Recommendations for conducting controlled clinical studies of dental restorative materials. Science Committee Project 2/98-FDI World Dental Federation study design (Part I) and criteria for evaluation (Part II) of direct and indirect restorations including onlays and partial crowns.

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Abstract
About 35 years ago, Ryge provided a practical approach to the evaluation of the clinical performance of restorative materials. This systematic approach was soon universally accepted. While that methodology has served us well, a large number of scientific methodologies and more detailed questions have arisen that require more rigor. Current restorative materials have vastly improved clinical performance, and any changes over time are not easily detected by the limited sensitivity of the Ryge criteria in short-term clinical investigations. However, the clinical evaluation of restorations not only involves the restorative material per se but also different operative techniques. For instance, a composite resin may show
good longevity data when applied in conventional cavities but not in modified operative approaches. Insensitivity, combined with the continually evolving and nonstandard investigator modifications of the categories, scales, and reporting methods, has created a body of literature that is extremely difficult to interpret meaningfully. In many cases, the insensitivity of the original Ryge methods leads to misinterpretation as good clinical performance. While there are many good features of the original system, it is now time to move on to a more contemporary one. The current review approaches this challenge in two ways: (1) a proposal for a modern clinical testing protocol for controlled clinical trials, and (2) an in-depth discussion of relevant clinical evaluation parameters, providing 84 references that are primarily related to issues or problems for clinical research trials. Together, these two parts offer a standard for the clinical testing of restorative materials/procedures and provide significant guidance for research teams in the design and conduct of contemporary clinical trials. Part 1 of the review considers the recruitment of subjects, restorations per subject, clinical events, validity versus bias, legal and regulatory aspects, rationales for clinical trial designs, guidelines for design, randomization, number of subjects, characteristics of participants, clinical assessment, standards and calibration, categories for assessment, criteria for evaluation, and supplemental documentation. Part 2 of the review considers categories of assessment for esthetic evaluation, functional assessment, biological responses to restorative materials, and statistical analysis of results. The overall review represents a considerable effort to include a range of clinical research interests over the past years. As part of the recognition of the importance of these suggestions, the review is being published simultaneously in identical form in both the Journal of Adhesive Dentistry and Clinical Oral Investigations. Additionally, an extended abstract will be published in the International Dental Journal, giving a link to the web full version. This should help to introduce these considerations more quickly to the scientific community.

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