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Research Araştırma

Assessment Of The Readability Of Informed Consent Forms Used In An Oral And Maxillofacial Surgery Clinic

Ağız, Diş Ve Çene Cerrahisi Kliniğinde Kullanılan Bilgilendirilmiş Onam Formlarının Okunabilirliğinin Değerlendirilmesi

ABSTRACT

Objective: Informed consent documents should be written in a manner that is easy to read and understand. This study aims to evaluate the readability of informed consent documents utilized before surgical procedures in the department of oral and maxillofacial surgery at a university in Türkiye.

Materials and Method: This study analyzed twenty consent forms used in a university's maxillofacial surgery clinic. The number of sentences, words, syllables, words per sentence, syllables per word, and the frequency of medical terms were calculated for each form. The readability levels of the consent forms were evaluated using the Ateşman formula.

Results: The mean number of words in the consent forms was 11.8, the mean number of syllables was 2.9, and the proportion of medical terms was 3.38. Based on the Ateşman readability formula, the readability scores of the consent documents used in surgery ranged from 37.1 to 68.8. Among the 20 consent forms analyzed, six were deemed 'difficult' in readability, while 14 were rated as 'moderate difficulty'.

Conclusion: Based on study findings, informed consent forms used in oral and maxillofacial surgery are difficult to read and generally require a high school or higher level of education. Given Türkiye's average education level and health literacy rate, it is recommended that consent forms used in oral and maxillofacial surgery be revised to enhance readability.

Key Words: Atesman Readability Formula**,** Informed Consent Form, Oral and Maxillofacial Surgery, Readability.

ÖZ

Amaç: Bilgilendirilmiş onam belgeleri okunması ve anlaşılması kolay bir şekilde yazılmalıdır. Bu çalışmada Türkiye'deki bir üniversitenin ağız, diş ve çene cerrahisi anabilim dalında cerrahi işlemlerden önce kullanılan aydınlatılmış onam belgelerinin okunabilirliğinin değerlendirilmesi amaçlanmıştır.

Gereç ve Yöntemler: Bu çalışmada bir üniversitenin çene cerrahisi kliniğinde kullanılan yirmi onam formu analiz edilmiştir. Her form için cümle, kelime, hece, cümle başına kelime, kelime başına hece ve tıbbi terimlerin sıklığı hesaplanmıştır. Onam formlarının okunabilirlik düzeyleri Ateşman formülü kullanılarak değerlendirilmiştir.

Bulgular: Onam formlarındaki ortalama kelime sayısı 11,8, hece sayısı ortalaması 2,9 ve tıbbi terimlerin oranı %3,38 olarak hesaplanmıştır. Ateşman okunabilirlik formülüne göre onam formlarının okunabilirlik puanları 37,1 ile 68,8 arasında değişmiştir. İncelenen 20 onam formu arasında 6'sı "zor" iken 14'ü "orta zorluk" seviyesinde idi.

Sonuç: Çalışma bulgularına göre, oral ve maksillofasiyal cerrahide kullanılan bilgilendirilmiş onam formları okunması zor formlardır ve genellikle lise veya daha yüksek eğitim seviyesi gerektirir. Türkiye'nin ortalama eğitim seviyesi ve sağlık okuryazarlığı oranı göz önüne alındığında, oral ve maksillofasiyal cerrahide kullanılan onam formlarının okunabilirliğini artırmak için revize edilmesi önerilir.

Anahtar Kelimeler: Ateşman Okunabilirlik Formülü, Bilgilendirilmiş Onam Formu, Ağız ve Maksillofasial Cerrahi, Okunabilirlik.

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INTRODUCTION

Informed consent forms are documents designed to inform patients about the procedures or interventions to be performed and to obtain their consent. Securing informed consent from patients before initiating any medical treatment is both an ethical and legal obligation. During the informed consent process, mandated by various national and international regulations, patients are provided with information in an understandable manner regarding their condition and disease, the benefits and risks of the proposed intervention, alternative treatments, and the potential consequences of refusing treatment. The process concludes with the patient voluntarily accepting or declining the proposed intervention. Medical procedures can only be performed after the patient has been fully informed and has provided their consent. The primary purpose of informed consent is to enable patients to exercise their right to make decisions about their care and to safeguard their autonomy. Furthermore, the consent process fosters trust, a cornerstone of the relationship between healthcare providers and patients (1). Guidelines across specialties have established that the consent process should provide information that is clear, detailed and tailored to each patient (2). This information, which should be clear, legible, and accurate, should be documented, stored, and made available to the patient to protect the patient, clinician, and healthcare provider (3). In recent years, with the digitalization of healthcare services, computer-aided personal record forms have been developed using software programs in the healthcare field. Digital tools can improve patient information and streamline consent management (4). Electronic approval (e-Approval), which uses digital technologies to enable the approval process, can include status boards, multimedia to complement text-based content, interactivity (e.g., explaining definitions, testing knowledge), electronic signatures, and version control technologies. It has been reported that e-Approvals have the potential to improve the quality and consistency of documentation, eliminate unreadable or misplaced forms, and increase patient safety (5). A systematic review published in 2023 showed that compared with patients using paper-based consent, patients using e-consent better understood clinical trial information, engaged more with the content, and rated the consent process as more acceptable and usable (6) . However, when evaluating the legal validity of sharing the consent form with the patient in an electronic environment and the patient signing this form with an electronic signature, issues such as whether the consent form contains personal explanations and whether the consent is provided remotely should be considered. In cases where a standard form is used or information is provided only electronically, it cannot be claimed that the information is legally valid (7). Readability refers to the ease or difficulty experienced by a reader when reading a text and can be objectively assessed using various mathematical formulas. It provides numerical data on the readability of the text by analyzing the syllable, word, and sentence characteristics of the language (8). Readability formulae have been devised to assess readability based on parameters like word and sentence length and syllable count. When The Gunning Fog index (9) and Flesch Kincaid index (10) are widely used to evaluate the readability level of English texts, and the Ateşman formula (11) is widely used to determine the readability level of Turkish texts. It is vital that patients fully understand their informed consent forms before undergoing any medical procedure (8). The effectiveness of the information provided is limited by the patient's ability to comprehend it; therefore, the "readability" and "comprehensibility" of the material are as crucial as its accuracy and validity (12). As patients' level of understanding and comprehension increases, clinical outcomes improve, patient satisfaction increases, and patients' psychological stress decreases. Oral and maxillofacial surgery is a branch of dentistry where surgical interventions and surgeries are frequently performed. In a study conducted on dental malpractice cases in Türkiye, it was reported that the lawsuits filed were mostly related to patients of prosthetic dentistry and oral and maxillofacial surgery (13). In the literature review, no studies were found that examined the readability levels of informed consent documents associated with oral and maxillofacial surgery procedures. This study aims to evaluate the readability of informed consent forms used before surgical operations in a university oral and maxillofacial surgery clinic using the Ateşman readability formula.

MATERIAL AND METHODS

This research received approval from the Clinical Research Ethics Committee of Afyonkarahisar Health Sciences University (approval date: December 1, 2023; approval number: 2023/499) and was conducted by the principles outlined in the Helsinki Declaration. Additionally, permission for the study was obtained from the dean's office of the Faculty of Dentistry at Afyonkarahisar Health Sciences University.

The consent forms used for maxillofacial surgery in the oral and maxillofacial surgery clinic were identified, and each consent document was electronically transferred to Microsoft Word. The total number of

sentences, words, syllables, and characters in the documents was calculated. Additionally, the mean number of words per sentence, the mean number of syllables per word, and the medical term ratio were determined. To ensure accurate readability results, the headings in the forms were removed. The legibility of the informed consent documents was assessed using the Ateşman formula, which is used to determine the readability level of Turkish texts.

Ateşman Readability Formula

The Ateşman readability formula was established by Ateşman in 1997 by converting the Flesch reading ease test to Turkish (11). According to the formula, the readability level of a text is interpreted such that the closer the score is to 100, the easier the text is to read, whereas the closer the score is to 0, the more difficult it is to read. The following formula was used to calculate the Atesman score:
Readability Score =198.825 – 40.175 x (total syllables/total words) – 2.610 x (total words/total sentences). The result obtained from this formula indicates which class level an article addresses in the Turkish education system (Table 1).

Table 1. Reading levels according to Ateşman readability formula.

Atesman Score	Readability Level By Education Level	Readability Level
90-100	It can be read with primary school 4th grade and below education.	Very easy
80-89	It can be read with 5th or 6th-grade level education.	Easy
70-79	It can be read with 7th or 8th-grade level education.	
60-69	It can be read with 9th or 10th-grade level education.	Medium difficulty
50-59	It can be read with 11th or 12th-grade level education.	
40-49	It can be read with 13th or 15th-grade level education.	Difficult
30-39	It can be read with undergraduate level (16th grade) education.	
≤29	It can be read with postgraduate (>16th grade) level education.	Very difficult

RESULTS

The research involved 20 consent forms commonly used in the oral and maxillofacial surgery department. Among the consent forms analyzed, the implant surgery consent form had the highest number of sentences, words, syllables, and characters. The periapical surgery consent form had the highest average number of words per sentence (n=14.8), while the soft tissue grafting consent form had the lowest average number of words per sentence (n=8.74). Additionally, the cyst tumor surgery consent form had the highest average number of syllables per word (n=3.25), whereas the impacted tooth extraction consent form had the lowest average number of syllables per word (n=2.64). The consent form with the highest medical term rate (9.55%) was the autotransplantation consent form, while the consent form with the lowest medical term rate (1.36%) was the soft tissue grafting consent form (Table 2).

In the research, each consent document's score and readability degree were calculated based on the Ateşman readability formula. According to the Ateşman readability formula, the readability score of the consent documents used in surgery ranged between 37.1 and 68.8. When the consent documents were assessed using the Ateşman formula, the readability of 6 consent documents was at the "difficult" level, and the readability of 14 consent forms was at the "medium difficulty" level. Of the 14 consent forms with a medium level of reading difficulty, 10 had a readability level of "11th or 12th grade," while only 4 had a readability level of "9th or 10th grade." The cyst-tumor surgery consent form was the most difficult to read (undergraduate level), while the impacted tooth extraction consent form was the easiest to read (9th and 10th grade level) (Table 3).

Table 2. Numerical values of the consent forms used.

	Word Count	Syllable Count	Sentence Count	Character Count	Mean Words Per Sentence	Mean Syllables Per Word	Medical Term Ratio (%)
Abscess Drainage	110	318	8	862	13.75	2.89	1.81
Biopsy	116	376	9	971	12.89	3.24	3.44
Tooth Extraction	449	1231	46	3421	9.76	2.74	1.55
Electrosurgery	156	476	15	1295	10.40	3.05	3.20
Frenectomy	315	923	34	2489	9.26	2.93	2.22
Impacted Tooth Extraction	472	1246	48	3483	9.83	2.64	1.90
Implant Surgery	1109	3393	84	9217	13.20	3.06	1.08
Cyst Tumor Surgery	55	179	4	477	13.75	3.25	9.09
Laser Surgery	112	331	8	896	14.00	2.96	1.78
Local Anesthesia	123	358	9	967	13.67	2.91	5.69
Maxillofacial Trauma	156	441	11	1204	14.18	2.83	6.41
Closure Of Oro-Antral Opening	99	303	10	801	9.90	3.06	2.02
Autotransplantation	178	542	15	1472	11.87	3.04	9.55
Periapical Surgery	222	629	15	1708	14.80	2.83	2.25
Preprosthetics Surgery	454	1388	41	3757	11.07	3.06	1.54
Hard Tissue Grafting	303	916	28	2531	10.82	3.02	2.31
Sinus Lift Surgery	279	813	28	2274	9.96	2.91	3.58
Temporomandibular Joint Treatments	240	706	24	1927	10.00	2.94	2.50
Platelet Concentrate Applications	156	441	11	1204	14.18	2.83	4.48
Soft Tissue Grafting	367	1081	42	2908	8.74	2.95	1.36
Total	5471	16091	490	43864	11.80	2.95	3.38

Table 3. Readability scores and reading levels of informed consent forms based on the Ateşman readability formula.

	Ateşman Score	Readability Level By Education Level	Readability Level
Abscess Drainage	51.9	11th-12th grade	Medium difficulty
Biopsy	44.2	13th-15th grade	Difficult
Tooth Extraction	65.6	9th-10th grade	Medium difficulty
Electrosurgery	52.4	11th-12th grade	Medium difficulty
Frenectomy	62.1	9th-10th grade	Medium difficulty
Impacted Tooth Extraction	68.8	9th-10th grade	Medium difficulty
Implant Surgery	45.1	13th-15th grade	Difficult
Cyst Tumor Surgery	37.1	Undergraduate	Difficult
Laser Surgery	47.8	13th-15th grade	Difficult
Local Anesthesia	52.2	11th-12th grade	Medium difficulty
Maxillofacial Trauma	52.5	11th-12th grade	Medium difficulty
Closure Of Oro-Antral Opening	56.9	13th-15th grade	Difficult
Autotransplantation	48.4	11th-12th grade	Medium difficulty
Periapical Surgery	50.9	11th-12th grade	Medium difficulty
Preprosthetics Surgery	50.5	13th-15th grade	Difficult
Hard Tissue Grafting	49.7	11th-12th grade	Medium difficulty
Sinus Lift Surgery	55	11th-12th grade	Medium difficulty
Temporomandibular Joint Treatments	58.2	11th-12th grade	Medium difficulty
Platelet Concentrate Applications	52.5	9th-10th grade	Medium difficulty
Soft Tissue Grafting	63.3	11th-12th grade	Medium difficulty

DISCUSSION

Informed consent forms are documents used to apprise patients of procedures or interventions and to acquire their consent. For the consent to be valid, patients must understand the nature, purpose, risks, and benefits of the procedure. If this information is not understood, any consent given may be considered invalid, and healthcare providers may be subject to legal liability (14). In this study, consent forms used in a university oral and maxillofacial surgery clinic were evaluated in terms of readability using the Ateşman readability formula. The study results showed that informed consent forms used in maxillofacial surgery generally have “moderate” or “difficult” readability. The Patient Rights Regulation states that patient information should be sufficiently understandable, clear, and concise, and should be able to answer the patient's questions about medical practice (15). Consent forms should be written in simple, plain, and understandable language that includes sufficient information. Whenever possible, it is considered best practice to obtain written consent from the patient rather than verbal consent (16). Based on the research, patients may retain up to 20% of spoken information, possibly due to concerns, discomfort, fear of the unknown, time constraints, and a lack of medical understanding. However, when combined with written materials, retention rates can increase to around 50% (17). Verbal information can be modified and conveyed at a level that the patient can comprehend, but written information is usually prepared with a fixed content and reading level. Therefore, the content, language use, and readability of these forms are extremely important. Readability studies are conducted to make the language more understandable and have become a universal concept that linguists are currently working on intensively. The readability of a text can vary based on both the complexity of the text itself and the comprehension level of the reader. Factors such as sentence and word length, the number of syllables per word, and the use of specialized terminology all contribute to the readability of a text (18). Each language's readability may be measured using methods tailored to its structure. According to the Ateşman formula, the mean sentence length in the Turkish language is typically 9–10 words, while the Bezirci–Yılmaz formula suggests it is 10–11

words. Furthermore, both calculations indicate that the mean word length in the Turkish language is 2.6 syllables (11,19). When all consent forms were evaluated in this study, the mean number of words was calculated as 11.8, and the average number of syllables was calculated as 2.9. These values are above the average determined for Turkish. In general, consent forms contain very complex information that is difficult for patients to understand (20). The readability of consent forms dominated by medical terminology will be further reduced. It has been reported that the rate of medical terms in informed consent forms used before anesthesia in Türkiye is at the level of 4% (8). In this study, the rate of medical terms was found to be 3.38%, similar to the literature. Limiting sentence length to 8-10 words to increase readability, preferring short and more commonly used synonyms instead of long and multi-syllable words, and using commonly used simple terms instead of medical terminology are some strategies that can be applied (21). Sönmez et al. recommended that patient consent forms be visually enriched with diagrams and videos to increase their understandability (12). In this study, 20 consent forms used in the oral and maxillofacial surgery clinic of a university were evaluated in terms of readability using the Ateşman Readability formula, which is widely used in evaluating the readability of Turkish texts. In light of the study findings, the consent forms examined were evaluated as “moderately difficult” or “difficult” by the Ateşman formula. This situation is consistent with studies conducted in many countries across different branches. A study conducted in the United States reported that invasive consent forms were written at an average of the 15th grade level, which is roughly equivalent to the reading level expected in the third year of university education (22). In Türkiye, urological surgery and emergency medical intervention consent forms have been reported to exhibit a difficult readability level, typically understandable at a high school level (23). Boztaş et al. reported that consent forms used before anesthesia were difficult to read (8). Similarly, a study conducted in Spain revealed that the readability of anesthesia informed consent forms was low and their understandability was limited (24). A research examining the readability of consent documents used in cardiology clinics reported that the readability level was at the 11th or 12th-grade level based on the Ateşman index (25). In a study evaluating the readability of informed consent documents for intravenous and intramuscular injections, all forms were rated as "moderately difficult" based on the Ateşman formula (1). In studies conducted, it has been concluded that there is a correlation between the level of education and the level of understanding. Determining the education level of a text provides a certain indication of its understandability. In the United States, it is recommended that texts be written at a 6th-8th grade reading level in order to ensure they are easily understood by the general population (26). The mean education period of individuals aged 25 and older in Türkiye was 9.3 years in 2023 (27). In this research, it was noted that the consent documents utilized in oral and maxillofacial surgery exhibited readability levels corresponding to the 9th and 10th grades or higher, according to the Ateşman formula. Therefore, it was revealed that these consent forms did not meet the recommendations in the literature. Since oral and maxillofacial surgery procedures cover a wide range of patient ages, care should be taken to ensure that consent forms are easily understood, even by the least educated patient group. It has been shown that inadequate health literacy levels cause various difficulties in understanding medical information and implementing instructions, which leads to problems in the effective use of health services (28). Şahin et al. found in their study that only 29.6% of patients who underwent orthopedic surgery read the forms from beginning to end, and 41.5% did not remember the possible complications (29). As stated by the American National Institutes of Health, about 40% of the American population has insufficient health literacy. (30) The results of a study conducted in Turkey in 2014 revealed that 64.6% of the population had insufficient or problematic health literacy (31). Considering the inadequate level of health literacy, it is clear that consent forms prepared in Türkiye should be written in more understandable language. Enhancing the readability of consent forms and supplementing them with visual aids, such as videos and diagrams, can improve patient comprehension of procedures and enhance their retention of potential risks (32,33). Handwritten consent forms have been associated with a high error rate and a high rate of missed core risks (34). Introducing a semi-digital consent app with modifiable procedure-specific content has reduced variability and omission of core risks, while improving error and readability rates (35). The use of electronic resources for surgical consent has been shown to improve patient knowledge of the procedure (36). A study has shown that e-consent forms reduce error rates and offer the potential to increase clinical efficiency when compared to paper-based consent forms (37). A recently published systematic review concluded that digital consent has the potential to improve the overall informed consent process when compared to paper forms (38). In a study in the United Kingdom evaluating patient experience and the effectiveness of digital consent, those who gave consent digitally reported significantly higher levels of satisfaction than those who gave consent using a paper form, stating that the form was easier to read and understand, and that possible complications were easier to understand. In

addition, 86% of patients who gave consent digitally received a copy of the consent form, compared to 18% of patients who gave consent using paper (39). E-consent is environmentally friendly and eliminates the need to fax, scan, copy or file, allowing support staff to focus on direct patient care. An e-Consent exists permanently in the electronic health record and cannot be lost. Incomplete or incomplete consent is the most common cause of first case delay in operating rooms, affecting patient and staff satisfaction and having significant financial implications (37). Digital consent can be as time-consuming or even faster than paper consent (40). A study published in 2025 reported that digital consent forms potentially provide cost advantages over paper consent forms (41). In addition, a recently published study demonstrated the importance of digitization in reducing the spread of infections by showing that filling out consent forms with a tablet containing a software program significantly reduced surface contamination compared to filling out a paper consent form (42). However, barriers to e-consent adoption include the clinical and technical expertise required to create a consent application specific to a pan-specialty procedure and concerns about digital access for patients (43). This study emphasizes that texts containing informed consent information should be easy to read, whether prepared using traditional or digital methods. Future studies can address and evaluate the relationship between the use of different tools and readability and understandability. This study has several limitations, including the fact that it only examined the consent forms used in a university's maxillofacial surgery clinic and evaluating them solely according to the Ateşman readability index. Even if similar procedures are performed, the results cannot be generalized to all maxillofacial clinics. The study did not assess whether the consent forms were sufficient in terms of medical and legal content, nor did it determine the extent to which patients could understand these forms. Additionally, the font type, size, and patient anxiety, which may affect the readability of the forms, were not evaluated. Further research is needed to evaluate the accuracy and comprehensibility of the consent forms. Despite these limitations, this study is the first to assess the readability of consent forms used in oral and maxillofacial surgery.

CONCLUSION

Insufficient readability and comprehensibility of informed consent forms can render them invalid, potentially exposing healthcare providers to legal liability. For these reasons, informed consent forms should be drafted to be easily readable and comprehensible in both content and format.

The study results revealed that the comprehensibility levels of informed consent forms employed in oral and maxillofacial surgery are quite low. Considering the low average education level and health literacy in Türkiye, it is recommended that the content of consent documents used in maxillofacial surgery be reviewed. The language used in informed consent forms should be suitable for the reading comprehension level of the intended audience, employing a clear and legible writing style with visual aids wherever feasible. When preparing consent forms, it's crucial to ensure readability at or below a 6th-grade level, minimize medical terminology, opt for words with three or fewer syllables, and employ concise and straightforward sentences. In addition, digital technologies such as e-consent, which include multimedia and which patients can interact with, supported by visual content such as figures and videos, can be used to increase the readability and understandability of texts.

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