ADA CE Program ARTICLE 1

COVER STORY

Informed consent comprehension and recollection in adult dental patients

A systematic review

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ABSTRACT

Background. Patients' ability to recollect and comprehend treatment information plays a fundamental role in their decision making.

Types of Studies Reviewed. The authors considered original studies assessing recollection or comprehension of dental informed consent in adults. The authors searched 6 electronic databases and partial gray literature and hand searched and cross-checked reference lists published through April 2015. The authors assessed the risk of bias in the included studies via different validated tools according to the study design.

Results. Nineteen studies were included: 5 randomized clinical trials, 8 cross-sectional studies, 3 qualitative studies, 2 mixed-methods studies, and 1 case series. Conventional informed consent processes yielded comprehension results of 27% to 85% and recollection of 20% to 86%, whereas informed consent processes enhanced by additional media ranged from 44% to 93% for comprehension and from 30% to 94% for recollection. Patient self-reported understanding ranged positively, with most patients feeling that they understood all or almost all the information presented. Results of qualitative data analyses indicated that patients did not always understand explanations, although dentists thought they did. Some patients firmly stated that they did not receive any related information. Only a few patients were able to remember complications related to their treatment options.

Conclusions and Practical Implications. Results of this systematic review should alert dentists that although patients in general report that they understand information given to them, they may have limited comprehension. Additional media may improve conventional informed consent processes in dentistry in a meaningful way.

Key Words. Informed consent; decision making; dentist-patient relations; evidence-based dentistry.

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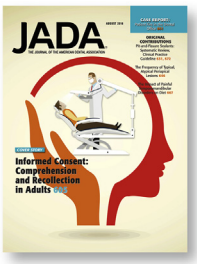
People have the right to self-determination through the informed consent process.[1,2] Despite the importance of legal aspects of informed consent,[3,4] attention also should be given to providing patients with appropriate information needed to make an autonomous choice that best represents their own interests.[5] Important issues related to the patient's treatment, including risks, benefits, treatment alternatives, and costs, have to be explained fully by the health care professional and understood by the patient, so the patient can make an informed decision.[1] However, available evidence shows that even after being informed, a high proportion of patients do not understand fully the proposed treatment explanations and associated risks and benefits.[6] The patient's or guardian's complete comprehension of information shared during the informed consent process is of paramount importance[6,7]; otherwise, the signed document may represent the patient's acceptance of a partially comprehended procedure.[5]



This article has an accompanying online continuing education activity available at: http://jada.ada.org/ce/home.

Although comprehensive reviews about this topic in the medical literature point to an overall unsatisfactory patient understanding[8,9] and recollection[9] of the information presented during informed consent processes, investigators in only a few empirical studies in dentistry[10-12] have explored these issues. Although results of these studies suggest that similar problems occur in the dental field during the informed consent process, the reality is that the informed consent process in dental settings is not necessarily similar to that in medical settings. Several relevant factors are different: multiple oral health problems may occur simultaneously,[13] there often is an aesthetic effect, and there is a fee-for-service aspect of dental services. To our knowledge, no attempt has been made to synthesize available evidence of the effectiveness of the informed consent process in dentistry. In this systematic review, we assess available evidence regarding adult dental patients' ability to comprehend effectively the oral health treatment information provided during informed consent processes and to recollect that information immediately or more than 1 week after the informed consent process was completed.

Supplemental material is available online.

METHODS

This systematic review adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.[14] We registered this systematic review protocol at PROSPERO under the protocol number CRD42015020345.

Eligibility criteria. Inclusion criteria were as follows:

- original studies, regardless of the methodology used, in which the investigators assessed adult patients' ability to comprehend effectively the oral health treatment information provided during informed consent processes and to recollect that information immediately or more than 1 week after the informed consent process was completed;
- studies in which the investigators compared standard informed consent processes with different kinds of information delivery, such as multimedia or smart consents;
- no language restriction.

During phase 2, the reviewers added 1 extra inclusion criterion:

- Studies in which the investigators included personal interaction between the dental care provider and patient before an assessment of their informed consent comprehension or recall was completed.

Exclusion criteria were as follows:

- studies in which the investigators analyzed informed consent for participation in research trials and exclusively assessing readability of consent forms;
- studies in which the investigators included patients with cognitive deficit or impairment, as well as letters, reviews, and personal opinions.

Information sources. We comprehensively searched the following databases: MEDLINE via OvidSP, PubMed, Cochrane Library, Embase, LILACS (Literatura Latino Americana em Ciências da Saúde), and Web of Science up to the first week of April 2015; we used detailed individual search strategies for each database. We performed a partial gray literature search by using Google Scholar and limited it to the first 100 most relevant articles. We also checked reference lists of included articles and conducted hand searches for additional citations that were not identified during the electronic searches.

Search. We adapted truncation and word combinations according to each specific database search (eTable 1, available online at the end of this article). We managed all references by using reference manager software (RefWorks-COS, ProQuest) and removed all duplicates.

Study selection. We completed study selection in 2 phases. In phase 1, 2 of us (N.C.F.M., C.P.P.) independently assessed the titles and abstracts of all identified electronic database citations. We selected all abstracts that met the inclusion criteria and retrieved full-text articles for phase 2. Whenever abstracts did not provide enough information to make a decision, we obtained the full-text articles to support a final decision. In phase 2, the same 2 reviewers independently reviewed the full-text articles and applied the same selection criteria to confirm eligibility. In both phases, disagreements about whether a study met the inclusion criteria were settled by discussion between the 2 reviewers. A third author (C.F.M.) was involved when an initial agreement was not possible.

Data items. We extracted the following data elements from each included study: authors, year of publication, sample size, study objectives, methods, dental procedure performed or dentistry area (when the procedure was not clear), results related to outcomes of interest, methodology of standard informed consent within the study, experimental informed consent method of comparison (when applicable), and time frame for information recall. If any required data were not available, we tried to contact the authors to retrieve any missing information.

Data collection process. One author (N.C.F.M.) collected all required information from each selected article. A second author (C.P.P.) cross-checked the retrieved information. Following a systematic process, we resolved any disagreement by means of discussion. The third author (C.F.M.) was involved when an agreement could not be reached.

ABBREVIATION KEY. **DB:** Decision board. **EndoDB:** Endodontic decision board. **LILACS:** Literatura Latino Americana em Ciências da Saúde. **NHS:** National Health Service. **WTL:** Wisdom Tooth Leaflet.

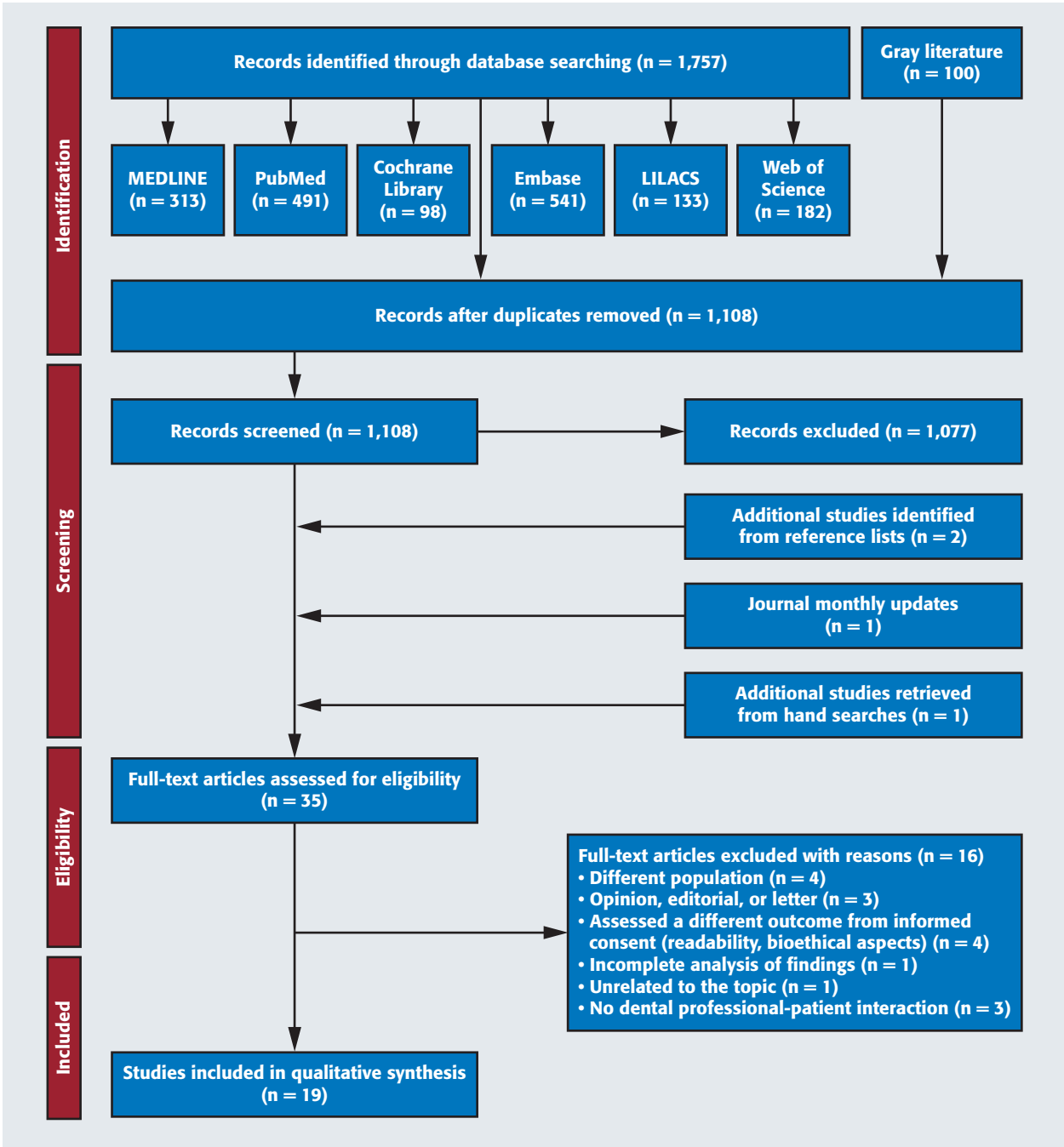


Figure. Flowchart showing the results of the search process. LILACS: Literatura Latino Americana em Ciências da Saúde. *Source: Moher and colleagues.*[14]

Risk of bias in individual studies. We used 4 tools for risk of bias assessment to evaluate the methodology of individual included studies: the Cochrane Collaboration's tool[15] for assessment of randomized studies; the National Heart, Lung, and Blood Institute tool[16] for cross-sectional studies; the methodological index for nonrandomized studies tool[17] for the case series; and the Critical Appraisal Skills Programme tool[18] for qualitative studies. We used a combination of these tools to assess mixed-methods studies. Two of us (N.C.F.M., C.P.P.) independently assessed the risk of bias in each selected study. The third reviewer (C.F.M.)

TABLE 1

Summary of descriptive characteristics of included articles.

STUDY	COUNTRY	SAMPLE SIZE (N)	STUDY DESIGN	PSYCHOMETRIC TOOL RELATED TO UNDERSTANDING AND RECALL	DENTAL PROCEDURE, DENTISTRY FIELD, CLINICAL SETTING
Ader and Colleagues,[19] 1992	United States	60	Randomized clinical trial	Multiple-choice quiz	Third-molar extraction surgery Tertiary care hospital
Layton,[30] 1992	United Kingdom	100	Cross-sectional	Structured, open-ended questions interview (prompted whenever necessary)	Mandibular third-molar extraction surgery under general anaesthesia NHS† hospital dental clinic
Layton and Korsen,[31] 1994	United Kingdom	94 and control group (n = 100) from their previous study	Cross-sectional	Structured, open-ended questions interview (prompted whenever necessary)	Mandibular third-molar extraction surgery under general anaesthesia NHS hospital
O'Neill and Colleagues,[32] 1996	United Kingdom	66	Randomized clinical trial	Wisdom Tooth Knowledge Scale (a previously validated questionnaire)	Third-molar extraction surgery under local anaesthesia University dental hospital
King,[28] 2001	United Kingdom	50 (12 of them were approached qualitatively)	Mixed-methods: cross-sectional and qualitative	Structured fixed choice questionnaire and interview	Different types of dental treatment within the NHS scope NHS dental clinics
Atchison and Colleagues,[21] 2005	United States	34	Qualitative	Focus group discussion using open-ended interview style	Third-molar extraction surgery under general anaesthesia or treatment for a mandibular fracture County hospital for minority patients
Johnson and Colleagues,[27] 2006	United States	67	Randomized clinical trial	Questionnaire	Endodontic treatment or extraction (with possible tooth replacement) University dental clinic
Stirling and Colleagues,[34] 2007	United Kingdom	59	Mixed-methods: cross-sectional and qualitative	Patient questionnaire and semistructured telephone interviews	Orthognathic treatment 4 different clinics
Hu and Colleagues,[26] 2008	People's Republic of China	174	Case series	Questionnaire	Prosthodontic treatment 2 offices in a public general dental hospital and 4 individual clinics
Brons and Colleagues,[22] 2009	The Netherlands	24	Cross-sectional	Multiple-choice and open-ended question questionnaire	Orthognathic surgery University dental clinic
Brosnam and Perry,[10] 2009	United Kingdom	75	Cross-sectional	Multiple-choice questionnaire and 1 open-ended question for suggestions	Third-molar extraction surgery under local or general anaesthesia University dental clinic
Alfaro-Carballido and Garcia-Rupaya,[20] 2011	Peru	49	Cross-sectional	Self-applied questionnaire	Oral surgery, periodontics, endodontics, prosthesis, orthodontics University dental clinic

* Researchers warranted that information given to the participants was calibrated previously or attained a minimum level required to be tested.
† NHS: National Health Service.
‡ EndoDB: Endodontic decision board.
§ DB: Decision board.

TABLE 1 (CONTINUED)

INFORMED CONSENT PROCESS (NO. OF PATIENTS)	RECOLLECTION TIME FRAME	CALIBRATED INFORMATION GIVEN TO THE PATIENTS*
Surgeon only (n = 25) Interactive video disk and surgeon (n = 18) Noninteractive videotape and surgeon (n = 17)	Immediate	The multimedia groups were calibrated, but the surgeon group was unclear.
Structured verbal warnings about specific complications or risks Group preadmission: warned 10 d before the operation at a preadmission clinic Group on admission: warned 1 d before the operation on their admission to the hospital	13 or 22 d after the informed consent process	Yes
Control group: structured verbal warnings about specific complications or risks Experimental group: verbal explanation similar to the control groups' and a written sheet (same warnings, in lay language) Both control and experimental groups were divided into 2 groups: ▬ Group A: verbal warning and a warning sheet to read and take home, then bring back and sign on admission (1-2 wks before the operation) ▬ Group B: verbal warning and a warning sheet to read and sign on admission (1 d before the operation)	Group A: 19 to 26 d after consent Group B: 13 d after consent	Yes
Verbal explanation (all groups) in addition to the following: ▬ Wisdom Tooth Leaflet and prompt group (n = 16): the Wisdom Tooth Leaflet was provided and patients were verbally prompted to read it ▬ Wisdom Tooth Leaflet group (n = 18): the Wisdom Tooth Leaflet was provided, without prompting Control group 1 (n = 16): a dental health education leaflet unrelated to the surgery procedure was provided, without prompting Control group 2 (n = 16): no reading material was provided	Timing 1: immediately after the verbal explanation (at first consultation) Timing 2: 2 wks later, just before surgery	Yes
Usual informed consent process conducted by different NHS dentists across different cities	Not available	No
Third-molar patients: routinely informed at a separate preparation clinic visit Fracture patients: informed in emergency department or in the in-patient ward (emergent nature)	Unclear; it seems to have ranged among participants, with an example of a patient who underwent surgery more than 7 mo earlier	No
4 residents were trained for an EndoDB.‡ In both the standard informed consent process (usual care) and EndoDB, the nature of information presented was the same	Immediate	The EndoDB was calibrated before its use, and usual care informed consent was not.
Usual informed consent process conducted by different dentists across the 4 assessed clinics	Prospective patients: 4 wks after first consultation Retrospective patients: 18 to 42 mo after patient had made treatment choice	No
3 different times: ▬ Baseline: professional-patient interaction with no media assistance ▬ First visit: professional-patient interaction assisted by computer, using a dental multimedia system ▬ Second visit: after treatment was performed, professional-patient interaction assisted by computer, using a dental multimedia system	Immediate	Yes
1 surgeon verbally provided explanation and illustrated by pictures and drawings	Immediate	Yes
1 surgeon and 3 leaflets to take away and read	Immediately after the first consultation or immediately after the second consultation, if applicable	Yes
Usual informed consent process in that clinical setting No details provided	Patients received informed consent before questionnaire Sometimes more than 6 appointments before the survey application date	No

TABLE 1 (CONTINUED)

Summary of descriptive characteristics of included articles.

STUDY	COUNTRY	SAMPLE SIZE (N)	STUDY DESIGN	PSYCHOMETRIC TOOL RELATED TO UNDERSTANDING AND RECALL	DENTAL PROCEDURE, DENTISTRY FIELD, CLINICAL SETTING
Ferrus-Torres and Colleagues,[24] 2011	Spain	87	Cross-sectional	Postoperative open-ended question interview (prompted whenever necessary)	Impacted third-molar extraction surgery University dental clinic
Ryan and Colleagues,[33] 2011	United Kingdom	30	Cross-sectional	Questionnaire	Orthognathic treatment University dental hospital
Singh and Colleagues,[12] 2012	India	500	Cross-sectional	Structured interview schedule generating scores according to the responses	Different outpatient departments Tertiary care dental teaching hospital
Clayton and Colleagues,[23] 2013	United States	24	Qualitative, multimethod approach	Semistructured interviews and direct observation	Included, but not limited to, routine cleaning, restorations, extractions, crowns, bridges, or endodontic treatment Private practices and at a school of dental medicine
Kupke and Colleagues,[29] 2013	Germany	81	Randomized clinical trial	Questionnaire	Class II defect treatment University dental clinic
Flett and Colleagues,[25] 2014	United Kingdom	10	Qualitative, cross-sectional	Semistructured interviews	Orthognathic surgery Dental teaching hospital
Choi and Colleagues,[35] 2015	South Korea	51	Randomized clinical trial	Open-ended questions questionnaire	Impacted third-molar extraction surgery Military dental clinic

resolved any disagreement if a final decision was required.

Summary measures and synthesis of results. We considered comprehension or recollection of informed consent by the adult patient using any type of summary measurement (categorical or continuous variables) to be the primary outcome. We planned a meta-analysis, provided that data were sufficiently homogeneous.

RESULTS

Study selection. Among the 35 full-text articles considered, 4 were not identified from an electronic database. We retrieved 2 by cross-checking reference lists, 1 from a journal monthly update, and 1 directly identified by searching the local library. Subsequently, we excluded 16 articles because they did not meet the inclusion criteria (eTable 2, available online at the end of this article). Ultimately, we included 19 articles in this review (Figure[14]).[10,12,19-35]

Study characteristics. Although some studies included audio or visual information such as leaflets[10,24,31-33] or use of multimedia devices[19,25,26,33,35] to help informed consent processes, only 4 had a methodology to evaluate the effectiveness of these auxiliary methods of information transfer during informed consent processes.[19,31,32,35] The investigators assessed decision-making aids in 2 other studies[27,29]; the investigators evaluated the usual informed consent process already in use in a specific clinical setting (Table 1[10,12,19-35]) in 9 studies.[12,20-23,25,28,30,34] Tables 1[10,12,19-35] and 2[10,12,19-35] present summaries of characteristics of the included articles.

Risk of bias within studies. We assessed the reported methodological quality of randomized studies as *unclear* to *high risk of bias*. For example, *attrition* was a domain with less risk of bias. Similarly, we assessed cross-sectional studies as poor to fair quality. Investigators in only 1 study justified their sample size,[20] and none reported adjustment for confounding variables. We assessed the case series as fair quality. Although the initial intention was to assess risk of bias in the mixed-methods studies by using 2 different tools according to their methodology, the quantitative methodology part of these studies did not provide assessment of any of the outcomes of interest; therefore, we assessed only the qualitative portion for quality. Methodologically, the studies were heterogeneous, and the quality of the qualitative studies varied significantly, from poor[23] to good[25] (Table 3[10,12,15-35] and eTables 3-6,[10,12,15-35] available online at the end of this article).

TABLE 1 (CONTINUED)

INFORMED CONSENT PROCESS (NO. OF PATIENTS)	RECOLLECTION TIME FRAME	CALIBRATED INFORMATION GIVEN TO THE PATIENTS*
A trained resident verbally explained the risks and provided an informative leaflet to read (not to take home) with the same information in lay language	7 d after surgery	Yes
Verbal and visual information (leaflets and DVD) Unclear regarding whether all patients were able to take home a DVD	Immediate	Yes
Usual care process in that hospital	Unclear	No
Usual informed consent process conducted by different dental professionals across the different assessed clinics	Unclear; it seems to have varied because most of the patients were not in active treatment	No
DB§ group: the student left DB with the patient for at least 5 min. After that, the patient and the student made a conjoint decision on further treatment Non-DB group: the treatment options were discussed without using the DB Completion of the informed consent took place in a separate room in the absence of the student on finalization of the treatment session	Immediate	Yes All students received training in shared decision making as part of their routine curriculum, and it was used irrespective of whether a DB was used
Patients underwent the regular initial consultation in that department and British Orthodontic Society DVD taken home	2 wks after consultation and immediately to up to 2 wks after watching the DVD (because the DVD was received at the day of consultation)	No
Control group: Korean Dental Association informed consent document and verbal explanation Audiovisual group: Korean Dental Association informed consent document and verbal explanation and slide-show presentation	1 wk after the operation and provision of information	Yes

Synthesis of results. ***Assessed comprehension and recollection.*** Investigators in 11 studies[10,12,19,22,24,27,29-32,35] objectively assessed patient comprehension or recollection. Of those assessing information provided by means of conventional approaches (that is, direct professional-patient interaction), patient understanding ranged from 27% to 85%,[12,19,27,29,32] and recollection fluctuated between 20% and 86%.[22,30,31,35] However, when explanation interventions such as leaflets, multimedia, or decision boards were included as adjuncts to the informed consent process, understanding ranged from 44% to 93%[19,27,29,32] and recollection from 30% to 94%.[10,24,31,35] In studies in which the investigators compared conventional with enhanced processes,[19,27,29,31,32,35] all showed significantly better results for the intervention groups. The only exception was a group that received a leaflet without any prompting to read the provided material.[32]

Self-reported understanding. Investigators in some studies assessed patients' subjective understanding of information provided for informed consent.[10,20,21,23,25,26,28,33,34] Most presented similar findings—for instance, 100% of the patients ranked their understanding as *favorable* or *very favorable*,[20] felt they understood the information that was provided,[33] or rated their understanding as *very good* or *excellent*.[26] In other studies, 92% self-reported that they understood all or most of the information,[10] and 83% self-reported that they fully understood the explanations.[23]

Patients' perceptions of the process. Investigators in some studies used qualitative analysis to assess informed consent processes performed in the usual way within a clinical setting[21,28,34]; among these studies, investigators in 1 found that some patients did not remember having received any kind of information.[21] Patients in another study reported that previous experience with dental treatment made them feel that they already understood it anyway, whereas other patients stated that when dentists were rushed there was no time for explanations or questions.[28] Not all patients had access to accurate and complete information; some chose not to attend to information that was presented, and few patients were able to report postoperative or long-term complications related to the surgery they were about to undergo.[34]

Timing of assessment. Among all included studies, investigators in only 1 objectively assessed the outcomes of interest more than once over time.[32] However, they did not assess time effects directly on recollection or understanding, just the effect of introducing a leaflet to facilitate recollection.

TABLE 2

Summary of results of included articles.

STUDY	COUNTRY	OUTCOMES	STATISTICAL FINDINGS RELATED TO OUTCOME OF INTEREST	CONCLUSION
Ader and Colleagues,[19] 1992	United States	Mean percentage of quiz surgeon only group: 40% Interactive video disk and surgeon group: 72.6% Noninteractive videotape and surgeon group: 85%	Analysis of variance: $P < .0001$ Tukey test: difference between each of them	Interactive video disk participants were better informed than those in the surgeon group but less informed than videotape participants.
Layton,[30] 1992	United Kingdom	Number of warnings recalled (with or without prompting): ▬ 5 (all): 61% ▬ 4: 20% ▬ 3: 11% ▬ 2: 5% ▬ 1: 1% ▬ 0: 2% Overall patients' recall*: ▬ Recalled unprompted: 35.8% ▬ Recalled prompted: 49.8% ▬ Total recall: 85.6% ▬ Total overall of patients with no recall: 14.4% Overall percentage of patients with no recall and timing of consent*: ▬ Preadmission group (n = 49): 17.2% ▬ On admission group (n = 51): 11.6%	χ^2 test and Yates correction Patients with no recall comparing the different timing of consent groups (preadmission versus on admission): None of the warnings were significantly different between the groups.	There is no difference to patients' recall of information, whether this information is given at a preadmission clinic or on admission.
Layton and Korsen,[31] 1994	United Kingdom	Total overall of patients' recall (with or without prompting)*: ▬ Written and verbal: 93.6% ▬ Verbal only: 85.6% Overall patients with no recall*: ▬ Written and verbal: 6.4% ▬ Verbal only: 14.4% Overall patients with no recall in the written and verbal group*: ▬ Group A (n = 51): 4.7% ▬ Group B (n = 43): 9.3%	χ^2 test and Yates correction Patients with no recall: Written and verbal group versus verbal-only group: ▬ Dysesthesia lip: $P < .01$ ▬ Dysesthesia tongue: $P < .001$ ▬ Swelling, trismus, pain: NS† Group A versus group B: None of the warnings were significantly different between the groups.	Written preoperative information improved the quality of the informed consent process.
O'Neill and Colleagues,[32] 1996	United Kingdom	Preleaflet mean (SD‡) score (ranging from 0 to 58) Postleaflet mean (SD) score Increase in knowledge WTL§ and prompt group: 26.81 (1.87) 29.00 (1.63) 2.19 WTL group: 25.50 (4.32) 27.28 (1.74) 1.78	Kruskal-Wallis: $P > .25$ Analysis of variance: $P < .001$ Paired *t* tests and Bonferroni correction WTL and prompt: $P < .001$ WTL: $P = .059$ Control 1: $P = .841$ Control 2: $P = .596$	A well-designed information leaflet resulted in increased knowledge in patients undergoing third-molar extraction in a clinical setting.

* Calculated from the article's data.
† NS: No significant difference.
‡ SD: Standard deviation.
§ WTL: Wisdom Tooth Leaflet.
¶ EndoDB: Endodontic decision board.
# P1: Baseline.
** P2: First visit.
†† P3: Second visit.
‡‡ Statistical significance.
§§ DB: Decision board.

TABLE 2 (CONTINUED)

STUDY	COUNTRY	OUTCOMES	STATISTICAL FINDINGS RELATED TO OUTCOME OF INTEREST	CONCLUSION
		Control group 1: 25.19 (2.48) 25.31 (2.94) 0.12 Control group 2: 26.56 (2.66) 26.81 (2.29) 0.25		
King,[28] 2001	United Kingdom	Some people felt that they understood reasonably well what was explained to them. With previous experience of treatment, some felt that they already understood what to expect. Sometimes, assumptions were made that people understood when they did not. Patients mentioned that when dentists were rushed, there was not always time for explanations or questions.	No statistical analysis related to the outcome of interest	There is a wide variation in consenting practice, from patients who feel that they have given consent freely to those who feel that it is the dentist who takes control.
Atchison and Colleagues,[21] 2005	United States	20 (of 34) patients recorded being given treatment risk information. 5 fracture patients stated firmly that they had not been informed.	No statistical analysis regarding the outcome of interest	Informed consent perception varied among patients, with some feeling adequately prepared, whereas communication was not always ensured to others.
Johnson and Colleagues,[27] 2006	United States	Mean knowledge scores (SD) (ranging from 0 to 5) Pretrial (run in): 4.09 (1.03) Usual care group: 4.26 (0.78) EndoDB[¶] group: 4.63 (0.55)	Analysis of variance: $P = .03$ *t* test: Pretrial × usual care: $P = .47$ EndoDB × usual care: $P = .03$ χ^2 test (to analyze whether there were differences in specific questions): $P = .07$	The EndoDB improved knowledge regarding treatment information.
Stirling and Colleagues,[34] 2007	United Kingdom	Overall patients' perception of consequences of treatment*: ▬ Positive consequences: 63.33% ▬ Short-term negative consequences: 42.33% ▬ Postoperative negative consequences: 17% ▬ Long-term negative consequences: 10.33% 90% of the patients provided positive comments about the information. 46% were unhappy with aspects of the information. Some statements suggest that not all patients had access to accurate and complete information before making their choices, whereas others chose not to attend to information that was presented. In general, few patients mentioned negative consequences of treatment.	No statistical analyses presented Frequency data were generated from qualitative analysis	Some patients receiving orthognathic treatment do not appear to be making informed decisions about their treatment.

TABLE 2 (CONTINUED)

STUDY	COUNTRY	OUTCOMES	STATISTICAL FINDINGS RELATED TO OUTCOME OF INTEREST	CONCLUSION
Hu and Colleagues,[26] 2008	People's Republic of China	Understanding of the decision and treatment plan rated as excellent: (P1,[#] P2,[**] P3[††]): 37.4%, 50.6%, 54% (on a 6-point scale, no responses in the lowest 4 levels) Preferred the multimedia system–assisted approach over the traditional communication pattern (P2 and P3): 70.1% and 70.1%	Understanding of the decision and treatment plan rated as excellent (odds ratio [95% confidence interval]): P2 versus P1: 10.646[‡‡] (4.812-23.550) P3 versus P1: 5.492[‡‡] (2.567-11.749)	The introduction of the dental multimedia system appeared to have positive effects on professional-patient communications, improving the mutual understanding between them.
Brons and Colleagues,[22] 2009	The Netherlands	Overall percentage of recall*: ▬ Consequences and possible complications of operation: 47.5% ▬ Reasons for treatment: 15.38% ▬ Reasons to refrain from surgical intervention: 25% Total overall: 29.29%	No statistical analysis presented	Recall rate of risks and complications immediately after an informed consent interview for surgical orthodontic treatment was 42%.
Brosnam and Perry,[10] 2009	United Kingdom	Overall percentage of patients' awareness of complications: ≈69.5%* Patients' awareness of the risk of complications: 87% knew about *all* or *some* of the risks. Information understood: 92% understood *all* or *most of it*.	Patients who had a second consultation were significantly more aware of "bleeding" and "infection": Fisher exact test, $P < .01$	The criterion standard in the informed consent process was met only partially in most cases, yet most patients felt that the process had been appropriate for their needs.
Alfaro-Carballido and Garcia-Rupaya,[20] 2011	Peru	17 (35%): Very favorable 32 (65%): Favorable 0: Unfavorable	No statistical analysis considering patient participants separately	The patients had a clear perception of the informed consent and the planned treatment.
Ferrus-Torres and Colleagues,[24] 2011	Spain	Recall of complications Overall percentage: ≈80.5%* (70 patients)	No statistical analysis presented	Patients did not remember most of the information received before providing informed consent.
Ryan and Colleagues,[33] 2011	United Kingdom	100% of patients felt they understood the information given.	No statistical analyses presented	The new style of clinic consistently provided a high level of information to help patients in the decision-making process.
Singh and Colleagues,[12] 2012	India	Overall understanding score: 53.1% Author's classification of the patients' level of understanding: ▬ Poor: 17% ▬ Unsatisfactory: 33% ▬ Satisfactory: 32% ▬ Good: 18%	Patients with higher education levels understood better ($P < .01$)	Current consent procedures seem inadequate.
Clayton and Colleagues,[23] 2013	United States	20 patients *fully* understood the explanations. 3 patients asked questions whenever they did not understand. 1 patient sometimes did not understand.	None	Patient education should be integrated meaningfully into the workflow shared by dentists, their team members, and patients to maximize its outcomes.

TABLE 2 (CONTINUED)

STUDY	COUNTRY	OUTCOMES	STATISTICAL FINDINGS RELATED TO OUTCOME OF INTEREST	CONCLUSION
Kupke and Colleagues,[29] 2013	Germany	Total knowledge score mean (SD) (ranging from 0 to 15) DB[§§] group (n = 50): 10.04 (3.5) Non-DB group (n = 31): 4.16 (2.5)	Mann-Whitney *U* test (DB versus non-DB): $P < .0001$ Mann-Whitney *U* tests and Bonferroni correction (difference between the groups within single questions) Survival rate, total costs, self-payment, treatment time: $P < .0001$ Characteristics: $P = .226$ Wilcoxon test (Total costs versus share of self-payment, regardless of the group) Total costs less than self-payment (reported as significant but no *P* value provided)	The use of a DB yielding information regarding treatment options led to a significantly higher level of patient knowledge compared with that in those who received consultation alone.
Flett and Colleagues,[25] 2014	United Kingdom	The virtual animations seemed to improve the participants' understanding of what the surgery involved. Patients commented that the moving images were better than the explanation in the clinic. Most people felt the DVD was important to watch before coming to a decision because they felt they gained knowledge and information that they did not gain from the clinical consultations or other sources.	None	The DVD was useful, providing information that patients could not get or process from professional or external sources; therefore, if used properly, it has a role in the decision-making process.
Choi and Colleagues,[35] 2015	South Korea	Overall recall*: Control group: 20.19% Audiovisual group: 30%	From 8 potential postoperative complications, the audiovisual group significantly recalled trismus and allergic reactions more than did the control group (χ^2 test: $P < .05$).	The audiovisual slide presentation reduced anxiety and improved patient knowledge of the potential postoperative complications involved in surgical extraction of an impacted mandibular third molar.

Risk of bias across studies and additional analysis. Data from the included studies were notably heterogeneous. Therefore, we did not consider a meta-analysis suitable.

DISCUSSION

Informed consent is an essential component of the decision-making process. In this study, we sought the best evidence regarding understanding or recollection of adult dental patients when presented with information related to their planned dental treatment. Limited evidence suggests that patients' comprehension or recollection of that information is not always adequate, particularly when explanations are given in verbal format only. Although most of the time patients indicated that they understood the information, when assessed objectively, they did not perform as well. This discrepancy is an important clinical consideration when assessing the real effect of informed consent processes in dental clinical practice.

The identified evidence was of limited strength because all the studies in which the investigators assessed the outcomes objectively were classified as having unclear to high risk of bias. Investigators in the 1 good quality methodology study[25] only assessed the outcomes subjectively. Another limitation is that investigators in only 1 study[32] used a validated instrument to measure outcomes, weakening the strength of the results overall.

We included a wide array of designs: randomized clinical trials, observational cross-sectional studies, case series, qualitative studies, and mixed-methods studies. This diversity allowed this review to provide different insights that a specific study type alone would not be able to provide. The downside is that a wide range of study designs is not suitable for an all-inclusive meta-analysis.

TABLE 3

Risk of bias assessment of included studies.*

STUDY	STUDY DESIGN	RISK OF BIAS OR QUALITY
Ader and Colleagues,[19] 1992	Randomized clinical trial	High risk of bias†
Layton,[30] 1992	Cross-sectional	Fair quality‡
Layton and Korsen,[31] 1994	Cross-sectional	Poor quality‡
O'Neill and Colleagues,[32] 1996	Randomized clinical trial	Unclear risk of bias†
King,[28] 2001	Mixed methods	Moderate risk of bias§¶
Atchison and Colleagues,[21] 2005	Qualitative	Moderate risk of bias§¶
Johnson and Colleagues,[27] 2006	Randomized clinical trial	Unclear risk of bias†
Stirling and Colleagues,[34] 2007	Mixed methods	Moderate risk of bias§¶
Hu and Colleagues,[26] 2008	Case series	Moderate risk of bias¶#
Brons and Colleagues,[22] 2009	Cross-sectional	Fair quality‡
Brosnam and Perry,[10] 2009	Cross-sectional	Poor quality‡
Alfaro-Carballido and Garcia-Rupaya,[20] 2011	Cross-sectional	Poor quality‡
Ferrus-Torres and Colleagues,[24] 2011	Cross-sectional	Poor quality‡
Ryan and Colleagues,[33] 2011	Cross-sectional	Fair quality‡
Singh and Colleagues,[12] 2012	Cross-sectional	Poor quality‡
Clayton and Colleagues,[23] 2013	Qualitative	High risk of bias§¶
Kupke and Colleagues,[29] 2013	Randomized clinical trial	Unclear risk of bias†
Flett and Colleagues,[25] 2014	Qualitative	Low risk of bias§¶
Choi and Colleagues,[35] 2015	Randomized clinical trial	Unclear risk of bias†

* For more details, see eTables 3, 4, 5, and 6 (available online at the end of this article).
† Source: Higgins and Greene.[15]
‡ Source: National Heart, Lung, and Blood Institute.[16]
§ Source: Critical Appraisal Skills Programme.[18]
¶ Risk of bias gradation attributed by the authors. For more details, see eTables 5 and 6, available online at the end of this article.
# Source: Slim and colleagues.[17]

We found that literature about informed consent commonly used the following terms interchangeably: understanding, comprehension, knowledge, recollection, and recall. We considered objectively assessed knowledge[19,27,29,32] as the same as understanding or comprehension. Recollection or recall commonly was assessed together with recognition either by prompting the patient when not able to recall spontaneously[24,30,31] or by showing patients all possible options and asking them if they could remember them.[10] In other words, most studies in which the investigators attempted to assess recollection of consent information used assessment methods that essentially prompted the patient's response. Therefore, it is questionable to imply that they really assessed what the patient actually recalled.

Educating patients is not only fundamental but also an essential part of the informed consent process. Although some studies in which the investigators appraised recall of information in patient education by using different methods exist in the literature,[36-38] we decided not to include studies in which the investigators did not attempt to include a professional-patient interaction in some way because we believe that patient education alone should not be considered a comprehensive informed consent process. Historically, the courts and higher courts considered the professional-patient relationship to be the core of informed consent, whereas the extent of information to be disclosed varies significantly in different countries.[39]

Although objectively assessed understanding ranged significantly (27-85%),[12,19,27,29,32] most of the time patients self-rated their understanding rather high.[10,20,23,26,33] More interesting would be having both objective and self-reported understanding assessments within the same study so that the quality of the information delivery could be compared equally. This method is foundational because there could be significant clinical decision implications if there are differences between what patients think they understood compared with what they actually were told.

Eli and colleagues[40] assessed the effect of anxiety on a person's ability to recollect information. They found statistically higher values related to patients' self-reported understanding when compared with real knowledge in both stressful and nonstressful situations. In our systematic review, investigators in only 1 study[10] evaluated both recall and self-reported understanding, showing an assessed recollection of 70%, whereas 92% of the patients felt that they understood all or most of the information presented. Although this difference may, at a glance, seem similar, an in-depth analysis of their methodology revealed that the method they used to assess recollection biased patients to have higher levels of recall than normally expected. The researchers asked patients questions regarding their recollection, but at the same time showed them all the possible responses, which made it more of a recognition assessment than a natural recall. The patients' true recollection actually may have been lower than the value measured with their instrument. Other studies also had a design that asked the patients to recognize information instead of recalling it. In those studies, patients were prompted whenever they could not recall the information spontaneously, making the results sound more optimistic than they would have been if no

prompting was provided.[24,30,31] This assumption is supported by the findings from Layton[30] who recorded the patients' total overall recall (prompted and unprompted) as 86%; however, the reported unprompted findings accounted for only 36% of their recall.

Although participant reports from prospective studies seemed to be positive most of the time,[10,23,26,33] this was not always the case when retrospective informed consents were conducted in the standard way within a clinical setting, from the patients' point of view, without involvement of the researchers or any attempt to standardize the process in any way. According to the results of some of these studies, few patients firmly stated that they had not been informed,[21] others commented that sometimes dentists were rushed and there was not always time for explanations or questions, and occasionally assumptions were made that patients understood when they did not.[28] Although these findings were from studies in which the investigators did not attempt to intervene in the standard informed consent process performed in that particular clinical setting, they cast doubt on whether all the dentists always take time to inform patients when they are not being evaluated. Findings obtained from qualitative analysis help confirm the importance of qualitative design research when there is a need to understand patients' perspectives better. However, the authors could not determine how well the information was presented to the patients; they could not identify whether the flaw was in the information delivery process or as a direct result of the patients' ability to process the information that was provided.

Differences in points of view between patients and professionals may have critical consequences in the decision-making process, particularly when it comes to elective treatments. In other words, if patients cannot comprehend risks and benefits of an elective treatment fully, they will not be able to weigh all relevant information and make the decision that best applies to their values. This discrepancy may result in patients undergoing an intervention only because of professional recommendation, increasing the likelihood of feeling regret and dissatisfaction at the end.[41,42]

Health literacy becomes a potential and relevant patient-related barrier within informed consent processes because it directly affects how well patients can process and understand the basic health information needed to make proper health decisions.[43] However, none of the eligible included studies addressed this issue.

It was not possible to assess whether time influenced a patient's recollection because the only study in which the investigators assessed recollection more than once over time did not assess how time affected patients' recall of information.[32] To our knowledge, there is no study in the dental literature in which the investigators have appraised this issue. Although medical findings[44,45] show that recall tends to decrease over time, regardless of interventions used to enhance understanding, the same cannot be stated in dentistry.

The dental literature points toward the concept that additional media likely should be added to the dental informed consent process: leaflets, interactive or noninteractive multimedia, and decision boards. These tools yield significantly more positive results than do the conventional standard process of verbal explanations. Although the studies included were not free of bias, all of them in which the investigators aimed to assess the effectiveness of these tools showed similar results regarding this issue,[19,27,29,31,32,35] with only 1 of the intervention groups showing an improvement that was not statistically significant.[32] However, the favorable results in our review regarding the effectiveness of these adjunct interventions were obtained together with verbal explanations from a dental care provider. Therefore, how effective those same additional media would be in the absence of verbal explanations is unknown and could be answered only by a study that specifically addresses both informed consent strategies.

It also could be argued that clinicians should face the informed choice process as an opportunity for teaching patients how to weigh the risks and benefits for the current decision and for future health care decisions. This initial investment of education time with the patient implies their value as an equal partner in the decision-making process.[46]

On the basis of the available evidence, clinicians should endeavor to include adjunct resources, such as leaflets, decision boards, and audiovisual material, when sharing important treatment information with patients. Dentists should not rely solely on patients' self-reported comprehension of information imparted because it might not be representative of their real understanding. Although the wide range of patients' comprehension (27-93%) and recollection (20-94%) in this review precludes affirming that, in general, dental patients demonstrate appropriate levels of comprehension and recall, the informed consent process in dentistry has room for improvement.

Future research in the following areas would be relevant to dental practitioners. Researchers should evaluate whether adults' comprehension and recollection improved if the informed consent process was repeated periodically over a long-term treatment period. This repetition would be of particular interest in orthodontics and periodontics because of the long-term treatment or long-term follow-up, respectively, which are key factors to treatment success. Researchers should assess whether improved informed consent processes enhance comprehension and recollection among

patients with low health literacy. In-depth investigation of patients' perspectives on the barriers and facilitators to the comprehension and recollection of information shared during the informed consent process also would be useful.

CONCLUSION

According to the available literature, adult dental patients do not always show adequate levels of understanding and information recollection from their informed consent processes, although they usually think that they understood the information provided well. Usually, an immediate improvement of understanding and recall capabilities among adult dental patients was gained when adjunct information methods were used. No data are available regarding long-term information recollection capabilities in adult dental patients after the process has been completed. ■

SUPPLEMENTAL DATA

Supplemental data related to this article can be found at http://dx.doi.org/10.1016/j.adaj.2016.03.004.

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eTABLE 1

Databases and search terms.

DATABASE	SEARCH TERMS
MEDLINE **Cochrane Library** **Embase**	1. informed consent.mp. or exp Informed Consent/ 2. consent.mp. 3. consent*.mp. 4. exp Geriatric Dentistry/ or exp Dentistry, Operative/ or exp Dentistry/ or exp Public Health Dentistry/ or dentistry.mp. 5. dental care.mp. or exp Dental Care/ 6. dent*.mp. 7. orthodontics.mp. or exp Orthodontics, Corrective/ or exp Orthodontics/ 8. orthodont*.mp. 9. endodontics.mp. or exp Endodontics/ 10. endodont*.mp. 11. prosthodontics.mp. or exp Prosthodontics/ 12. prosthodont*.mp. 13. periodontics.mp. or exp Periodontics/ 14. periodont*.mp. 15. exp Dental Implants/ or exp Dental Implantation/ or implantology.mp. 16. oral surgery.mp. or exp Surgery, Oral/ 17. exp Radiography, Dental/ or oral radiology.mp. 18. (oral medicine and pathology).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] 19. oral pathology.mp. or exp Pathology, Oral/ 20. oral medicine.mp. or exp Oral Medicine/ 21. dental surgery.mp. 22. comprehension.mp. or exp Comprehension/ 23. comprehend*.mp. 24. understanding.mp. 25. understand*.mp. 26. exp Mental Recall/ or exp Memory/ or recollection.mp. 27. recollect*.mp. 28. retention.mp. or exp "Retention (Psychology)"/ 29. recall.mp. 30. recall*.mp. 31. retrieval.mp. or exp "Information Storage and Retrieval"/ 32. retriev*.mp. 33. remembering.mp. 34. remembrance.mp. 35. remember*.mp. 36. reminding.mp. 37. remind*.mp. 38. knowledge.mp. or exp Knowledge/ 39. 1 or 2 or 3 40. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 41. 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 42. 39 and 40 and 41
PubMed	((((“Informed Consent”[MeSH]) OR (((informed consent) OR consent) OR consent*))) AND ((((((((((((((((((((((((“Dentistry” [MeSH] OR “Public Health Dentistry”[MeSH] OR “Geriatric Dentistry”[MeSH] OR “Dentistry, Operative”[MeSH])) OR dentistry) OR dent*) OR (“Orthodontics”[MeSH] OR “Orthodontics, Corrective”[MeSH])) OR orthodontics) OR orthodont*) OR “Dental Care”[MeSH]) OR “Surgery, Oral”[MeSH]) OR oral surgery) OR dental surgery) OR “Dental Implants”[MeSH]) OR implantology) OR endodontics) OR endodont*) OR prosthodontics) OR prosthodont*) OR periodontics) OR periodont*) OR (oral and maxillofacial surgery)) OR dental care) OR dental implant*) OR oral medicine) OR oral pathology) OR (oral medicine and pathology)) OR dental public health)) AND ((((((((((((((((((((“Comprehension”[MeSH]) OR comprehension) OR comprehend*) OR understanding) OR understand*) OR understood) OR recollection) OR recollect*) OR retention) OR “Mental Recall”[MeSH]) OR recall) OR recall*) OR (“Information Storage and Retrieval”[MeSH])) OR retrieval) OR retriev*) OR remember*) OR remembrance) OR remind*) OR knowledge)) OR “Memory”[MeSH])
LILACS*	consentimento esclarecido OR consentimento livre e esclarecido OR consentimiento informado OR informed consent OR consentimento OR consentimiento OR consent OR consent$ [Palavras] and odontologia OR odontología OR dentistry OR ortodontia OR ortodoncia OR orthodontics OR endodontia OR endodoncia OR endodontics OR cirurgia oral OR cirurgia buco OR cirugía maxilofacial OR cirugía bucal OR cirugía oral OR oral surgery OR dental surgery OR prótese OR prostodoncia OR prótesis dental OR prosthodontics OR periodontia OR periodoncia OR periodontics OR implantodontia OR implantología OR implantology OR implant dentistry OR radiologia oral OR oral radiology OR dental radiology OR patologia oral OR patología bucal OR oral pathology OR dent$ [Palavras] and compreensão OR compreend$ OR comprensión OR comprehension OR comprehend$ OR entendimento OR entend$ OR entendimiento OR understand$ OR lembr$ OR record$ OR recuerdo OR recollect$ OR recall$ OR remember$ OR retriev$ OR remind$ OR conhecimento OR conocimiento OR knowledge [Palavras]

* LILACS: Literatura Latino Americana em Ciências da Saúde.

eTABLE 1 (CONTINUED)

DATABASE	SEARCH TERMS
Web of Science	(TOPIC: (informed consent) *OR* TOPIC: (consent) *OR* TOPIC: (consent*)) AND (TOPIC: (dentistry) *OR* TOPIC: (dent*) *OR* TOPIC: (orthodontics) *OR* TOPIC: (orthodont*) *OR* TOPIC: (endodontics) *OR* TOPIC: (endodont*) *OR* TOPIC: (oral surgery) *OR* TOPIC: (oral and maxillofacial surgery) *OR* TOPIC: (dental surgery) *OR* TOPIC: (dental care) *OR* TOPIC: (prosthodontics) *OR* TOPIC: (prosthodont*) *OR* TOPIC: (periodontics) *OR* TOPIC: (periodont*) *OR* TOPIC: (implantology) *OR* TOPIC: (dental implant*) *OR* TOPIC: (oral radiology) *OR* TOPIC: (dental radiology) *OR* TOPIC: (oral medicine and pathology) *OR* TOPIC: (oral medicine) *OR* TOPIC: (oral pathology)) AND (TOPIC: (comprehension) *OR* TOPIC: (comprehend*) *OR* TOPIC: (understanding) *OR* TOPIC: (understand*) *OR* TOPIC: (understood) *OR* TOPIC: (recollection) *OR* TOPIC: (recollect*) *OR* TOPIC: (retention) *OR* TOPIC: (recall) *OR* TOPIC: (recall*) *OR* TOPIC: (retrieval) *OR* TOPIC: (retriev*) *OR* TOPIC: (remember*) *OR* TOPIC: (remembrance) *OR* TOPIC: (remind*) *OR* TOPIC: (knowledge))
Google Scholar	Any idiom; Without patents and citations; Classified by relevance (100 most relevant articles). ("informed consent" OR consent) (dentistry OR dental OR orthodontics OR endodontics OR "oral surgery" OR "oral and maxillofacial surgery" OR prosthodontics OR periodontics OR "dental implant") (comprehension OR understanding OR recollection OR recall)

eTABLE 2

Excluded articles and reason for exclusion.

STUDY	REASON
Witt and Bartsch,[e1] 1993	Different assessed population (parents, dentists, nonpatient volunteers)
Schouten and Frielle,[e2] 2001	Assessed a different outcome from informed consent that was not comprehension of information (readability, bioethical aspects)
Schouten and Colleagues,[e3] 2002	Assessed a different outcome from informed consent that was not comprehension of information (readability, bioethical aspects)
Naidoo,[e4] 2004	Personal opinions, letters, reviews, or editorials
Knobel and Hassfeld[e5] 2005	No dental professional-patient interaction
Wolf and Colleagues,[e6] 2006	Unrelated to the topic
Eli and Colleagues,[e7] 2008	No dental professional-patient interaction
Padron Chacon and Colleagues,[e8] 2008	Assessed a different outcome from informed consent that was not comprehension of information (readability, bioethical aspects)
Ghafurian,[e9] 2009	Assessed a different outcome from informed consent that was not comprehension of information (readability, bioethical aspects)
Amarilla Guirland,[e10] 2011	Different assessed population (parents, dentists, nonpatient volunteers)
Avramova and Yaneva,[e11] 2011	Different assessed population (parents, dentists, nonpatient volunteers)
Sharma and Colleagues,[e12] 2011	Personal opinions, letters, reviews, or editorials
Cleeren and Colleagues,[e13] 2014	No dental professional-patient interaction
Di Prospero,[e14] 2014	Personal opinions, letters, reviews, or editorials
El Azem and Colleagues,[e15] 2014	Different assessed population (parents, dentists, nonpatient volunteers)
Valenza and Colleagues,[e16] 2014	Incomplete analysis of findings

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eTABLE 3

Risk of bias assessment of included randomized studies.*

CRITERION	ADER AND COLLEAGUES,[19] 1992	O'NEILL AND COLLEAGUES,[32] 1996	JOHNSON AND COLLEAGUES,[27] 2006	KUPKE AND COLLEAGUES,[29] 2013	CHOI AND COLLEAGUES,[35] 2015
Random Sequence Generation (Selection Bias)	UN†	UN	LR‡	UN	UN
Allocation Concealment (Selection Bias)	HR§	UN	UN	LR	UN
Masking of Participants and Personnel (Performance Bias)	UN	UN	UN	LR	UN
Masking of Outcome Assessment (Detection Bias)	UN	UN	LR	UN	UN
Incomplete Outcome Data (Attrition Bias)	UN	LR	LR	LR	UN
Selective Reporting (Reporting Bias)	UN	LR	LR	LR	UN
Other Bias	HR	LR	LR	LR	UN
Overall Rating	HR	UN	UN	UN	UN

* Source: Higgins and Greene.[15]
† UN: Unclear risk.
‡ LR: Low risk.
§ HR: High risk.

eTABLE 4

Risk of bias assessment of included cross-sectional studies.*

CRITERION	LAYTON,[30] 1992	LAYTON AND KORSEN,[31] 1994	BRONS AND COLLEAGUES,[22] 2009
Was the Research Question or Objective in This Article Clearly Stated?	N†	Y‡	Y
Was the Study Population Clearly Specified and Defined?	Y	Y	N
Was the Participation Rate of Eligible People at Least 50%?	NR¶	NR	NR
Were All the Participants Selected or Recruited From the Same or Similar Populations (Including the Same Period)? Were Inclusion and Exclusion Criteria for Being in the Study Prespecified and Applied Uniformly to All Participants?	Y	N	Y
Was a Sample Size Justification, Power Description, or Variance and Effect Estimates Provided?	N	N	N
For the Analyses in This Article, Were the Exposures of Interest Measured Before the Outcomes Being Measured?	N	N	N
Was the Time Frame Sufficient So That One Could Reasonably Expect to See an Association Between Exposure and Outcome if It Existed?	Y	Y	Y
Were the Exposure Measures (Independent Variables) Clearly Defined, Valid, Reliable, and Implemented Consistently Across All Study Participants?	Y	Y	N
Were the Outcome Measures (Dependent Variables) Clearly Defined, Valid, Reliable, and Implemented Consistently Across All Study Participants?	Y	Y	Y
Were Key Potential Confounding Variables Measured and Adjusted Statistically for Their Effect on the Relationship Between Exposures and Outcomes?	N	N	N
Classification	Fair	Poor	Fair

* Source: National Heart, Lung, and Blood Institute.[16] We removed 4 original criteria because they were not applicable: "For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?"; "Was the exposure(s) assessed more than once over time?"; "Were the outcome assessors blinded to the exposure status of participants?"; and "Was loss to follow-up after baseline 20% or less?"
† N: No.
‡ Y: Yes.
§ CD: Cannot determine.
¶ NR: Not reported.

eTABLE 4 (CONTINUED)

BROSNAM AND PERRY,[10] 2009	ALFARO-CARBALLIDO AND GARCIA-RUPAYA,[20] 2011	FERRUS-TORRES AND COLLEAGUES,[24] 2011	RYAN AND COLLEAGUES,[33] 2011	SINGH AND COLLEAGUES,[12] 2013
Y	Y	Y	Y	Y
N	CD[§]	Y	CD	Y
Y	NR	NR	NR	Y
Y	Y	Y	CD	NR
N	Y	N	N	N
N	N	N	N	N
Y	CD	Y	Y	NR
N	N	Y	Y	Y
N	CD	Y	N	Y
N	CD	N	N	CD
Poor	Poor	Poor	Fair	Poor

eTABLE 5

Risk of bias assessment of included nonrandomized studies.*

CRITERION	HU AND COLLEAGUES,[26] 2008†
A Clearly Stated Aim	2
Inclusion of Consecutive Patients	2
Prospective Collection of Data	2
End Points Appropriate to the Aim of the Study	2
Unbiased Assessment of the Study End Point	0
Follow-up Period Appropriate to the Aim of the Study	2
Loss to Follow-up Less Than 5%	2
Prospective Calculation of the Study Size	0
Total	12 of 16

* Source: Slim and colleagues.[17]
† 0: Not reported. 2: Reported and adequate.

eTABLE 6

Risk of bias assessment of included qualitative methodology studies.*

CRITERION	KING,[28] 2001	ATCHISON AND COLLEAGUES,[21] 2005	STIRLING AND COLLEAGUES,[34] 2007	CLAYTON AND COLLEAGUES,[23] 2013	FLETT AND COLLEAGUES,[25] 2014
Was There a Clear Statement of the Aims of the Research?	Yes	Yes	Yes	Yes	Yes
Is a Qualitative Methodology Appropriate?	Yes	Yes	Yes	Cannot tell	Yes
Was the Research Design Appropriate to Address the Aims of the Research?	Cannot tell	Yes	Yes	Cannot tell	Yes
Was the Recruitment Strategy Appropriate to the Aims of the Research?	No	Yes	Yes	Yes	Yes
Were the Data Collected in a Way That Addressed the Research Issue?	Cannot tell	Yes	No	No	Yes
Has the Relationship Between Researcher and Participants Been Considered Adequately?	Yes	Yes	No	No	Yes
Have Ethical Issues Been Taken Into Consideration?	Yes	Yes	Yes	Yes	Yes
Was the Data Analysis Sufficiently Rigorous?	No	No	No	No	Yes
Is There a Clear Statement of Findings?	Cannot tell	Cannot tell	Cannot tell	Cannot tell	Yes
How Valuable Is the Research?	Yes	Yes	Yes	Yes	Yes
Overall Rating	5 of 10	8 of 10	6 of 10	4 of 10	10 of 10

* Source: Critical Appraisal Skills Programme.[18]