

# Corrective rhinoplasty: medical and legal aspects

## *La rinoplastica correttiva: aspetti medico-legali*

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### Key words

Nasal surgery • Rhinoplasty • Medical liability • Computer simulation

### Parole chiave

Chirurgia nasale • Rinoplastica • Responsabilità medico-legale • Simulazione computerizzata

### Summary

*Preoperative planning of any surgical procedure, especially rhinoplasty, is crucial in order to achieve an optimal outcome which will satisfy both the surgeon and patient. Use of imaging and the possibility of virtually displaying the changes planned by the surgeon definitely lead to a better understanding between doctor and patient. Although these new technologies have led to undeniable advantages, they have also generated unprecedented medical and legal problems. The Authors discuss a number of reflections on the legal consequences of image digital processing, the problems related to the storage of such images, and the appropriate way to draft an informed consent.*

### Riassunto

*La programmazione preoperatoria di ogni intervento chirurgico, e della rinoplastica in particolare, rappresenta una condizione essenziale per il conseguimento di un risultato ottimale che soddisfi tanto il chirurgo quanto il paziente. L'impiego di immagini e la possibilità di visualizzare virtualmente le modifiche pianificate dal chirurgo sono di sicuro ausilio nel facilitare la comprensione medico-paziente. Queste nuove tecnologie hanno portato degli innegabili vantaggi, ma hanno generato problematiche medico-legali del tutto nuove. Gli Autori espongono delle riflessioni riguardanti le conseguenze legali dell'elaborazione digitale delle immagini, delle problematiche connesse alla loro archiviazione e della corretta stesura del consenso informato.*

## Introduction

Corrective rhinoplasty is one of the most commonly performed surgical procedures in aesthetic plastic surgery departments. However, it is also one of the procedures presenting the highest risk of patient dissatisfaction in terms of results.

However, the subjective wish of the patient to modify his/her appearance according to his/her own aesthetic criteria and desires should meet certain criteria to guarantee harmony and objective proportions<sup>14</sup>.

To this end, appropriate planning of surgery is crucial to achieve optimal results. Furthermore, it is the expression not only of the surgeon's experience, skill and aesthetic taste, but also of the analysis of the parameters and proportions of the face which, in our culture, are considered reference points for male and female beauty.

The pre-operative interview gives the patient and the surgeon the chance to discuss their different points of view. On the other hand, it is often difficult for the surgeon to explain the technical concepts, based on specific anatomical references, in comprehensible terms for the patient<sup>15</sup>.

In this context, the use of photographic images and

the possibility of illustrating the changes planned by the surgeon contribute to a mutual understanding, and to meeting, as far as possible, the patient's aesthetic expectations<sup>7</sup>.

In the past, this was feasible only with conventional drawings and photographs (Fig. 1 a, b). Instead, over the last few years, with the advent of information technology, it has been possible to use not only the computer but also digital media to obtain, classify and store images and technical outlines of rhinoplasties.

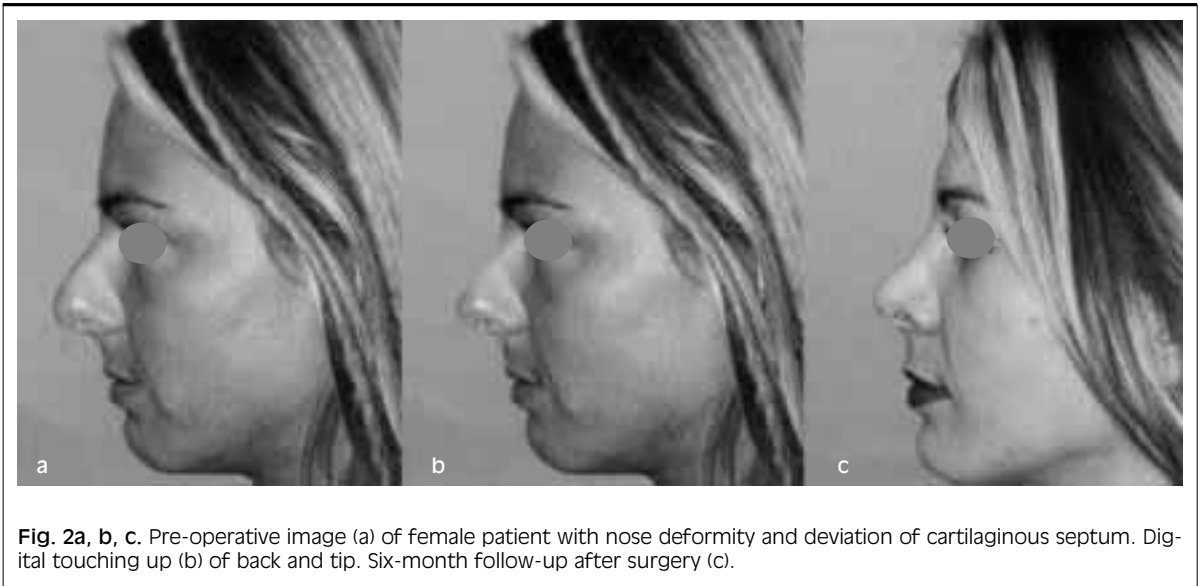
The continuous improvement in technical quality and greater computer memory, together with the availability of increasingly versatile and powerful application programmes as well as the constant and significant reduction in hardware and software costs, have led to the use of image processing systems in an increasing number of patients<sup>4</sup>. Indeed, as recently as 1999, Koch and Chavez reported that in the United States about 8-10% of aesthetic plastic surgeons used digital photograph processing systems, and estimated that this percentage would increase four-fold within 2 years<sup>10</sup>.

The graphic quality of digital imaging systems is comparable to that of traditional systems (Fig. 2 a, b, c). In



our opinion, however, digital systems present numerous advantages inasmuch as they are more manageable in terms of cataloguing, transport and use, as well

as being cheaper and less prone to deterioration. Indeed, they make the pre-operative interview easier by effectively highlighting surgical alternatives and



offering the possibility to reliably predict the final outcome of rhinoplasty. Furthermore, they also improve the organization of a surgeon's clinical practice inasmuch as they offer a more practical image management and storage, with great savings in terms of costs, time and space <sup>17</sup>.

In addition to considerably improve the strictly clinical aspects of the surgeon's practice, computer imaging methods may be successfully used also in the training of young surgeons and support staff. Indeed, the importance of images in the training of physicians should be stressed. From anatomic tables to digital photographs, the visual impact effectively offers the possibility to visualize, memorize, plan and predict <sup>9</sup>.

The increasing use of information technology in image processing in aesthetic rhinoplasty, together with the substantial contribution of the mass media, has created a public perception whereby modern surgeons performing rhinoplasty should use these supports to improve their results, as if "operating with a computer" were a sort of certificate guaranteeing the expertise of surgeon. In other terms, technology has been assigned an inappropriate role, since it is no

longer considered as a support to provide useful information in the surgeons' task, but rather as a system to "commercially" promote their activity <sup>16</sup>.

These concepts are further confirmed by the growing number of Web sites using digital images to provide cable examinations and opinions. Evidence of this is found by simply searching for the "rhinoplasty-computer" association using Italian and international search engines.

Therefore, although the use of digital images provides a series of undeniable advantages, it is equally true that the surgeon is faced with new medical and legal problems concerning plastic surgery and especially aesthetic plastic surgery, due to their peculiarities and purposes.

For these reasons, the use of processed images by inexperienced or untrained surgeons may be a double-edged sword.

As far as concerns the medical and legal problems related to the use of photographic images, these are identical to those related to the processing of digital images, which are simply a computerized version. There is no medical or legal difference as far as concerns whether the patient's profile was processed



**Fig. 3a, b.** Pre-operative image (a) of female patient with nasal deformity and deviation of cartilaginous septum and hypoplasia of third middle of face. Digital touching up (b) of nasal dorsum, reduction of antero-posterior diameter and advancement of upper maxillary.

with a felt pen or a computer. Indeed, in both cases, the surgeon is bound by a contractual obligation to exactly achieve the aesthetic result illustrated to the patient.

However, these images cannot take into account the variability in the biological evolution of the healing processes, which can often significantly affect the final outcome, regardless of the surgeon's expertise, both in the preliminary and operational phase (Fig. 3 a, b) <sup>10</sup>.

In the early '80s, Avecone, in his report "La responsabilità penale del medico", challenged the opinions of the most authoritative scholars, physicians and legal experts of that time when, in relation to aesthetic plastic surgery, he vigorously claimed that "... aesthetic plastic surgery has become part of normal surgical and medical treatment. Thus, it is outmoded to generally consider it as a useless practice, or as a practice based on the "whims" of the individual undergoing it" <sup>1</sup>. His colleagues still considered this discipline in a rather restrictive way, based on the fact that surgeons operated on a healthy anatomical structure, and that the aesthetic purpose alone did not justify the risks of surgical treatment. Today, this vision of surgery has finally been superseded, and also this discipline has been assigned a therapeutic role. Indeed, aesthetics also contributes to complete physical, psychological and social well-being, which the WHO has defined as a prerequisite to the concept of health.

However, when it comes to professional liability, both penal and civil, aesthetic plastic surgery differs from the other medical and surgical specialties. Its peculiarity lies in the fact that patients may be relieved of their psychological distress only if the expected results discussed with the surgeon are achieved.

With respect to the professional liability of plastic surgeons, especially in terms of civil liability, i.e., compensation for damage, Buzzi suggested adopting "an extremely rigorous standard", essentially inspired by the concept of contractual liability, with the obligation, on the part of the surgeon, to achieve a given result, and not only to employ certain means <sup>5</sup>. Although this interpretation is appropriate in essence, it should not be accepted or applied acritically, otherwise few plastic surgeons would continue to practice and, presumably, few insurance companies would be willing to accept the risk of covering them. Indeed, even a well performed procedure may not lead to the results expected by the patient and, indeed illustrated by the surgeon. This may be the case if the final aesthetic outcome is different from the result foreseen by the patient, or because there may be complications unrelated to the surgeon (pathological scars, for example).

For this reason, there was recently an evolution in the

concept of obligatory outcome in plastic surgery. This followed the introduction of the concept of "biological individuality", that is, the subjective reactivity of the tissues submitted to surgery, which is thought to influence the outcome of surgery regardless of the surgeon's skill <sup>6</sup>. It is thus evident that the patient's real informed consent to the surgical operation is needed <sup>2</sup>. Medical, legal and juridical doctrine, as well as case law (see the ruling of the *Cassazione Civile* Section II of 2 August 1985, no. 4394), converge in stating that any plastic surgery procedure should be preceded by informed consent, as detailed as possible. While for any surgical procedure, it would theoretically be sufficient to inform the patient about operating risks and possibly alternative techniques, in the case of plastic surgery, the patient must be informed, in detail, about the results that may be obtained, the margins of variability compared to the expected outcome, and possible complications independent of the technical procedure <sup>3</sup>.

Obviously, consent does not relieve the surgeon of his obligations in terms of the means to be employed. Risky, inexperienced or negligent behaviour will, indeed, lead to the surgeon being prosecuted under criminal or civil law <sup>11</sup>.

As far as concerns the documentation proving that the patient gave his/her consent, there are no obligations in terms of the form in which the consent should be obtained. However, it should be stressed that the activity of the cosmetic surgeon is considered akin to the provision of a service under a contract. Thus, in the case of legal proceedings, the burden of proof will be required. In other words, the surgeon will have to show that he/she operated in a technically appropriate manner, and that the different outcome was independent of his/her behaviour or any actions he/she may have taken, not in accordance with the state of the art <sup>13</sup>.

Thus, in the case of cosmetic surgery, due to the reasons illustrated above, a signed consent on the traditional "pre-printed" form may be of no value in terms of proof. Consent, written, at least in part, in the patient's own handwriting, or which proves unequivocally that the patient received appropriate and exhaustive information, would certainly be preferable <sup>12</sup>.

It should be clearly stated that the surgeon is not in the position to guarantee the results of surgery, above and beyond the technical appropriateness of his conduct.

Furthermore, the surgeon must carefully retain all documentation concerning the case (including images) and indeed, he should scrupulously collect all such material in order to be able to subsequently produce it, should the need arise.

In the past, some Authors actually advised that the images produced at the end of the interview with the patient be destroyed.



**Fig. 4a, b.** Pre-operative image (a) of patient with post-traumatic nasal deformity associated with presence of osteocartilaginous hump and prognathism. Digital modelling (b) of nose and mandibular profile.

However, in the event of litigation, this sort of conduct may lead to the suspicion of malpractice and of conduct, not in accordance with the state of the art. It is certainly advisable to keep the processed images, perhaps digitally authenticated, together with the consent, signed by the patient<sup>8</sup>. It should not be forgotten that in many countries, including the United States, images are an integral part of the clinical record.

Special attention should be focused on the virtual reconstruction of a cosmetic correction by means of computerized processing of the patient's images (Fig. 4 a, b). From a "clinical" point of view, this technique offers the possibility of producing an image which is very close to reality, while on the other hand, it "forces" the surgeon to achieve that result. Furthermore, using this technique, the patient will have to be informed, in detail, about the possible outcome that may differ considerably from the virtual reconstruction. This information will have to be clearly stated in the consent undersigned by the subject. Only thus will the surgeon be able to prove that his/her behaviour was not negligent in the event of failure.

It would be advisable for the virtual reproductions shown to and accepted by the patient to be stored in

hard copy and signed both by the patient and surgeon. Storing the images only in a virtual format may be challenged in the case of legal proceedings (civil or criminal), on the grounds that such images are easy to modify without leaving a trace.

Digitalization of images allows for easier storage and reduces the space required to preserve this material. Consequently, the costs involved in keeping the photographic archive are also reduced.

Also in this case, however, the recent provisions regarding privacy compel the surgeon to limit access to these data exclusively to the staff in charge, and to collect the informed consent of the patients concerned.

Any cosmetic surgery procedure, therefore, must necessarily be preceded by an adequate evaluation of the risks and likely advantages. The surgeon is thus advised not to incautiously exaggerate their surgical ability and the results that may be obtained. If the surgeon chooses to show the results of other cases it is best to present a broad range of results, including average or mediocre outcomes.

The one fundamental and crucial element, however, is to collect the patient's written consent, which specifies surgical alternatives, risks and complications related to the surgical procedure.

Whilst the use of processed images is a sort of contractual constraint with the patient, common sense

and some simple precautions may protect the surgeon against undesired legal action.

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