

Knowledge and awareness of informed consent among orthodontists and patients: A pilot study

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Abstract

Aim: Despite fixed professional opinion of what might constitute optimal treatment, patients must be informed of the various treatment options available in orthodontics to manage their clinical problem. The purpose of this study was to compare and evaluate the knowledge and awareness among practicing orthodontists and patients with regard to informed consent in clinical practice and research. **Materials and Methods:** Twenty-five orthodontists and 25 patients were enrolled in a questionnaire study which was descriptive and cross-sectional in the nature. The questionnaire focused on the following aspects; contents of informed consent, at what age and who can give consent. **Results:** The study showed a majority of orthodontists (79.14%) were aware of knowledge regarding informed consent when compared to patients(35.14%). **Conclusion:** The overall result showed the huge gap that exists between orthodontists and patients and thus making it categorical for patients to be more involved in the decision-making process.

Keywords: Informed consent, orthodontics, questionnaire

Introduction

Orthodontic treatment is a composite of various objective and subjective factors. While objective factors are derived from diagnosis and are definitive, subjective factors depend primarily on esthetics, and psychological considerations.^[1] Orthodontist's view of the subjective factors may vary considerably from patient to parent. So to come to an agreement regarding various procedures, there should be an open dialogue between the orthodontist and the parent-patient party.^[2] Seeking and obtaining this perspective in a clinical setting is possible through informed consent.

The autonomy of individuals lies in the rational concept of informed consent.^[3,4] It is imperative that orthodontists

treat patients with respect and act in their best interests. The three main goals of informed consent process are: To inform individuals of necessary details regarding treatment, to document that the individuals were informed, and to establish individual's voluntary and autonomous decision to participate.^[5] Currently in orthodontics, informed consent forms an integral part of any treatment and research. Adequately informing a patient confirms that the patient-doctor relationship is based on trust. Another important objective of informed consent is the fulfillment of legal obligation by the orthodontist to inform the patient to best of his/her knowledge regarding the clinical situation.^[6] If a patient has not consented to any proposed investigations or treatment, any clinical activity can leave the practitioner open to allegations of negligence for which damages are liable.^[7]

As a clinician, his/her goal should be to bridge the gap between the professional's and patient's point of view and thereby achieve consensus. The objectives of this pilot study were to compare and evaluate the knowledge and awareness of informed consent between orthodontists and patients, to identify the areas where lacuna exists in planning the protocol for obtaining informed consent and thereby suggest changes in clinical situations to better comprehend the role of informed consent for both orthodontists and patients.

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Table 1: The questionnaire**Multiple choice questions**

1. A 12-year-old girl comes to the clinic with spacing and tongue thrust habit. A Hawley's appliance with tongue crib is planned. Choose the most appropriate method of consent from the options given below
 - a. An assent should be taken from the child
 - b. An assent should be taken from the child as well as informed consent from the child's parent or guardian
 - c. A clear description of the procedure should be explained to the child's parent/guardian
 - d. No need to have an assent or informed consent as the treatment is needed and will be helpful for the patient
2. A 20-year-old male patient comes for orthodontic treatment. Extraoral and intraoral photographs are needed to be taken for treatment planning. Choose the most appropriate method of consent for taking photographs
 - a. Only an assent is sufficient
 - b. Informed consent should be taken only if the patient agrees for the treatment
 - c. Informed consent can be taken after the treatment has started
 - d. Informed consent should be taken before taking the photographs, whether the patient is willing for the treatment or not
3. For an orthodontist to judge whether a patient has the capacity to give Informed consent, what must the patient be able to demonstrate after all explanations have been given?
 - a. The information about the proposed treatment is both understood and retained
 - b. The patient can use and weigh this information in the decision-making process
 - c. The patient can leave the final decision to the orthodontist as he/she knows best
 - d. Any suggestions made by the patient cannot be entertained during the decision-making process
4. An 18-year-old female patient comes to the clinic for orthodontic treatment
 - a. The patient's parent has to sign the informed consent for the treatment
 - b. The patient can sign the informed consent for the treatment without the parents
 - c. An assent from the patient and informed consent from the parent is needed
 - d. An informed consent is not needed, since the patient has voluntarily come for the treatment
5. A 15-year-old competent child does not want to undergo orthodontic treatment, but the parents have signed the informed consent and given permission to go ahead with the treatment
 - a. The orthodontist can refuse treatment if the patient is unwilling
 - b. The orthodontist can forcefully make the patient undergo orthodontic treatment since he's already got permission from the child's parents
 - c. Uncertain
6. A 25-year-old male patient mentally challenged, needs orthodontic treatment to improve his overall health
 - a. He can give an informed consent
 - b. His parent/guardian can give an informed consent
 - c. May not be treated as it is a nonemergency situation
 - d. Uncertain
7. A 19-year-old female patient consents to undergo orthodontic treatment against parent's will
 - a. The parents can legally override the consent
 - b. No objections to the treatment can be given by the parents
 - c. The orthodontist can legally refuse treatment
 - d. Uncertain
8. For a patient to be able to consent to a course of orthodontic treatment, the clinician must explain the following
 - i. The risks of proposed treatment
 - ii. The risks and benefits of proposed treatment and alternative treatments
 - iii. The consequences of remaining untreated
 - iv. Other alternative treatment approaches may not be included in the informed consent form
 Choose the right answer
 - a. ii
 - b. i and iii

Contd...

Table 1: Contd...**Multiple choice questions**

- c. iv
d. ii and iii
9. When extraction of all third molars under general anesthesia is to be undertaken as a part of orthodontic treatment, who has the responsibility for obtaining the consent for the procedure of anesthesia
- The anesthetist
 - The orthodontist
 - A separate consent is not needed as the procedure was explained, and an informed consent was taken before starting the orthodontic treatment
 - Uncertain
10. After termination of orthodontic treatment, retainers have to be worn to prevent relapse
- Informed consent is not needed because an explanation is simple enough to be understood by the patient
 - Duration of the retainer wear should be included in the informed consent which is taken before starting the orthodontic treatment
 - Duration of the retainer wear may not be included in the informed consent as it varies; only the indication for retainer wear is sufficient enough to be mentioned
 - Uncertain
11. A 15-year-old male patient has completed his fixed orthodontic mechanotherapy and is in the retention phase. The case can be published in a well-known journal
- An informed consent should be taken from the patient
 - Informed consent from the parent should be taken after the treatment is complete
 - Informed consent should be taken from the parent before and after the orthodontic treatment
 - Uncertain
12. 100 children of both sexes, age range from 8–12 years were randomly selected from the orthodontic outpatient. The examined children will be divided into two groups. One group will have their severe malocclusion corrected while the other group will be kept under observation, and no intervention will be provided to them (control group)
- A clear description of the study should be explained to all children's parent/guardian
 - An assent should be taken from all the children
 - An Assent should be taken from every child as well as written informed consent from the children's parent or guardian for the control group
 - An assent should be taken from every child as well as written informed consent from the children's parent or guardian from both groups
 - An assent should be taken from every child as well as written informed consent from the children's parent or guardian only for the treatment group
 - No need to have an assent or informed consent as the children were already enrolled in the outpatient clinic and ready to receive any type of treatment
13. A study is being conducted on the extracted teeth from the patients who are undergoing orthodontic treatment
- An informed consent should be taken before the teeth are used in the study
 - Informed consent is not needed as they had already agreed to undergo extraction of their teeth before starting the orthodontic treatment
 - An informed consent can be taken before the treatment has started, that any biological sample taken from the patient may be used in the study
 - In clinical practice, studies cannot be conducted on patient's extracted teeth
14. A randomized clinical trial of rapid maxillary expansion is being done in the clinic
- Patients need not be told about the potential risks as they might not enroll in the study
 - Each patient should consent to the treatment as it presents greater than minimal risks
 - A verbal agreement is sufficient as there is no life-threatening situations arising from the study
 - Uncertain
- Likert scale**
15. When a patient returns to start the orthodontic treatment following an examination or assessment, they should be given a written treatment plan?
- Strongly agree; b. Agree; c. Not sure; d. Disagree; e. Strongly disagree

Contd...

Table 1: Contd...**Likert scale**

16. A research on cleft lip/palate patients is to be commenced in a clinical practice, and the informed consent needed for the study has to be reviewed by the research ethics committee
- a. Strongly agree; b. Agree; c. Not sure; d. Disagree; e. Strongly disagree
17. In order to save time in some cases, investigators can start their study without taking informed consent from their subjects
- a. Strongly agree; b. Agree; c. Not sure; d. Disagree; e. Strongly disagree

Materials and Methods

The study was conducted after approval from the Ethical Committee of A. J. Institute of Medical Science, Mangalore. Fifty participants from Dakshina Kannada consisting of 25 orthodontists and 25 patients were included in the study. This questionnaire-based study was descriptive and cross-sectional in nature [Table 1].^[3,7] Subjects who met the inclusion/exclusion criteria were selected by using purposive sampling technique.

Inclusion criteria

- Patients aged between 18 and 35 years
- Patients undergoing orthodontic treatment for duration of 6 months and above
- Orthodontists having private practice
- Orthodontists practicing in Dakshina Kannada district.

Exclusion criteria

- Patients undergoing removable orthodontic therapy
- Patients with any mental illness
- Patients who cannot read or write.

The questionnaire was validated by four subject experts. It was structured and consisted of 14 multiple choice questions (Q1–Q14) and three Likert format statements (Q15–Q17). The Likert format statements consisted of five response choices (strongly agree, agree, not sure, disagree, and strongly disagree). Positive statements were scored from five to one; score five for the most accurate response and score one for the least accurate response. The time taken to complete the questionnaire was 10–15 min. It was found to be clear, feasible, and there was no ambiguity in the language (the patient's questionnaire was replaced with few layman terms). A participant information sheet was provided to all, and an informed consent was taken from each participant before starting the study. The data collected were tabulated and analyzed statistically using Chi-square test and *P* value.

Results

The first part of the study was to compare the results between the two groups with respect to multiple choice questions. Comparison of results (no. of correct answers) between orthodontists and patients is shown in Table 2. Significant differences were seen with respect to Q1, Q4, Q6, and Q9.

Table 2: Comparison of results between orthodontists and patients for multiple choice questions

Question number	Orthodontists		Patients		χ^2	<i>P</i>
	Number of correct answers	n%	Number of correct answers	n%		
Q1	16	64	3	12	14.346	<0.001*
Q2	13	52	15	60	0.325	0.569
Q3	14	56	3	12	10.784	0.001
Q4	20	83.30	8	32	13.176	<0.001*
Q5	17	68	13	52	1.333	0.248
Q6	24	96	13	52	12.578	<0.001*
Q7	17	68	9	36	4.573	0.032
Q8	13	52	9	36	1.299	0.254
Q9	16	64	2	8	17.014	<0.001*
Q10	17	68	9	36	5.128	0.024
Q11	13	52	11	44	0.321	0.571
Q12	16	64	14	56	0.333	0.564
Q13	14	56	7	28	4.023	0.045
Q14	21	84	9	36	12	0.001

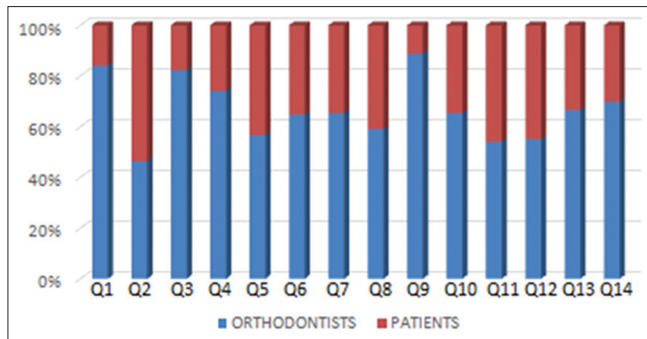
*Statistically significant, *P*<0.001 calculated using Chi-square test

Comparison of total results between orthodontists and patients is shown in Table 3. While orthodontists accounted for 79.14% of correct answers and patients only 35.14%, vast differences were seen between the two groups. From Graph 1 it is clearly seen that except for Q2, significant differences were seen in the answers between the two groups.

The second part of the study was to compare the results between the two groups with respect to Likert scale. Comparison of results between orthodontists and patients is shown in Table 4. Both groups scored above average in Likert scale. Q15 was scored higher by patients than the orthodontists.

Discussion

Adequate information should be provided to the parent-patient party concerning any treatment or intervention that is to be undertaken. This can be achieved through the process of informed consent which will enable them to make a well-informed decision. Not many studies are presently available in the literature to acknowledge the



Graph 1: Comparison of overall results between orthodontists and patients for multiple choice questions. *Q = Question number

lack of awareness that exists about informed consent in orthodontics.

The present study focuses on this concept by designing a questionnaire to reinforce its significance. The investigations revealed that majority of orthodontists (79.14%) were well-informed about the consent process than patients (35.14%) as seen in Table 4. A study conducted by Wardah *et al.*^[2] showed that 99% of the dental practitioners considered informed consent to be an integral part of dentistry and verbal consent (84%) was a favored method of acquiring consent compared to the written form. While verbal consent is generally acceptable for less complex dental procedures; the documentation must be thorough. Since orthodontic treatment is an elective procedure with inherent risks and limitations, written consent is a prerequisite. However, various deterrents like excessive patient overload, fear of refusal of treatment by the patient, or negligence by the orthodontist may make the process of gaining written consent cumbersome.^[8]

Our study was also helpful in identifying key areas where lack of knowledge about informed consent exists among the patients undergoing orthodontic treatment especially with regard to; contents of informed consent, at what age and who can give consent. According to the American Association of Orthodontists, an informed consent for orthodontic treatment should consist of the following details: Results of treatment, length of treatment, presence of discomfort, chances of relapse, and extractions; if needed, orthognathic surgery; if needed, occurrence of decalcification and dental caries, possibilities of root resorption; nerve damage, periodontal diseases; injury from orthodontic appliances, prospect of temporomandibular joint dysfunction, presence of impacted; ankylosed; unerupted teeth, occlusal adjustments; if any, nonideal results, status of third molars, allergies, general health problems, consequences of use of tobacco products, and use of temporary anchorage devices for treatment. It should also contain attached copies of acknowledgement, consent to undergo orthodontic treatment, authorization for release of patient information and consent to the use of records.^[3] The legal age for giving a competent consent in

Table 3: Comparison of overall results between orthodontists and patients for multiple choice questions

Total number of correct answers	Number of correct answers by orthodontists	Number of correct answers by patients
350	277	123
100%	79.14%	35.14%

Table 4: Likert scoring of results between orthodontists and patients

Question number	Orthodontists	Percentage	Patients	Percentage
Q15	90	72	91	72.8
Q16	113	90.4	92	73.6
Q17	100	80	87	69.6

India is 18 years of age or older as per the Indian Majority Act.^[9] For a person below this age, or of unsound mind, his/her guardians/person in whose lawful custody he/she is can give consent.^[10] In our present study, the significant differences seen between the two groups may be attributed to lack of education in school/college curriculum about informed consent as well as inadequate knowledge provided by the orthodontists to patients before starting treatment.

Patient photographs are used for many purposes in orthodontic practice. They are placed in medical records as an adjunct to clinical care, displayed to colleagues, student and audiences in educational setting, and published in medical/dental journals or other media as part of the research. Hood *et al.*^[11] emphasized in his study that “the inherent and electronic publishing are powerful tools for the dissemination of medical information and have created a demand for medical images and that medical images of patient stated, in most circumstances not to be used without consent.” In the digital age, however, the links between images and individuals are complex and nonintuitive. In our study, patients scored higher for Q2 (60%) compared to orthodontists (52%). The reason for this difference could be patient’s awareness toward protecting their privacy and confidentiality especially in this day and age when social media plays a major role in individual’s life. In our study, just half the orthodontists were able to understand the necessity of obtaining consent for records. This could be attributed to the fear of refusal of permission from the patient or oversight by the orthodontist.^[12]

Ernst *et al.*^[13] conducted a study to determine the level of patient and/or parent recall of previous consent to orthodontic treatment. Patients and parents demonstrated a high level of recall for the consent process concerning appliance type (89.8%), the reasons for treatment (96%), risks (75.5%), length of treatment (83.3%), the opportunity to ask questions (96%), and whether other information was provided (94%). However, further questioning on risks demonstrated poor recall for important factors such as

decay (36.8%), root resorption (<21%), retention (56.3%), and length of retention (35%). They concluded that overall the consent process works well but specific areas of concern center around the risks of orthodontic treatment. However, our study showed significant differences regarding the same.

In this study, enlightening the area with more effort is required by the educators and service providers to equip patients with right for information concerning the various protocols needed to be fulfilled, so that the patient is fully aware of all that is to be done before enrolling for orthodontic treatment.

Conclusion

Other than providing a safeguard to the practitioner from medico-legal issues, the process of informed consent will also help to build a good rapport toward the patients and parents. This will further enhance trust and cooperation and thus improve the overall outcome.^[14,15] The present study was an attempt to evaluate the knowledge and awareness among practicing orthodontists and patients in Dakshina Kannada with regard to informed consent in clinical practice. While the results showed that orthodontists were perceptive, it was not the same with patients. The lack of knowledge displayed by the patients as revealed by this investigation will help the orthodontists to develop an effective approach to involving the patient's interest and respecting their decisions along the line of treatment.

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Conflicts of interest

There are no conflicts of interest.

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