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

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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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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