

Evaluating Clinical Research - a 10 point guide

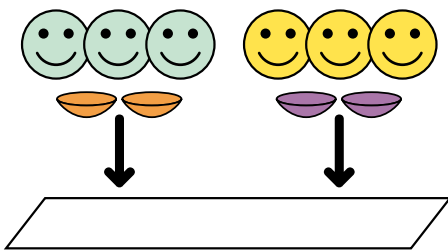
1. Study objective

Without an objective and hypotheses, a clinical study cannot move beyond the question phase. The objective should be clearly stated from the outset. The hypotheses are the individual questions that the study seeks to answer.

2. Study design

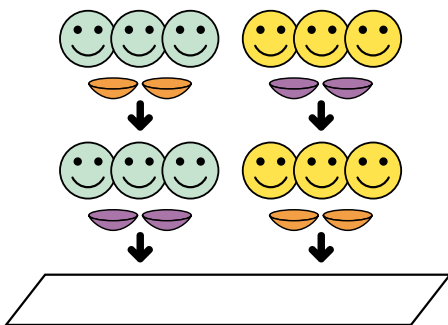
A randomised controlled study is considered the gold standard and two principal types of study design are used in contact lens research: the parallel group (monadic) and crossover design. The most appropriate study design depends on the objective(s). Whatever the study design, subjects must be randomly assigned to each group to minimise bias.

PARALLEL DESIGN



Ideal for assessing subjective lens performance as reflects 'real life' experiences, but requires larger sample size.

CROSSOVER DESIGN



Ideal for corneal physiology assessments as easier to control variables, but watch out for carryover effects.

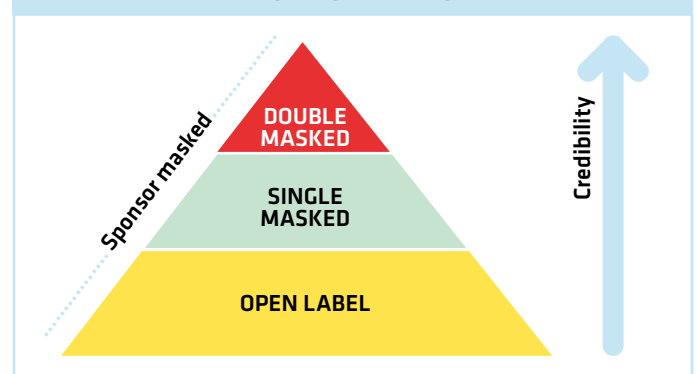
3. Controlling variables

Check whether there are any factors in addition to the test variable(s) that may have an influence on the results (e.g. previous lens-wearing experience, investigator's lens of choice, subject age, gender, refractive cylinder etc). If so, the analysis should adjust for differences within these factors with appropriate statistical analysis.

4. Reducing bias

Masking is used to reduce bias in the subjective reporting and evaluation of lenses and in the analysis of data. Check the type of masking carefully.

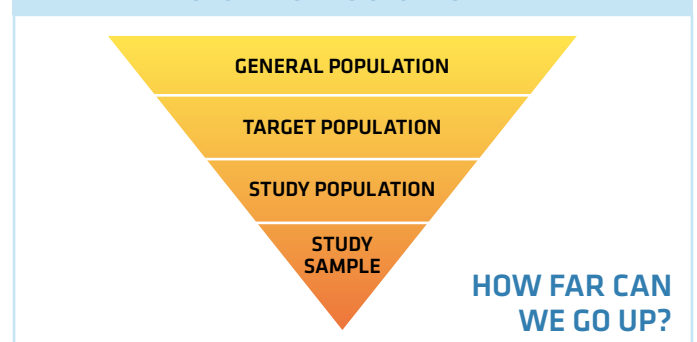
MASKING HIERARCHY



5. Representative sample

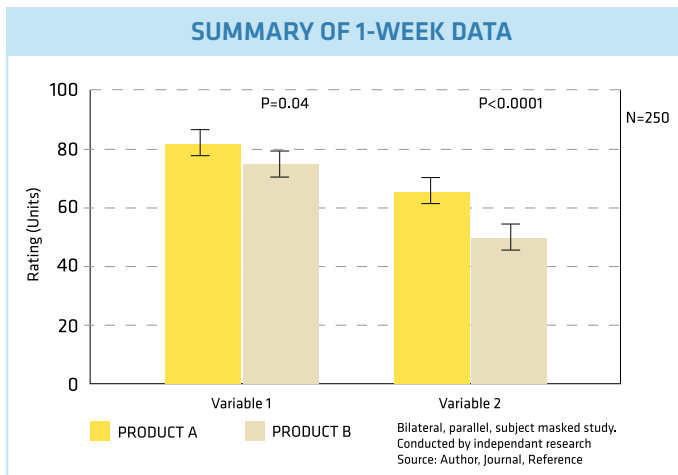
Sample size should be calculated in advance and depends on study design, the sensitivity of the scales used, and the size of difference the study is looking for. Statistical power is the probability of detecting an effect that is truly present and is directly related to sample size. An unbiased representative sample is imperative.

POPULATION TO STUDY SAMPLE



6. Analysis and results

To determine whether results represent a reliable finding, pay close attention to statistical analysis and how results are presented. The following is an example of a 'well dressed' graph.



7. Performance differences

If there is a known level of clinical significance for a particular finding, then differences should be interpreted with regard to both statistical and clinical significance.

8. Relevance to practice

Having evaluated the results, consider whether the conclusions drawn are meaningful and relevant.

9. Appropriate recommendations

Any recommendations made should also reflect any cautions with interpreting the results and suggest where further research is needed.

10. Where published

Peer-reviewed publications offer the reader a greater degree of confidence, in the knowledge that the work has been reviewed by at least two experts in the field, and typically provides more information on study design and methodology compared to marketing materials. When presented with clinical data, use the checklist below to assess the quality of information.

10 important steps in any clinical study

Clinical Evaluation checklist

1. What is the objective and hypotheses of the study?	✓
2. Is study design and randomisation appropriate?	✓
3. Have all variables been controlled?	✓
4. Are subjects/investigators unbiased/masked and trained?	✓
5. Has appropriate number and composition of subjects been used?	✓
6. Are statistical tests appropriate? Has multiple testing occurred and been adjusted for?	✓
7. Are performance differences meaningful?	✓
8. Are conclusions relevant and accurate based on results?	✓
9. Are recommendations appropriate?	✓
10. Has data been published and where?	✓