

# The CONSORT Statement: Application within and adaptations for orthodontic trials

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High-quality randomized controlled trials (RCTs) are an integral part of evidence-based medicine. RCTs are the bricks and mortar of high-quality systematic reviews, which are important determinants of health care policy and clinical practice. For published research to be used most effectively, investigators and authors should follow the guidelines for accurate and transparent reporting of RCTs. The consolidated standards of reporting trials (CONSORT) statement and its extensions are among the most widely used reporting guidelines in biomedical research. CONSORT was adopted by the *American Journal of Orthodontics and Dentofacial Orthopedics* in 2004. Since 2011, this *Journal* has been actively implementing compliance with the CONSORT reporting guidelines. The objective of this explanatory article is to highlight the relevance and implications of the various CONSORT items to help authors to achieve CONSORT compliance in their research submissions of RCTs to this and other orthodontic journals. (*Am J Orthod Dentofacial Orthop* 2015;147:663-79)

Randomized controlled trials (RCTs) are an integral part of evidence-based medicine. Readers of reports of RCTs must be able to understand exactly how the trial was conducted to assess its relevance and methodologic rigor. Two key principles are that the trials could be replicated from the information provided and that the methods and findings should be described in enough detail to allow inclusion of the trial in a subsequent systematic review.<sup>1</sup>

The consolidated standards of reporting trials (CONSORT) statement was developed to help improve the reporting of RCTs with guidance to researchers preparing reports of their clinical trials. The CONSORT checklist consists of 25 items covering all key aspects

of clinical trials, setting standards on how to report the design, conduct, analysis, and interpretation of such studies.<sup>2</sup> Several extensions to the main CONSORT guidelines cover more complicated designs such as cluster randomized and noninferiority trials; updated information is available at the CONSORT Web site (<http://www.consort-statement.org/extensions>). Over 600 biomedical journals, including the *American Journal of Orthodontics and Dentofacial Orthopedics* (AJO-DO) in 2004, have adopted the CONSORT guidelines, and many have also adopted additional CONSORT guidelines on abstract reporting.<sup>3</sup> Despite the widespread acceptance of these recommendations, there remains considerable scope for improving the reporting of clinical trials.<sup>4-8</sup>

The AJO-DO recognized that adoption does not guarantee compliance with the CONSORT guidelines and in 2011 implemented a scheme geared at improving compliance with CONSORT and so improve the reporting of RCTs in the *Journal*. This scheme includes videos, links to the CONSORT Web site, and active guidance for authors submitting reports of RCTs regarding compliance with the CONSORT guidelines. More recently, the reporting of RCTs by the AJO-DO has been reformatted with the introduction of subheadings to promote complete reporting and, by extension, to allow more efficient data extraction during the systematic review process.

Since these changes were introduced in the AJO-DO, published RCTs have shown dramatic improvements in

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reporting quality; this improvement reflects successful interactions among the editors, reviewers, and authors.<sup>9</sup> All published trials submitted between 2011 and 2013 reported 33 of the 37 CONSORT items and subitems. CONSORT items referring to changes to methods (3b), changes to outcomes after the trial commenced (6b), interim analysis (7b), and trial stopping (14b) were not fully reported. However, there is still a need to improve the reporting in the initial submissions to limit the need for editorial input to improve CONSORT compliance. The objectives of this article are to explain the requirements of the *AJO-DO* for RCT submissions and to describe and communicate the importance of each item in the CONSORT checklist as it relates to orthodontics. This article is based on the CONSORT 2010 explanation and elaboration document for reporting parallel group randomized trials.<sup>2</sup> A CONSORT-compliant published RCT has been uploaded on the *AJO-DO* Web site (Annotated RCT Sample Article) and will serve as the illustrative example.

## DESCRIPTION OF THE CHECKLIST ITEMS AND IMPORTANCE

The following explanations are based on the explanation and elaboration CONSORT document and are appropriately adapted to better target the *AJO-DO*'s audience (Table I).<sup>2</sup>

### TITLE AND ABSTRACT

CONSORT item 1a is "identification as a randomized trial in the title."

Example: "Survival of bonded lingual retainers (outcome) in orthodontic patients (participants) with chemical (intervention) or photo polymerization (comparison) over a 2-year period: A single-center, randomized controlled clinical trial."

Explanation: To help ensure that a study is appropriately indexed and easily identified, authors should use the word "randomized" in the title to indicate that the participants were randomly assigned to their comparison groups.<sup>10</sup> Authors are also encouraged (not a CONSORT item) to structure the title in the PICO+ format, providing information about participants, interventions, comparisons, and outcomes. The + sign indicates the possible inclusion of additional information pertaining to blinding, number of centers, time, and so on.

CONSORT item 1b is "structured summary of trial design, methods, results, and conclusions" (for specific guidance, see CONSORT for abstracts).

Explanation: There is specific guidance for reporting abstracts of RCTs (Table II). Well-written and detailed abstracts clearly describing the trial facilitate the initial

assessment of an article and aid the retrieval of trials from databases for inclusion in systematic reviews. The abstract is the only component of an article that is read by many clinicians; hence, the accuracy and the quality of its information are critical. Reporting of the abstract items will be considered at the end of this article, since almost all information relevant to the abstract will be discussed in detail in under the main CONSORT guideline items.

## INTRODUCTION

The introduction includes the background and the objectives.

### Background and objectives

CONSORT item 2a is "scientific background and explanation of rationale."

Example: "A significant problem continues to relate to bond failures, estimated at 6% to 25%, depending on the placement technique and the observation period... Although light-cured materials offer longer working times and improved moisture control, no randomized controlled trial has been published investigating the importance of these theoretical advantages."

Explanation: It is good practice at the planning stage of the trial to first search the literature to identify the available evidence on the topic of interest. This evidence can be limited or abundant, and identification of a high-quality systematic review, if available, is desirable. A recent high-quality systematic review, which summarizes the existing evidence, can serve as a reference in terms of what is known and what remains unclear regarding the efficacy and safety of the intervention of interest. The Declaration of Helsinki considers research on human subjects without thorough knowledge of the existing literature as unethical. It is also unethical to plan a trial to answer a question that has already been answered. A trial is justified when there is genuine uncertainty (equipoise), based on the existing evidence, regarding the effectiveness of the intervention at hand.<sup>11</sup>

In the RCT example, a systematic review is not cited, but the authors explicitly stated that no RCT has been published investigating the theoretical advantages of light curing vs chemical curing.

CONSORT item 2b is "specific objectives or hypotheses."

Example: "In this study, we aimed to compare the survival of mandibular lingual retainers placed by using either chemical or photopolymerization after orthodontic treatment."

**Table I.** CONSORT 2010 checklist of information to include when reporting a randomized trial<sup>2</sup>

<i>Section/topic</i>	<i>Item (n)</i>	<i>Checklist item</i>
Title and abstract		
	1a	Identification as a randomized trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance, see CONSORT for abstracts)
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
Interventions	5	Interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
Randomization		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomization; details of any restriction (such as blocking and block size)
Allocation concealment	9	Mechanism used to implement the random allocation sequence (eg, sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results		
Participant flow (diagram is strongly recommended)	13a	For each group, numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome
	13b	For each group, losses and exclusions after randomization, with reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up
	14b	Why the trial ended or was stopped
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis, and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance, see CONSORT for harms)
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalizability	21	Generalizability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (eg, supply of drugs) and the role of funders

**Table II.** CONSORT for abstracts checklist of items to include when reporting a randomized trial<sup>3</sup>

<i>Item</i>	<i>Description</i>
Title	Identification of the study as randomized
Authors*	Contact details for the corresponding author
Trial design	Description of the trial design (eg, parallel, cluster, noninferiority)
Methods	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomization	How participants were allocated to interventions
Blinding (masking)	Whether participants, care givers, and those assessing the outcomes were blinded to group assignments
Results	
Numbers randomized	Number of participants randomized to each group
Recruitment	Trial status
Numbers analyzed	Number of participants analyzed in each group
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision
Harms	Important adverse events or side effects
Conclusions	General interpretation of the results
Trial registration	Registration number and name of trial register
Funding	Source of funding
*This item is specific to conference abstracts.	

Explanation: The objectives are the questions that the trial was designed to answer. They often relate to the efficacy of a particular therapeutic or preventive intervention. Hypotheses are prespecified questions being tested to help meet the objectives. Hypotheses are more specific than objectives and are amenable to explicit statistical evaluations. In practice, objectives and hypotheses are not always easily differentiated.

## METHODS

### Trial design

CONSORT item 3a is “description of the trial design (eg, parallel, factorial) including the allocation ratio.”

Example: “This was a parallel-group, randomized, active controlled trial with a 1:1 allocation ratio.”

Explanation: The most common type of trial design is the parallel design; however, other designs such as cross-over, cluster randomized, noninferiority, factorial, and hybrids of those exist and should be specified. A study design commonly used in dentistry is the split-mouth design,<sup>12</sup> as well as studies including elements of clustered designs. Such designs occur when several observations are collected from each patient from multiple sites and tissues such as the number of teeth or periodontal sites or structures.<sup>13</sup> Different trial designs have characteristics that may influence the conduct and analysis of the

trial; these details should, therefore, be described clearly. It is important that specific details (design and allocation ratio) are given as shown under this subheading.

CONSORT item 3b is “important changes to methods after trial commencement (such as eligibility criteria), with reasons.”

Example: “No changes to the methods after trial commencement occurred.”

Explanation: Changes between the study protocol and how the trial was actually done are common and should be documented appropriately. Possible reasons for changes—eg, to eligibility criteria or duration of follow up—include new external evidence, inability to recruit a sufficient number of patients, and financial constraints. For some “adaptive” trials, the protocol allows for limited changes following prespecified rules, when the sample size and duration of the trial are not determined before commencement. The protocol should indicate the adjustments planned under the different change scenarios, and the changes should be documented, explained, and justified in the published article.<sup>14</sup> Any modifications to the trial design should be fully reported to help the reader interpret the results, whether they were anticipated in the protocol or in response to changing circumstances.

The RCT at hand reported no changes after the commencement of the trial; however, no published protocol allowed this to be verified, and this is reported at the end of the abstract.

## Participants

CONSORT item 4a is “eligibility criteria for participants.”

Example: “The following selection criteria were applied: no active caries, restorations, or fractures on the mandibular anterior teeth; no periodontal disease; and adequate oral hygiene.”

Explanation: Eligibility criteria and information on participants and settings should be outlined clearly because they have implications for the relevance of the trial results to other settings (generalizability). Because eligibility criteria are applied before randomization, they do not affect the internal validity (methodologic quality) of a trial.<sup>15</sup> The common distinction between inclusion and exclusion criteria is unnecessary; the same criterion can be phrased to include or exclude participants.<sup>16</sup>

CONSORT item 4b is “settings and locations where the data were collected.”

Example: “Consecutive patients who had completed orthodontic treatment with fixed appliances were recruited at the private practice of the first author (N.P.) from April 2009 to November 2010.”

Explanation: A clear description of the setting and locations where the data were collected is important to allow the reader to decide whether the findings are relevant to her or his own setting. Information on the geographic location, the number of participating centers, the available facilities, the involved care providers, and their levels of expertise should also be clearly described. Trial results may differ substantially, for example, between centers with state-of-the-art facilities with highly trained personnel and studies undertaken by relative novices in poorly equipped clinics.<sup>15</sup>

## Interventions

CONSORT item 5 is “interventions for each group with sufficient details to allow replication, including how and when they were actually administered.”

Example: “All patients received a soft bonded lingual retainer of 0.022-in (Tru-Chrome multi-stranded wire; Rocky Mountain Orthodontics, Denver, Colo) that was fabricated intraorally... In the chemical polymerization group, Maximum Cure 2-part liquid adhesive (Reliance Orthodontic Products, Itasca, Ill) was mixed and applied on the wire and the teeth, and Excel 2-part paste (Reliance Orthodontic Products) was mixed, loaded on a syringe dispenser, and applied. The dental floss was removed after 7 minutes. In the photopolymerization group, a light-cured liquid (Assure; Reliance Orthodontic Products) and a paste in 2 layers (Flow-Tain; Reliance Orthodontic Products) were placed on the wire and the

adjacent enamel, and light-cured for 9 seconds per tooth with a plasma light (Ortholite; 3M Unitek, Monrovia, Calif).”

Explanation: A clear description of each intervention in sufficient detail to allow a knowledgeable researcher to duplicate the experiment should be provided.<sup>17</sup> For example, in a multicenter trial, as a minimum, the exact method of standardization of the administration, the duration, and the timing of the treatment should be outlined.<sup>18</sup> A pharmacologic intervention would require explanation of the drug administered in conjunction with the mode of delivery, dosage, and frequency, and whether the control or placebo was indistinguishable from the “active pill” in terms of shape, color, smell, and taste. For other types of interventions, the CONSORT extension for nonpharmacologic trials describes the reporting requirements.<sup>19</sup> Some important issues are the standardization of the delivery of the interventions, description of the various components of the interventions, and how adherence of the care providers to the protocol was assessed. A clear description further facilitates the implementation of valid comparisons and informed decisions regarding the inclusion of the primary study in systematic reviews.<sup>17</sup>

## Outcomes

CONSORT item 6a is “completely defined prespecified primary and secondary outcome measures, including how and when they were assessed.”

Example: “The main outcome was any first-time failure of the lingual retainer. The secondary outcome was the pattern of failure based on the adhesive remnant... The patients were advised to visit the orthodontist initially at 1, 3, and 6 months after retainer placement, followed by scheduled appointments at 12, 18, and 24 months... When scheduled appointments were unfeasible, particularly approaching the end of the trial, an assessment of retainer integrity was made over the telephone.”

Explanation: It is common for trials to have several outcomes, often identified as primary and secondary. All outcomes should be clearly defined and prespecified with an explicit description of how and when they were assessed. The definition of each outcome should be clear enough to allow other investigators to use the same outcome in a trial or to be confident of the similarities and differences of the outcome in the context of a systematic review. Declaration of prespecified outcomes, especially the primary outcome, is important, since, like registration and protocol prepublication, it mitigates against the problem of selective reporting of “interesting” outcomes. This is more likely when multiple



outcomes or multiple time points of data collection are planned.<sup>20</sup> Additionally, recording of several outcomes, and consequently multiple testing, invokes the problems associated with multiplicity and misleading interpretations.<sup>21</sup>

When assessing the evidence for or against the effectiveness of an intervention, the balance of benefits and harms is an important consideration. A clear description of harms that were recorded should be provided.<sup>22</sup> In nonpharmacologic trials, it is particularly important to specify the skills and the number of persons assessing the outcomes.

CONSORT item 6b is “any changes to trial outcomes after the trial commenced, with reasons.”

Example: “There were no outcome changes after trial commencement.”

Explanation: Reviews of publications show that discrepancies between planned and presented outcomes are common.<sup>23</sup> Outcomes initially planned to be the primary outcomes in the original trial protocol may be portrayed as secondary outcomes, whereas new primary outcomes can be introduced in the published article. Selective outcome reporting and presentation of “interesting” findings has also been documented.<sup>20</sup> Therefore, clear descriptions of any outcome changes with the reasons for the alterations will enhance transparency. No outcome changes are reported in the RCT described; however, there is no prepublished protocol to confirm this.

### Sample size

CONSORT item 7a is “how sample size was determined.”

Example: “Calculation of sample size was based on the ability to detect a clinically relevant difference in the risk of first-time failure (primary outcome) of 20% between the 2 trial arms (15% vs 35% with  $\alpha = 0.05$  and power of 85%). Foek et al found a 35% failure rate for light-cured lingual retainers; we used this value as our reference for the sample calculation. This calculation indicated that 93 participants were required in each arm; this was rounded up to 110 to account for losses to follow-up.”

Explanation: RCTs should have enough power to detect a clinically important difference between the treatment groups if such a difference exists, or to confirm the lack of a difference. It is an obligation of the investigators to conduct appropriate sample-size calculations driven by clinical importance and reasonable assumptions.

Authors should provide enough information so that a knowledgeable reader can reproduce the sample-size

calculation.<sup>24,25</sup> The sample-size calculation is usually based on the primary outcome, which should be clearly identified. For continuous outcomes, the authors should report the expected result in the control group, the expected difference of the intervention group from the control, the standard deviations, and the alpha and power levels. For binary outcomes, the same information is required, except for the standard deviation. In designs where clustering effects are expected, the value of the intracluster correlation coefficient should be provided.<sup>26</sup> For split-mouth designs, common in orthodontics, the assumed correlations between sites should be specified.<sup>12,27</sup> Finally, any provisions for expected losses to follow-up should also be described. Authors should ideally explain the rationale for the values used in the calculation.

A post hoc analysis to justify the sample size is considered inappropriate: power can be judged by inspecting the effect size and confidence intervals and the uncertainty that they convey.<sup>28</sup>

CONSORT item 7b is “when applicable, explanation of any interim analyses and stopping guidelines.”

Example: “Not applicable.”

Explanation: Participants can be recruited and treated over a prolonged period. If an obvious difference between interventions emerges early in the trial, the study may be stopped prematurely for ethical reasons. This eventuality can be addressed by inspection of the interim results, ideally by an independent data-monitoring committee. However, performing multiple statistical examinations without appropriate corrections can lead to erroneous results and interpretations.<sup>21</sup> Authors should report whether they or a data-monitoring committee took several “looks” at the data; if so, how many were there, what triggered them, what statistical methods were used (including any formal stopping rule), and whether they were planned before the start of the trial, before the data-monitoring committee saw any interim data by allocation, or some time thereafter.

No interim analyses or stopping guidelines were reported in the example study.

### RANDOMIZATION

Randomization is the key advantage of RCTs compared with other prospective studies. Randomization in clinical trial methodology has a specific meaning and should be implemented so that neither the investigator nor the participants can predict the next treatment allocation. The terms “alternating allocation,” “randomly assigned,” and allocation based on some deterministic measure—eg, date of birth or day of the week—are not considered robust or explicit enough,

although they are often encountered in the dental literature.<sup>5,29</sup> Such inappropriate allocation schemes are not true randomization and have been associated with biased results. The process of randomization requires treatment allocation completely by chance, with a mechanism to conceal the treatment allocation before it actually occurs.

### Sequence generation

CONSORT item 8a is “method used to generate the random allocation sequence.”

Example: “Randomization was accomplished by using the “-ralloc-” command<sup>20</sup> in Stata software (StataCorp, College Station, Tex).”

Explanation: Random number generation is usually produced by using random tables or software capable of producing random sequences. It is important that authors clearly describe how the random number list was generated for the reader to make a judgment as to whether the method was appropriate.

CONSORT item 8b is “type of randomization; details of any restriction (such as blocking and block size).”

Example: “... in random permuted blocks of 20 patients, ensuring equal distribution in the 2 groups.”

Explanation: Several methods such as simple and permuted block randomization, stratified randomization, and minimization have been used in dental research.<sup>29</sup> Simple randomization resembles a toss of a coin and, although it is the most secure method because it is truly random, in small trials the probability of unequal sizes of the treatment arms is high. Use of permuted blocks ensures nearly balanced treatment groups, depending on the block size, whereas stratified randomization or minimization ensures balance of treatment groups with respect to the important outcome predictors.

Authors should clearly describe the randomization method and any restrictions applied. When permuted blocks are used, this should be indicated along with the block size and whether block size was fixed or variable, since this influences the predictability of subsequent allocations.

### Allocation concealment

CONSORT item 9 is “mechanism used to implement the random allocation sequence (eg, sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned.”

Example: “Allocation concealment was achieved with sequentially numbered, opaque, sealed envelopes

containing the treatment allocation cards, which were prepared before the trial.”

Explanation: Allocation concealment ensures unpredictability of treatment allocation by patients and investigators and is always feasible, unlike blinding, which is often difficult to implement in dental trials.<sup>30</sup> Methods of allocation concealment may include the use of sequentially numbered sealed opaque envelopes, or allocations assigned from an external center. The best method to conceal the allocation is to use an independent and centralized assignment protocol. With the latter, the randomization lists are generated and held securely in remote locations, thus reducing the chance of subverting the process.

### Implementation

CONSORT item 10 is “who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions?”

Example: “Baseline information was written on the outside before opening the envelope. The practice manager was responsible for opening the next envelope in sequence and implementing the randomization process.”

Explanation: Implementation of randomization pertains to who, when, where, and how the procedures of randomization (generation of randomization lists, allocation concealment, and treatment assignment) were implemented. In small studies, it is likely that the same investigators perform all tasks. However, it would be preferable to have different people perform the separate randomization procedures, because this would decrease the chance of biasing the process.

Lack of appropriate randomization and allocation concealment may introduce bias, thus rendering the results of the study questionable.<sup>30</sup> Among the various study designs, the RCT is considered to provide the highest quality of evidence; however, there is substantial evidence in the biomedical literature including dentistry that randomization and RCT quality, in general, are suboptimal, and that often clinical trials described as RCTs are mislabeled.<sup>5,31</sup> Therefore, a clear description of all the elements of randomization is required to allow the knowledgeable reader to assess the rigor of the methods.

### Blinding

CONSORT item 11a is “if done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how.”

Example: “Blinding of either patient or operator was not possible.”

Explanation: Authors should describe who was blinded (patients, investigators, data assessors, or data analysts). Differential follow-up (performance bias), outcome recording (detection bias), losses to follow-up (attrition bias), and biased data analysis associated with lack of blinding may bias the trial results.<sup>32</sup> Terminology regarding blinding varies and is confusing; therefore, a clear explanation is encouraged, rather than use of terms such as “single blind” or “double blind.”<sup>33</sup> Giving specific information allows the reader to better assess the potential risk of bias. If there are multiple outcomes, a clear description of blinding is required for each outcome.

CONSORT item 11b is “if relevant, description of the similarity of interventions.”

Example: “Blinding of either patient or operator was not possible; however, outcome assessment was blind because it was not possible to distinguish the light cured from the chemically cured composite.”

Explanation: Authors should clearly report, if applicable, any similarities between interventions that facilitate blinding. In dentistry, interventions often differ widely; however, blind outcome assessment can be feasible if, for example, it is done by a person not otherwise involved in the trial, and even when interventions are grossly dissimilar. Testing for the effectiveness of blinding is not recommended because responses may reflect accurate assumptions about the efficacy of the intervention<sup>34</sup>; known compromises to blinding such as unblinding any participants at any point during the conduct of a trial should be reported.

## Statistical methods

CONSORT item 12a is “statistical methods used to compare groups for primary and secondary outcomes.”

Example: “Comparisons of the survival of lingual retainers bonded with the 2 techniques were carried out with statistical methods for survival analysis. The log-rank test was used and Kaplan-Meier plots were produced. Hazard ratios (HRs) and associated 95% confidence intervals (CIs) were calculated using Cox regression modeling. The Nelson-Aalen plot was used to assess the proportional hazards assumption.

Explanation: Give specific details of implemented statistical analyses.

The principle is to provide “enough detail to enable a knowledgeable reader with access to the original data to verify the reported results” ([www.icmje.org](http://www.icmje.org)).<sup>1,35</sup> It is also important to describe details of who is included in each statistical analysis rather than rely on ambiguous labels such as an intention-to-treat (ITT) analysis.<sup>36</sup>

Additionally, a clear description of the handling of any missing data should be provided with clarification of whether the analysis followed the per-protocol or the ITT principle.<sup>36,37</sup> An ITT analysis is one in which all participants in a trial are analyzed according to the intervention to which they were allocated, regardless of whether they received it. ITT is favored in assessments of effectiveness (especially in pragmatic trials) because they mirror the noncompliance and treatment changes that are likely to occur when the intervention is used in practice, and because of the risk of attrition bias when participants are excluded from the analysis. ITT analysis requires participants to be included even if they did not fully adhere to the protocol. An important problem with ITT is missing data for participants in a clinical trial.

The terminology around ITT analysis is confusing and often interpreted differently by different authors; therefore, a clear delineation of the mechanism of data analysis is preferable to a simple statement related to ITT or per-protocol analysis or other alternatives such as treated, available, or consecutive patients. If there are missing data, any imputations and sensitivity analyses undertaken using plausible scenarios should be reported and compared.<sup>36,37</sup>

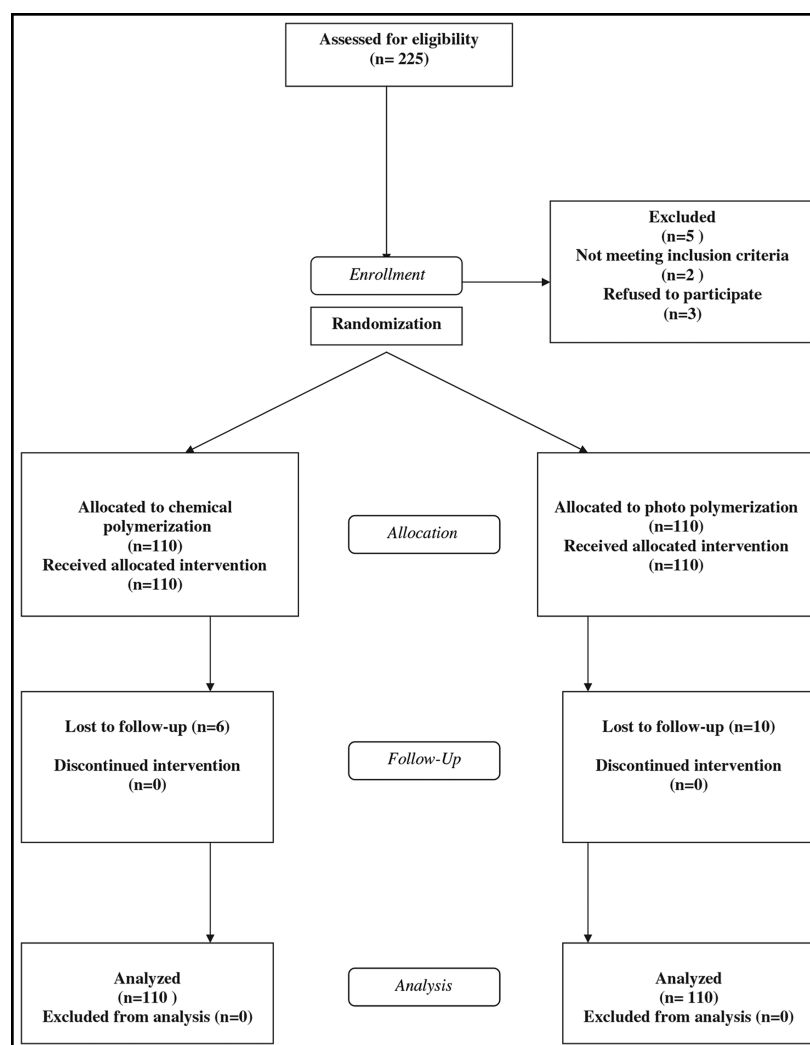
In this RCT, methods used for data analysis were outlined clearly in addition to assessments of the assumptions underpinning the statistical methods. Handling of missing data and sensitivity analyses were also discussed. Secondary analyses for the adhesive remnant index are shown; however, no subgroup analyses were conducted.

Standard methods of analysis assume that the data are “independent.” For RCTs, this usually means that there is 1 observation per participant. Treating multiple observations from 1 participant as independent data is a serious error; such data are produced when outcomes can be measured on different parts of the body, as in dentistry. Data analysis should be based on counting each participant once or should be done by using more complex statistical procedures suitable for nonindependent data.<sup>13</sup> Empirical evidence has shown that statistical methods are not clearly described and that observations that are not independent, such as bond failures nested within patients, are often inappropriately treated as independent observations.<sup>38,39</sup>

CONSORT item 12b is “methods for additional analyses, such as subgroup analyses and adjusted analyses.”

Example: “Missing outcome data were imputed by using the variables of intervention type, sex, and age. Imputations were performed under the missing-at-random assumption: ie, assuming that with the given intervention type, sex, and age, the distribution of





**Fig 1.** Example of a CONSORT flow chart showing patient flow during the trial.

outcomes was the same whether or not we were able to observe it. Imputations were implemented using the “-mi-” family of commands adapted for Cox regression. Adhesive remnant index scores between composites were compared by using the Fisher exact test.”

**Explanation:** It is important to realize that as the number of statistical tests conducted increases, the chance of a false-positive result also increases.<sup>21</sup> Although multiple subgroup analyses are discouraged, they are common in dental trials<sup>40</sup> and may result in selective reporting of “interesting” results and incorrect interpretations.<sup>20</sup> Authors should limit the number of subgroup analyses and should clearly indicate whether those analyses were prespecified or post hoc and exploratory.

## RESULTS

### Participant flow

CONSORT item 13a is “for each group, numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome.”

**Example:** “Figure 1 is an example of a CONSORT flow chart showing the flow of patients through a trial.”

**Explanation:** The flow diagram is a quick visual aid that shows the flow of participants through the different stages of the trial. Any losses to follow-up, balanced or unbalanced, are easily observed as well as the numbers of eligible, randomized, and analyzed patients. Participants assessed for eligibility should also be reported, if available, since it is a useful indicator of whether the trial

**Table I.** Baseline characteristics of patients in each treatment group

	Total n = 220 Median or %	IQR	Excel n = 110 Median or %	IQR	Flow-Tain n = 110 Median or %	IQR
Demographic characteristics						
Age (y)	16.0	15-17	16.0	15-17	15.0	15-17
Sex						
Female	72.7		71.8		73.6	
Male	27.3		28.2		26.4	
Clinical characteristics						
Gingival index	1.5	1-2	1.3	1-2	1.5	1-2
Cooperation						
Bad	26.4		27.3		25.5	
Average	55.9		59		52.7	
Excellent	17.7		13.7		21.8	
Angle Class						
I	59.2		56.4		62	
II	39		40.9		37	
III	1.8		2.7		1	
IQR, Interquartile range; Excel, chemically cured adhesive; Flow-Tain, light-cured adhesive.						

**Fig 2.** Example of a table reporting the baseline characteristics of patients in different treatment groups.

participants were likely to represent all eligible participants.

CONSORT item 13b is “for each group, losses and exclusions after randomization, with reasons.”

Example: “Two hundred twenty patients (median age, 16 years; interquartile range, 2 years; range, 12-47 years) were randomized in a 1:1 ratio to either chemical or light curing; 16 patients were lost to follow-up (Figs 1 and 2). Patient recruitment commenced in April 2009 and ended in November 2010.”

Explanation: Authors should clearly report losses and exclusions after randomization with the reasons. This allows assessment of how reasonable were the exclusions.<sup>41</sup> Additionally, the loss in power from the reduced sample size can also be gauged.

The example RCT includes a flow diagram containing specific information relating to participant flow and losses to follow-up.

### Recruitment

CONSORT item 14a is “dates defining the periods of recruitment and follow-up.”

Example: “Patient recruitment commenced in April 2009 and ended in November 2010.”

Explanation: Reporting the timing and the duration of participant recruitment provides historical context and may be of value to future investigators. In some trials, especially in studies assessing time to event outcomes, the length of follow-up is not fixed for all participants; rather, follow-up may be ended at a

prespecified time point, perhaps when a fixed number of outcome events have been observed.

CONSORT item 14b is “why the trial ended or was stopped.”

Explanation: Results from trials that are completed as planned are more trustworthy than trials ending prematurely, especially if the decision was based on examining the data. Authors should clearly indicate whether the trial ended early, including information on the timing and reasons for early termination.

This study did not stop early and contained details of recruitment and follow-up.

### Baseline data

CONSORT item 15 is “a table showing baseline demographic and clinical characteristics for each group.”

Example: “Baseline characteristics of the patients in the treatment groups are reported in the Table.” (Fig 2 is an example of a table reporting baseline characteristics.)

Explanation: If randomization has been carried out properly, treatment groups should be similar in respect of baseline characteristics. Baseline data collected from all participants may include demographic variables (ie, age, sex, and ethnicity) and clinical characteristics including type of malocclusion, baseline measurements of crowding, and oral hygiene status. Baseline data should be collected before random allocation, so that the data collection is not influenced by knowledge of the treatment allocation. For example, an investigator

**Table II.** Number of failures (%), total follow-up periods in person-years per treatment group, median follow-up periods, and ranges

<i>Risk factor</i>	<i>Total number (%)</i>	<i>No. of failures observed (%)</i>	<i>Follow-up period in person years</i>	<i>Median (y)</i>	<i>Range (y)</i>
Adhesive					
Excel	110 (50)	47 (42.7)	206.30	2.22	0.003-3.64
Flow-Tain	110 (50)	55 (50.0)	201.68	2.16	0.005-3.58

*Excel*, Chemically cured adhesive; *Flow-Tain*, light-cured adhesive.

**Fig 3.** Example of a table reporting the number of failures and the follow-up period.

favoring the newer treatment may unconsciously record baseline data in a biased manner (eg, round up or down the amount of crowding) and in a way that would prove preconceptions about the new treatment.

Baseline data displayed in a table allow for quick assessment of similarities between the treatment group participants. Small differences between groups in baseline characteristics are expected due to chance, especially in small trials. Large and important differences between group participants at baseline may be associated with improper randomization.

For continuous variables, such as intermolar width or root length, means (and standard deviations) or medians (and interquartile ranges) should be included. Variability should not be reported by using standard errors and confidence intervals because they are inferential and not descriptive. Variables with a small number of ordered categories should not be treated as continuous variables; instead, numbers and proportions should be reported for each category.<sup>1</sup> Statistical testing with the objective to assess the balance of baseline characteristics between treatment arms is not recommended and is potentially misleading.<sup>42</sup> It is more sensible that “comparisons at baseline should be based on consideration of the prognostic strength of the variables measured and the size of any chance imbalances that have occurred.”<sup>2</sup>

### Numbers analyzed

CONSORT item 16 is “for each group, number of participants (denominator) included in each analysis, and whether the analysis was by original assigned groups.”

Example: “Two years after entry of the final patient, 47 of 110 (42.7%) and 55 of 110 (50.0%) retainers bonded with chemically cured and light-cured adhesives had failed, respectively. The primary analysis was carried out on an intention-to-treat basis involving all patients randomized after imputation of missing data.” (Fig 3 is an example of a table reporting the number of failures and the follow-up period.)

Explanation: The number of participants per group should be clear for all analyses. For binary outcomes (ie, risk ratio and risk difference), the denominators or event rates should also be reported. Expressing results as fractions aids the reader in assessing whether some randomly assigned participants were excluded from the analysis. It follows that results should not be presented solely as summary measures, such as relative risks.

### Outcomes and estimation

CONSORT item 17a is “for each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI).”

Example: “The hazard ratio (HR) with the imputed data was 1.15 (95% CI, 0.88-1.70;  $P = 0.47$ ). There was weak evidence indicating that age might be a significant predictor of lingual retainer failure (HR, 0.96; 95% CI, 0.93-1.00;  $P = 0.08$ ). Imputed analysis gave similar HRs with both; the data with no imputations assumed that all missing observations were censored. Adhesive remnant index scoring was possible for only 66 of the 102 (64.7%) failures and did not differ between composites (Fisher exact test,  $P = 0.16$ ); most confirmed failures occurred at the enamel adhesive level.” (Fig 4 is an example of a table reporting hazard ratios from Cox regression.)

Explanation: For the primary outcome, authors should report the results as a summary of the outcome in each group (eg, the number of participants with or without the event, or the means and standard deviations of the measurements), together with the contrast between groups, known as the effect size. For binary outcomes, the effect size could be the relative risk, relative risk reduction, odds ratio, or risk difference. For survival time data, the measurement could be the hazard ratio or difference in median survival time. For continuous data, the effect measure is usually the difference in means. Authors should present confidence intervals for the contrast between groups and as a measure of the precision (uncertainty) of the estimate of the effect. The more

**Table III.** Hazard ratios from Cox regression for type of adhesive adjusted for age using imputed data for unobserved failures from losses to follow-up and censoring for unobserved failures

Risk factor	Hazard ratio imputed (95% CI)	P value*	Hazard ratio observed (95% CI)	P value*
Adhesive				
Excel	Referent		Referent	
Flow-Tain	1.15 (0.88-1.70)	0.47	1.16 (0.78-1.72)	0.44
Age (per year)	0.96 (0.93-1.00)	0.08	0.97 (0.93-1.01)	0.09

Excel, Chemically cured adhesive; Flow-Tain, light-cured adhesive.

\*Wald test.

**Fig 4.** Example of a table reporting hazard ratios from Cox regression.

clinically relevant and important pieces of information obtained from the results would be the actual difference or the effect size and its uncertainty. *P* values, although indicating a statistically significant result, provide limited insight into the clinical relevance of the findings. Reporting confidence intervals moves the interpretation of the results from the dichotomy of significant or nonsignificant to the size of the effect or the association and its range of plausible values given by the data under study.<sup>1</sup> For paired designs such as split-mouth studies, the within-patient correlation coefficient should be provided to inform future sample calculations.<sup>12</sup> Similarly, for designs with clustering effects, the intraclass correlation coefficient or the coefficient of variation ( $\kappa$ ) should be provided.<sup>13,43</sup>

CONSORT item 17b is “for binary outcomes, presentation of both absolute and relative effect sizes is recommended.”

Example: “Two years after entry of the final patient, 47 of 110 (42.7%) and 55 of 110 (50.0%) retainers bonded with chemically cured and light-cured adhesives had failed (risk difference: 7.3%; 95% CI: -5.9%, 20.5%), respectively.”

Explanation: Preferably, for binary data, both absolute and relative risks should be provided, since an interpretation of either in isolation can be misleading.<sup>44</sup> For example, a small absolute difference of 2 risks (4% - 2% = 2%) equates to a risk ratio of 2 (risk ratio, 4/2 = 2). However, a larger absolute difference between risks (40% - 20% = 20%) may present the same difference in a ratio scale (risk ratio, 40/20 = 2); interpretation based on absolute differences (2% vs 20%) may, however, be quite different. Effect estimates in a relative scale, like risk ratios and odds ratios, are more generalizable across populations than risk differences (difference in proportions), since the latter depend on the baseline risk of the control group that varies across populations.

Patients were analyzed according to the ITT principle after missing-data imputations. The estimated hazard ratio and the absolute risk difference with associated

95% confidence intervals for the main comparisons are provided. For the secondary outcome (adhesive remnant index), the numbers analyzed and the *P* values are only provided, since only 66% of the failures were examined for this outcome.

### Ancillary analyses

CONSORT item 18 is “results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory.”

Example: “Adhesive remnant index scoring was possible for only 66 of the 102 (64.7%) failures and did not differ between composites (Fisher exact test, *P* = 0.16); most confirmed failures occurred at the enamel adhesive level.”

Explanation: Participants in clinical trials vary in demographic or clinical baseline characteristics, and it is possible that response to interventions may be influenced by baseline characteristics. Subgroup analyses may be undertaken to identify whether treatment effects vary across patient groups defined by baseline characteristics such as same sex, age, socioeconomic status, oral hygiene, and cooperation with orthodontic treatment. As the number of analyses increases, so does the probability of observing some false-positive results (multiplicity problem).<sup>21</sup> Reporting of subgroup comparison results may be manipulated, with “interesting” results overemphasized creating false impressions of treatment effectiveness; subgroup comparisons should ideally be prespecified.<sup>20</sup> Similarly, any adjustments for baseline variables should preferably be prespecified; it should be stated whether they were carried out as a result of observing baseline imbalances.

### Harms

CONSORT item 19 is “all important harms or unintended effects in each group (for specific guidance, see CONSORT for harms).”



Example: “No serious harm was observed other than gingivitis associated with plaque accumulation.”

Explanation: When assessing the evidence for or against the effectiveness of an intervention, the balance of benefits and harms is an important consideration. A clear description of harms assessed and their frequency by treatment group should therefore be provided. An extension of the CONSORT statement on reporting harms in RCTs is available<sup>22</sup>; in the present trial, no harms other than gingivitis associated with plaque accumulation were reported.

## DISCUSSION

### Limitations

CONSORT item 20 is “trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.”

Example: “Our study’s limitation might be that it was not possible to examine all patients to inspect the failures, particularly near the end of the study.”

Explanation: In the discussion section, the limitations of the trial—particularly potential sources of biases, including measurement bias and attrition bias—should be mentioned. The degree of imprecision of the observed effect estimates should be discussed with reference to the reported confidence intervals; emphasis should be placed on clinical significance rather than *P* values and statistical significance.<sup>37,44,45</sup>

Similarly, greater attention should be given to outcomes from the primary, prespecified analysis; results from subgroup analyses and after multiple testing should be interpreted with caution.<sup>45,46</sup>

### Generalizability

CONSORT item 21 is “generalizability (external validity, applicability) of the trial findings.”

Example: “The generalizability of these results might be limited because this research was undertaken in a single center by 1 clinician (N.P.) experienced in both chemically cured and light-cured bonding.”

Explanation: Applicability of the results of a trial to other settings and populations is often feasible as long as the trial’s inclusion and exclusion criteria are similar and under the assumption of consistent biologic responses.<sup>15,47</sup> For example, would the results of an RCT from the United States assessing bond failures of brackets bonded with self-etching primers or conventional acid etching with only adult subjects be applicable to adults in the United Kingdom? Probably yes. Would the same results apply to adolescents? Important differences in cooperation between adults and adolescents may influence the results; age-

related differences should therefore be considered when assessing external validity.

External validity relies on internal validity; therefore, if trial results are invalid due to biased methods, the question of external validity is irrelevant. External validity depends on the setting and the characteristics of the subjects, interventions, and outcomes of the trial as they are defined by the inclusion and exclusion criteria.

### Interpretation

CONSORT item 22 is “interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.”

Example: “Although no significant difference in retainer failure rates was noted, the numbers of recorded failures were considerable, ranging from 43% to 50% over a 2-year period after debonding. This preponderance of failures is compatible with a recent prospective...”

“Our relatively high failure rate... might be related to the prospective design and the relatively lengthy follow-up. Similarly, any breakage was recorded as such; therefore, even minor fractures of little consequence, which might have been overlooked in other retrospective studies, were recorded as failures in this study.”

Explanation: The discussion should consider the evidence as a whole, ideally in the context of a systematic review, rather than focusing on just the current trial or on selected studies, perhaps those that corroborate the trial results.

This trial discusses the results in the context of the existing evidence, highlighting the limitations of the study and the complexity of achieving prolonged follow-up, with comments on the generalizability of the findings, because the treatment was confined to 1 experienced operator.

## OTHER INFORMATION

### Registration

CONSORT item 23 is “registration number and name of trial registry.”

Example: “This trial was not registered.”

Explanation: To minimize the likelihood of nonpublication and data withholding, selective reporting, and duplicate publications, trial registration has been required for publication by the International Committee of Medical Journal Editors.

This position has resulted in a dramatic increase in the number of trials that are registered. In an abstract reporting a trial, the authors should provide details of the trial registration number and the name of the trial register.<sup>48</sup> This enables readers to obtain more information about the trial and its results. Registration information



also helps to link a report with subsequent full publications (or multiple reports from the same trial) and thus reduces the risk of inadvertent double counting in systematic reviews.

Unregistered trials continue to be published in *AJO-DO*; this allows for unregistered ongoing trials to be considered for publication. At present, the lack of registration will not preclude publication; the key is that registration or otherwise is transparent. However, this situation is likely to change in the future; investigators are therefore strongly encouraged to register trials at the outset (eg, via <https://clinicaltrials.gov/>).<sup>49</sup>

### Protocol

CONSORT item 24 is “where the full trial protocol can be accessed, if available.”

Example: “The protocol was not published before trial commencement.”

Explanation: Prepublication of the trial protocol is important because it gives all the prespecified details of the trial. Having the protocol in a public domain allows comparisons between what was intended and what was actually done, and therefore discourages selective reporting of only “interesting” results.<sup>20</sup> Publication of the protocol also informs the scientific community of planned and ongoing trials and allows for better communication and increased efficiency for researchers and systematic reviewers. The SPIRIT guidelines describe in detail the requirements for drafting an RCT protocol.<sup>50</sup>

Ideally, whether and where the protocol is available should be made clear. Transparency is paramount; CONSORT focuses on accurate reporting of what was done during the research study without judging this.

### Funding

CONSORT item 25 is “sources of funding and other support (ie, supply of drugs), and the role of funders.”

Example: “No funding or conflict of interest is declared.”

Explanation: Funding and other forms of support should be declared explicitly. It has been shown that trials sponsored by the pharmaceutical industry have higher odds of having outcomes favoring the sponsor than do studies funded by other sources.<sup>51</sup> Typically, sources of funding are reported at the end of the abstract or in the “acknowledgments” section of the article.

### ABSTRACT

In the final section of this explanatory article, we address how to report the abstract of a randomized trial, following CONSORT for abstracts guidelines.<sup>3</sup> These

items have all been described above; however, a short description is necessary, since orthodontic abstracts are often reported incompletely.<sup>6</sup>

The checklist for what to include in the abstract is shown in Table II. The key points are as follows.

1. An important reason for clarifying the trial design is to ensure appropriate indexing in electronic databases, ensuring greater ease of identification.

Example: “2-arm parallel trial.”

2. Clear descriptions of the trial participants and the setting in which they were studied are needed so that readers can assess the external validity (generalizability) of the trial and determine the applicability to their own setting.

Example: “Eligibility criteria included no active caries, restorations, or fractures in the mandibular anterior teeth, and adequate oral hygiene.”

3. The essential features of each experimental and comparison intervention should be described.

Example: “Patients having undergone orthodontic treatment at a private orthodontic office were randomly allocated to fixed retainers placed with chemically cured composite or light-cured composite.”

4. The abstract should provide a clear statement of the specific objective or hypothesis addressed in the trial.

Example: “The objective of this trial was to compare the survival rates of mandibular lingual retainers bonded with either a chemically cured or a light-cured adhesive after orthodontic treatment.”

5. The authors should explicitly state the primary outcome for the trial and when it was assessed (eg, the time frame over which it was measured).

Example: “The main outcome was any type of first-time lingual retainer breakage; pattern of failure (adapted adhesive remnant index scores) was a secondary outcome. Patients were reviewed at 1, 3, and 6 months and then every 6 months after placement of the retainer until completion of the study.”

6. It is important to give details of the random sequence generation method, the randomization method, and the restrictions implemented, and also of the concealment of the allocation sequence from those assigning participants to the intervention groups. Allocation concealment prevents

investigators from influencing which participants are assigned to an intervention group (ie, selection bias).

Example: "Randomization was accomplished with random permuted blocks of 20 patients with the allocations concealed in sequentially numbered, opaque, sealed envelopes."

7. Authors should clarify whether the participants, those administering the intervention (usually health care providers), and those assessing the outcome (data collectors and analysts) were blinded to the group allocation.

Example: "Blinding was applicable for the outcome assessment only."

8. The number of participants randomized to each intervention group should be explicit because it is an essential element of the results of a trial. This number defines the sample size, and readers can use it to assess whether all randomized participants were included in the data analysis.

Example: "Two hundred twenty patients (median age, 16 years; interquartile range, 2 years; range, 12-47 years) were randomized in a 1:1 ratio to either chemical or light curing."

9. For the primary outcome, the authors should report the results as a summary of the outcome in each group (eg, the number of participants with or without the event, or the means and standard deviations of the measurements), together with the contrasts between the groups, known as the effect size. For binary outcomes, the effect size could be relative risk, relative risk reduction, odds ratio, or risk difference. For survival time data, the measurement could be the hazard ratio or the difference in median survival times. For continuous data, the effect measure is usually the difference in means. Authors should present confidence intervals for the contrasts between groups and as a measure of the precision (uncertainty) of the estimate of the effect.

Example: "At a minimum follow-up of 2 years, 47 of 110 (42.7%) and 55 of 110 (50.0%) retainers had some type of failure with chemically cured and light-cured adhesives, respectively (log-rank test,  $P = 0.35$ ). Data were analyzed on an intention-to-treat basis, and the hazard ratio (HR) was 1.15 (95% CI, 0.88-1.70;  $P = 0.47$ ). There was weak

evidence that age is a significant predictor for lingual retainer failures (HR, 0.96; 95% CI, 0.93-1.00;  $P = 0.08$ ). Adhesive remnant index scoring was possible for only 66 of the 102 (64.7%) failures and did not differ between composites (Fisher exact test,  $P = 0.16$ )."

10. To make balanced decisions, readers need information about the relative benefits and harms of an intervention. Important adverse (or unexpected) effects of an intervention should be alluded to in the abstract. If no important adverse events have occurred, the authors should state this explicitly.

Example: "No serious harm was observed other than gingivitis associated with plaque accumulation."

11. The conclusions of the trial, consistent with the results reported in the abstract, should be clearly stated along with their clinical applications (avoiding generalizations). When applicable, authors should also note whether additional studies are required before the results are used in clinical settings.

Example: "The results of this study indicated no evidence that survival of mandibular lingual retainers differs between chemically and light-cured adhesives. The overall failure rate was 46.4%; however, this included any type of failure, which could have exaggerated the overall failure rate."

12. Registration of the trial and the details of the research protocol, although not a CONSORT statement item, and funding should be documented.

Examples: "This trial was not registered," "the protocol was not published before trial commencement," or "no funding or conflict of interest is declared."

## CONCLUSIONS

When making clinical decisions, the evidence-based dentistry approach amalgamates the best available evidence, clinical expertise, and patients' preferences and values. High-quality RCTs form the backbone of systematic reviews, which should be at the forefront of evidence-based decision-making. Complete and transparent trial reporting facilitates accurate assessment of the quality of the study and correct interpretation of the results. Moreover, identification of studies suitable

for inclusion in systematic reviews, appraisal of primary studies, and data extraction are expedited by clear reporting. Empirical evidence has shown that reporting of RCTs in medicine and dentistry remains suboptimal and is compromised by failure to publish, and by incomplete, selective, and misleading reporting. The CONSORT guidelines provide influential and important answers to these problems, and should be adhered to when reporting clinical trials in orthodontics. They can also inform the design and conduct of trials.

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