

CLINICAL STUDY

CLEARFIL MAJESTY™ Esthetic – an esthetic filling therapy combined with a self-etching adhesive

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CLEARFIL MAJESTY™ Esthetic – clinical study

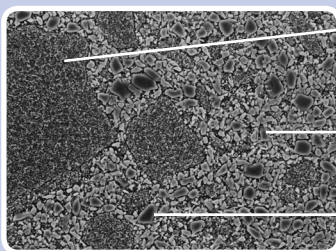
Clinical investigation by Dr. Toshimoto Yamada, DDS, PhD, Toranomon Hospital, Japan

This study is a clinical trial of the the resin-based restorative material CLEARFIL MAJESTY™ (the product name of CLEARFIL MAJESTY™ Esthetic in the Japanese market, also with a difference in shade colors) together with the self-etching adhesive CLEARFIL™ S3 BOND (CLEARFIL™ tri-S bond). A total of 30 restorations were placed in 30 human subjects in caries-free Class V eroded/abraded areas in permanent teeth.

The reports after 18 months recorded the satisfactory status of all restorations following recovery from the operative procedure of placement. At the 18 month recall, all restorations that were reviewed were satisfactory in all clinical criteria specified. No failures have so far been observed at all recalls and the Kaplan-Meier probability of survival rate for these restorations after 18 months is 1.00.



Esthetic filler in a unique composition



Light-diffusion filler

Newly developed organic filler including nanofillers with high transparency. It diffuses light like natural tooth substance.

Highly refractive index matrix

The matrix shows a high refraction, which reduces color change after polymerization.

Radiopaque nanofiller

Thanks to this new filler CLEARFIL MAJESTY™ Esthetic can be clearly recognized on an X-ray and can also be polished to a high shine.

By courtesy of Dr. Toshimoto Yamada, DDS, PhD, Toranomon Hospital

Objective of the investigation

This trial will determine the short-term efficacy of CLEARFIL MAJESTY™ with the self-etching adhesive CLEARFIL™ S3 BOND (CLEARFIL™ tri-S bond) as a dentine and enamel adhesive material, in a group of patients under conditions which represent its normal conditions of use.

Design of the investigation

The investigation is a short-term, uncontrolled trial. The design is based on the guidelines of the American Dental Association for assessment of dentine and enamel adhesive materials of 2001. The study originally set out to examine the performance of cervical restorations of at least 30 subjects at recalls at baseline, 3 months, 6 months, 12 months, and 18 months.

History of the study

During the months of March and May 2006, 30 trial restorations were placed in a total of 30 patients using the resin-based restorative CLEARFIL MAJESTY™ in combination with the self-etching adhesive CLEARFIL™ S3 BOND (CLEARFIL™ tri-S bond). Two operators in general dental practices placed all

the restorations. Baseline records were made by the practitioners immediately after placement. Patients were followed up routinely at recall intervals that were appropriate to their oral health status, and at each recall the restorations were evaluated for clinical acceptability.



V-shape defect of the lower left bicuspid and canine teeth



The cavity was completed



Just after placement (shade: A4)



At 3 months after placement



At 6 months after placement



At 12 months after placement



At 18 months after placement

Discussion

It is noted to be interesting that all the restorations showed Alpha rating 18 months after placement, and were deemed to be clinically satisfactory in all aspects examined. It seems that the observation period was relatively short but according to the laboratory studies* the bond strength of this resin bonding system was

quite high, as much as 20 MPa to bovine enamel and dentine. Also the FE-SEM study revealed that the tight interfacial junction was obtained between the resin and enamel/dentine, creating the hybrid layer at the dentine interface. These findings support the clinical results of this study.

* Uno S et al.: Evaluation of bond efficacy of an experimental all-in-one adhesive system SSB-200, Adhes Dent 22(3): 245-253, 2004

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Conclusion

The resin-based restorative material CLEARFIL MAJESTY™ and the self-etching adhesive CLEARFIL™ S3 BOND demonstrated to be a satisfactory dentine and enamel

adhesive material for the restoration of caries-free Class V eroded/abraded areas in permanent teeth over a period of 18 months.

Criterion		6 months	12 months	18 months
RESTORATION	A: satisfactory B: moderate C: severe	100 % A	100 % A	100 % A
MARGINAL DISCOLORATION	A: none B: potential failure C: failure	100 % A	100 % A	100 % A
MARGINAL ADAPTATION	A: excellent B: good C: fair D: poor	100 % A	100 % A	100 % A
SURFACE TEXTURE	A: smooth B: slightly rough C: rough	100 % A	100 % A	100 % A
ABRASION	A: none B: slight C: severe	100 % A	100 % A	100 % A
MARGINAL FRACTURE	– : none + : detected	100 % –	100 % –	100 % –
BODY FRACTURE	– : none + : detected	100 % –	100 % –	100 % –
SECONDARY CARIES	– : none + : detected	100 % –	100 % –	100 % –
PAIN*	A: none B: slight C: severe	100 % A	100 % A	100 % A
IRRITATION**	– : none + : detected	100 % –	100 % –	100 % –

* Spontaneous, cold water, hot water, occlusal

** Gingival, soft tissue

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