

Patients' understanding of "informed consent" in plastic surgery

José Neder Netto^{1*} , Roberto Augusto de Carvalho Campos^{2,3} , Reginaldo Raimundo Fujita² 

SUMMARY

OBJECTIVE: To assess the patient's understanding of the informed consent form before and after plastic surgery.

METHODS: This was a prospective analytical descriptive study that utilized a questionnaire on informed consent before and after plastic surgery procedures.

RESULTS: Comprehension of informed consent was higher before surgery than after surgery ($p=0.016$; question 15). The higher the scholary, the higher the comprehension ($s=0.151$; $p=0.045$) before surgery (question 4). For the other questions, it was not possible to find a difference in the pattern of understanding and in the association with the educational attainment level after surgery ($s=0.180$; $p=0.046$; question 1). **CONCLUSIONS:** The patients' level of comprehension of the details, outcomes, possible complications, and postoperative evolutions of surgical procedures, as stated by the informed consent form, is high.

KEYWORDS: Consent forms. Comprehension. Physician-patient relations. Duty to warn. Surveys and questionnaires.

INTRODUCTION

Consent is defined as the permission a person gives for the performance of any type of medical treatment. It should be facultative and informed; the person must be suitable for such a decision. It should also be obtained in advance before the start of the chosen treatment^{1,2}. It serves as material proof that the physician fulfilled their obligation to inform the patient and that the patient declared that they understood and agreed to undergo the treatment. Communication before and after any procedure should be clear and done using simple language. There is a risk of the doctor-patient relationship transforming into a formal contract, and the rapport and harmonious bond, which are characteristics of the medical practice, may be lost³. In lawsuits on aesthetic plastic surgery, for which informed consent term (ICT) was properly obtained, the judicial expert was mostly favorable toward doctors⁴.

The worsening of the doctor-patient relationship, due to the change in the health care model, is associated with the increase in complaints against physicians in Brazil⁵.

The exercise of medicine is considered a process-centric activity, without promise of results⁶. As a counterpoint, the courts of justice consider plastic surgery as an end activity, aiming for social acceptance of the individual⁷.

The ICT does not include all possibilities in medicine because it is an inexact science. It should include clarifications for the patient that the procedure to be performed will bring some benefits, but that there will be possible complications independent of the skill, training, and performance of the medical professional. The term gives the patient the freedom to choose the most favorable option of treatment, while removing the idea that the doctor is always responsible for the outcome^{8,9}. The complexity of the information process is high, and great attention should be paid to this important phase¹⁰.

¹Sociedade Brasileira de Cirurgia Plástica – São Paulo (SP), Brazil.

²Universidade Federal de São Paulo, Escola Paulista de Medicina – São Paulo (SP), Brazil.

³Universidade de São Paulo, Faculdade de Direito, Departamento de Direito Penal, Medicina Legal e Criminologia – São Paulo (SP), Brazil.

*Corresponding author: jnnetto@yahoo.com.br

Conflicts of interest: the authors declare there is no conflicts of interest. Funding: none.

Received on June 11, 2021. Accepted on June 27, 2021.

There is a large increase in the number of lawsuits against plastic surgeons. One reason is the inadequate use and formulation of the ICT¹¹. The understanding of patients regarding the ICT for the treatment to be performed is inappreciable. Despite all efforts, there appears to be a great difference in the understanding of this by doctors and courts. The term, as required by law, has not been fully achieved, and the same difficulty has subsisted for decades¹².

Research on patient difficulty in absorbing the information included in the term has determined three related factors: education, health status, and care in and attention to reading the ICT before signing¹³.

There have been several studies that utilized questionnaires to evaluate the patient's understanding of the ICT, using several different ways as follows: repeating the term, doubts orally recorded, and standardized term versus reinforcement methods, by video or information by nurses. The results were as follows: the greatest difficulty in understanding was found in patients of different ethnicities due to their schooling and their difficulty in understanding the language^{14,15}; information and questions answered orally during consultations were better understood¹⁶; the vast majority of patients were satisfied with the information given about the procedure to be performed¹⁷; there was no difference in the understanding and satisfaction of patients who received the standardized term and those who underwent reinforcement methods; and they may, therefore, be unnecessary¹⁸.

In contrast, American studies have observed that the use of supplementary, written, audiovisual, and other materials increase satisfaction after the procedure and may limit litigation^{19,20}. In another study, 75% of the plastic surgeons interviewed were defendants in at least one malpractice lawsuit, and most of the investigated cases involved complaints of unsatisfactory results, excessive scarring, or lack of ICT²⁰.

This study aimed to evaluate the patient's understanding of the informed consent form before and after plastic surgery.

METHODS

This was a prospective descriptive analytical study. Data were collected from July 2017 to September 2018. The study population included people who underwent any plastic surgery, who were seen in the office of any of the 23 participating physicians, and who agreed to participate in the research.

A questionnaire was administered to the patients before the day of the surgery and readministered during the postoperative period in the office of each participating physician. It was distributed in the states of São Paulo and Mato Grosso.

All of the administrators were plastic surgeons recognized by the Regional Council of Medicine of São Paulo (CREMESP) and the Brazilian Society of Plastic Surgery (SBCP).

The questionnaire is composed of 21 questions, with 5 options for each answer, that evaluated the degree of understanding of the patient as follows:

- 0 = none;
- 1 = a little;
- 2 = regular;
- 3 = moderate; and
- 4 = very.

The questionnaire was first administered on any date until the day of surgery and was administered for the second time at least 1 month after surgery.

The inclusion criteria were patients who underwent plastic surgery performed by the participating physicians, with the completion of the ICT and questionnaires of this study. The exclusion criteria were those who presented the ICT without the signature of one of the participants (physician or patient) and those who completed them after the stipulated deadline.

The descriptive statistical analyses were performed through measures, such as means and minimum, maximum, absolute, and relative frequencies.

The inferential analyses employed to confirm the descriptive analysis were as follows:

1. Wilcoxon²¹, for the comparison of the answers to the questionnaire before and after surgery;
2. Spearman's correlation coefficient²¹, in the study of the relationship between schooling and each question in the questionnaire.

The alpha significance level of 5% was used in all the conclusions. The evaluations were performed using the statistical software Statistical Package for the Social Sciences (known as SPSS) version 2019 (IBM Corp., Armonk, NY, USA).

The study was approved by the Research Ethics Committee of UNIFESP, under number 69248/2017 and the approval of the Brazil platform.

The patients signed a consent form to participate in the study.

RESULTS

The research collected 178 questionnaires before and 124 questionnaires after the surgical procedure.

We had 54 unanswered questionnaires after the surgery, which were considered as losses only if the second questionnaire was administered.

The questionnaire was first administered from 103 days before to the day of the surgery.

The questionnaire was readministered from 30 to 320 days after the surgery. The predominant educational attainment levels

Table 1. Number of patients who answered the questionnaire on informed consent, according to sex and education.

Sex	Schooling				
	No study	Fundamental	Medium	Superior	Total
Male	0	0	2	5	7
Female	3	15	75	76	169
Total	3	15	77	81	176*

*Two people did not answer about their schooling.

Table 2. Distribution of responses to the questionnaire on informed consent before and after surgery. (Question 15: Are you aware that the outcome depends on postoperative care?)

Issue	Answer										
	No		Little		Regular		Quite		Very		p
Q15	0	0	1	0.6%	4	2.2%	51	28.7%	122	68.5%	0.016*
R15	0	0	1	0.8%	4	3.2%	38	30.6%	81	65.3%	

*Wilcoxon signed-rank test (p<0.05).

of the patients were higher education (45.50%), followed by high school (43.25%) (Table 1).

Comparisons were made between the answers of each question before (Q1, Q2, Q3,...Q21) and after (R1, R2, R3,...R21) surgery and whether these differences were statistically different, considering p<0.05.

With the exception of question 15 (Are you aware that the outcome depends on postoperative care?), where understanding before surgery was better than after surgery (p=0.016), there was no difference in the pattern of understanding for the other questions (Table 2).

In the relationship between schooling and each question in the questionnaire, according to the estimates of Spearman's correlation coefficient(s), we noticed that the higher the educational attainment level, the greater the understanding, as shown in the analysis of question 4 (Are the risks and potential complications acceptable?) (s=0.151; p=0.045) from before the surgery and by question 1 (Did you resolve all doubts during the medical consultation about the surgery that is going to be performed?) (s=0.180; p=0.046) after the surgery. For the other questions, this relationship was not confirmed (Table 3).

DISCUSSION

The growth of studies and production of data on informed consent have been essential due to the judicialization of medicine in recent years, with the significant increase in lawsuits in Brazil. At any time, the plastic surgeon is faced with a lawsuit simply because the patient is dissatisfied with the outcome of the procedure or with the information previously obtained, although these data are completely subjective.

Table 3. Relationship between the patients' education and each question before and after surgery.

Schooling	Before		Then	
	s	p*	s	p*
Question 1	0.046	0.541	0.180	0.046
Question 2	-0.012	0.876	0.036	0.689
Question 3	-0.060	0.430	0.094	0.302
Question 4	0.151	0.045	0.122	0.177
Question 5	-0.051	0.504	0.030	0.740
Question 6	0.089	0.242	0.115	0.204
Question 7	-0.031	0.686	-0.047	0.604
Question 8	-0.041	0.587	0.058	0.522
Question 9	-0.079	0.296	0.102	0.260
Question 10	0.026	0.732	0.076	0.406
Question 11	0.045	0.552	0.010	0.911
Question 12	0.067	0.378	0.022	0.809
Question 13	0.058	0.443	0.032	0.722
Question 14	-0.023	0.760	0.032	0.729
Question 15	-0.001	0.987	-0.016	0.864
Question 16	0.050	0.513	0.114	0.210
Question 17	0.052	0.491	0.052	0.566
Question 18	0.030	0.696	0.100	0.271
Question 19	0.046	0.546	-0.071	0.432
Question 20	-0.055	0.466	-0.089	0.327
Question 21	0.007	0.924	0.087	0.341

*p<0.05.

It is important that the doctor always acts within their area of specialization and is qualified by the CREMESP and SBCP, in the case of plastic surgery. Otherwise, they will be subject to ethical-professional lawsuits and suffer the appropriate punishments if negligence, lack of skill, or imprudence is proven.

The basis of the use of the ICT is the autonomy of the individual, which is a premise of the code of medical ethics. The patient can also make their own decision as to whether it is worth undergoing the procedure with the risks and potential complications inherent to the procedures and possible outcomes. Signing the term confirms awareness and agreement with everything involving the proposed procedure.

From a legal point of view, there is no lack of arguments for the use of the ICT, and the printed form is a physical proof of the patient's consent.

No ideal ICT has yet been found, and there is no protocol to follow in its formulation. This leaves doubts as to what information should be included and how it should be applied with patients for better guidance and understanding, because any area of medicine is an inexact science, and it will always be impossible to list all of the possible complications.

We should remember that the given information and resolved doubts during all preoperative consultations, and in addition, whatever is implicit in the content during the process, must be added to the signed term⁴.

There is great difficulty in assessing the patient's understanding of the ICT because when it is evaluated through questionnaires, the result is a great understanding of the information also obtained during the preoperative consultations, in addition to that contained in the term²².

The understanding of and satisfaction with the ICT is good or excellent in the preoperative period as described^{18,23}. At 6 weeks after surgery, there was a drop in the understanding in all the groups, showing that forgetfulness appears to occur quickly. Using several ways in combination does not statistically change the level of understanding.

It is complicated to say currently that the patient or any individual who has access to plastic surgery is fully a layman and does not know that every surgery has inherent risks, because,

according to a national survey conducted by IBGE²⁴, 74.9%, or three of every four Brazilian households had access to information through the Internet in 2017. The proportion of people who accessed the Internet was higher, the higher the level of educational attainment.

The closer and better the physician-patient relationship is, the lower the chance of a future lawsuit, regardless of whether any complication occurred⁵.

In a survey by CREMESP²⁵, 90% of the physicians sued were not specialists. The high incidence of ethical lawsuits involving plastic surgery is due to the invasion of the area by medical and nonmedical specialists, performing procedures specific to the area, without adequate training for such.

The patient should be informed that they may have certain benefits through the procedure and that the occurrence of the expected benefits is limited by risks inherent to the body of each individual and independent of the medical professionals will and skill⁸.

CONCLUSION

The level of patient understanding of surgery information, outcomes, possible complications, and postoperative developments is high when they are given an informed consent form.

ACKNOWLEDGMENT

We thank all the physicians and patients who participated in the survey.

AUTHORS' CONTRIBUTIONS

JNN: Conceptualization, Formal analysis, Methodology, Project administration, Research, Software, Writing – original draft, Writing – review & editing. **RACC:** Conceptualization, Formal analysis, Methodology, Project administration, Writing – original draft, Writing – review & editing. **RRF:** Data curation, Formal analysis, Project administration, Supervision, Writing – review & editing.

REFERENCES

1. Ricketts D, Roper T, Rogers B, Phadnis J, Elsayed S, Sokol D. Informed consent: the view from the trenches. *Ann R Coll Surg Engl.* 2019;101(1):44-9. <https://doi.org/10.1308/rcsann.2018.0140>
2. Mallardi V. The origin of informed consent. *Acta Otorhinolaryngol Ital.* 2005;25(5):312-27. PMID: 16602332
3. Campos RAC, Camargo RAE, Neves LR. The judicialization of the medical act. *Braz J Otorhinolaryngol.* 2016;82(1):1-2. <https://doi.org/10.1016/j.bjorl.2015.12.002>
4. Doncatto LF. Uso do termo de consentimento informado em cirurgia plástica estética. *Rev Bras Cir Plást.* 2012;27(3):353-8.
5. Fujita RR, Santos IC. Denúncias por erro médico em Goiás. *Rev Assoc Med Bras.* 2009;55(3):283-9. <https://doi.org/10.1590/S0104-42302009000300020>
6. Conselho Regional de Medicina do Estado de São Paulo. Resolução CREMESP nº 81, de 9 de junho de 1997. *Diário Oficial do Estado; Poder Executivo, São Paulo, SP, n. 115, 19 jun.*

1997. Seção 1, p. 60. Available from: <https://www.cremesp.org.br/?siteAcao=PesquisaLegislacao&dif=s&ficha=1&id=3204&tipo=RESOLU%C7%C3O&orgao=Conselho%20Regional%20de%20Medicina%20do%20Estado%20de%20S%C3%A3o%20Paulo&numero=81&situacao=VIGENTE&data=09-06-1997>
7. Menezes JA. Litígio judicial entre paciente e cirurgião plástico em Minas Gerais [dissertação]. São Paulo: Universidade Federal de São Paulo, 2017.
 8. Cavalcanti MA. Consentimento informado: Por que e como? *Rev Bras Cir Plást.* 2005;20(4):241-4.
 9. Jaimovich CA, Kfoury Neto M, Almeida ÁHT, Pinheiro AG, Loma DC. Consentimento informado e cirurgia plástica. *Rev Bras Cir Plást.* 2007;22(3):188-93.
 10. Leclercq WKG, Sloot S, Keulers BJ, Houterman S, Legemaate J, Veerman M, et al. Challenging the knowledge base and skillset for providing surgical consent by orthopedic and plastic surgeons in the Netherlands: an identified area of improvement in patient safety. *Patient Saf Surg.* 2016;10:21. <https://doi.org/10.1186/s13037-016-0110-0>
 11. Cooper L, Mosahebi A, Henley M, Pandya A, Cadier M, Mercer N, et al. Developing procedure-specific consent forms in plastic surgery: lessons learnt. *J Plast Reconstr Aesthet Surg.* 2017;70(3):428-30. <https://doi.org/10.1016/j.bjps.2016.11.015>
 12. Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Informed consent -- why are its goals imperfectly realized? *N Engl J Med.* 1980;302(16):896-900. <https://doi.org/10.1056/NEJM198004173021605>
 13. Shokrollahi K. Request for treatment: the evolution of consent. *Ann R Coll Surg Engl.* 2010;92(2):93-100. <https://doi.org/10.1308/003588410X12628812458851>
 14. Fink AS, Prochazka AV, Henderson WG, Bartenfeld D, Nyirenda C, Webb A, et al. Predictors of comprehension during surgical informed consent. *J Am Coll Surg.* 2010;210(6):919-26. <https://doi.org/10.1016/j.jamcollsurg.2010.02.049>
 15. Clark S, Mangram A, Ernest D, Lebron R, Peralta L. The informed consent: a study of the efficacy of informed consents and the associated role of language barriers. *J Surg Educ.* 2011;68(2):143-7. <https://doi.org/10.1016/j.jsurg.2010.09.009>
 16. Agozzino E, Borrelli S, Cancellieri M, Carfora FM, Di Lorenzo T, Attena F. Does written informed consent adequately inform surgical patients? A cross sectional study. *BMC Med Ethics.* 2019;20(1):1. <https://doi.org/10.1186/s12910-018-0340-z>
 17. Oosthuizen JC, Burns P, Timon C. The changing face of informed surgical consent. *J Laryngol Otol.* 2012;126(3):236-9. <https://doi.org/10.1017/S0022215111003021>
 18. Johnson MR, Singh JA, Stewart T, Gioe TJ. Patient understanding and satisfaction in informed consent for total knee arthroplasty: a randomized study. *Arthritis Care Res (Hoboken).* 2011;63(7):1048-54. <https://doi.org/10.1002/acr.20475>
 19. Raggio BS, Harris WC, Winters RD, Graham HD. Analysis of factors associated with malpractice litigation in rhinoplasty. *The American Journal of Cosmetic Surgery.* 2019;36(3):151-7. <https://doi.org/10.1177/0748806819827408>
 20. Boyll P, Kang P, Mahabir R, Bernard RW. Variables that impact medical malpractice claims involving plastic surgeons in the United States. *Aesthet Surg J.* 2018;38(7):785-92. <https://doi.org/10.1093/asj/sjx182>
 21. Siegel S. Estatística não-paramétrica para ciências do comportamento. 2a ed. Porto Alegre: Artmed, 2006.
 22. Hallock JL, Rios R, Handa VL. Patient satisfaction and informed consent for surgery. *Am J Obstet Gynecol.* 2017;217(2):181.e1-181.e7. <https://doi.org/10.1016/j.ajog.2017.03.020>
 23. Turner P, Williams C. Informed consent: patients listen and read, but what information do they retain? *N Z Med J.* 2002;115(1164):U218. PMID: 12552294
 24. Instituto Brasileiro de Geografia e Estatística. Pesquisa Nacional por Amostra de Domicílios Contínua. Acesso à internet e à televisão e posse de telefone móvel celular para uso pessoal 2017. Rio de Janeiro: Instituto Brasileiro de Geografia e Estatística, 2018. Available from: https://biblioteca.ibge.gov.br/visualizacao/livros/liv101631_informativo.pdf
 25. Conselho Regional de Medicina do Estado de São Paulo. CREMESP divulga levantamento inédito sobre cirurgia plástica e procedimentos estéticos. CREMESP. 2008;253(10). Available from: http://www.cremesp.org.br/library/modulos/noticias/pdf/processos_plastica_2008.pdf

