SCIENTIFIC REPORT

Futurabond U / GrandioSO – 12-Month Clinical Study

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The latest generation of dental adhesives can be used universally. On the one hand, this frees the dentist to decide whether to etch the dental hard tissue additionally or not. On the other hand, their universal nature means these adhesives are compatible with all materials used in dentistry. In addition to composites, these include metals and various types of ceramics. Moreover, the universal adhesives from VOCO are compatible with all types of methacrylate-based composites, irrespective of whether they are light-curing, chemical-curing or dual-curing. This scientific report compiles the preliminary results of a clinical study designed to run for a total of 24 months, concerning the evaluation of direct and indirect composite restorations with the nanohybrid composite GrandioSO. The study was conducted by the research group headed by Prof. Dr. Torres at the University of São José dos Campos in Brazil.^[1]

In this study Prof. Dr. Torres investigated the quality of direct and indirect restorations, i.e., conventional fillings and chairside-produced composite inlays. The restorations were assessed based on the FDI criteria; so far the evaluations were performed initially and after 6 and 12 months respectively. [2] [3]

Study design

30 patients complying with the specified criteria were selected for the study. The criteria included:

- The presence of cavities, fractures or cosmetic requirements
- At least two Class II restorations per test subject in the first or second molars
- Contact between the antagonist and the neighbouring teeth
- Vital pulp and no painful symptoms in the tooth to be restored
- Permanent dentition
- Good oral hygiene with no sign of periodontal disease

Each test subject was treated with at least two restorations. The direct restorations were produced with the light-curing composite GrandioSO in accordance with the rules of the conventional adhesive technique in combination with Futurabond U in the selective etch mode. In the case of the indirect restorations, the composite inlays were produced in the chairside technique using GrandioSO and the die silicone. They were then luted with the dual-curing luting composite Bifix QM and Futurabond U (selective etch mode).

The evaluation criteria for this study are classified into aesthetic, functional and biological properties. Each criteria has the following classes: "clinically outstanding / excellent", "clinically good", "clinically acceptable / satisfactory", "clinically unacceptable" and "clinically inadequate". An exact description of each of the classes is given in Table 1. The restorations were evaluated by two independent dentists.



Table 1: Explanation of the individual evaluations

Evaluation	Explanation
Clinically outstanding / excellent	The quality of the restoration is excellent and satisfies all the quality criteria. The tooth and/or surrounding tissue are sufficiently protected.
Clinically good	The quality of the restoration is most acceptable, although one or more criteria vary from the ideal. The restoration can be improved to excellent status through reworking, but this is not normally necessary. There is no risk of the tooth or the surrounding tissue being injured.
Clinically acceptable / satisfactory	The quality of the restoration is satisfactory with some weak points, which cannot be resolved without injuring the tooth due to their number or the area where they occur. Nevertheless, no damaging side effects are to be expected.
Clinically unacceptable	The quality of the restoration is not acceptable. However, the restoration can be repaired.
Clinically inadequate	The quality of the restoration is unacceptable and the filling needs to be replaced.

Results

A total of 60 restorations were produced for 30 patients. On expiry of the investigated period, all 60 direct and indirect restorations were intact. The results are shown in Fig. 1-3.

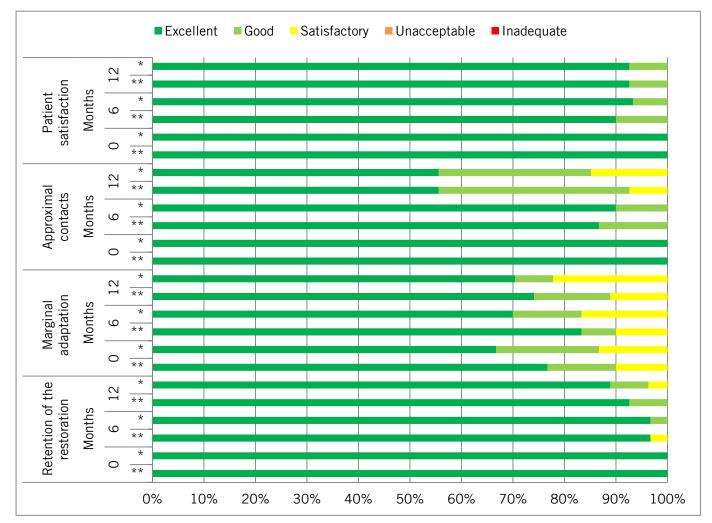


Figure 1: Functional properties of the direct (*) and indirect (**) restorations



Figure 2: Aesthetic properties of the direct (*) and indirect (**) restorations

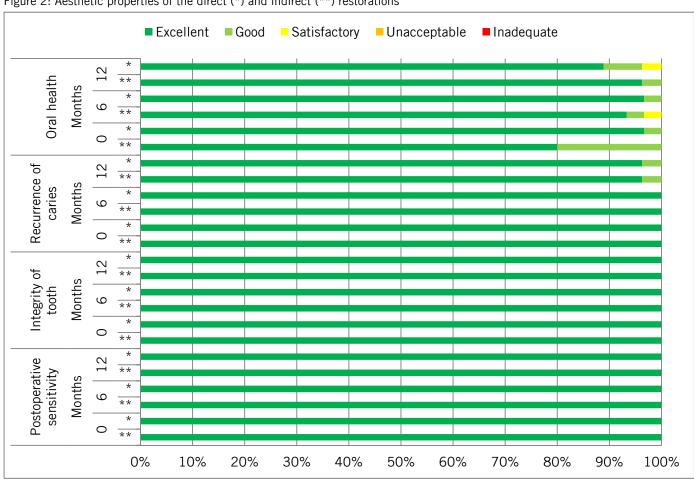


Figure 3: Biological parameters following placement of direct (*) and indirect (**) restorations

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Both the aesthetics and function of the produced restorations amaze across the board after 12 months. The combination of Futurabond U and GrandioSO – irrespective of whether it is used in direct or indirect techniques – achieves outstanding results. Particularly noteworthy were the functional parameters of retention and patient satisfaction. The VOCO material impressed with the retentive bond being evaluated as excellent in approx. 90 % of the restorations. For the especially important patient satisfaction criteria, Futurabond U in combination with GrandioSO was even evaluated as outstanding for approx. 90 % of the placed restorations.

The restorations produced with Futurabond U / GrandioSO were also evaluated as being excellent in terms of the aesthetic criteria. The marginal discolouration criteria was assessed as being outstanding in more than 75 % of the cases for direct and indirect restorations alike. It was also possible to achieve excellent results in the evaluation of the surface discolouration. In this category approximately 75-90 % of the restorations were assessed as being excellent.

Biological parameters are also an important criteria for the evaluation of a restoration. In terms of oral hygiene and the recurrence of caries, the restorations made of Futurabond U and GrandioSO impressed with excellent results. 100 % of the fillings placed were classified as clinically outstanding in relation to these parameters. Postoperative sensitivity is an unpleasant experience for patients following a restorative treatment. Futurabond also convinces across the board in terms of this criteria: just 11 % of patients reported minimal adverse effects 12 months after the direct placement of restorations. Minimal sensitivity was only reported by barely 4 % of the patients who received indirect restorations.

In conclusion, all the direct and indirect restorations produced displayed good clinical results for all parameters after 12 months. In the investigation into cytotoxicity, it was not possible to determine any differences between x-tra fil and Filtek Z250; the study confirmed the biocompatibility of a standard resin-based composite for both materials.

Conclusion: In combination with the nanohybrid composite GrandioSO, Futurabond U achieves excellent results with both direct and indirect restorations, which once again proves that Futurabond U and GrandioSO can be used together for all applications. The free choice of the etching technique and the wide range of indications paired with the excellent clinical results displayed here confirms once more the outstanding quality of Futurabond U and its versatile range of applications.

- [1] Torres CRG, Clinical evaluation of direct and indirect composite restorations using the chairside technique, Report to VOCO, Universidade Estadual Paulista Júlio de Mesquita Filho, São José dos Campos, São Paulo, 2013.
- [2] Hickel R, Roulet JF, Bayne S, Heintze SD, Mjor IA, Peters M, et al. Recommendations for conducting controlled clinical studies of dental restorative materials. Clin Oral Investig 2007;11(1):5-33.
- [3] Hickel R, Peschke A, Tyas M, Mjor I, Bayne S, Peters M, et al. FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples. Clin Oral Investig 2010;14(4):349-66.

