**Development of a RoB Tool for Systematic Reviews of Dental Materials Laboratory Studies (DELPHI Round 1)**

**Dear Voter,**

First of all we would like to thank you for taking the time to answer this form and to participate in the development of the novel RoB Tool. We believe your response is important to build solid feedback that will help us shape this upcoming tool for systematic review projects. This is a collaborative project undertaken with the Dental Materials Group of the International Association for Dental Research (DMG-IADR) and the European Federation of Conservative Dentistry (EFCD).

In order to design such tool, an online survey round will be conducted, following the DELPHI method, for invited voters which are experts in the field, to rate the RoB items and proposals. A feedback form will be generated for this round and subsequent rounds, if need be. This is the first DELPHI Round.

For this DELPHI round we will vote on the items and domains of the RoB tool, the scoring scale, the averaged final score and the name (acronym) of the tool. In some questions you will have multiple choice answers, whereas in others you will be asked to rate each response on a 5-point Likert scale from "Strongly disagree" to "Strongly agree" with a box for optional comments underneath. We encourage each voter to argument their decisions. This will help the feedback and progress into the following rounds.

For those unfamiliar with RoB tools, please click the links below for some existing official examples, not related to laboratory studies (which do not yet exist):

Cochrane's RoB2 Tool for RCTs

<https://drive.google.com/file/d/1Q4Fk3HCuBRwIDWTGZa5oH11OdR4Gbhdo/view>

RoB Tool for Animal Experimentation Studies-

<https://www.researchgate.net/profile/Yuan-Li-275/publication/321059485/figure/fig2/AS:560642843463684@1510679078652/Risk-of-bias-RoB-measured-using-the-Systematic-Review-Centre-for-Laboratory-animal_W640.jpg>

Note that not all domains may apply to all studies, but that researchers should make a conscious decision as to which domains to assess or not and justify this.

Many thanks for your participation and help in achieving this,

António HS Delgado and Falk Schwendicke

**Domain 1 (D1): Bias in Planning and Allocation**

This is the first domain of the RoB tool. In this domain, reviewers should assess in depth bias arising from planning the study and allocating samples. Bias in this domain will influence the experimental design.

Please vote on the items belonging to this domain, shown below.

𝐃𝟏 𝐁𝐢𝐚𝐬 𝐢𝐧 𝐏𝐥𝐚𝐧𝐧𝐢𝐧𝐠 𝐚𝐧𝐝 𝐀𝐥𝐥𝐨𝐜𝐚𝐭𝐢𝐨𝐧

𝐃𝟏.𝟏 There is a c𝐨𝐧𝐭𝐫𝐨𝐥 𝐠𝐫𝐨𝐮𝐩

- In this first source of bias, studies are judged on whether they have an adequate control group, which may be positive or negative, within their experimental design.

𝐃𝟏.𝟐 There is a s𝐚𝐦𝐩𝐥𝐞 𝐬𝐢𝐳𝐞 𝐜𝐚𝐥𝐜𝐮𝐥𝐚𝐭𝐢𝐨𝐧 𝐚𝐧𝐝 it is 𝐫𝐞𝐩𝐨𝐫𝐭ed

- The second source of bias evaluates whether a sample size calculation was performed prior to planning the study and if it was reported allowing replication.

𝐃𝟏.𝟑 There was a random allocation of 𝐬𝐚𝐦𝐩𝐥𝐞𝐬

- Samples should be randomly allocated to different groups. The method for generating the randomization sequence (e.g., computer generated sequence, random number attribution table shuffling envelopes or cards etc.) should be reported along with the method of concealing the sequence until the experimental intervention was applied.

**Do you agree with the first source of bias identified within this domain, which is "There is a control group"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you agree with the second source of bias to be included in this domain: "There is a sample size calculation and it is reported"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you agree with the third source of bias identified within this domain, which is "There was a random allocation of samples"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you agree with the order of the sources of bias within this Domain? Please write "Yes" or "No". If "No" please explain why and give us other suggestions.**

**Answer:**

**Domain 2 (D2): Bias in Specimens Preparation**

The second domain proposed for this RoB tool is bias arising from preparing specimens. In this domain, reviewers should judge whether the researchers minimized bias when specimens were being prepared or repetitions were being carried out.

The sources of bias identified within this domain are shown below.

𝐃𝟐 𝐁𝐢𝐚𝐬 𝐢𝐧 𝐒𝐩𝐞𝐜𝐢𝐦𝐞𝐧 𝐏𝐫𝐞𝐩𝐚𝐫𝐚𝐭𝐢𝐨𝐧

𝐃𝟐.𝟏 There were i𝐝𝐞𝐧𝐭𝐢𝐜𝐚𝐥 𝐞𝐱𝐩𝐞𝐫𝐢𝐦𝐞𝐧𝐭𝐚𝐥 𝐜𝐨𝐧𝐝𝐢𝐭𝐢𝐨𝐧𝐬 𝐚𝐜𝐫𝐨𝐬𝐬 𝐠𝐫𝐨𝐮𝐩𝐬.

- In this first source of bias, judgment on the experimental conditions among different groups is required. Were the conditions standardized, was this sufficiently documented or could there have been systematical differences between the conditions of experimental groups? Were the same materials used (except for the material of interest, for example) and applied without variation (i.e. two different types of glue to fix the jigs)? Were factors such as temperature, humidity, time and equipment settings fixed and controlled?

𝐃𝟐.𝟐 There was a s𝐭𝐚𝐧𝐝𝐚𝐫𝐝𝐢𝐳𝐚𝐭𝐢𝐨𝐧 𝐨𝐟 𝐬𝐚𝐦𝐩𝐥𝐞𝐬 𝐚𝐧𝐝 𝐦𝐚𝐭𝐞𝐫𝐢𝐚𝐥𝐬

- Were samples and materials used standardized, e.g. only sound teeth, teeth free of restorations, caries and other defects, resin composites of specific colours which affect polymerisation properties etc.. Were manufacturer's recommendations followed? Are there sufficient data regarding polymerisation of samples, with correct reporting of irradiance output, wavelength, tip distance? Was thickness of the material controlled?

- Overall, this subdomain should allow replication of the sample preparation.

**Do you agree with the first source of bias to be included in this domain: "There were identical experimental conditions across groups"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you agree with the second source of bias to be included in this domain: "There was a standardization of samples and materials"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you have any other suggestions for this Domain? Please write "Yes" or "No". If "Yes" please explain which.**

**Answer:**

**Domain 3 (D3): Bias in outcome assessment**

The third domain proposed for this RoB tool is bias arising from the testing procedures and assessment. This relates to whether the tests carried out are appropriate to meet the objectives of the study and whether the operator was blind to which samples were being tested.

The sources of bias identified within this domain are shown below.

𝐃𝟑 𝐁𝐢𝐚𝐬 𝐢𝐧 𝐨𝐮𝐭𝐜𝐨𝐦𝐞 𝐚𝐬𝐬𝐞𝐬𝐬𝐦𝐞𝐧𝐭

𝐃𝟑.𝟏 𝐀n a𝐝𝐞𝐪𝐮𝐚𝐭𝐞 𝐚𝐧𝐝 𝐬𝐭𝐚𝐧𝐝𝐚𝐫𝐝𝐢𝐳𝐞𝐝 𝐭𝐞𝐬𝐭𝐢𝐧𝐠 𝐩𝐫𝐨𝐜𝐞𝐝𝐮𝐫𝐞 was conducted 𝐚𝐧𝐝 𝐨𝐮𝐭𝐜𝐨𝐦𝐞𝐬 fitting to the question of the study were reported.

- In this item, reviewers should assess whether the tests carried out in the study were appropriate for the outcomes set out by the researchers. Was the measuring equipment/instrument or test choice adequate to meet the objectives set out in the study? Were testing procedures standardized and, when applicable, were ADM guidances for dental materials or ISO/ASTM standards followed (e.g., microtensile bond strength, mechanical properties, shrinkage and polymerisation)?

𝐃𝟑.𝟐 There was b𝐥𝐢𝐧𝐝𝐢𝐧𝐠 𝐨𝐟 𝐭𝐡𝐞 𝐭𝐞𝐬𝐭𝐢𝐧𝐠 𝐨𝐩𝐞𝐫𝐚𝐭𝐨𝐫

- If applicable to the study design and whenever possible, was the operator blind to the experimental groups being tested? Were tests carried out by the same operator that prepared the specimens, and if so, how was blinding carried out?

**Do you agree with the first source of bias to be included in this domain: "An adequate and standardized testing procedure was conducted and outcomes fitting to the question of the study were reported"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you agree that the second source of bias to be included in this domain should be: "There was blinding of the testing operator"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you have any other suggestions for this Domain? Please write "Yes" or "No". If "Yes" please explain which.**

**Answer:**

**Domain 4 (D4): Bias in data treatment and outcome reporting**

The fourth domain proposed for this RoB tool is bias arising from the testing procedures and assessment. In this domain, reviewers should judge the statistical analysis undertaken in the study and whether the outcomes were correctly reported, with no missing relevant data.

The sources of bias identified within this domain are shown below.

𝐃𝟒 𝐁𝐢𝐚𝐬 𝐢𝐧 𝐝𝐚𝐭𝐚 𝐭𝐫𝐞𝐚𝐭𝐦𝐞𝐧𝐭 𝐚𝐧𝐝 𝐨𝐮𝐭𝐜𝐨𝐦𝐞 𝐫𝐞𝐩𝐨𝐫𝐭𝐢𝐧𝐠

𝐃𝟒.𝟏 The 𝐬𝐭𝐚𝐭𝐢𝐬𝐭𝐢𝐜𝐚𝐥 𝐚𝐧𝐚𝐥𝐲𝐬𝐢𝐬 was a𝐩𝐩𝐫𝐨𝐩𝐫𝐢𝐚𝐭𝐞

- In this item, reviewers should judge whether the study chose appropriate descriptive statistics and statistical tests were chosen and if enough information is given regarding to judge these choices and comprehensively assess the reported data and test results. Are descriptive statistics fitting to the scale and distribuition of the data? Are inferential statistical tests and significance level chosen, mentioned in the methods and appropriate to the study? Do the statistical tests take into account the variables and study design (e.g., factorial designs, repeated measures)? Do the reviewers identify any missing information required to support and substantiate the study conclusions?

𝐃𝟒.𝟐 There was a comprehensive 𝐫𝐞𝐩𝐨𝐫𝐭𝐢𝐧𝐠 𝐨𝐟 𝐨𝐮𝐭𝐜𝐨𝐦𝐞𝐬

- Reviewers should assess whether there is missing or incomplete data regarding the outcomes initially set out by the researchers in their study. Are outcome data available for all variables, in sufficient detail? (e.g., are failure modes and fractographic analysis missing in bond strength studies?) Are measures of precision given (confidence intervals or standard errors) when reporting outcome data?

**Do you agree with the first source of bias to be included in this domain: "The statistical analysis was appropriate"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you agree with the second source of bias to be included in this domain: "There was a comprehensive reporting of outcomes"?**

Strongly Disagree  Disagree  Neutral  Agree  Strongly Agree

**Comment:**

**Do you have any other suggestions for this Domain? Please write "Yes" or "No". If "Yes" please explain which.**

**Answer:**

**Scale: Types of response choices**

When the reviewers reach the stage where they have to classify the risk of bias of the studies included in the systematic review, the team will judge each item listed in the domains shown before, using an answering scale.

In this vote, we ask the experts to choose the scale that should be used with the items previously voted.

Please indicate your preferred choice by selecting the options below.

Dichotomous (Yes/No)

Categorical (Yes/No/Not reported or Not Applicable)

Categorical (Not reported, insufficiently reported and sufficiently reported)

**Acronym of the RoB Tool**

The final step of this DELPHI method vote is the choice of the acronym for the RoB tool. This is an important step, since the tool will be known for its name. The guidance and accompanying paper will feature the acronym of the tool.

It should be easy, catchy, coherent and logical.

Please vote your preference below, or add a new one if you have a better idea!

RoBDeMat

RobLMat

RoBYMat

RobLyMat

RoBLym

RoBLabDent

**Comment:**