Informed Consent in Orthognathic Surgery

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Craniomaxillofac Trauma Reconstruction 2014;7:108–111

Abstract

Keywords

- informed consent
- medico-legal
- orthognathic surgery

Historically, the patient–doctor relationship has been based on trust. Adequately informing a patient confirms this relationship and fulfills the legal obligation of the physician to inform the patient to the best of his knowledge. Informed consent is the process of providing patients with the realistic and necessary information in a manner which they can understand and recall and allows them voluntarily to make an informed choice on the treatment. In this article, the current knowledge about informed consent in orthognathic surgery is reviewed and discussed.

Historically, the patient–doctor relationship has been based on trust. Adequately informing a patient confirms this relationship and fulfills the legal obligation of the physician to inform the patient to the best of his knowledge.^{1–8} The surgeon is authorized to act only in the presence of an explicit manifestation of the patient's agreement, as no person can be forced to undergo medical/surgical therapy against his will, except when a specific law provides otherwise.⁷

Informed consent is the process of providing patients with the realistic and necessary information in a manner which they can understand and recall, to allow them voluntarily to make an informed choice on the treatment. The information therefore must include the benefits and alternatives, and the potential risks, of the proposed procedure.^{3,6}

Nowadays, informed consent takes on special importance as the single most mentioned entity in many malpractice suits, emphasizing the importance of open communication between surgeons and their patients regarding the potential risks, benefits, and alternatives of a procedure.⁹ In particular, understanding the factors involved in determining legal responsibility takes on special importance in today's litigious environment.⁹

Orthognathic surgery, as well as other interventions that belong to facial aesthetic surgery, requires that appropriate information has been provided to the patient and that the patient voluntarily makes an informed choice on the treatment.

Information Provided in Orthognathic Surgery Informed Consent

There is no absolute regulation about how much information should be provided as part of the informed consent process; guidance is often provided on the basis of legislation, case law, and legal precedent, and it is quite different from country to country. Current UK case law asserts that the surgeon must inform patients of serious complications of surgery even if they are rare or small.³ The informed consent process must include discussion of the benefits, risks, and potential complications of the proposed procedure, and any alternative (including doing nothing).³

The potential risks that can be explained before orthognathic surgery are as follows:

1. Pain and swelling of face, neck, and lips
2. Postoperative TMJ derangement (TMJ disorders, condylar resorption)
3. Neural alteration (injuries to inferior alveolar nerve, infraorbital nerve, lingual nerve, and facial nerve)
4. Infection that can extend hospitalization and antibiotic therapy
5. Tooth damage, avulsion, and periodontal disease
6. Ophthalmic complications
7. Reduction of auditory capacity
8. Dysphagia

received

June 18, 2013

accepted after revision

July 7, 2013

published online

February 24, 2014

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Tel: +1(212) 584-4662.

DOI <http://dx.doi.org/10.1055/s-0034-1371447>.
ISSN 1943-3875.

9. Psychological sequelae
10. Vascular complications (severe intraoperative hemorrhage that could require blood transfusion, postoperative bleeding, formation of false aneurisms)
11. Misunion or nonunion of osteotomy segments
12. Postsurgery sequelae to the maxillary sinus and nasal cavity
13. Unfavorable postoperative reactions to medications, such as nausea, vomiting, and allergic reactions
14. Malocclusion relapse
15. Keloid scars in the transcutaneous approach for mandibular osteotomy fixation
16. Loss of vascularity of the mobilized portion (localized gingival recession, loss of teeth or bone segments, loss of the complete maxilla)^{3,5}
17. Unanticipated fractures (especially in bilateral sagittal split osteotomy and genioplasty)

However, the decision to inform about risks has to be balanced against the potential emotional damage done to a patient if a surgeon would list every possible risk, no matter how trivial or rare.⁸ In fact, we do not think that very rare, although catastrophic, events should be mentioned before orthognathic surgery; otherwise, before every orthognathic surgical intervention, the possibility of death, damage to the optic, oculomotor, abducens, trochlear, vagus, and hypoglossal nerves, and of auriculotemporal (Frey) syndrome should also be told.³ We think that surgeons should not be considered guilty if they do not mention the rarest risks associated with orthognathic surgery.

Finally, the removal of internal fixation plates and screws is a contentious area in orthognathic surgery. Some surgeons remove them routinely, but in several countries the practice is to remove plates only when necessary because of loosening, exposure, or infection.³ Therefore, it could be advisable to inform the patients about the possibility of the removal of internal fixation plates and screws if needed.

Options and Methodology of Informed Consent

Obtaining informed consent for orthognathic surgical interventions is a process that begins at the first visit when treatment is proposed and continues until the operation.³⁻⁵ Information can be shared verbally or in writing, and by the nature of orthognathic surgery, it is often repeated at several points during planning. Written consent is generally obtained at the time of the operation. Until this point, consent could therefore be said to be implied because the patient has voluntarily attended and accepted treatment, but has not given consent in writing.¹⁻⁷ In literature, different opinions have been presented about the need of written consent.

Some authors stated that permission should always be in a written form so that the doctor may prove its existence, and it must be included in the patient's file. With written informed consent, the patient would have a full understanding of the agreement's contents.^{4,7} In contrast, other authors stress the

importance of personal surgeon-patient communication as superior to written information.^{10,11}

We think that the use of written information, audiovisual recordings, and other decision aids, as an adjunct to face-to-face discussions, may strengthen the patient's ability to make an informed decision, and we also think that surgeons and patients should always remember that the patient-doctor relationship should be based on trust.

Therefore, we believe it is not necessary that a witness be present to countersign the consent form.¹² A particular mention should be given about the aesthetic result in the graphic representation of visual treatment objective. Both surgeons and patients should remember that it has a reference value, which is not to be considered fully reliable, because the recovery and shift of soft tissues are not completely foreseeable and may differ on an individual basis.^{5,7}

In fact, the cephalometric prediction of orthognathic treatment outcome is an important part of the surgical planning, and it could be included in the informed consent process. However, potential limitations in the prediction of the lips area remain.^{5,7} In the field of surgery, accurate prediction is highly critical, as predictions are only a guide and not the actual result of the surgical outcome and as such, they should be implemented.¹

Patients and Informed Consent

To obtain consent for a medical treatment, the patient must be legally able to give his consent; he must give it voluntarily; he must be free from emotional situations, drugs, or medicines that could influence his understanding; and he must be appropriately informed.⁷ To make this agreement legitimate, the patient must give consent personally, with specific reference to his situation. Only in case of danger and risk to the patient, the surgeon has to operate independently of what the patient's relatives decide.⁷

However, patients' recollections of information provided as part of the consent process may be poor,³ even though the information has been given in written form. Some patients fail to recall risks, despite full and clear information has been provided preoperatively.¹¹ Furthermore, some patients do not want and agree with being informed of possible risks. Another important issue is the too positive preoperative advice that may lead to patients having a feeling of dissatisfaction with the final outcome of their treatment.^{2,9}

Conclusion

In conclusion, surgeons, patients, and judges should always remember that the patient-doctor relationship is based on trust. Unfortunately, nowadays, a correctly obtained consent form can no longer protect the doctor from civil risks and penalties. Surgeons often have to face elevated medico-legal risk due to unrealistic patient expectations and aggressive plaintiffs' lawyers, in spite of careful treatment and without malpractice.

Obviously, the informed consent process is extremely different from legal system to legal system and this variability does not allow a generalizability of considerations. However, the trust of patients toward doctors is always fundamental, as the surgeons trust the patients on their compliance during postoperative behavior (diet, smoking). From a medico-legal perspective, doctors who perform orthognathic surgery should take special care to determine and explain the risks, benefits, and possible outcomes that matter most to patients.

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Commentary

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The informed consent process is a necessary component of patient care. Not only does some level of this process fulfill a legal requirement but it should also assist the physician in obtaining the actual goals and expose the expectations of the prospective patient. This can be quite critical, as unrealistic goals and expectations will never be reached and best to learn that before surgery. Obtaining informed consent is in fact a process. Some patients achieve an understanding rapidly, while others never achieve such satisfactory level of understanding. Old studies on informed consent describe a 35% recall of discussed details suggesting poor retention of discussions. This is now challenged by incorporating learning styles available to the physician during the patient–physician interactions. Auditory—listening to a discussions of risks; Visual—using demonstrative drawings, schematics, videos, and pictures to explain risks; and Kinesthetic—personalizing such interactions to care all assist in helping the patient achieve an understanding of such discussions. Using all of these learning styles might bring the understanding levels much higher than using auditory alone.

The U.S. legal system uses two informed consent standards—a Reasonable Person Standard and a Reasonable Physician Standard, varying by state. It behooves the surgeon to be aware of their state standard. This article suggests that this process is based on trust. While I do agree that choosing a surgeon is based on trust, a complication or inherent risk that occurs erodes such trust. Informed Consent issues are commonly included in a malpractice claim. In reality, it is rarely

the significant issue, as all consent documents include death. When a patient accepts and acknowledges death as a risk, a scar or nerve injury is difficult to claim that reaches a higher level of risk than death. It becomes an issue when the spoken language is different, and there is not a “team” approach in presenting risks, complications, inherent risks, and alternatives. I might argue this is a nondelegable duty of the actual surgeon. There can be assistance by the office team, but ultimately the surgeon is responsible.

There is no right or wrong answer as whether to use a laundry list or an open dialogue template when presenting and discussing such risks. The concern of the laundry list is you are demonstrating how complete and exact you are, and unfortunately might omit a risk that the patient ultimately develops. The argument will be made that you intended to leave that specific risk out while the plaintiff patient might say that had they known about that risk, they would never have accepted the procedure. I actually believe it is wise to refer to such a list until it becomes second nature, and also have a discussion about what else might happen leaving a door open for other issues—sort of the best of both worlds. More important than which method is used is the ability to interact and learn from the patient their goals and expectations. In reviewing hundreds of malpractice lawsuits, I am astounded when a claim ensues and the complication is one prominently listed. The plaintiff alleges the surgeon said, “Oh, that’s rare and won’t happen to you.” The balance in honestly discussing experiences and the necessary risks versus promoting and encouraging the patient is an important one. An honest assessment is then necessary whether you can achieve those goals and expectations. Many believe that a good way to

learn such valuable information is to listen to the patient and have complete interactions while discussing the relevant risks, inherent and complications, alternatives, doing nothing, medications, and postoperative care instructions. This process, no matter how conducted, often reveals much about the patient's goals. Informed consent is an important topic for surgeons. My emphasis is not to dwell on the legal requirements but on patient selection and matching the appropriate procedure that attempts

to meet their goals and expectations. The educational process of informed consent is invaluable in creating satisfied and loyal patients.

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