Patient demand and expectations for plastic surgery have significantly increased over recent decades, leading to an increasing trend in claims. This—arguably, the result of a progressive lack of communication between surgeons and patients—becomes apparent in inadequate informed consent, as previously highlighted by Patel et al.1 Surgeons have the moral and legal obligation to adequately clarify for their patients everything concerning such operations and cannot perform any procedure without written patient consent. In fact, this aspect of the process allows patients to take active part in their own health care.2 Well-informed patients generally have good compliance and few anxieties and malpractice claims to raise. Despite this, the everyday clinical process may offer a different scenario: the legal formula of informed consent often becomes a mere act of hurriedly signing a form. As a result, the surgeon deprives patients of information they deserve.

Nevertheless, patients usually tend to sign the consent form to accelerate the process. Such lack of information opens the door to possible future malpractice claims. The success of informed consent is based not only on the surgeon providing adequate information but also on the patient thoroughly understanding the procedure and process. A standard informed consent does not indicate evidence of effective communication and thorough understanding on the patient’s part at the time of signing; a signed informed consent does not prove the patient has fully understood its content. This is such a risky deficiency that the surgeon may be prosecuted even if information has been properly disseminated, due to a patient’s later denial of either sufficient comprehension (“If I had understood, I would have never undergone the procedure!”) or time (“I did not have time enough to read the consent form carefully.”). This scenario is why we felt the need for a consent document that includes the patient’s self-assessment of his or her understanding. The proposal is to insert the question, “How do you evaluate both the written and oral information provided?” and have patients fill in their answer in the space provided next to the question. Only positive comments such as “good,” “very good,” and “excellent” will indicate understanding and readiness for surgery.

Additionally, the patient will be provided sufficient time to assess his or her level of understanding and awareness of the operative risks. Thus, no future complaints predicated on misunderstanding and lack of preoperative information can result. Moreover, on the consent form, it must be possible to formalize a patient’s refusal of treatment, which can occur even in cases of proper elucidation; the “disagree” option should also be present, so that even an adequately informed patient may refuse the suggested treatment. Such solutions clearly demand a surgeon’s patience and availability for explanations. In order to improve and reestablish an unproblematic relationship between patients and medical institutions, it would be better if the information is given well in advance of the operation3 and if specific consents were defined for each different procedure.

The aforementioned model was first introduced into our everyday practice about 1 year ago (Figure 1), and we have found it to be extremely productive and beneficial. Patients have appreciated the enhanced clarity, and no malpractice claims have been raised. In a few cases, patients needed more detailed explanations before signing. After adequate clarification, these patients were thankful, became confident about their choices, and opted to undergo the procedures.

In conclusion, written informed consent is mandatory before any surgical procedure. The increasing rise in legal issues involving plastic surgeons demands prompt improvement and initiative. The possibility of patients self-assessing both their level of understanding and the quality of information provided could be a first step toward a solution.

From the Department of Plastic and Reconstructive Surgery, Catholic University of the Sacred Heart, Rome, Italy.
I have been informed in detail about the operation of augmentation mammoplasty which I desire to undergo: techniques, limits and complications. In particular, the following issues have been adequately explained to me by Dr/Prof. ……………………………… during clinic consultations before the operation date, when I gave my oral consent.

The undersigned ……………………………………………………………….. remembers well that:

1. The operation cannot be considered definitive because: implants have a limited duration and future removal and substitution will be necessary; mammary soft tissues change over time, negatively affecting the aesthetic results.

2. Augmentation mammoplasty, as well as any other procedures, may have not-preventable complications due to an intrinsic operative risk.

3. An implant is a foreign body and the individual response to that is crucial in defining postoperative results. If my body does not tolerate them, as in the case of aberrant wound healing surrounding the prosthesis plus breast hardening and unpleasant aesthetic results (capsular contracture: 3-5%), the implant will need to be substituted or even permanently removed, leading to evident unaesthetic scars and psychologically negative consequences. Months or years after the operation, mammary tissues may experience fibrous contracture surrounding the implant, causing deformities due to prosthesis change of position or rotation. In this case, asymmetries may appear, necessitating further operation and even implant substitution.

4. During upper limb movements or pectoralis muscle contraction, mammary shape and implant become deformed. Sometimes, after those movements, the prosthesis may rotate and overturn. In case of spontaneous or traumatic implant rupture, it will be necessarily removed by another operation.

5. As surgery is not an exact science, it is not possible to guarantee the result: no assurances of a specific result have been given by Dr/Prof. ………………………… or his collaborators. Postoperative scars are inevitable. Defect amelioration rate, implant tolerance and its duration, symmetry, scar quality, hematoma and seroma formation, mostly depend on individual response rather than the techniques adopted.

6. I understand that complications are part of the operation risks. In case of complications, I accept to undergo the necessary treatments, which may be surgical. Infections are rare, but possible. In that case, implant removal plus substitution after weeks/months may be necessary, leading to both aesthetic and psychological problems.

7. I understand that the breast implant is visible and palpable, especially on lateral and inferior borders, showing creases and wrinkles. During palpation, prosthesis consistency is different from normal mammary gland.

8. Breast implants’ presence does not prevent any diagnostic procedures (e.g. mammography) even though interpretation may be more difficult during breast cancer screening. I will
inform the radiologist at the time of radiological examination about the presence of breast prostheses.

9. I accept to undergo general anesthesia, aware of its life-threatening risks and possible negative health consequences.

10. I authorize the surgeons and anesthetists to change, according to the best of their knowledge and their consciences, the scheduled surgical procedures and to interrupt them in case they consider it necessary. I agree to undergo medical and physical treatments which will be prescribed postoperatively, aware that, otherwise, I could impair the results.

11. I declare I have followed/will follow the pre- and postoperative instructions provided by Dr/Prof. ……………………………, in order to minimize additional complications. In particular, I confirm I stopped smoking at least 10 days before the operation and I will not smoke for at least 30 days after surgery. In addition, I declare I did not take any drugs containing acetylsalicylic acid in the last 10 days.

12. Many factors may compromise breastfeeding. Although surgical procedures preserve galactophorous ducts, it is not possible to guarantee future breastfeeding, which can also alter the aesthetic results.

13. The breast is composed of changing soft tissues: weight gain/loss, mastopathy, hormonal variations, lumps and processes of aging may alter the aesthetic results over years. Thus further operations may be necessary.

14. I consent, in accordance with the Privacy Act (n° 675 of 31st.12.1996 and further modifications), to be photographed pre-, intra- and postoperatively and I authorize the use of the photographs for educational purposes.

15. I declare that I am not pregnant.

16. Work and ordinary physical activities should be reduced for at least two weeks postoperatively. Driving is not advisable before 15 days postoperatively. Sexual activity should be avoided for four weeks postoperatively. Sports activities should be avoided for the first two months.

How do you evaluate both the written and oral information provided? ……………………………

……………………………………………………………………………………………………………………………………..

Based on the oral and written information provided, exercising my complete freedom of choice, I state that:

I do NOT agree ………………………………… I agree …………………………………

Surgeon’s Signature ……………………………… Rome, …………………………………..
Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

REFERENCES

