Guest Editorial
Sample Size Considerations for Restoration-Longevity Randomized Controlled Trials

Dear Readers,

One of the most powerful research methods to determine the effectiveness of dental restorative materials is to conduct a clinical Randomized Controlled Trial (RCT).

However, clinical researchers know that such studies are very time consuming and that often contradicting aspects need to be reconciled.

For example, the quality of a clinical study is often assessed by the statistical power of the study, which by definition is the probability that the test will reject a false null hypothesis. Failure to do so is called a type II error. The higher the power of the study, the more the chance of a type II error decreases. Even though the power of a study can be influenced by many factors, the most common way to enhance it is by increasing the sample size.

Although every researcher dreams of large studies with many subjects, reality shows that it is often very difficult to recruit sufficient suitable patients within a feasible time. For example, if one wants to compare two materials (experimental versus control or "gold standard") and the clinical investigator performs only two restorations per patient following a so-called split-mouth or pairwise study design (one restoration per condition) in order to have independent data within each condition,[2] researchers may end up with studies with a small sample size and hence relatively low statistical power.

It is correct that treating more than one lesion per condition within one mouth introduces a "patient factor", as the data will be dependent; however, this does not necessarily mean that the power of the study cannot be increased by doing so. Provided that a suitable (but unfortunately more complex) statistical analysis is used, the supplementary restorations may add new information and may thus enhance the power of the study.

Such a multirestoration approach does not necessarily lead to loss of quality of a clinical study, given that the statistical analysis accounts for the correlation induced by the repeated measurements.[1] Obviously, the increase in power will depend on the strength of correlation between the repeated measurements. The lower the correlation, the more unique the amount of information provided by each additional restoration and the higher the increase in power will be. In the worst case, when the outcome is completely determined by patient factors, the power of the study would be equal to a study with the preferred one-restoration-per-condition-per-patient study design. On the other hand, when there is no patient-related effect at all, the restorations could theoretically be considered as independent, and the power of the study would be as high as a study with the same number of independent restorations in many more patients. Most often, however, the situation is somewhere in between. The patient factor will have a certain influence, but will never completely determine the outcome, and thus the power will increase accordingly. This indicates that it will never be as high as a study with the same number of independent restorations in many more patients, but also that it will be higher than in a study with the same number of patients with fewer, but independent restorations.[3]

In conclusion, since patients often present with multiple lesions, treating more lesions per patient is an easy and valid option to prevent studies with low sample size and power.

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