Effectiveness of a new one-step self-etch adhesive in the restoration of non carious cervical lesions: a paired-tooth design study

Final REPORT (5 April 2010)

This report provides final scientific results on the Bond Force study (results at 24 months).

Non-carious cervical lesions have a multifactorial etiology (erosion, abrasion and tooth flexure are the three principal putative causal mechanisms suggested). The restoration of non-carious cervical lesions presents some inconvenience, mainly concerning the location of their margins, because They are located in the cement and /or dentine most of the time. This characteristic makes the cervical margin more susceptible to microleakage, causing cavosurface stains, postoperative sensitivity and the incidence of carious lesions. Besides, the substratum in this type of lesions presents sclerotic and/or vitrified dentine in most cases.

The development of the acid-etching technique of the enamel and of the dentine resulted in a notable increase in durability and longevity of the restorations, since the adhesion of the resin composite to the dental tissues reduces or eliminates the need to remove healthy dental structure.
New adhesive systems are being continually developed with the purpose of increasing the adhesion of resin composite to the dental structure, favoring its retention and reducing marginal microleakage. At the same time, these systems provided the simplification of clinical procedures in the execution of adhesive aesthetic restorations. In vitro tests are necessary to evaluate their performances. It is also well admitted that even if in vitro tests are now well performed (Van Meerbeek et al, 2010), only randomized controled study allow a good level of scientific evidence (Forrest, 2009).
Generally, these trials are funded by public and private institutions with well recognized, experienced and specially trained clinicians. But these clinicians work without time constraints. Recently, practice based clinical research formally entered the dental research and seems to be closer to real life (Mjör, 2008).
The aim of this study was to evaluate the clinical performance of a new one-step self-etch adhesive system (Bond Force/Tokuyama) in the restoration of non-carious cervical lesions, with and without selective phosphoric-acid etching of enamel. The null hypothesis is that there is no significant difference regarding to the marginal adaptation, between the two procedures, after a two-year follow-up period.

Material and methods

The clinical effectiveness of Tokuyama Bond Force was evaluated when applied strictly following a self-etch approach according to manufacturer's instructions, and compared to the application of the same application protocol, but after the enamel cavity margins were selectively acid-etched with 40% phosphoric acid. This clinical controlled, single blind, multi-centric (5 dentists involved) trial follows a paired-tooth design, with a consecutive inclusion of subjects. The total follow-up period for each subject is 24 months, beginning 4th September 2007.

Inclusion, non-inclusion and exclusion criteria

The inclusion criteria are as follows: subjects have to be affiliated to a social welfare organization, aged > 18 years, presenting at least 2 cervical erosions to be restored on 2 different teeth (non-carious lesions, >1 mm depth, interesting both enamel and dentin of a vital incisor, canin or premolar without mobility), with acceptable level of personal oral hygiene level. Prior to participating in the study all patients signed a written consent. Non-inclusion criteria are: compromised medical history, periodontal disease, bruxism and/or traumatic occlusion and carious lesions.

Finally, exclusion criteria are defined as modification of the restorations by an other dentist during the follow-up period and loss or fracture of a tooth supporting a restoration, for independent reasons.

Restorative procedure

Operative procedures were performed in their dental office by 5 specially instructed and experienced dentists. A pre-set table mentioning, for each dentist, 10 pairs of an experimental and a control treatment protocol in random order was used to assign the procedure protocol to each tooth. Only one pair of restorations was placed in each patient. The two procedures protocols were mutually compared per restoration pair. If needed to prevent patient discomfort during restorative procedures, local anesthesia was applied. Isolation of the tooth was done using aspiration and cotton rolls, with the help of a dental assistant. A preliminary cleaning of the tooth surface aimed to remove salivary pellicle and remaining dental plaque. Then sclerotic dentin and/or discolored tooth tissue was removed, and a short enamel bevel (1-2 mm) was prepared. Lesions were restored according to the manufacturer's instructions, except for the control group, for which the enamel margins were beforehand selectively etched with 40% phosphoric acid. After moderate rinsing and air-drying, the self-etch adhesive was applied for 20 seconds, then indirectly air-dried for 5 seconds and finally directly air-dried for 5 seconds. Polymerization was performed during 10 seconds with a light output not less than 550 mW/cm^2. Estelite Flow Quick-Tokuyama, first, and Estelite Sigma-Tokuyama, second, were used as restorative composite for all the restorations. After a final 10 seconds polymerization, restorations were finished and polished using pinetree-shaped contouring diamonds, rubber points and flexible discs.

Evaluation criteria and procedure

Restorations were examined at baseline, 6, 12 and 24 months.

Relevant outcomes were marginal adaptation (0: no clinically detectable gap, or marginal integrity deviates from the ideal, but can be upgraded to ideal by polishing, or several small marginal fractures that are unlikely to cause long-term effects, and 1: localized or generalized gap resulting in exposure of dentine or base. Repair is necessary.

Other outcomes taken into consideration are retention of the restoration, post-operative sensitivity, marginal staining at the enamel or marginal staining at the cement, and restoration staining. All parameters were recorded using a simplified scoring system initially introduced by Hickel et al (2007). All dentists received a standardized notebook for data management.

Statistical analysis

Statistical analysis compared on a pair-wise basis the ratings of marginal adaptation, retention, post-operative sensitivity and staining between the two procedures, using the Chi-2 McNemar test at a significance level of 5%.
All statistical analysis were performed using Stata software (version 9.1).

Results

● Baseline - Visit 1

Subjects characteristics at baseline are summarized in Table 1.

Number of subjects	28
Mean Age	53.2 ± 13.7
Gender	11M ; 17 F
Mean number of teeth	27.8 ± 2.9

Table 1 - Subjects characteristics at baseline

Each tooth included for restoration of a cervical lesion was randomly assigned into a procedure protocol (with or without preliminary phosphoric-acid etching). Table 2 shows this assignation by type of tooth.

	Procedure with phosphoric-acid etching	Procedure without phosphoric-acid etching
Incisors (n)	2	2
Canins (n)	3	4
Premolars (n)	23	22

Table 2 - Restorative procedure by type of tooth

- Visit 2

The recall rate at visit 2 (6 month-recall) was 86% (24/28 subjects), with a mean delay of 197.4 ± 23 days. Table 3 shows the clinical results of the different parameters evaluated at visit 2 (**in percentage**).

	Procedure with phospho-ric-acid etching n=24	Procedure without phos-phoric-acid etching n=24	p-value
Retention rate	100	96	NS
	Procedure with phospho-ric-acid etching n=24	Procedure without phos-phoric-acid etching n=23	p-value
Good mar-ginal adapta-tion	100	100	NS
Absence of post-operative sensitivity	100	100	NS
Absence of marginal staining (enamel)	100	100	NS
Absence of marginal staining (cement)	100	100	NS
Absence of restoration staining	100	100	NS
Absence of Minor margin defects	96	39	0.004

Table 3 - Clinical results at visit 2.

One restoration was lost in the non-phosphoric-acid etching group. Minor defects rate appeared to be significantly higher in this group (p=0.004).

- Visit 3 (12 months)

The recall rate at visit 3 was 78% (22/28 subjects), with a mean delay of 185.4 ± 31 days since Visit 2.

None of the restorations was lost during the latter period (between 6 months and 12 months), resulting in an **excellent 100% retention rate.**

Table 4 shows the clinical results of the different parameters evaluated at visit 3 (**in percentage**).

	Procedure with phosphoric-acid etching n=22	Procedure without phosphoric-acid etching n=22	p-value
Retention rate	100	100	NS
Marginal adaptation	100	90	0.48
Absence of post-operative sensitivity	100	100	NS
Absence of marginal staining (enamel)	95	80	0.34
Absence of marginal staining (cement)	100	100	NS
Absence of restoration staining	100	95	1.00
Total (absence of major defects)	95	75	0.18
Absence of minor defects	100	77	0.048

Table 4 - Clinical results at visit 3.

If one looks carefully at the evolution of the restorations :

In the group with Phosphoric acid
- 1 major defect appeared
- 1 minor defect was lost
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In the group without Phosphoric acid
- 2 major defects appeared
- 1 minor defect appeared
- 4 minor defects (at 6month recall) remained minor
- 3 minor defects (at 6month recall) became major
- 1 minor defect was lost

Visit 4 (24 months)

The recall rate at visit 2 was 75% (21/28 subjects), with a mean delay of 405 days since Visit 3.

None of the restorations was lost during the latter period (between 12 months and 24 months), resulting in an **excellent 100% retention rate.**

Table 5 shows the clinical results of the different parameters evaluated at visit 4 (**in percentage**).

	Procedure with phosphoric-acid etching n=22	Procedure without phosphoric-acid etching n=22	p-value
Retention rate	100	100	NS
Marginal adaptation	95	90	1
Absence of post-operative sensitivity	100	100	NS
Absence of marginal staining (enamel)	95	71	0.093
Absence of marginal staining (cement)	95	90	NS

Absence of restoration staining	100	95	1.00
Absence of minor defects	100	81	NS

Table 5 - Clinical results at visit 4.

If one looks carefully at the evolution of the restorations :

In the group with Phosphoric acid
- 2 major defects appeared

In the group without Phosphoric acid
- 1 major defect appeared
- 1 minor defect appeared
- 4 minor defects (at 12 month-recall) became major defect

Discussion

The objective of this controlled randomized clinical study was to evaluate the influence of the enamel etching before realizing a classe 5 composite restoration with a Bond Force / Estelite sigma association.

This issue is of clinical significance because many studies have shown an increased prevalence of cervical lesions with age (Wood et al., 2008).

The recall rate was 86% at the 6 months recall, 78% at the 12 months recall and 75% at the 24 months recall. Only one patient was lost between the twelfth and the twenty-fourth month. Reasons for not showing up were not related to any negative appreciation of the patient for the restorative work done.

In this clinical trial, operative procedures were performed in their dental office by 5 specially instructed and experienced dentists who belong to a Practice Based Research network (Mjör, 2008).

Isolation of the tooth was done using aspiration and cotton rolls, with the help of a dental assistant. Isolation was not done with rubber dam, seldom used by general practitioners. So the results of this study were expected to be as good as those published in the literature where rubber dam was always used. Nevertheless, this paired-tooth design study revealed excellent performance of the Bond Force adhesive up to 24 months of clinical service.

First of all, patients who were treated with Bond Force restorations hardly reported any post-operative sensitivity. This indicates that dentin tubules must have been adequately sealed by the self etching adhesive.

During the 24 months-period, only one restoration (in the group without phosphoric acid) was lost in the first 6 month-period resulting in an excellent 100% cumulative retention rate in the experimental etch group and 96% cumulative retention rate in the experimental non etch group. None of the restorations was lost during the period between 6 months and 24 months.

Much less favorable clinical effectiveness is commonly recorded for adhesives in class 5 cavities (Van Dijken, Dent Mater, 2008).

After 2 years of clinical service, the retention rate exceeds (that recommended by) the ADA guidelines (less than 10% restoration loss at 18 months).

Concerning the evaluation parameters, one can note only 2 new defects (2 major) in the group with phosphoric acid and two in the group (one major and one minor) without phosphoric acid.

With time, minor defects tend to become major defects (4 examples) especially in the group without phosphoric acid.

However, no significant difference between groups was recorded with regard to the endpoints of clinical success. The null hypothesis can't be rejected.

At the 12 month recall, the only parameter that appeared significantly different between both group was the higher prevalence of minor defects recorded when Bond Force was applied following a

solely self etch approach (p = 0.048). **At the 24-onth recall**, it was not the case anymore.

In any case, it should be emphasized that these defects were small. They did require neither repair nor restoration replacement. These small defects should therefore be regarded as being of clinically negligible relevance. These results confirm several studies (Van Meerbeek et al, 2005; Van Dijken and Pallesen, 2008).

Conclusion

One can summarize this study with the following 4 conclusions:

1) Absence of post-operative sensitivity in the two groups
2) Almost absence of marginal staining at the dentin level in the two groups.
3) Very good retention rate in the two groups
4) Almost absence of restoration staining indicating **that the composite used in this study (Estelite sigma) performs very well after 24 months of linical service**.

This final report (**24 months recall**) shows that the clinical effectiveness of the Bond Force adhesive was excellent after 2 years. Although no significant difference was found between the groups tested, a slight trend for the procedure without phosphoric-acid etching to be at higher risk of minor margin defects was observed. Long-term recalls should be planned
to find out if differences in clinical performance between the experimental and control groups will occur with the aging of restorations.

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