

XP BOND in self-cure mode used for luting porcelain restorations: 3 year recall

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Abstract

Purpose: The aim of this clinical study was to evaluate, after 3 years of clinical service, certain clinical parameters of Empress II restorations luted under clinical conditions with XP BOND in combination with SCA and Calibra cured in self-cure mode. **Materials and methods:** Fifty-three restorations were placed in 38 patients from March 2006 until April 2006. No patient received more than two restorations. Luting procedures were performed following manufacturers' instructions. The restorations were evaluated for post-op sensitivity, marginal discoloration, marginal integrity, secondary caries, maintenance of interproximal contact and fracture at baseline, after 2 weeks, 6 months, 1-, 2- and 3 years of clinical service. **Results:** At the 3-year recall, 51 restorations were re-evaluated. Clinical examinations found no restoration affected by post-operative sensitivity. Of the 51 restorations, only 5 showed bravo score and 2 charlie score for marginal integrity/stain. 1 restoration showed bravo score at vitality test. All other parameters showed alpha scores. **Conclusions:** All the evaluated restorations were in place and acceptable. Post-operative sensitivity recorded after using XP BOND with SCA and Calibra in self-cure mode was clinically acceptable.

Key Words *Ceramic crowns, Self-curing, Clinical Trial, Bonding*

Introduction

When introduced, experimental tests showed XP BOND having high values in microtensile bond strength data compared to other systems when the adhesive was used with SCA and Calibra in self-cure mode.¹ Then, the baseline, 1-year and 2-year reports of post-operative sensitivity and clinical parameters on XP Bond, (DENTSPLY De Trey, Konstanz, Germany) used in combination with SCA and Calibra dual cure resin cement for luting indirect posterior porcelain restorations were published.^{2,3,4} Post-operative sensitivity can be commonly found in vital teeth in which porcelain crowns were luted.⁵

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When porcelain restorations are luted on vital abutments, a perfect bonding, which has to integrate all parts into one coherent structure, is necessary.⁶ Luting material and technique, as well as the substrate characteristics, therefore represent success determining factors.⁷

Among different combinations of adhesive-luting materials dual-curing bonding systems are often the first choice,⁸⁻¹⁷ as they allow polymerization of the adhesive materials and resin cement below thick ceramic restorations.

The aim of the present prospective clinical trial was to evaluate the 3-year clinical behaviour of Empress II restorations (Ivoclar-Vivadent, Schaan, Liechtenstein), luted with the adhesive system XP BOND (DENTSPLY DeTrey, Konstanz, Germany) with SCA (DENTSPLY Caulk, USA) and Calibra resin cement (DENTSPLY Caulk, USA), both used in self-cure mode.

Materials and Methods

A consecutive sample of 53 restorations in 38 patients in need of one or two single-units was placed. Partial or full restoration was performed from the pool of patients

Table 1

Changes in pre- and post-operative sensitivity during the observation period of 3 years (1 = lowest sensitivity, 10 = highest sensitivity).

Restoration	XP Bond / SCA / Calibra [n]		
	Pre-operative sensitivity and/or post-operative sensitivity 2 weeks after placement	Type of restoration	Post-operative sensitivity (3 year)
1 (#5)	6	Inlay (OD)	0
2 (#7)	1	Inlay (MOD)	0
3 (#10)	1	Inlay (MO)	0
4 (#11,14)	2	Onlay	0
5 (#26)	1	Onlay	0
6 (#20,29)	3	Inlay (OMD) and onlay	0
7 (#32)	1	Inlay(OM)	0
8 (#39)	4	Onlay	0
9 (#43)	3	Onlay	0
10 (#46)	1	Inlay (OMD)	0
11 (#53)	3	Inlay(OMD)	0

accessing the department of Restorative Dentistry of the University of Siena. Patients' written consent to the trial was obtained after having provided a complete explanation of the aim of the study.

Inclusion criteria

Males and females aged 18-60 years in good general and periodontal health were included.

Exclusion criteria

Patients with the following factors were excluded from the clinical trial:

1. Nonage (< 18 years); 2. Known pregnancy; 3. Disabilities; 4. Potential prosthodontic restoration of teeth; 5. Pulpitic, non-vital or endodontically treated teeth; 6. (Profound, chronic) periodontitis; 7. Deep carious defects (close to pulp, < 1mm distance) or pulp capping; 8. Heavy occlusal contacts or history of bruxism; 9. Systemic disease or severe medical complications; 10. Allergic history concerning methacrylates; 11. Rampant caries; 12.

Xerostomia; 13. Lack of compliance; 14. Language barriers.

Test stimuli and assessment

Before restoring the tooth, a pain measurement was performed utilizing a simple pain scale based on the response method. Response was determined by a one-second application of air from a dental unit syringe (at 40-65 p.s.i. at approximately 20°C), directed perpendicularly to the root surface at a distance of 2 cm and by tactile stimuli with a sharp #5 explorer. The patient was asked to rate the perception of the sensitivity experienced during this thermal/evaporative stimulation by placing a mark on a visual analog scale or line beginning at 0 and ending at 10 (where 0 = no pain and 10 = excruciating pain). In order to translate these scores into easily understood pain levels, a score of 0 was defined as no pain, 1-4 as mild sensitivity (which was provoked by the dentist air blast), and 5-10 as strong sensitivity (which was spontaneously reported by the patient during drinking and eating). Only patients scoring low on the analog scale were included in

Table 2a, 2b and 2c

Performance criteria according to Ryge at 6 month (Table 2a), 1 year (Table 2b), 2 year (Table 2c) and 3 year recall (Table 2d)

Table 2a

Criteria and number of restorations evaluated at 6 month recall		XP Bond / SCA / Calibra			
		alpha	bravo	charlie	delta
Marginal discoloration and integrity	53	53	0	0	0
Secondary caries	53	53	0	0	0
Vitality test	53	53	0	0	0
Interproximal contacts	53	53	0	0	0
Retention	53	53	0	0	0
Fracture	53	53	0	0	0

Table 2b

Criteria and number of restorations evaluated at 1 year recall		XP Bond / SCA / Calibra			
		alpha	bravo	charlie	delta
Marginal discoloration and integrity	53	51	2	0	0
Secondary caries	53	53	0	0	0
Vitality test	53	53	0	0	0
Interproximal contacts	53	53	0	0	0
Retention	53	53	0	0	0
Fracture	53	53	0	0	0

Table 2c

Criteria and number of restorations evaluated at 2 year recall		XP Bond / SCA / Calibra [n]			
		alpha	bravo	charlie	delta
Marginal discoloration and integrity	53	49	2	2	0
Secondary caries	53	53	0	0	0
Vitality test	53	52	1	0	0
Interproximal contacts	53	53	0	0	0
Retention	53	53	0	0	0
Fracture	53	53	0	0	0

Table 2d

Criteria and number of restorations evaluated at 3 year recall		XP Bond / SCA / Calibra [n]			
		alpha	bravo	charlie	delta
Marginal discoloration and integrity	51	44	5	2	0
Secondary caries	51	51	0	0	0
Vitality test	51	50	1	0	0
Interproximal contacts	51	51	0	0	0
Retention	51	51	0	0	0
Fracture	51	51	0	0	0

the study, whereas high score cases were excluded by the assumption that irreversible pulp inflammation may be sustaining the high sensitivity. The status of the gingival tissues adjacent to the test sites was observed at baseline and at each recall. Patients were recalled to the department for testing post-operative sensitivity after 2 weeks, 6 months, 1- 2- and 3 years.

Clinical Procedure

For standardization purposes the same operator performed all the clinical procedures. Following anaesthesia, rubber dam was placed, all carious structures were excavated, and any restorative material was removed. Preparation was performed using conventional diamond burs in a high-speed hand piece, with no bevel on margins. The preparation design was dictated by the extent of decay and pre-existing restorations. The Residual Dentin Thickness (RDT) was evaluated on a periapical radiograph, and teeth with RDT thinner than 0.5 mm were excluded. After preparation, the impression of the prepared tooth was taken and sent to the laboratory. A temporary restoration was inserted. One week after, the ceramic restorations were luted following manufacturer's instructions. The restorations were placed in the time period between March and April 2006 and examined for post-op sensitivity at baseline, after 2 weeks, 6 months, 1-, 2- and 3 years by the same operator. At each recall, data regarding post-operative sensitivity, stability and longevity were collected with reference to the USPHS criteria. The following parameters were therefore assessed: Post-operative sensitivity - the patient comfort with the restoration under function, cold and warm stimuli, and a gentle air stream was assessed. Sensitivity was defined by a scale from 0-10 as described above.

The null hypothesis tested was that the XP Bond in self-cure mode cannot prevent post-operative sensitivity after 3 years of clinical service.

The other evaluated clinical parameters were: marginal discoloration and integrity, secondary caries, fracture, vitality test, retention and interproximal contacts.

Results

The results are summarized in Tables 1-2. All 53 teeth were evaluated at baseline, after 2 weeks, after 6 months, 1 - 2 years. Only 51 restorations were evaluated after 3 years. At baseline 3 patients showed pre-operative sensitivity in 5 teeth. 10 cases of post-operative sensitivity were observed at the two week recall and only 3 after 6 months. In one case, post-operative sensitivity increased from 0 to 6 immediately after luting the restoration (after

the anesthetic effect wore off), but dropped to grade 3 after 6 months. In the 7 cases showing an increase in post-operative sensitivity after 2 weeks, hypersensitivity disappeared completely after 6 months. In 2 cases, a residual post-op sensitivity of grade 2 remained after 6 months. After 2 years of clinical service, minor post-operative sensitivity was present only in one patient. No adverse events/ effects did occur. All other parameters showed alpha scores. After 3 years of clinical service, no post-operative sensitivity was reported in any of 51 re-evaluated restorations (Table 2). 5 restorations showed bravo scores and 2 charlie scores for marginal parameters. 1 restoration showed bravo score for pulp vitality. After 3 years of clinical service all restorations were still clinically acceptable.

Discussion

According to the results of this clinical study, XP Bond in self-cure mode could prevent post-operative sensitivity over 3 years of clinical service and the null hypothesis was rejected..

With the intention of controlling any additional source of variation beside the patient related variability, in this clinical trial all the restorations were placed by one operator. 2 weeks after the placement of all restorations, post-operative sensitivity was found in around 19% (11 cases) of the restored teeth with a medium score of 1.9. Only one of these 11 cases showed a high degree of post-operative sensitivity (score 6), whilst in other cases the sensitivity was not spontaneous. The case in which the post-operative sensitivity was high at the beginning (score 6) showed residual sensitivity after 1 year but with a clinically acceptable score 2. This observation is in agreement with a study that reported hypersensitivity to be the most common post-operative complication (16). However, at the 6 month recall, the score dropped from grade 6 (strong) to grade 3 (mild) and after 1 year, to grade 2. At 2 year recall almost no post-operative sensitivity was found.

After 1 year of clinical service, two restorations scored bravo for marginal stain/integrity, a score still clinically acceptable. This observation might be explained by the marginal wear of the composite luting cement undermining the mechanical support.^{8,13} This observation was confirmed after 2 and 3 years of clinical service and lower scores were found for marginal stain/integrity. To prevent excessive marginal wear, it is therefore mandatory to have the narrowest gap possible between cavity preparation and ceramic restoration. Optimal fit (ranging from 50 to 100 µm) is preferred,⁸ particularly if the margins

extend below the cemento-enamel junction^{2,5}. Further clinical recalls will clarify if the margins can be affected during longer clinical service.

The utilization of a correct bonding technique is mandatory to achieve good clinical results in ceramic inlay luting². In direct resin restorations, the bonding agent is routinely light-cured prior to the insertion of the composite. In ceramic luting procedures, pre-curing of the adhesive resin may make restoration seating more difficult. The use of a self-cure bonding agent is also advantageous. In the present study, a self-curing cement was chosen for luting the restorations. Self-cure cements are also able to achieve an adequate degree of conversion at sites where light-curing may be hindered by the thickness of the ceramic. The setting time of the resin cement can also be directly correlated to room temperature, glass plate and mouth temperature.

It is important to understand the underlying chemical principles for each system. In the case of XP BOND, mixing with the self-cure activator SCA activates components of the SCA that are able to polymerize the adhesive interface on contact with the initiator from sufficiently initiated self- or dual-cure materials. Therefore, the self-cure mode for luting ceramic restorations of XP BOND mixed with SCA is guaranteed only when applied in combination with Calibra.

According to the data of this study, the mix of XP BOND with SCA in combination with self-activated Calibra showed clinically acceptable control of post-operative sensitivity at the 3 year recall. These findings will be re-evaluated during the next recalls at 4- and 5 years.

Conclusions

XP BOND with SCA and Calibra used in self-cure mode showed no residual post-operative sensitivity in 51 luted porcelain restorations after 3 years of clinical service.

Clinical relevance: The results of this 3 years study reveal good clinical performance of XP BOND in combination with SCA and Calibra in self-cure mode.

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