

A clinical study of a new Ca₃SiO₅-based material for direct posterior fillings

S. Koubi, H. Tassery, G. Aboudharam, J.L. Victor, G. Koubi

*Département d'Odontologie Conservatrice, Centre Dentaire Gaston Berger,
17-19 rue Mireille Lauze 13010 Marseille F*

INTRODUCTION: A new cement-based material for direct restorative posterior fillings (RD 94, Septodont, France) has been developed to circumvent the shortcomings of the traditional filling materials. This material is inorganic and non-metallic, and the main components are Ca₃SiO₅, CaCO₃, ZrO₂, and water. After evaluation of the genotoxicity, the cytotoxicity, the effects on the specific functions of target cells, and the marginal sealing of this new material, a multicentric clinical study was initiated to evaluate, in a three-year follow-up, the performance of this experimental calcium silicate cement (RD 94), versus a traditional resin composite (Z 100, 3M, US), in Class I and Class II restorations.

METHODS: From June 2005, every patient from 18 to 80 years old who, at the examination performed at the authors' University Clinic, needed a posterior restoration, was invited to join this randomized trial, under cover of Huriet's law. Each patient provided informed consent to participate in the study, which was approved by the ethics committee of the University of Marseilles (CCPPRB 1). All the patients invited participated in the study.

Two operators, both familiar with the new material, placed all restorations. All treated teeth were in occlusion, and the cavities were prepared with slightly convergent cavity walls, without bevels, and under rubber dam isolation. In Class II cavities, a thin metallic matrix band and wood wedges were used. All cavities were sprayed with water, and for the RD 94, no conditioning of the cavity or base material was recommended by the manufacturer. The restorations were finished after two weeks with polishing stones and strips. An examination book was created for each restoration, and a slight modification of the USPHS (United States Public Health System) criteria was used to evaluate the quality of the restorations by two calibrated observers [1-3]. Periapical radiographs and color slides were taken of all restorations, at dates D 0, D +15 days and D +6 months.

RESULTS: After ten months, 140 restorations had been performed in the Marseilles Dental School,

70 with RD 94 and 70 with Z 100. Forty-two of the restorations were Class I and ninety-eight Class II cavities. Ninety-four molars were treated, and forty-six premolars. Eighty teeth were treated in the upper maxillary and sixty in the lower.

In April 2006, thirty restorations had been evaluated at six months, including 11 Z 100 and 19 RD 94 restorations, and no non-acceptable clinical result was observed. Post-operative sensitivity was reported for two Z 100 restorations. A very good marginal adaptation and surface finish was observed on RD 94 restorations, although the color match of this new product was not yet perfect. None of the nineteen patients treated with RD 94 has lodged a complaint for pain, unpleasant physiologic or pathologic sensations, or objective or subjective reactions related to the material.

DISCUSSION AND CONCLUSIONS:

Randomized clinical trials are considered the optimal way to validate the outcome of dental materials. However, randomized control groups require broad patient support, and are therefore time consuming and extremely demanding to conduct, thus contributing to the expensiveness of such studies. Nevertheless, the biological properties of this new material, combined with its interesting physicochemical characteristics, and with these hopeful preliminary results, justify the follow-up of this clinical study. After six months, the results indicated no significant differences, for direct restorations in medium sized cavities in posterior teeth, between a classical resin composite and the new Ca₃SiO₅-based material under test.

REFERENCES: ¹ N.J. Opdam, B.A. Loomans, F.J. Roeters, E.M. Bronkhorst (2004) *J Dent* **32**: 379-383. ² J.W. Van Dijken and K. Sunnegard-Grönberg (2005) *Swed Dent J.* **29**:45-51. ³ R.C. Spreafico, I. Krejci and D. Dietschi (2005) *J Dent* **33**:499-507.

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