Informed Consent in Facial Plastic Surgery

Effectiveness of a Simple Educational Intervention

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Objective: To evaluate the effectiveness of oral communication about the risks of facial cosmetic procedures compared with oral and written communication.

Design: A prospective randomized study conducted in an ambulatory surgery center. One hundred twenty consecutive patients were included; they presented for consultation for rhinoplasty, rhytidectomy, or laser resurfacing. Patients were randomly assigned to 1 of 2 groups: (1) those receiving oral discussion of the risks of the procedure and (2) those receiving oral and written communication about the risks. Two weeks after the initial consultation, patients were surveyed for recall of the risks.

Results: The group that received a pamphlet had a better risk recall than the group that did not (2.5 vs 1.5 of 5 risks; \(P<.001\)). The recall rate in the following groups that received a pamphlet was also better: (1) university-educated patients \((P=.02)\), (2) patients who underwent rhinoplasty \((P<.001)\), (3) patients who underwent laser resurfacing \((P=.02)\), and (4) female patients \((P<.001)\).

Conclusions: Written disclosure of the risks of cosmetic procedures enables patients to retain and understand more clearly those potential risks. They are, therefore, able to give an informed consent to the proposed procedure. This study also identifies patient groups who may require more intensive presurgical teaching. The medicolegal implications are apparent.

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Informed consent is the core principle of modern medical and surgical practice. Studying and discussing informed consent would not be complete without making reference to New York Judge Benjamin Cordozza, who formulated the foundations and principles of informed consent in 1914 with the following statement: “Every human being of adult years and sound mind has a right to determine what shall be done with his body, and a surgeon who performs an operation without the patient’s consent commits an assault for which he is liable in damages.”

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The medical literature is replete with information and articles on informed consent. There are several studies that have specifically considered and analyzed the issue of informed consent in plastic surgery. However, further discussion on this matter is futile if one does not pose and answer the following essential question: what constitutes informed consent? The basic concepts of informed consent are as follows: the patient has the fundamental right to make a decision regarding treatment, including refusal to treatment; and the health care professional will disclose to the patient the necessary information regarding the disease, the condition, and the treatment in simple, concise, nontechnical, and nonjudgmental terms. The following factors are the legal and moral requisites for the patient to give informed consent: (1) the patient is legally competent, (2) consent is given voluntarily, and (3) appropriate and adequate information are given. The discussion of the potential risks and complications of a treatment plan does not, in itself, constitute informed consent. Surgeons must inform their patients of the following for informed consent to be valid and meet the standard of care: (1) the nature of the disease, condition, or injury; (2) the nature, purpose, benefits, disadvantages, and limitations of any treatment plan; (3) the alternatives of the treatment available, including no treatment; (4) the risks and complications of the treatment; and (5) who will be performing the treatment.

Therefore, how much is a health care professional to disclose and what is considered adequate? There are 2 standards...
that the courts use to judge the adequacy of a physician's disclosure of information to a patient: the reasonable physician standard and the reasonable patient standard. Some states use the former, while others use the latter; however, the national trend is the application of the reasonable patient standard. Briefly, the reasonable physician standard asserts that a physician has a duty to disclose information that any reasonable physician would disclose under similar circumstances. This standard, in principle, is considered contrary to the objectives of informed consent because the primary focus is on the physician rather than on what the patient needs to know. The reasonable patient standard, on the other hand, asserts that a physician has the duty to disclose information that is material in determining what the reasonable patient would want to know to consent to the proposed treatment. In other words, a reasonable physician will inform his or her patient of all risks a reasonable person in the patient's position would likely consider significant in making his or her decision.

We limited our study to only 1 aspect of the informed consent requirements: the risks and complications in facial plastic surgery. Our objective was to examine the rate of recall by patients of the preoperative risks, with and without written reinforcement of the oral discussion of the risks. Therefore, the next logical question to pose was as follows: how do surgeons disclose to patients all the information necessary in the process of informed consent and how much does the patient understand and remember? The simplest and the most common form used is oral disclosure during the initial consultation. There have been several studies conducted examining this important question. One study, in particular, reported a mere 38% recall rate of the preoperative warnings in patients undergoing cosmetic surgery. Therefore, patients remember less than half of the information provided to them. As a result, other modalities of disclosure must be considered if we want to improve this situation, such as providing written or printed material in the form of pamphlets or brochures to reinforce and increase the retention of the preoperative risks discussed. This, however, is in no way a substitute for the face-to-face discussion of all aspects of informed consent with the patient.

This is a prospective randomized study involving 120 consecutive patients undergoing rhinoplasty, face-lift surgery, or laser resurfacing. The study was conducted in an ambulatory facial plastic surgery center. A standard initial consultation was performed, explaining to the patient the nature, the purpose, and the details of the operation and the associated risks and complications of the procedure that the patient was seeking. Before the implementation of the study, a list of the most significant risks and complications of the particular facial plastic surgery procedure deemed most common by the surgeon was formulated, and these risks were communicated during the consultation. All questions pertaining to the procedure were answered. The risks discussed with patients planning to undergo face-lift surgery were as follows: hematoma, lumpiness or depression of the skin in the cheek and the neck areas, thick scar formation at the incision sites, facial weakness or paralysis, and numbness of the lower half of the ears. The risks discussed pertaining to laser resurfacing were as follows: more than 1 procedure (or session) may be required to improve the rhytids, permanent scarring, herpes simplex breakout, prolonged erythema, and hyperpigmentation or hypopigmentation. The patients were assigned to either a group receiving a pamphlet outlining the risks of that particular facial cosmetic procedure (pamphlet group) or a group that was not given a pamphlet reinforcing the risks discussed orally (no pamphlet group). The assignment of patients to each group was done randomly by computer-generated roll of a die. Patients with an even number were placed in the pamphlet group, and patients with an odd number were placed in the no pamphlet group. At no time during the initial consultation were the patients informed of this study. Approximately 2 weeks after the initial consultation, each patient was telephoned by one of us (A.S.M.). During the telephone conversation, the purpose of the call and the objective of the study were explained to the patient. The patients were asked to repeat the risks and the complications of the particular procedure that were discussed during the initial consultation at the surgeon's office. The answers were recorded on a standard checklist outlining the risks of that particular procedure. Demographic information was collected at the initial consultation, such as the highest level of formal education attained, sex, age, occupation, and type of procedure that the patient was to undergo. A statistical analysis was performed using the Mann-Whitney test and the unpaired t test.

There were 120 patients enrolled in the study (32 males and 88 females). The average age was 41 years (range, 14-72 years). For educational background, 54 patients had a university or higher (doctorate or postdoctorate) education and 66 had no university education (pre-high school, high school, or post-secondary school). Sixty-five patients were seen for a rhinoplasty consultation, 22 for a face-lift consultation, and 33 for a laser-resurfacing consultation. The average follow-up from the date of the consultation to the telephone call was 15 days. A total of 48 patients actually underwent surgery. The number of patients in the group that received a pamphlet outlining the risks associated with the specific facial plastic surgery procedure was 63, and the number of patients in the group that did not receive a pamphlet was 57. The overall recall rate of the risks was 1.97 of 5 risks. The risks recalled in the 2 different groups are shown in Figure 1.

The recall success for patients undergoing rhinoplasty, face-lift surgery, and laser resurfacing is shown in Figures 2, 3, and 4, respectively.

The sex of the patient did not seem to influence recall success (P = .15). Males recalled 1.7 of 5 risks, while females recalled 2.0 of 5 risks. There was no statistically significant (P = .15) difference in recall rate for age either. In contrast, educational background did make a difference in the recall rate of the preoperative risks. Patients with a university or higher education recalled 2.3 of 5 risks, while patients without a university education recalled 1.8 of the preoperative risks (P = .02, unpaired t test).
TYPE OF PROCEDURE AND RISK RECALL IN THE NO PAMPHLET VS THE PAMPHLET GROUP

The rhinoplasty group (n=65) was divided into 2 subgroups: one that received a pamphlet outlining the risks of the procedure and another that did not receive a pamphlet. The recall success in the subgroup that received a pamphlet was 2.4 and in the subgroup that only had an oral discussion of the risks of the procedure, 1.4 (Figure 5). This difference was statistically significant (P<.001, unpaired t test). This was also the case in the laser-resurfacing group (n=33). The subgroup that received a pamphlet recalled 2.4 of the risks, while the subgroup that did not receive a pamphlet recalled only 1.4 of the risks (P=.02, Mann-Whitney test) (Figure 6). The recall success in the face-lift group (n=22) was not statistically significant (P=.19).

SEX AND RISK RECALL IN THE PAMPHLET VS THE NO PAMPHLET GROUP

There was no statistically significant (P=.32) difference in recall rate in the male patient group (n=32) when disclosure of risks with printed pamphlets was introduced. The subgroup that received a pamphlet outlining the preoperative risks recalled 1.9 of the risks. The subgroup that did not receive a pamphlet recalled 1.5 of the risks. In contradistinction, there was a statistically significant (P<.001, Mann-Whitney test) difference in the recall rate...
in the female patient population (n=88) when a pamphlet was given reinforcing the oral disclosure of the preoperative risks. The subgroup that received a pamphlet recalled 2.7 of the risks. The subgroup that did not receive a pamphlet only recalled 1.5 of the risks. If we compare the male patient subgroup that received a pamphlet with the female patient subgroup that also received a pamphlet, we see a statistical difference in recall rate ($P = .02$, Mann-Whitney test). The male patient subgroup recalled 1.9 of the risks, while the female patient subgroup recalled 2.7 of the risks, when given a pamphlet outlining the risks of the procedure. This was not the case when the sex subgroups (male and female) that did not receive a pamphlet were compared. There was no statistical difference between these 2 subgroups.

**EDUCATIONAL BACKGROUND AND RISK RECALL IN THE PAMPHLET VS THE NO PAMPHLET GROUP**

There was a statistically significant improvement in risks recalled by the subgroup of patients who did not have a university education when a pamphlet (outlining the risks of the procedure) was given in the initial consultation ($P < .001$, unpaired $t$ test). Patients in this subgroup recalled 2.2 of the risks compared with 1.1 of the risks recalled in the subgroup of patients who did not receive a pamphlet. Risk recall was also improved in patients who received a pamphlet and who had a university education. The risk recalled was 2.8 in this subgroup. Patients with a university education who did not receive a pamphlet had a 1.8 recall rate of the risks ($P = .001$, unpaired $t$ test). A comparison of university-educated patients with non–university-educated patients who received a pamphlet reveals no statistically significant difference in risks recalled (2.8 vs 2.2; $P = .08$). However, a comparison of university-educated patients with non–university-educated patients who did not receive a pamphlet reveals a statistically significant difference in risks recalled (1.8 vs 1.1; $P = .006$, unpaired $t$ test).

There is a paucity of studies in the English-language medical literature that have investigated the question of improving recall and retention of the information discussed and disclosed during the first patient-physician contact. In fact, a search on MEDLINE of the English-language medical literature revealed only 1 study from England, by Armstrong et al, that specifically studied patient recall of verbal vs written preoperative risks. The population consisted of patients undergoing cosmetic surgery, elective hand surgery, and excision of minor skin tumors. The patients were counseled on the risks and benefits of the procedure during the initial consultation. There were 132 patients in the verbal group and 137 in the written group. One week after the surgery, the patients were interviewed and recall of the risks of the procedure was recorded. The average recall rate of preoperative risks (7 risks in total) was 2.95 (42%). This average increased to 3.64 (51.9%) when written preoperative warnings were given. Interestingly, the mean number of warnings recalled was fewer than 3 in the verbal group and fewer than 4 in the written group. These numbers reflect the commonly held view that patients forget most of the information disclosed to them during the consultation. On the other hand, there are few studies that have surveyed only the patient recall rates of the preoperative information during the preoperative consultation. Leeb et al interviewed 100 consecutive preoperative and emergency department patients, and information for informed consent was disclosed at that interview, including risks and complications of the procedure. There were 69 patients undergoing elective noncosmetic procedures, 8 patients undergoing cosmetic procedures, and 23 emergency department patients. They were reinterviewed at 7 days for recall of the information disclosed to them a week earlier. The average recall rate for the different groups was as follows: 29% for the elective preoperative group, 38% for the cosmetic surgery group, and 39% for the emergency department group. The overall recall rate was 35%. In a study conducted by Hekkenberg and colleagues, the researchers investigated the effectiveness of informed consent in head and neck surgery by testing patient recall of the potential risks and complications associated with thyroidectomy, parathyroidectomy, and parotidectomy. There were 54 patients included in this prospective study. The risks and complications of each procedure were verbally discussed with each patient during the consultation. From 1 week to 2 months after the informed consent was obtained, the patients were surveyed for recall of the potential complications. The overall recall rate for all the procedures was 48%. The significant determinants of patient recall about the risks of a procedure in this study were age and level of education. The younger and better-educated patients recalled more than 50% of the risks and complications of the procedures they were to undergo.

In our study, the overall recall rate of the risks and complications of the 3 facial cosmetic procedures at 15 days after the initial consultation was approximately 40% (2 risks of a total of 5 for each procedure). There was an increase in recall rate from 1.5 to 2.5 when patients were given printed pamphlets outlining those surgical risks. This increase in risk recall with the introduction of informational printed pamphlets was statistically significant (unpaired $t$ test, $P < .001$).

Furthermore, an educational intervention in the form of printed pamphlets outlining the risks of the 3 facial cosmetic surgical procedures—rhinoplasty, face-lift, and laser resurfacing—had a significant effect in the retention rate and recall rate of those risks in the following situations: (1) patients consulting for rhinoplasty (the recall rate increased to 2.4, $P < .001$); (2) patients consulting for laser resurfacing (the recall rate increased to 2.4, $P = .02$); (3) female patients (the recall rate increased to 2.7, $P < .001$); (4) patients who did not have a university education (the recall rate increased to 2.3, $P < .001$); (5) patients who did have a university education (the recall rate increased to 2.8, $P = .001$); and (6) female patients compared with male patients (the recall rate was 2.7 vs 1.9; $P = .02$). Other observations made in this study were the following: (1) the recall rate was higher in patients with a university education compared with patients without a university education (2.3 vs 1.8; $P = .02$) and (2)
there were no significant differences in recall rate with respect to male sex and age.

In our study, the recall rate in patients who only received oral discussion of the risks is in accord with the rates given in the other studies previously mentioned. To our knowledge, this is the first study investigating the issue of recall and retention of surgical risks and complications in facial plastic surgery, the results of which are quite impressive and revealing. Patient recall of the preoperative oral discussions of risks and complications is poor, even at 2 weeks. The introduction of other cues to enhance and reinforce the verbal aspect of the consenting process has been demonstrated to be effective. One such method of promoting retention and recall of the oral declarations at the initial consultation is the addition of printed material outlining the important points discussed, specifically the potential risks and complications of the procedure. This concept is demonstrated and confirmed in this study.

In 2 groups—rhinoplasty and laser resurfacing—the patient recall rate increased significantly, to about 2.4, with the printed pamphlets. There was no statistical difference in the face-lift group. This may be because of the fewer numbers in that group. Female patients were able to demonstrate that they are more concerned and cognizant about the potential disadvantages of the cosmetic surgical procedure than their male counterparts. In the female patient group, the recall rate increased to 2.7 when they were given printed pamphlets. In the male patient group, this increase was minimal and not statistically significant. This, however, may be because of the small numbers in this group. Another important revelation in this study was the effect of patient educational level on risk recall. Patients with or without a university education increased their recall rate with the printed pamphlets. However, patients with a university education or higher were able to increase their recall rate to more than 2.5 with the pamphlet intervention.

We divided the group sample into those 40 years and younger and those older than 40 years based on the average age of the patient population. At this cutoff point, there was no difference in recall rate: the recall rate was at approximately 2.0% in both subgroups.

The following interesting observations are made with respect to the most commonly remembered risks of each procedure. In the rhinoplasty group, the potential risk most commonly recalled was bruising and the risk least commonly recalled was the possibility of postoperative asymmetry in the nasal tip and the supratip areas. One possible explanation as to why patients did not list asymmetry of the tip as a potential complication of rhinoplasty would be because of patients’ lack of understanding, insight, and appreciation of what this asymmetry in that particular anatomical area would look like. In the face-lift group, the risks most commonly recalled were facial weakness or paralyses and postoperative hematoma that will necessitate returning to the operating room to drain the hematoma. It is logical that most patients would recall these potentially serious complications. However, it is interesting that hypertrophic scarring at the incision site was the least-remembered complication, considering the unesthetic, albeit hidden, quality of this potential complication. In the laser-resurfacing group, most patients remembered to list postoperative pigmentation changes to the skin as a potential complication. The least-remembered complication was the failure of the surgical objective of the procedure and the need for another procedure at a later time.

Why do we want a more informed patient, a patient who has a good recollection and retention of the risks and complications of the facial plastic surgical procedures? The answer is simple; the hope is that better-informed patients will become more cognizant of the advantages, and the disadvantages, that lie ahead should they decide to proceed with the proposed facial plastic surgical procedure. Perhaps more important, patients given printed information pamphlets at the initial consultation will have the time in their own homes, at their leisure, to consider and review the risks and complications of the proposed facial plastic surgical procedure. This, in itself, will engender more effective recall. Hence, in the event of an undesirable surgical outcome, the chances for litigation, at least on the grounds of lack of informed consent, would be reduced.

Recently, there have been publications recommending local, regional, and national plastic surgery societies to develop and adopt standard information cards outlining each plastic surgery procedure, including all the information necessary to constitute informed consent in simple and comprehensive language. One such authority, the National Medical French Council, recommended to its medical societies to propose to their members such standard index cards. As indicated, these information cards would also contain the important points that satisfy informed consent, including the risks and complications. We support and recommend such a task on this side of the Atlantic Ocean.

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