Ethics of a Clinical Trial

In the globalization era, technology is rapidly advancing in all fields of dentistry, making it urgently necessary to collect longitudinal clinical data to be shared in the world dental community. Hundreds of laboratory studies performed following different techniques are continually published in international peer-reviewed journals (with impact factor) and they are useful to provide comparative data among several products within a given category. Such investigations have the potential to predict to some extent the clinical performance of new materials and techniques. However, in vivo trials based on predictable and reproducible protocols should always precede the large-scale clinical use of recently introduced products. Clinical validation is indeed a cornerstone of evidence-based dentistry. If this requirement is understandably strict with new adhesive materials, it should be even more so when dealing with, for instance, implant surgery techniques.

Based on the Declaration of Helsinki on ethical principles for medical research involving human subjects, a clinical research protocol should first include the written approval of the pertinent Ethics Committee, and should clearly state the study's inclusion and exclusion criteria. Patients should be fully informed on the objectives of the research, as well as on the methods and possible related risks. Patients' written informed consent to the study should be obtained. All the researchers performing clinical studies should conform to this policy and the editorial boards of scientific journals should verify that all the requirements are met. Nevertheless, when reading some of the internationally published literature, one cannot escape the impression that ethical issues are not always given due consideration by the authors, and are then also overlooked by the journals reviewers. Not uncommonly, published papers are found to lack relevant details on ethical aspects of the clinical study, for instance, whether or not the protocol was approved by the respective Ethics Committee, what were the contents of the patient informed consent, or who was the principal investigator. Such incomplete information can limit the scientific value of the research.

Moreover, some published clinical studies have been conducted in countries where the regulation on research in humans is more permissive than that of the Helsinki Declaration. Of course, false declarations, although disreputable, are also always possible. We who agree that credibility is a researcher's best quality cannot help feeling that in some studies, patients are used as experimental animals or even worse, if one considers that in some advanced countries animal research is actually strictly regulated.

Certainly, imposing a more ethical approach to clinical research will not be an easy task. Nevertheless, from this perspective, it would be advisable for peer-reviewed journals to request – as a condition for publication of clinical studies – that the authors provide evidence of Ethics Committee approval and that reviewers verify with the authors that a list of required ethical issues related to the study has been properly addressed. Although it is likely that such a policy would initially affect the submission rate of clinical studies, it would also limit the spread of research that does not have a solid, ethical foundation.

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