- What are the perspectives of failure of the treatment?
- To sum up, how can the patient benefit from the treatment in question?

49.6.2 Patients' Preferences

In all medical treatments, patients' preferences, based on their own values and perceptions as to the benefits and risks, are ethically relevant. The following points must be clarified before making a decision:

- Did the patient express preferences concerning the treatment?
- Was the patient correctly informed about the risks, benefits, and consent?
- Is the patient mentally capable and legally competent?
- If the patient is incapable, who is the legally responsible individual?
- To sum up, is the patient's autonomy being respected?

49.6.3 Quality of Life

Besides preserving the life of the patient, another major target of medical intervention is to reestablish, keep, and improve the quality of life. What is the expectation with and without the treatment for the patient to return to a normal life? The questions that must be clarified are:

- What problems may impede the evaluation of the patient's quality of life?
- What physical, mental, and social limitations will the patient have after the treatment?
- Is the present or future condition of the patient considered undesirable?
- What are the plans to offer the patient some comfort or palliation?

49.6.4 Contextual Aspects

The care of patients is influenced either positively or negatively by the family and by a variety of contexts, such as personal, emotional, psychological, religious, financial, educational, legal, institutional, scientific, and social contexts. The questions that must be clarified are:

- Are there family problems that may influence therapeutic decisions?
- Are there any financial problems?
- Are there any medical or nursing problems?
- Are there any religious or cultural problems involved?
- What about the allocation of resources?
- Is there any reason for breaking confidentiality?
- And how about legal matters?
- Is there any research/teaching involved?
- Is there any conflict of interest?

Some important points emerge from this type of methodology. One of the most important of them is that no bioethical analysis of clinical problems should be performed without a deep scientific knowledge and clinical experience of the matter. A lack of knowledge invalidates any conclusion a posteriori. The second one is that a bioethical background is fundamental to the specialist's decision.

By applying Albert Jonsen's method to help the breast surgeon find an answer to the clinical dilemma, one can find:

1. *Medical indications* This refers to a 37-year-old patient with a breast neoplasia in the seventh week of pregnancy who is asking to maintain the pregnancy (in some countries it is not allowed to perform an abortion unless the patient is at risk of dying), and wants a breast reconstruction. The patient is not a good candidate for neoadjuvant chemotherapy owing to the risk of malformation. Since the patient is not in an urgent situation, there is no need to make an immediate decision—the

decision can be discussed with the bioethical committee, the patient, and the family. Breast reconstruction in this case can be done with less aggressive techniques such as expander/implants without compromising the pregnancy or oncologic treatment.

2. *Patient's preferences* The patient requested a breast reconstruction and to maintain the pregnancy. She is legally competent.
3. *Quality of life* The quality of life without reconstruction is expected to be worse. The patient has a chance to return to a normal life and the absence of the breast will damage to her quality of life in the near future.
4. *Contextual aspects* There are medicolegal implications for abortion in Brazil and the patient would not terminate the pregnancy because she was influenced by her Catholic background [32]. Breast reconstruction in this case, once abortion is well documented in the medical records and properly authorized by the patient, is ethically acceptable in such a case.

Albert Jonsen's method improves knowledge about conflicts, protects patients' autonomy, and integrates medical decisions. On the other hand, although it examines these situations and organizes them systematically, it does not solve conflicts in all cases. Conflicts may occur within each of the points mentioned. Decision making is sometimes so complex that it is necessary to resort to technical support from a consultancy professional with bioethical competence in the resolution of problems or, preferentially, a bioethical committee.

49.7 Medicolegal Aspects in Breast Cancer Reconstruction

According to the American Society of Plastic Surgeons in 2010, 93,083 breast reconstruction procedures were performed; 74 % of these used either saline (20 %) or silicone (54 %) implants. Another 19.5 % were accomplished using various flaps, including a transverse rectus abdominis myocutaneous flap, a latissimus dorsi flap, and a deep inferior epigastric perforator flap. Further, 22 % of the implants were ultimately removed. According to Mark Gorney from The Doctors' Company [33, 34], 31 % of claims against plastic surgeons involve elective breast operations. Of these, 55 % are related to scarring or tissue loss/necrosis and 45 % are related to augmentation or reconstruction of the breast with expanders and subsequent implants [34]. As oncoplastic surgery done by breast surgeons is a relatively new concept in the USA, further evaluation in this area is not available but there will soon be careful examination. This rest of section will outline several areas that both plastic and oncoplastic breast surgeons need to address to limit their liability. These include patient selection and expectations, communication, informed consent, documentation, and event management.

49.7.1 Patient Selection and Expectations

It is important to realize that patients who present for purely aesthetic breast procedures are very different in their expectations from those who need reconstruction as part of their breast cancer treatment. The former will want a result that is better than their baseline in terms of aesthetics and symmetry. These patients will not ordinarily present with a breast cancer diagnosis and may be unrealistic in their expectations. The ability of the surgeon to perform to these expectations is fundamental. The cancer patient will undergo a destructive procedure to cure the cancer and the final result is not usually expected to be as good as the original breast. Reconstructive surgeons should be well suited to this task with appropriate training. Although the expectations are somewhat lower, a near-normal breast with symmetry should be accomplished. This, of course, is made harder by the removal of breast tissue, chemotherapy, and radiotherapy. These patients may also return some time after their initial care for further aesthetic–functional adjustments and surgery. The surgeon should be able to handle this as well. Surgeons should learn to identify these patients when they present to serve them in the most appropriate manner.

When dealing with a patient's expectations, a careful history is very important to ascertain the patient's motives and desires. This requires good patient contact, empathy, attention, and questioning. It may also be useful to talk with significant others such as the spouse or family members to further determine the results desired.

Not only are patient factors important in planning surgery, but the surgeon's comfort level with the patient, experience, and training are also variables to consider before operating. The patient must have reasonable expectations regarding what is possible, and the surgeon must be confident that he or she can deliver the desired result. If the surgeon is not confident, then not operating or referring the patient to someone more qualified is certainly a good option.

49.7.2 Communication

Honest and timely communication is of utmost importance in any physician–patient encounter. Being on time in the office or giving the patient a cell phone number or e-mail address is powerful communication. Eye contact, body language, and choice of vocabulary also come together to send a message to the patient and her family, either good or bad. The ability to communicate and establish a relationship will significantly add to the credibility of the surgeon. The acronym HEAL [35] has been very useful in establishing and continuing relationships

with patients and their families especially in times of poor outcomes. "H" is for "hear." Hear what your patients and families are trying to say. "E" is "emotions." Address the patient's and the family's emotions. "A" is for "ask and answer." Ask patients and their families to tell you what they already know and answer what they want to know. Finally, "L" is for "loyalty." Foster already existing loyalty and rebuild that portion that may have been lost. Most medical malpractice cases are caused by no or misunderstood information and the patient's or the family's need to learn the facts of the care given [35, 36]. The surgeon must learn to be a good communicator and, thus, educator of his patients. This education informs the patient of the disease process, prognosis, treatments, and alternatives and explains possible negative outcomes. This begins with the first handshake and never ends.

49.7.3 Informed Consent

The process of informed consent is the foundation of the physician–patient relationship. Through this interaction the patient comes to understand her diagnosis, the options for management, the potential outcomes and risks of each option, and what can be expected as an ultimate result. From this information, the patient can choose a course of action by including her own preferences and desires. Informed consent is not a simple form the patient signs but a process that begins with the first consultation and continues with each encounter. It involves the previously mentioned areas of patient selection, communication, and management of expectations. It is the surgeon's best friend in malpractice litigation. It is one of the first areas of examination by the plaintiff's attorneys and, if it absent or weak, it is almost always included in complaints.

In documenting informed consent, one usually requires a preprinted form (Fig. 49.1), but, in addition, hospital or office notes should reflect the thought process the surgeon and patient have taken in support of the final written consent. These notes should include the patient's thoughts, expectations, and specific refusal of offered options. A specific summary statement should be included in the notes (e.g., "I have talked with the patient at length regarding her diagnosis, proposed procedure, potential risks, possible benefits, and alternative modes of therapy. Risks discussed included but were not limited to _____. She understands the procedure, accepts the risks, and wishes us to proceed. We will do so soon."). Risks should be listed, but the list is not meant to be all inclusive. The most commonest potential risks of oncoplastic surgery are as follows:

- Death
- Myocardial infarction
- Stroke
- Deep venous thrombosis
- Pneumonia
- Infection
- Bleeding
- Prolonged drainage
- Partial or total necrosis of skin or flaps
- Seroma
- Hematoma
- Multiple surgical procedures/reoperation
- Loss of implant or expander
- Nonsymmetry of breasts
- Expectations not met
- Recurrence of cancer
- Prolonged care/wound care
- Necrosis of nipple–areola complex
- Loss of sensation of nipple–areola complex
- Chronic pain
- Keloids/scars
- Discoloration
- Need for drainage/aspiration
- Lymphedema
- Pain, swelling, numbness, disability, dysfunction of arms
- Nerve or blood vessel damage
- Hernia
- Pneumothorax
- Fat necrosis
- Implant contracture, immediate or delayed
- Rejection of implant at any time
- Rupture of expander or implant.

A good informed consent process will not only protect the surgeon but will also enhance the relationship with the patient.

49.7.4 Documentation

Documentation is the cornerstone of any malpractice defense. Good documentation may convince a plaintiff's attorney not to pursue a case. In addition, it is certainly valuable when reviewing a patient's care and outcomes as well as making treatment plans. Documentation includes many aspects of the medical record. The hospital medical record should be completed in a timely manner, including the history, physical examination results, consents, operation notes, and discharge summary. The office records should include all interactions and contact with the patient, such as telephone calls, literature given to the patient, notes of office visits, consents, correspondence, and photographs (preoperative and postoperative). The office notes should include the history, physical examination results, diagnostic results, diagnosis, treatment plans, referrals, alternatives, risks, and the patient's desires and expectations. Of course, no record should be altered after being signed off as this greatly weakens the credibility of the medical record. Late entries are allowed if they are indentified as such. The records should also be legible.

CONSENT FOR SURGERY

1. I,..... according to my own will, hereby authorize doctor CICERO URBAN and all the other members of his team of professionals related to my medical assistance to perform the surgery herein described..... ...., as well as the medical treatments and follow-up care derived from it.
2. I certify that this surgery I now consent has been fully explained to me by doctor CICERO URBAN and his team both in person and through printed information material, therefore I understand that:

   A permanent **SCAR** will form as a result of the surgery, but all the necessary measures will be taken in order to minimize its effects and visibility.

   There might be a **SWELL** in the operated site, which may remain for weeks and even, though rarely, for a few months.

   SPOTS or **DEPIGMENTATION OR DISCOLOURATION AREAS** may also appear in the operated site for some time. In very rare cases they can remain permanently.

   Occasionally, **LIQUIDS** (blood or secretion or fluids) may accumulate in the operated site, so there is the need for draining, aspiration or surgical repair. This is more frequent after axillary dissection.

   There may be **LOSS OF SENSITIVITY AND/OR MOBILITY** in the operated site for an indefinite period of time, which varies from patient to patient. It occurs more frequently after axillary dissection.

   There may be **LOSS OF BIOLOGICAL VITALITY** in the operated site, caused by blood vascularisation reduction, which may result in alterations of the skin and, in more rare cases, necrosis, which demands repair through another operation or even operations.

   There may be **POSTOPERATIVE PAIN**, in either higher or lower levels of intensity, for an indefinite period of time, which varies from patient to patient.

   Every surgery may demand better **FINISHING** or small complementary surgeries performed to achieve better results.

   Considering that I have been informed of all the above:

3. **I assume** that throughout the surgical procedure there may be unexpected situations that had not previously been identified and, as a result, **ADDITIONAL PROCEDURES OR**

Fig. 49.1 Informed consent model for oncoplastic and reconstructive surgery from the Breast Unit of Hospital Nossa Senhora das Graças, Curitiba, Brazil

49.7.5 Event Management

Despite the surgeon's best efforts, poor outcomes do occur. Patients and their families are often very disappointed with these results. They have trusted the surgeon to meet their expectations and when that does not occur, trust is shaken and the surgeon is likely to be second-guessed. It is at this point that the relationship with the patient may be lost. The surgeon must continue to communicate. It is necessary to give a full and honest explanation to the patient and the patient's family. Sincere and empathic apologies may also help to ease the disappointment. In this regard, many lawsuits are filed simply because of lack of explanation [37]. These patients and their families may not have been

DIFFERENT ONES from those that had been arranged may be needed. Bearing that in mind, I allow the team to perform procedures that match such new situations.

4. **I assume** that Doctor XXXXXXXXX and his team will solely use all the necessary technical and scientific means at their disposal to achieve the results that are so desired, nevertheless such results are not guaranteed. Medicine is not an exact science, and consequently **GUARANTEES OF GOOD RESULTS CANNOT BE OFFERED.**

5. **I assume** that **TOBACCO SMOKING**, the use of **DRUGS** and **ALCOHOL**, though they are not able to prevent the surgery from being performed, are risk factors that can produce surgical-medical complications.

6. **I allow** the recording (photos, sound and/or filming) of the surgical procedures to be made because I understand that such registering is a legal-medical demand and a source of study and scientific information.

7. **I accept** that considering breast implants, the possibility of hardening may occur, as well as shape alterations, local pain and loss of sensitivity, and implant rupture, which derive from the use of silicon (or other kind of implants), and reactions of my body to it. This effect might imply that new surgeries be performed.

8. **I am aware** that I may experience limitations to perform everyday activities for an indefinite period of time.

I have had the opportunity to **CLARIFY ALL OF MY DOUBTS** concerning the surgery that I am voluntarily about to undergo, reason why **I ALLOW Doctor CICERO URBAN and his team** to perform all the necessary procedures.

Location:

Date: _____

Doctor's signature: _____

ID:_____

Witnesses:

1._____

ID:_____

2._____

ID:_____

Fig. 49.1 continued

personally approached by their surgeon or may feel something may be being "covered up". Many plaintiffs file complaints to find out the truth.

In addition, some progressive malpractice insurers wish to be notified of adverse events when they happen to help guide the surgeon in recovering the patient's trust. This interaction is important as the surgeon and his or her ego are most vulnerable at this time. The initial impulse is to avoid the situation, and that is precisely the wrong approach[38–40]. Advice from an event manager can prove to be quite helpful in avoiding litigation. Many feel that this transparency is full of potential problems but, in fact, this approach can actually decrease the frequency of lawsuits, increase credibility, and maintain the physician–patient relationship.

49.8 Conclusions and Perspectives

Bioethics has been walking together with the development of biotechnology and with its dilemmas, which go far beyond the technical–scientific debate. Within reconstructive breast cancer surgery specifically, there is the need for introducing bioethics and medicolegal aspects into the educational programs for specialists. It is true that technological development has improved the possibilities for the diagnosis and treatment of breast cancer, but the individual experience of those who deal with this malady daily is not the only object of scientific calculation. In addition to scientific competence, physicians must have the humility to recognize their role and their limits: taking care above curing. This is the most important virtue to be cultivated by the breast surgeon with the aid of bioethics, reducing claims and improving the breast cancer patient's survival and quality of life.

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