



GLUMA® Bond Universal

Clinical study – University of Leipzig, Germany

Clinical 3 years-study to evaluate GLUMA Bond Universal for the direct restoration of non-carious cervical lesions

Within the last decade many simplified all-in-one adhesives were developed. They were developed because they show a lower technique sensitivity than multi-steps adhesives. But the performance of these simplified adhesives was in the past regarded as lower as that one of 3-step etch and rinse adhesives*. The following study demonstrates that this statement is not any longer applicable. The new GLUMA Bond Universal is a multi-mode universal adhesive which can be applied in a self-etch mode or in combination with prior phosphoric etching in a selective enamel etching or etch & rinse-mode. After 6 months of service, the restorations with GLUMA Bond Universal did not differ, regardless of their mode of etching, from the 3-step etch & rinse- gold standard adhesive.

*Peumans M *et al.*: Clinical effectiveness of contemporary adhesives: a systematic review of current clinical trials. Dent Mater. 2005 Sep;21(9):864-81.

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KULZER
MITSUI CHEMICALS GROUP

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Objectives

Aim of this randomised clinical trial is to compare the clinical performance of the universal adhesive GLUMA Bond Universal in combination with the flowable resin composite Charisma Opal Flow in non-carious cervical lesions to the 3 step etch & rinse adhesive Optibond FL over a period of 36 months.

GLUMA Bond Universal was applied in different etching strategies: self-etch, selective enamel etch and etch & rinse.

Methods

50 patients with three or four non-carious cervical lesions each received composite restorations (Charisma Opal Flow). Adhesives were randomised applied in a splitmouth-design to the different lesions of each patient. GLUMA Bond Universal was applied with three different etching protocols: self-etch (n = 50), selective-enamel-etch (n = 29) and etch-and-rinse (n = 50). One group restored with the etch-and-rinse adhesive OptiBond FL (Kerr) served as a control. Recall evaluations have taken place at 14 days and 6 months so far (12-, 24- and 36-months recall will follow). For the investigation of the restorations the FDI criteria (Hickel *et al.*, 2010) were used: for each biological, aesthetical and functional parameter a 5-step score was used (score 1: clinically excellent, score 2: clinically good, score 3: clinically satisfactory, score 4: clinically unsatisfactory but repairable, score 5: clinically poor, replacement needed). Cumulative failure rate, retention rate were statistically investigated using McNemar test ($p < 0.05$) and Kaplan Meier.

Results

After 6 months the recall rate of the study teeth was 98 % for GLUMA Bond Universal in self-etch and etch & rinse-mode as well as in the Optibond FL group. The recall rate for GLUMA Bond Universal in selective enamel etch was 96.6 %. No statistically significant differences were found between groups for cumulative failure rate. In the GLUMA Bond Universal self etch- and etch & rinse- as well in the Optibond FL group marginal adaptation showed statistically significant more 2 and 3 scores at 6 months.

Conclusions

After 6 months of clinical service, the performance of the simplified adhesive GLUMA Bond Universal was not significantly different compared to that of a 3-step etch & rinse-gold standard adhesive.

Comment

The clinical performance of GLUMA Bond Universal did not differ from the gold standard control which was an etch & rinse 3-step adhesive. Within the evaluation period no difference regarding the etching mode (self-etch, etch & rinse and selective enamel etching) was found.

Source

Haak R, Häfer M, Schneider H: Klinische 3-Jahres-Studie zur Bewertung des Universaladhäsivs GLUMA Bond Universal für die plastische Füllungstherapie nicht-kariöser Zahnhalsläsionen in Kombination mit quantitativer Randalanalyse und Abbildung mit optischer Kohärenztomographie. 6-months report. July 3rd, 2018. Unpublished data. Data on file.

The study was abbreviated, summarised and commented and all diagrams and titles have been established by Kulzer. The Kulzer products mentioned in this study are chemically equivalent to the originally tested Kulzer products.