FDI POLICY STATEMENT

Recommendations for Clinical Trials of Restorative Materials

Adopted by the FDI General Assembly: 26th September 2008, Stockholm, Sweden

Background

Criteria for the clinical evaluation of restorative materials (the 'Ryge', or 'United States Public Health Service (USPHS)' criteria) were published in the early 1970s. However, since then, numerous modifications have been made to these criteria in a non-coordinated way, and in addition restorative materials have improved considerably. Consequently, a new clinical evaluation protocol system is recommended.

Statement

- The high cost of clinical trials of restorative materials necessitates designs which are standardized, quantitative, sensitive, reliable and valid.

- Clinical trials are required both in an academic environment in order to assess new materials and techniques ('efficacy studies') and in a practice-based environment in order to assess their performance under 'field' conditions ('effectiveness studies').

- Appropriate ethical approval must be obtained prior to conducting a clinical trial.

- Biological, functional and aesthetic criteria should be evaluated for the appropriate period of time

- Statistical analysis should include provision for restorations unable to be evaluated, e.g., by using survival (life table) analysis.

- The FDI World Dental Federation recommends that researchers on dental restorative materials should use relevant study designs and evaluation criteria published in the following reference.

Bibliography

Hickel R, Roulet J-F, Bayne S et al. Recommendations for conducting controlled clinical studies of dental restorative materials. *Clin Oral Invest* 2007 11:5-33, *J Adhes Dent* 2007 9 (Supp 1): 121-147, *Int Dent J* 2007 57(5): 300-302