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ORIGINAL CONTRIBUTION

Personalized video consent in Blepharoplasty: A new paradigm in the preoperative consent giving process

Debraj Shome MD, FRCS, FACS, FAACS, MBA[1] | Komal Doshi MDS[2] | Sapna Vadera MDS[2] | Vaibhav Kumar MDS[3] | Supriya S. Vyavahare MDS[4] | Rinky Kapoor MD[5]

[1]Department of Facial Plastic & Facial Cosmetic Surgery & Director, The Esthetic Clinics, Mumbai, India

[2]Department of Facial Plastic Surgery and Facial Cosmetic Surgery, The Esthetic Clinics, Mumbai, India

[3]Clinical Research Coordinator, The Esthetic Clinics, Mumbai, India

[4]Faculty, Late Shri Yashwantrao Chavan Memorial Medical & Rural Development Foundation's Dental College, Ahmednagar, India

[5]Department of Dermatology, Cosmetic Dermatology & Dermato-Surgery, The Esthetic Clinics, Mumbai, India

Correspondence
Debraj Shome, MD, FRCS, FACS, FAACS, MBA, Consultant Facial Plastic & Facial Cosmetic Surgeon, The Esthetic Clinics, Mumbai, India.
Email: debraj.shome@theestheticclinic.com

Abstract

Background: Informed consent is not simply the signing of a form by the patient but more significantly, a process of an in-depth communication between the doctor and the patient.

Aim: The written informed consent process typically involves reading a lengthy document involving the medical terms which at times lead to misinterpretation. Therefore, the current research envisages assessing the effectiveness and acceptability of the video consent tool athwart the traditional written consent procedure.

Methods: A retrospective questionnaire study was carried out with 30 patients posted for Blepharoplasty surgery between ages of 18–50 years. They were divided into two groups randomly. All the participants were given written consent. Video consent was taken additionally for group 2 subjects. All the participants received pre-validated questionnaire. The evaluation scale used was a 5-point Likert scale.

Results: People with video consent group were more satisfied with the consent process. It was noted that all the patients who received video consent were happier and understood the consent process better than patients with written consent only.

Conclusion: The inference drawn from our study depicts that video consent is not just easy to understand and clarifies the doubts associated with the surgery but also significantly reduces the anxiety of the patient preoperatively. Also, in other 'quality of life' improving cosmetic procedures including rhinoplasty, face lift surgeries, jaw surgeries, botox, fillers, lasers etc., video consenting tool can be used to a maximum benefit. It is strongly recommended to adopt the practice of taking video consent format in all forms of cosmetic procedures.

KEYWORDS
blepharoplasty, cosmetic surgery, eyelid Surgery, personalized video consent, preoperative consent

1 | INTRODUCTION

Medical professionals have a tripartite legal, moral, and contractual duty to provide the best of the treatment to the patients. In today's era, it is imporatant that the patients are no longer pushed under the paternalistic umbrella of medical professionals, but a doctor is obliged to reveal all the knowledge to the patients in an intelligible manner so that based on the information, the patients can make their decisions.[1]

The term consent means voluntary and mutual agreement; enforcement or permission.[2] The first articulation of this basic principle, in view of protecting the human rights of the subjects involved in the clinical trials, based on sovereignty has been found in the Nuremberg Code of 1947. Likewise, the Helsinki Declaration adopted by the World Medical Association in 1964 emphasized the value of obtaining freely informed consent for medical study.[3]

The concept of personal liberty referred to in article 21 of the Indian constitution is of the widest variety and encompasses a broad range of rights, including the right to live. Thus, every human being has a right to decide what shall be done with his or her own body.[4]

Informed consent is not simply the signing of a consent form by the patient but more significantly, it is a process of an in-depth communication between the doctor and the patient.[5] It is indeed an agreement for an opportunity to decide regarding the best possible care in disease processes so that the patient can make a reasonable voluntary decision regarding what he/she wants to do. Majorly used consent procedures are verbal and written consent.[6]

Most of the patients have limited knowledge about the legal consequences of signing or not signing the consent forms and do not consider written consent as being solely in their interests.[7] Preoperative informed consent ought to be taken in the manner which properly delineate the procedures and is defined to the patients so that he or she understands the procedure and also the risks concerned, thereby agreeing on voluntary basis.[5] In the current era of increased awareness; patients want to seek more and more information about their operative procedure. The information given should not only be simple but it must be detailed and balanced.[8]

The written informed consent process typically involves reading a lengthy document about the details of the procedure being performed mostly involving the medical terms which at times lead to misinterpretation by the patients[9] hence, they may sometimes claim that they put their signatures without fully reading and understanding the content.[7] Busy preoperative clinics, inadequate communication techniques and skills, unanswered questions, anxiety, and poor comprehension are all obstacles for the patients not to retain the actual knowledge.[2] The written informed consent process is typically a key potential obstruction towards research participation, especially for older adults and minorities.

Health professionals need to be knowledgeable of this poor remembrance and may have to think about the modification of the agreement procedure.[10] Innovative approaches to make informed consent simpler and more patient friendly, like video informed consent, may help in overcoming this barriers.[9]

Video consent process may be beneficial to overcome the negative points of the written informed consent since the literacy of Indian population is not that appreciable. All the issues can be resolved with video consent procedure. There are lots of expected advantages of video consent like trustworthiness, transparency, and enhancement in quality of conduct of informed consent process. Most importantly, the process leads to the surgeon being able to reveal at anytime that all relevant details were clarified with the patients, before they agreed to undergo surgery.

Video consent which consists of verbal communication about indications for surgery, associated complications and benefits, alternative treatment options and allow patients to ask questions is not only advantageous for patients but is also beneficial for the doctors.[2] Video consent is a legitimate choice for participants who are not comfortable in reading and writing. In such cases, the researcher should record the reading of a consent statement, and the response of the participants demonstrating willingness to participate. The recording verifies informed oral consent.[11]

Blepharoplasty surgery is performed to correct changes to the eyelid caused by aging or genetic disposition. It is one of the most widely performed in cosmetic surgery procedures. However, it is also perceived as one of the unpredictable procedure amongst all the facial surgeries. Surgical success depends primarily on meeting the patients' expectations and achieving a uniform, symmetrical appearance after the operation. Blepharoplasty is a surgical intervention with a high success rate. The success rate in the various studies was identified at ratio of 91%–95%. Though, the overall rating for dissatisfaction of Blepharoplasty surgery is related to asymmetry. Therefore, it is essential to understand patient's expectations before the Blepharoplasty procedure, follow-up needed, time needed for complete healing and major/ minor complications.[12] On literature review, a limited number of experiments were found suggesting the efficacy of the video consent technique in the global population. Also, there was paucity of data showing usage of a video informed consent tool in Blepharoplasty Surgery.[12,13]

Also, apart from blepharoplasty, in other 'quality of life' improving cosmetic procedures including but not limited to rhinoplasty, chin/cheek augmentation, face lift surgeries, jaw reshaping surgeries, botox, fillers, threads and laser procedures, video consenting tool can be used to a maximum benefit. As these surgeries are done with the expectation of more esthetic results rather than to bring the quality of life back to normal, the given tool could be utilized to keep the expectations realistic. It is strongly recommended to adopt the practice of taking video consent format in not only blepharoplasty but in all form of cosmetic surgeries where recording of patient's expectations along the expected results with complications is necessary.

The aim of the current research envisages assessing the effectiveness and acceptability of the information provided by utilization of the video consent tool athwart the traditional written consent procedure for blepharoplasty of upper and lower eyelid.

2 | AIM

To investigate the utility and acceptability of a personalized video consent to enhance patient satisfaction in the preoperative consent giving process for blepharoplasty of upper and lower eyelid.

3 | MATERIALS AND METHODS

A retrospective questionnaire based study was carried out after validation of tools and ethical approval. And the study adheres to the ethical principles outlined in the Declaration of Helsinki as amended in 2013. A total of 30 patients posted for upper and lower lid Blepharoplasty surgery under general anesthesia from 1st July 2018 to 31st December 2019 and between age group of 35–70 years were included in the study.

3.1 | Data collection tools and procedure

Data was collected through a pretested, structured and self-administered questionnaire via an in-depth interview and focus group discussions as methods and tools. Details of questionnaire are mentioned in Table 1. The questionnaire was internally validated by conducting focus group discussion by subject experts including two oculo-plastic surgeons. The demographic characteristics of participants including age, gender, occupation and marital status were recorded.

The participants were divided into two groups (1 and 2) randomly. Participants in both the groups were given written consent. Video consent was taken additionally for group 2 subjects.

Written consent was a detailed consent contained all the information regarding surgery like indication of the surgery, type of anesthesia, possible complications related to surgery also postoperative care and follow-up. It also included hospital stay, cost and follow-up visits. For group 2 patients additional video consent has been taken regarding same. Process of video consent was taken in a manner in which a patient and doctor was being recorded on a camera with patients permission while doctor explained about the whole process verbally regarding the surgery, indications, other options, pros and cons of this procedure, type of anesthesia, complications, postoperative care, follow-up. Also in the end patient were asked if they have understood everything, any questions they have and if they are willingly giving consent for the surgery. Thus, it was not only a reading of written consent matter but was taken as an interactive session before surgery. To evaluate the anxiety level of both groups, we have used VAS-A (Visual analog scale for anxiety) scale. All the participants from both the group received pre-validated questionnaire. The evaluation scale used was a 5-point Likert scale, with 0 indicating least satisfaction and 5 indicating maximum satisfaction score.

3.2 | Inclusion criteria

1. Patients scheduled to undergo upper and lower lid Blepharoplasty under general anesthesia.

TABLE 1 Pre-validated questionnaire

No.	Questionnaire
1	Was the Blepharoplasty surgical procedure explained to you satisfactorily?
2	Was the consent useful to understand about your expectation after the Blepharoplasty procedure?
3	Did the consent help to make you understand the details about your surgery in a better way?
4	Did the consent make you aware about the risks related to Blepharoplasty surgery?
5	Was the consent helpful to understand about the benefits of the Blepharoplasty procedure?
6	Was the consent helpful in understanding the reason behind the Blepharoplasty procedure?
7	Did you feel consent improved your understanding regarding the postoperative complications related to the surgery?
8	Did the consent help to reduce your anxiety?
9	When you were done with the consent process, were you able to solve all your queries?
10	Were you explained about the postoperative instructions that need to be taken care of?
11	Were you given the opportunity to ask questions during the consent related to the procedure?
12	Was the consent helpful in stating the success rate of the Blepharoplasty surgery procedure?
13	Did the consent explained about the Blepharoplasty procedure in a way that you can basically explain to another person how it would occur?
14	Were you informed about the alternatives to the Blepharoplasty procedure?
15	Were you informed about possible consequences of not having the Blepharoplasty surgery?
16	Were you comfortable with the terms used in the consent?
17	Were you satisfied with the consent procedure before surgery?
18	Did you get all the information by the consent which was required to make a good decision about the Blepharoplasty procedure?

	Gender	Age range (years)	*N* (%)	Age (mean ± SD)	BMI (mean ± SD)
Group 1 (*N* = 15)	Male	35–70	7 (23.3%)	39.76 ± 2.36	24.7 ± 1.64
	Female		8 (26.7%)	46.4 ± 1.25	23.69 ± 2.19
Group 2 (*N* = 15)	Male		9 (30.0%)	38.9 ± 2.79	25.5 ± 1.41
	Female		6 (20.0%)	47.1 ± 1.01	27.51 ± 2.13

N, number of patients; SD, standard deviation.

TABLE 2 Demographic distribution according to the gender, age and BMI for the two groups (Group 1—Written consent and Group 2—Written + Video consent)

TABLE 3 Descriptive statistics using Median of the two groups (Group 1—Written consent and Group 2—Written + Video consent) for the perception of the response according to Liker scale

Questions	Group 1	Group 2
Q 1	2.0	4.0
Q 2	2.0	4.0
Q 3	2.0	4.0
Q 4	3.0	5.0
Q 5	2.0	4.0
Q 6	2.0	4.0
Q 7	2.0	4.0
Q 8	2.0	5.0
Q 9	2.0	5.0
Q 10	2.0	4.0
Q 11	2.0	5.0
Q 12	3.0	4.0
Q 13	2.0	4.0
Q 14	2.0	4.0
Q 15	2.0	4.0
Q 16	2.0	5.0
Q 17	3.0	4.0
Q 18	2.0	5.0

2. Patients between the age group of 35–70 years.
3. Conscious, co-operative patients and having capacity to make informed decision.
4. Patients with minimum education with higher secondary have been included.

3.3 | Exclusion criteria

1. Participants with visual or hearing impairment which may inhibit the ability to review the consent video.
2. Patients with intellectual disability and/or lack of capacity due to age or other co-morbidities and who would ordinarily require a third party to sign consent.
3. Patients with a language barrier such that an interpreter was required.

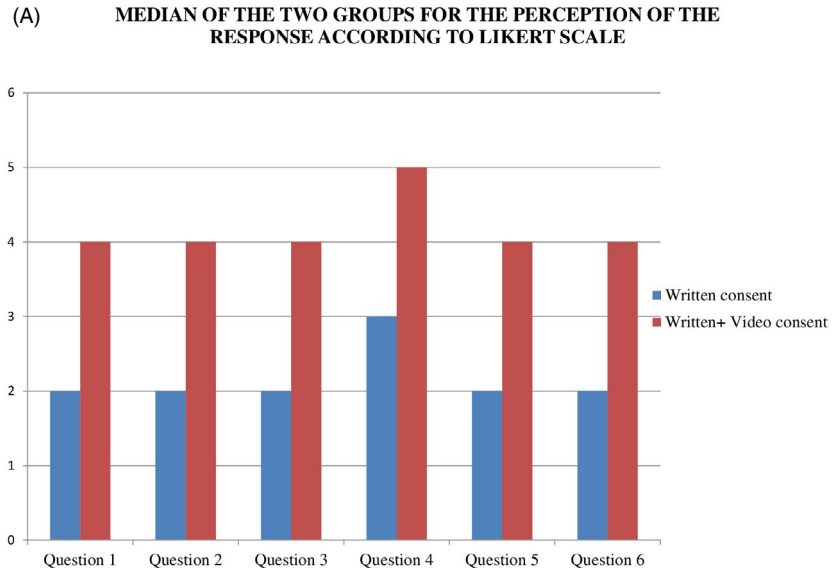
3.4 | Statistical analysis

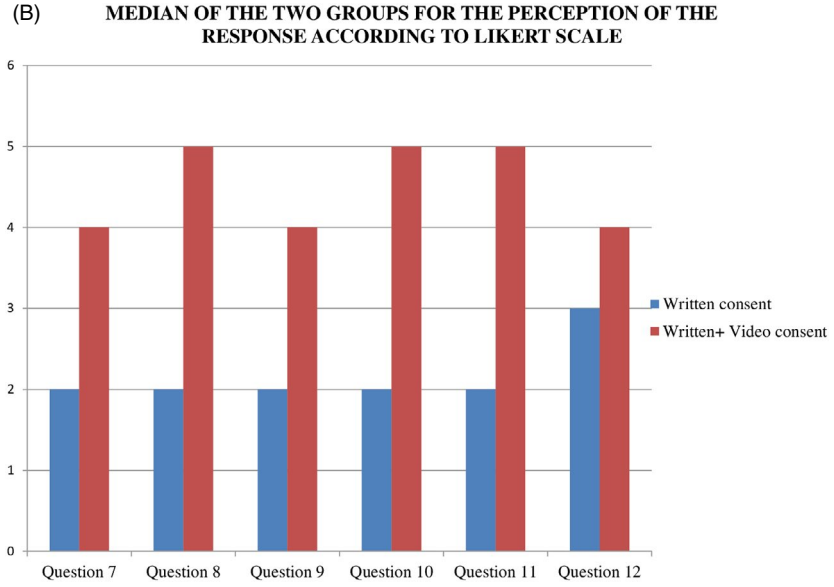
Data were first checked manually for completeness and then coded and entered into Microsoft excel. Independent variables like age of the participants and gender were represented in mean and percentage distribution, and other variables from the questionnaire were calculated using chi-square test at 5% level of significance. The software used was IBM SPSS Statistics for Windows version 21.0. IBM Corp.

4 | RESULTS

A single-center, randomized, comparative pilot study was conducted including 30 patients undergoing upper and lower lid Blepharoplasty procedure under general anesthesia. They were divided randomly into two groups—Group 1—Written consent and Group 2—Written + Video consent. Table 2 illustrates the Group-wise demographic distribution of the participants as per gender, their mean age and mean BMI. The study participants included 16 males and 14 females in the age group of 35–70 years descriptive statistics using the values demographic details of the study participants. Participants were randomly divided into two groups. Prior to consenting to take part, all patients received a Participant Information Sheet (PIS). All the participants in both the groups received and were subsequently asked to fill written consent information. In addition to this, patients from group 2 also received an additional video consent in the form of a personalized video consent procedure prior to the surgery. All the participants were given pre-validated questionnaire. Assessment was done on a five-point Likert scale. On a scale of 0–5 points, patient responded each question with 0 indicating least satisfied and 5 indicating the most satisfied score based on their satisfaction about consent procedure.

Descriptive statistics for Likert Scale (Table 3, Figure 1) showed that the median scores (perception for Likert scale are categorical/ordinal we take median) for the Group 2 was more showing higher satisfaction by the patients as compared to Group 1. The comparative association and frequency distribution for response of the patients was done using chi-square test (Table 4) with 5% level of significance. It showed that the difference between the groups was highly significant for all the questions except for the Q 12 that stated role of consent in explaining the success rate of the Blepharoplasty surgery procedure (0.086) Furthermore to check the normality of





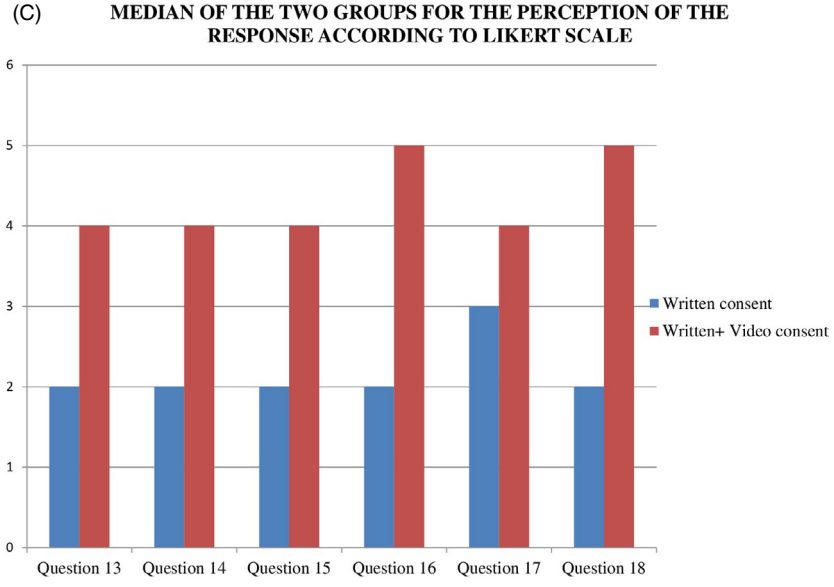


FIGURE 1 (A, B, C) Descriptive statistics using Median of the two groups (Group 1—Written consent and Group 2—Written + Video consent) for the perception of the response according to Likert scale

TABLE 4 Comparison of the two groups (Group 1—Written consent and Group 2—Written + Video consent) for the response of Questions using Chi-Square test

	Groups				
Likert scale	**Group 1**	**Group 2**	X^2	***df***	***p* value**
Q. 1: Was the Blepharoplasty procedure explained to you satisfactorily?					
1	1 (6.7%)	0	24.00	4	<0.001*
2	11 (73.3%)	0			
3	3 (20.0%)	3 (20.0%)			
4	0	10 (66.7%)			
5	0	2 (13.3%)			
Total	15 (100%)	15 (100%)			
Q. 2: Was the consent useful to understand about your expectation after the Blepharoplasty procedure?					
1	4 (26.7%)	0	27.33	4	0.002*
2	10 (66.7%)	0			
3	1 (6.7%)	2 (13.3%)			
4	0	7 (46.7%)			
5	0	6 (40.0%)			
Total	15 (100%)	15 (100%)			
Q. 3: Did the consent help to make you understand the details about your surgery in a better way?					
1	2 (13.3%)	0	25.20	4	0.001*
2	11 (73.3%)	0			
3	2 (13.3%)	3 (20.0%)			
4	0	5 (33.3%)			
5	0	7 (46.7%)			
Total	15 (100%)	15 (100%)			
Q. 4: Did the consent made you aware about the risks related to Blepharoplasty surgery?					
1	2 (13.3%)	0	26.44	4	0.002*
2	5 (33.3%)	0			
3	8 (53.3%)	1 (6.7%)			
4	0	6 (40.0%)			
5	0	8 (53.3%)			
Total	15 (100%)	15 (100%)			
Q. 5: Was the consent helpful to understand about the benefits of the Blepharoplasty procedure?					
1	3 (20.0%)	0	26.80	4	<0.001*
2	8 (53.3%)	0			
3	4 (26.7%)	1 (6.7%)			
4	0	10 (66.7%)			
5	0	4 (26.7%)			
Total	15 (100%)	15 (100%)			
Q. 6: Was the consent helpful in understanding the reason behind the Blepharoplasty procedure?					
1	2 (13.3%)	0	24.29	4	0.001*
2	8 (53.3%)	0			
3	5 (33.3%)	2 (13.3%)			
4	0	7 (46.7%)			
5	0	6 (40.0%)			
Total	15 (100%)	15 (100%)			
Q. 7: Did you feel consent improved your understanding regarding the postoperative complications related to the surgery?					

(Continues)

TABLE 4 (Continued)

Likert scale	Groups		X^2	*df*	*p* value
	Group 1	Group 2			
1	4 (26.7%)	0	24.00	4	<0.001*
2	8 (53.3%)	0			
3	3 (20.0%)	3 (20.0%)			
4	0	7 (46.7%)			
5	0	5 (33.3%)			
Total	15 (100%)	15 (100%)			
Q. 8: Did the consent help to reduce your anxiety?					
1	4 (26.7%)	0	30.00	4	0.001*
2	8 (53.3%)	0			
3	3 (20.0%)	0			
4	0	6 (40.0%)			
5	0	9 (60.0%)			
Total	15 (100%)	15 (100%)			
Q. 9: When you were done with the consent process, were you able to solve all your queries?					
1	3 (20.0%)	0	27.00	4	<0.001*
2	9 (60.0%)	0			
3	3 (20.0%)	1 (6.7%)			
4	0	8 (53.3%)			
5	0	6 (40.0%)			
Total	15 (100%)	15 (100%)			
Q. 10: Were you explained about the postoperative instructions that need to be taken care of?					
1	3 (20.0%)	0	30.00	4	<0.001*
2	9 (60.0%)	0			
3	3 (20.0%)	1 (6.7%)			
4	0	8 (53.3%)			
5	0	6 (40.0%)			
Total	15 (100%)	15 (100%)			
Q. 11: Were you given the opportunity to ask questions during the consent related to the procedure?					
1	7 (46.7%)	0	30.00	3	0.001*
2	8 (53.3%)	0			
4	0	7 (46.7%)			
5	0	8 (53.3%)			
Total	15 (100%)	15 (100%)			
Q. 12: Was the consent helpful in stating the success rate of the Blepharoplasty surgery procedure?					
2	2 (13.3%)	0	6.60	3	0.086
3	7 (46.7%)	3 (20.0%)			
4	6 (40.0%)	10 (66.7%)			
5	0	2 (13.3%)			
Total	15 (100%)	15 (100%)			
Q. 13: Did the consent explained about the Blepharoplasty procedure in a way that you can basically explain to another person how it would occur?					

(Continues)

TABLE 4 (Continued)

Likert scale	Groups		X^2	*df*	*p* value
	Group 1	Group 2			
1	3 (20.0%)	0	24.68	4	<0.001*
2	8 (53.3%)	0			
3	4 (26.7%)	2 (13.3%)			
4	0	8 (53.3%)			
5	0	5 (333.3%)			
Total	15 (100%)	15 (100%)			
Q. 14: Were you informed about the alternatives to the Blepharoplasty procedure?					
1	4 (26.7%)	0	21.70	4	<0.001*
2	7 (46.7%)	0			
3	3 (20.0%)	2 (13.3%)			
4	1 (6.7%)	7 (46.7%)			
5	0	6 (40.0%)			
Total	15 (100%)	15 (100%)			
Q. 15: Were you informed about possible consequences of not having the Blepharoplasty surgery?					
1	3 (20.0%)	0	27.00	4	<0.001*
2	11 (73.3%)	0			
3	1 (6.7%)	3 (20.0%)			
4	0	8 (53.3)			
5	0	4 (26.7%)			
Total	15 (100%)	15 (100%)			
Q. 16: Were you comfortable with the terms used in the consent?					
1	2 (13.3%)	0	30.00	4	<0.001*
2	12 (80.0%)	0			
3	1 (6.7%)	0			
4	0	3 (20.0%)			
5	0	12 (80.0%)			
Total	15 (100%)	15 (100%)			
Q. 17: Were you satisfied with the consent procedure before surgery?					
2	6 (40.0%)	0	17.71	3	0.001*
3	8 (53.3%)	3 (20.0%)			
4	1 (6.7%)	8 (53.3%)			
5	0	4 (26.7%)			
Total	15 (100%)	15 (100%)			
Q. 18: Did you get all the information by the consent which was required to make a good decision about the Blepharoplasty procedure?					
1	7 (46.7%)	0	30.00	3	0.001*
2	8 (53.3%)	0			
4	0	4 (26.7%)			
5	0	11 (73.3%)			
Total	15 (100%)	15 (100%)			

Abbreviations: *df*, degree of freedom; X^2, Chi-square coefficient.
*Highly significant.

the data, Shapiro-Wilk test (Table 5) was used. (Since the sample size is less than 50).

It was observed that the *p* value was <0.05, the data significantly deviated from a normal distribution. Hence, for the further comparison between the two groups, Mann Whitney *U*-test was used. (Table 6) It was observed that the results were statistically significant. The software used was IBM SPSS Statistics for Windows version 21.0. IBM Corp.

TABLE 5 Test of Normality using Shapiro-Wilk test for the two groups (Group 1—Written consent and Group 2–Written + Video consent)

Groups	Statistic	*df*	*p* value
QUE 1			
1	0.694	15	<0.001*
2	0.763	15	0.001*
QUE 2			
1	0.734	15	0.001*
2	0.798	15	0.003*
QUE 3			
1	0.716	15	<0.001*
2	0.783	15	0.002*
QUE 4			
1	0.755	15	0.001*
2	0.744	15	0.001*
QUE 5			
1	0.815	15	0.006*
2	0.734	15	0.001*
QUE 6			
1	0.801	15	0.004*
2	0.798	15	0.003*
QUE 7			
1	0.815	15	0.006*
2	0.817	15	0.006*
QUE 8			
1	0.815	15	0.006*
2	0.630	15	<0.001*
QUE 9			
1	0.799	15	0.004*
2	0.766	15	0.001*
QUE 10			
1	0.734	15	<0.001*
2	0.561	15	<0.001*
QUE 11			
1	0.643	15	<0.001*
2	0.643	15	<0.001*
QUE 12			
1	0.798	15	0.003*
2	0.763	15	0.001*
QUE 13			
1	0.815	15	0.006*
2	0.801	15	0.004*
QUE 14			
1	0.868	15	0.031**
2	0.798	15	0.003*
QUE 15			
1	0.694	15	<0.001*
2	0.815	15	0.006*
QUE 16			
1	0.631	15	<0.001*
2	0.499	15	<0.001*
QUE 17			
1	0.766	15	0.001*
2	0.815	15	0.006*
QUE 18			
1	0.643	15	<0.001*
2	0.561	15	<0.001*

*Highly significant.; **Significant.

5 | DISCUSSION

Medico-legal jurisprudence is increasing day by day and it is the right of every patient to have an in-depth knowledge about the treatment being rendered to them. The Informed consent process has the onus to safeguard the doctors' and patients' understanding while rendering or receiving any treatment or investigation.[1] Informed consent is a legal and ethical concept that is necessary prior to any intervention that may infringe autonomy.[2] A surgeon who conducts a surgery without the patient's consent commits an offense for which he might be legally responsible.[4]

In today's era, all over the world, consent is not just a hospital formality, but a procedure, which offers dignity to the patient by giving thoughtful consent.[6] The prospect of surgery is frequently a daunting one, and anxiety can be mitigated to a certain extent by a clear and thorough informed consent process. Thereby, helping the patients to grasp what is involved, as well as understands the potential complications with their respective incidences so as to make logical and rational decision.[8] The information should be simple and summarizing, and should emphasize possible complications to allow the patient to decide whether to undergo or decline a particular procedure.[5]

Written informed consent has its own restriction for patients to understand. Also, they may seem to be comprehensive to the patients owing to limited literacy and/or limited English proficiency, and misinterpretation with the vocabulary use.[9] In many ways, the lengthy and complex informed consent forms currently in use are designed more to document disclosures about risks, benefits, and alternatives to study participation than to truly inform participants.[3]

Enhancements in digital technology are driving changes in information practice.[2] The implementation of a video consent tool can therefore be considered as a beneficial change compared to the conventional consent approaches. The patient-clinician conversation can be recorded, registered, and preserved for future reference.[2]

In a study by Jawaid et al. on patient's perception of written informed consent, it was evaluated and interpreted that 34% of the patients said they were not aware of what the surgery itself consisted

TABLE 6 Comparison between the two groups (Group 1—Written consent and Group 2–Written + Video consent) using Mann Whitney *U*-test

Groups	*N*	Mean rank	Sum of ranks	*Z*	*p* value
QUE 1					
1	15	8.30	124.50	−4.705	<0.001*
2	15	22.70	340.50		
Total	30				
QUE 2					
1	15	8.07	121.00	−4.770	0.001*
2	15	22.93	344.00		
Total	30				
QUE 3					
1	15	8.20	123.00	−4.711	<0.001*
2	15	22.80	342.00		
Total	30				
QUE 4					
1	15	8.27	124.00	−4.636	<0.001*
2	15	22.73	341.00		
Total	30				
QUE 5					
1	15	8.13	122.00	−4.735	<0.001*
2	15	22.87	343.00		
Total	30				
QUE 6					
1	15	8.33	125.00	−4.579	0.001*
2	15	22.67	340.00		
Total	30				
QUE 7					
1	15	8.30	124.50	−4.585	0.002*
2	15	22.70	340.50		
Total	30				
QUE 8					
1	15	8.00	120.00	−4.803	0.001*
2	15	23.00	345.00		
Total	30				
QUE 9					
1	15	8.10	121.50	−4.739	<0.001*
2	15	22.90	343.50		
Total	30				
QUE 10					
1	15	8.00	120.00	−4.892	<0.001*
2	15	23.00	345.00		
Total	30				
QUE 11					
1	15	8.00	120.00	−4.819	<0.001*
2	15	23.00	345.00		
Total	30				

(Continues)

TABLE 6 (Continued)

Groups	N	Mean rank	Sum of ranks	Z	p value
QUE 12					
1	15	11.90	178.50	−2.486	0.013**
2	15	19.10	286.50		
Total	30				
QUE 13					
1	15	8.27	124.00	−4.618	<0.001*
2	15	22.73	341.00		
Total	30				
QUE 14					
1	15	8.57	128.50	−4.416	0.001*
2	15	22.43	336.50		
Total	30				
QUE 15					
1	15	8.10	121.50	−4.782	<0.001*
2	15	22.90	343.50		
Total	30				
QUE 16					
1	15	8.00	120.00	−4.998	<0.001*
2	15	23.00	345.00		
Total	30				
QUE 17					
1	15	9.27	139.00	−4.056	<0.001*
2	15	21.73	326.00		
Total	30				
QUE 18					
1	15	8.00	120.00	−4.871	<0.001*
2	15	23.00	345.00		
Total	30				

Note: Z, Test coefficient.

*Highly significant.; **Significant.

of. It was also reported that 31% of the patients stated that they would have liked more information about the surgery.[5] One in 10 patients reported that they had no knowledge of what they agreed to when they signed the consent form.[7]

In our study, 6.7% of the Group 1 patients were not satisfied about the procedure they were undergoing (Table 4, Que 1) and 13.3% of the patients said that the consent was unable to make them understand the details regarding the surgery (Table 4, Que 3). However, in our study all the patients' in the video consent group were satisfied about the procedure they were undergoing (Table 4, Que 1) and 46.7% of the patients understood and were satisfied with the explanation about the surgery (Table 4, Que 2). The results were significant.

Jawaid et al. conducted a study to assess the preoperative informed consent practice. Patients were given a series of common questions related to the knowledge they had received prior to surgery as part of the formal informed consent protocol. It was mentioned that 87.7% of the patients were informed about their condition but only few (3.4%) were briefed regarding the complications that may arise. Only 4.9% patients said they knew about the risks and complications of proposed anesthesia. Less than 39.4% of patients marked that they were allowed to ask questions before giving consent and only 48.9% of the interviewees were satisfied with the information they gained from the informed consent.[5] McKeague et al. also carried out a pilot study to find out the adequacy of written informed consent for elective general surgery procedures. Patients were interviewed with questionnaire before and after the surgery. One third of the patients were unable to mention even a single complication of the planned surgical procedure.[13]

In our study, we asked the participants about understanding of the procedure (Que 2) and got the mean value score of 2.0 and 4.0 in group 1 and 2 respectively. We also asked the questions pertaining to the risks, benefits, and postoperative complications (Que 4, 5, and 7) related to the Blepharoplasty surgery. The mean value (as

per Likert scale) for the question related to the awareness regarding the risks involved with the surgery was 3.0 and 5.0 for group 1 and 2 respectively. Similarly, the mean value of questions regarding awareness of benefits and postoperative complications were 2.0 and 4.0 for group 1 and 2 respectively. All these values were found to be significant as per chi-square test and difference is clearly depicts more understanding of group 2 patients.

Osuna et al. demonstrated in their study that patients were not satisfied with the information they were provided. They did sign the consent form but felt that they have not fully understood the risks involved with the surgery and anesthesia.[14] In our study, we got higher satisfaction rate related to explanation about procedure in group 2. Mean value for the question related to satisfaction regarding the consent procedure group 1 and 2 was 2.0 and 5.0 respectively.

Manta et al. conducted a study aimed to gather qualitative feedback on patient perceptions of informed consent forms. Sixty interviews were conducted, comprised of a literacy and numeracy evaluation, a comprehension questionnaire to test the acquisition of knowledge, and open-ended questions to evaluate responses. Although 68% of participants had schooling beyond high school, others lacked their grasp of the problems and considered the forms challenging to learn. Recurrent recommendations included: basic design improvements to increase readability, the need for extra sources of information.[15] In our study, we have included patients with minimum higher secondary education in both the groups to eliminate the bias for understanding of written consent related to education.

A retrospective study carried out by Shome et al. to evaluate the acceptability of video consent process for Rhinoplasty surgery also confirms more acceptability, and increased patients' understanding and satisfaction with Video consent group.[16] In our study, we asked the patients if they were satisfied with the terms used in the consent. The mean value on Likert scale for group 2 (5.0) was higher than group 1 (2.0) and was significant. We questioned the participants about the satisfaction of the words used in the consent, and the mean value of Group 1 was 2.0 and 5.0 of Group 2. Also, it was interesting to find out that the video consent helped in reducing the anxiety levels of the patients significantly (mean value of 2.0 for group 1 and 5.0 for group 2).

There have been several medico-legal cases reported in different parts of the world, including countries such as India, where people have expressed lack of understanding related to the written consent procedure including unanswered questions asked by the patients. The video consent can change this dramatically as it can be recorded in a language that patient understands and also it has the ability to record and save patients responses, hence it is probably more legally appropriate to prove that patient understood it well and all the queries were addressed.

The video consenting could be an authentic tool to make it certain that conduct is given more value over mere documentation of the entire course of action. Further, the same can also be used as evidence in the court of law. In case of any dispute/ litigation post-surgery, the surgeon would have a proven data to show that sufficient measures were acquired for consent rather than simply rely on the signed written informed consent and the documented narrative.[17]

In our study, all the patients who received video consent were happy to recommend it to others requiring preoperative video consent procedure, indicating that they were more satisfied and it would be acceptable for further use.

6 | CONCLUSION

The inference drawn from our study depicts that video consent is not just easy to understand and clarifies the doubts related to risks, benefits and postoperative complications associated with the surgery but also significantly reduces the anxiety level of the patient prior to surgery. It can be an easily acceptable tool for use, particularly in complex surgeries where decision-making and coordination can be more difficult for both the clinician and the patient. Because it is an interactive process, it is much more legitimately valid. We would therefore say that video consent is a new concept of the preoperative consent process.

To the best of our knowledge, this research is the first of its kind to include customized video consent as a tool in preoperative consent taking process. It certainly demands a greater sample size, as our analysis is constrained in the range and sampling size. Further research may also try to evaluate the views of patients within other surgical specialties.

CONFLICT OF INTEREST

The authors state no conflict of interests.

AUTHOR CONTRIBUTION

Dr. Debraj Shome: Research project: Conception, Execution, Manuscript: Review and Critique. Dr. Komal Doshi: Research project: Organization, Manuscript: Writing of the first draft. Dr. Vaibhav Kumar: Manuscript: Writing of the first draft. Dr. Sapna Vadera: Manuscript: Review and Critique. Dr. Rinky Kapoor: Manuscript: Review and Critique.

ETHICAL STATEMENT

The ethical clearance has been taken from the review board of the Institutional Ethics Committee of the Esthetic Clinics.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ORCID

Debraj Shome https://orcid.org/0000-0003-2163-1170

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