

Two-year clinical performance of two one-step self-etching adhesives in the restoration of cervical lesions

A. Schattenberg · U. Werling · B. Willershausen · C.-P. Ernst

Received: 26 July 2007 / Accepted: 14 February 2008 / Published online: 28 March 2008
© Springer-Verlag 2008

Abstract The aim of the study was to evaluate the clinical performance of two different one-step self-etching adhesives (Hybrid Bond/Sun Medical, Xeno III/Dentsply) in adhesive cervical resin composite restorations. In accordance with a split-mouth study design, 50 patients (57.3 ± 13.5) received at least one pair of restorations. In each of two comparable cervical cavities, either the adhesive systems Hybrid Bond or Xeno III was used with the resin composite Filtek Supreme (3M ESPE). After 6, 12 and 24 months, the restorations were scored according to the Ryge and California Dental Association criteria. After 2 years, the resulting scores (percent) of the Ryge evaluation for the groups Hybrid Bond/ Filtek Supreme and Xeno III/ Filtek Supreme were marginal integrity, Alpha (92/78), Bravo (8/2), Charlie (0/0) and Delta (0/10); anatomic form, Alpha (92/82), Bravo (8/8) and Charlie (0/10); secondary caries, Alpha (100/100) and Bravo (0/0); marginal discoloration, Alpha (80/84), Bravo (20/12), Charlie (0/0) and not available (0/4); color match, Oscar (39/47), Alpha (51/45), Bravo (10/4), Charlie (0/0) and not available (0/4); surface, Romeo (78/69), Sierra (22/22), Tango (0/0) and Victor (0/10); tooth vitality, Alpha (98/94), Bravo (2/6); and integrity of tooth, alpha 1 (96/96) and alpha 2 (4/4). After 2 years, all Hybrid Bond restorations were retained and showed clinically acceptable results, while five Xeno III restorations were lost in part or in toto. For marginal integrity, anatomic form and surface, signif-

icant differences ($p < 0.05$) were found but did not prove statistically significant after Bonferroni adjustment.

Keywords Cervical restorations · One-step self-etching adhesive · Clinical study · Two-year evaluation · Ryge/CDA criteria

Introduction

Photopolymerisable resin composites are well-established restorative systems worldwide; therefore, direct composite restorations have become an established procedure in dental practice in recent years [30]. The type of adhesive that is used for a restoration is one important factor besides the restorative material. There have been many changes in the adhesive systems in the past. In contrast to conventional three-step etch-and-rinse adhesive system, the development of self-etch adhesives simplified the application in a wide variety of applications. However, the one-step self-etching adhesives need an especially proper application protocol due to their particular technique-sensitivity [39]. When used properly, it is possible to obtain clinically acceptable and comparable results to traditional etch-and-rinse systems [9, 35]. Nevertheless, there are differences in quality concerning self-etching adhesives [37], which differed the most between the individual products and between the two-versus one-step approach than between etch-and-rinse and self-etch systems in total [31]. This is supported by De Munck et al. [6], who found the lowest micro-tensile bond strength data of all adhesives tested for a one-step self-etch adhesive (Adper Prompt), while two-step self-etch adhesives (Clearfil SE Bond, OptiBond Solo Plus Self Etch) were not different from the bond strength data obtained by the three-step etch-and-rinse control (OptiBond FL) when

A. Schattenberg (✉) · U. Werling · B. Willershausen · C.-P. Ernst
Clinic for Restorative Dentistry,
Johannes Gutenberg-University of Mainz,
Augustusplatz 2,
55131 Mainz, Germany
e-mail: schattan@uni-mainz.de

bonded to both, enamel and dentin. The bond strength to dentin of Xeno III, which was under examination, is discussed controversially [4, 8, 34].

There are different demands on an adhesive system depending on the location of the restoration.

Cervical lesions are often the focus for testing different adhesive systems, especially self-etching adhesives [1, 2, 32, 38]. Due to their location, a loss of bond strength and changes concerning the different categories are easy to control.

Kaaden et al. [22] found in their laboratory investigation on bond strength of different self-etching adhesives (Clearfil SE Bond, Prompt-L-Pop, Etch&Prime 3.0) that most of the self-etch adhesives bond effectively to enamel, but only one self-etching adhesive (Clearfil SE Bond) was able to obtain good results to superficial and deep dentin [22]. Since a cervical cavity often shows more superficial or deep dentinal substrates than enamel, this restoration demands special needs for a dental adhesive system concerning the bond strength to these both tissues [22].

Some one-bottle etch-and-rinse adhesives (OptiBond Solo, Prime&Bond 2.1) provide excellent clinical retention of cervical restorations without mechanical retention [32]. However, clinical investigations showed that adhesively bonded resin composite restoratives are still not able to completely prevent leakages [17], particularly at cervical margins [7, 16].

Nevertheless, there are some clinical advantages concerning the application of one-step self-etching adhesives in a cervical cavity compared to conventional etch-and-rinse adhesives in terms of handling properties: When the cavities are restored without rubber dam isolation, a gingival bleeding might occur after rinsing off the phosphoric acid gel, which incidentally contacted to the gingival margin. This might result in a severe contamination problem of the substrate, which will not take place, when a self-etch adhesive is used. In those cases, a mostly white superficial necrosis zone will be visible rather than bleeding, which does not seem to be a contamination problem [10].

Self-etching adhesives can still not be recommended for unrestricted clinical use in larger class II restorations [14], but they have significantly improved handling properties in cervical restorations. Therefore, due to the established bond strength to dentin and due to a reduction in contamination control problems, one-step self-etch adhesives are in the focus of research for cervical restorations. Additionally, the cervical cavity is the main focus of interest in this clinical research because it is one of the easiest to control and to follow up due to the location of cervical restorations.

Aim of this study

The aim of the study was to evaluate the clinical performance of two different one-step self-etching adhesives (Hybrid

Bond/Sun Medical, Xeno III/ Dentsply) in adhesive cervical resin composite restorations (Filtek Supreme/3 M ESPE).

The null hypothesis was that both adhesives systems obtain comparable results and perform clinically well in this cervical indication.

Materials and methods

A total of 50 patients (mean age, 57.3 ± 13.5 a; 55% female, 45% male) participated in this clinical study. This resulted in a pool of patients, balanced for gender and age. The patients were asked whether they wanted to participate in the study if they showed at least two comparable cavities to be restored with a resin restorative when they reported as patients to the dental clinic. The indications were primary caries, erosions, cervical defects, or replacement of existing insufficient restorations. There were no exclusion criteria; only the inability to show up for a re-evaluation after 6, 12 and 24 months had to be considered.

They were offered dental treatment of the selected teeth free of charge. It was not obligatory for the patients to return for the re-evaluation appointments; this was voluntary. When they returned after 2 years for the last follow-up examination, they received a reimbursement of Euro 50 for their overall travel expenses and for showing up at all three follow-up appointments. The study design was approved by the Ethic Committee of the State of Rhineland-Palatinate (IRB approval 837.361.03 (4023), Germany. Written informed consent was obtained from every patient in this investigation.

If patients fulfilled the inclusion criteria, the restorations were performed according to the same protocol to obtain comparable cavities and restorations. The clinical procedure of cavity preparation and placement of the restorations were performed by four experienced dentists of the Department for Operative Dentistry of the Dental Clinic of the University of Mainz. This study was performed in a split-mouth study design over an observation period of 2 years according to the Ryge/CDA criteria.

At least two resin composite restorations were placed in each patient, resulting in a total of 104 restorations. The distribution of lesions and their positions are shown in Table 1. The clinical procedure followed the same protocol.

The clinical situation of the tooth to be restored was photo-documented. After complete removal of existing restorations and caries, an adhesive cervical cavity design was prepared and finished using diamond burs (30 μ m) under constant water cooling (120,000 rpm). In contrast to the American Dental Association (ADA) recommendations [3] on non-carious lesions, a distinct roughening of the substrate was carried out by means of a finishing diamond

Table 1 Distribution of lesions of Hybrid Bond and Xeno III fillings and there position

| | Xeno III (%) | Hybrid Bond (%) |
|----------------------|--------------|-----------------|
| Upper premolars | 13 | 14 |
| Lower premolars | 17 | 13 |
| Upper molars | 4 | 2 |
| Lower molars | 2 | 3 |
| Upper anterior teeth | 8 | 13 |
| Lower anterior teeth | 7 | 7 |

bur. This was to obtain comparability to other indications as the removal of caries or existing restorations. No additional “extension for prevention” and no visible preparation of undercuts were performed after the lesions were completely excavated if needed. No further base or calcium hydroxide liner was used. The enamel margins received a distinct bevel preparation. The restorations were placed without rubber dam isolation; a potential contamination of the cavity from saliva, blood or sulcus fluid was sufficiently prevented by cotton roles, suction and retraction cords (Surgident, Sigma Dental, Jarplund-Weding, Germany).

The cavities were randomly assigned to the two different adhesives, which were investigated in this clinical study. Even though cavity size and location of the different lesions varies, this factor reflects the clinical reality, which should be captured in this clinical investigation. The use of the adhesive system followed manufacturer’s recommendations strictly. To avoid any interaction with the tooth substrate or the adhesive, no disinfection of the cavity was carried out. The adhesive systems to be compared were RZII (Sun Medical, Shiga, Japan) lot GV2, which was the experimental name of the later Hybrid Bond. According to information obtained from the manufacturer, no changes in the chemical formulation from RZ II to Hybrid Bond took place. The well-established Xeno III (Dentsply, Konstanz, Germany), lot. 0310000129, served as control. Both adhesives are two-component one-step self-etch adhesives. While in Xeno III, the adhesive has to be mixed from two separate bottles, in Hybrid Bond (RZ II), one component is incorporated in the filaments of the micro-brushes, delivered with the system. Therefore, only those micro-brushes can be used together with the Hybrid Bond adhesive. The

application protocol of Xeno III and Hybrid Bond is added in Table 2. Both adhesives were light-cured for 40 s (Translux CL, Heraeus, Hanau, Germany).

The restorative material Filtek Supreme (3M ESPE) was used to restore both cavities. For this clinical study, Filtek Supreme was available in the shades A2 Body, A3B and A3.5B. In addition, a resin restorative material was selected, which did not belong to one of the manufacturers of both adhesives and was designated to be used together with adhesives other than with those from the manufacturer of the resin composite.

The resin composite was applied in increments not exceeding 2 mm in thickness; the resin composite increments were light-cured (Translux CL, Heraeus-Kulzer, Hanau, Germany) for 40 s each. The last resin composite increment was applied by means of Hawe cervical foils (Kerr Hawe, Bioggio, Switzerland) in most of the cases (>80%). If those foils had been used in one tooth, the other tooth (second adhesive) was treated the same way.

Finishing was carried out with diamond burs (30 µm); for polishing, Enhance polishing cups (Dentsply) and polishing brushes (Okklu-Brush, Kerr Hawe, Bioggio, Switzerland) were used under constant water cooling.

There were no limitations regarding cavity size or location of cervical margins. Two comparable resin composite restorations were placed in each patient, resulting in a total of 104 restorations. All restorations were scored according to the Ryge and California Dental Association (CDA) Criteria [27, 28] and extended criteria [26] considering tooth vitality, marginal integrity, anatomical form, secondary caries, colour match, marginal discoloration, surface, postoperative sensitivity and the integrity of the tooth by two independent investigators not involved in the placement of the restorations. The examiners have been calibrated to a predetermined level of inter- and intra-examiner agreement of at least 95% per single criteria. Training was conducted on approximately 100 resin composite restorations from other patients from the clinical student courses in Operative Dentistry not enrolled in the present clinical study. In cases where the two examiners disagreed on a rating, both re-examined the restoration and arrived at a joint final decision. Each restoration was documented by photographs.

Table 2 Resin composite and adhesives investigated in the present study

| | Manufacturer | Shade/methods of use | Lot number |
|-------------------|-----------------------------------|---|------------|
| Resin composite | | | |
| Filtek Supreme XT | 3M ESPE, St.Paul, MN, USA | A3B | 20060601 |
| Adhesive | | | |
| Xeno III | DENTSPLY, Konstanz, Germany | Mixed from two separate bottles light curing for 40 s | 0310000129 |
| Hybrid Bond/RZII | Sun Medical Co, Ltd. Shiga, Japan | one component is incorporated in the filaments of the micro-brushes light curing for 40 s | GV2 |

According to Ryge [27, 28] scores for the criteria tooth vitality, marginal integrity, anatomical form, secondary caries and marginal discoloration were named Alpha, Bravo, Charlie and Delta. The surface was evaluated by scores, named Romeo, Sierra, Tango and Victor, the colour match by Oscar, Alpha, Bravo and Charlie, while the postoperative sensitivity and the integrity of tooth were stated Alpha 1 and 2, Bravo, Charlie and Delta. Alpha, Bravo, Romeo and Sierra scores meant “excellent” and “clinically acceptable” results, while Charlie, Delta, Tango and Victor scores meant “clinically not acceptable”—an indication to replace the restoration to prevent future damage or to remedy presently occurring damage. This evaluation, including a photo-documentation and a test of the tooth vitality (Coolan, Voco, Cuxhaven, Germany), was performed after 6, 12 and 24 months [11, 12, 29].

A summary of the Ryge/CDA criteria used in this investigation as well as the additional criteria are shown in Table 3.

If a restoration had been scored Charlie or Delta, the restoration was replaced or repaired at the same or a separate appointment. If that occurred, the Charlie or Delta scores were conferred to all further revaluations, even though the complete restoration could not be evaluated afterwards and no further evaluations on other criteria such as marginal discoloration was carried out.

A descriptive statistical analysis was performed by means of Microsoft Excel and SPSS 12.0. To determine statistically significant differences between both adhesives, the Wilcoxon signed-rank test was used at the 5% level of significance, followed by a Bonferroni adjustment.

Results

After 2 years, all patients (recall rate, 100%) could be re-evaluated and scored according to the Ryge and the extended clinical criteria. The results of the baseline and the re-evaluation after 6 months, 1 and 2 years are shown in Table 4. Five Xeno III restorations were lost in part or in toto within the observation period of 2 years. None of the Hybrid Bond restorations were lost.

Therefore, an overall clinical success rate for the Xeno III group, summing up all the Alpha and Bravo scores, of 90% according to the functional Ryge criteria was found. With the Hybrid Bond group, an overall success rate of 100% could be documented.

When taking the Ryge criteria “marginal integrity” into account, the percentage of Alpha scores for Hybrid Bond was 92%, while it was 78% in the Xeno III group.

After 2 years, 2% of the teeth restored with Hybrid Bond and 6% of the Xeno III group did not respond positively to the provocation on cold (Coolan-Spray), but no further measures

had to be taken into account because of a complete asymptomatic clinical situation. No secondary caries were observed. One of the Xeno III restorations (2%) showed a severe postoperative sensitivity at the 6 and 12 months recall. From the investigators, this was scored Charlie, but the patient did not show up for a renewal of the restoration as suggested but showed up for the 2-year follow-up, where the sensitivity was gone (tooth was still vital).

The Wilcoxon signed-rank test showed significant differences in the clinical performance between both adhesives in the evaluation criteria marginal integrity ($p=0.025$), anatomic form ($p=0.031$) and surface ($p=0.025$) in favor of Hybrid Bond. However, after the Bonferroni adjustment, none of those differences with $p<0.05$ proved statistically significant.

Discussion

A total number of 50 patients, who received a total of 104 restorations, were considered to be a sufficient number to cover most patients' variables. Due to the fact that the clinical performance of two self-etching systems in cervical restorations was the main focus of this investigation, all other variables such as the type of composite or isolation were standardised: Besides the selection of comparable cavity sizes, comparable accessibility and position of the teeth, all restorations were placed without rubber dam isolation; a sufficient contamination of the cavity with saliva, blood or sulcus fluid was prevented by cotton roles, suction and retraction cords.

In the present investigation, the cervical lesion was chosen to examine the different adhesives. Cervical lesions are regarded as the ideal cavities to test the effectiveness of adhesives: due to the absence of macro-mechanical undercuts, the restoration has to fit only adhesively. This might reduce the long-term prognosis due to the resulting higher stress build-up in that cervical area [38].

The same composite material, Filtek Supreme, was used for both restoratives. The idea behind the use of Filtek Supreme as the restorative was to select one resin restorative for both adhesives investigated to obtain a comparison of the adhesive solely and not of a system consisting of adhesive and resin composite. According to the resulting reduction in variables, one had the possibility to focus on the adhesive system itself and not to the adhesive system consisting of the resin composite plus the adhesive. This might contrast with recommendations of the manufacturer of the control material Filtek Supreme, which generally is recommended to be used in combination with an adhesive from the same manufacturer. But in this recommendation, there was no contraindication found using different adhesives with the restorative. The same with the

Table 3 Summary of the individual ratings of the Ryge/CDA criteria and additional clinical criteria according to Pelka et al. used in this clinical study on Hybrid Bond and Xeno III

| Category | Rating | Characteristic |
|------------------------|---------|---|
| Marginal integrity | Alpha | No visible evidence of a crevice along the margin into which an explorer will catch |
| | Bravo | The explorer catches a crevice along the margin, but there is no exposure of dentin or base |
| | Charlie | Visible evidence of a crevice with exposure of dentin or base |
| | Delta | The restoration is fractured or missing in part or in toto |
| Anatomic Form | Alpha | The restoration is not undercontoured |
| | Bravo | The restoration is undercontoured, but there is no dentin or base exposed |
| | Charlie | Sufficient restorative material is missing so that dentin or base is exposed |
| Secondary caries | Alpha | No evidence of recurrent caries along the margin of the restoration |
| | Bravo | Presence of softness, opacity at the margins as evidence of undermining or demineralisation, or etching or white spots as evidence of demineralisation in areas where explorer catches or resists removal after insertion |
| Marginal discoloration | Alpha | No existing marginal discoloration at all |
| | Bravo | Presence of discoloration at the margins between the restoration and the tooth structure; discoloration does not penetrate along the margins of the restoration toward the pulp |
| Color match | Charlie | The discoloration penetrated along the margins of the restoration in a pulpal direction |
| | Oscar | The restoration cannot be detected with a mirror |
| | Alpha | The restoration is visible, but there is no mismatch in color, shade and/or translucency between the restoration and the adjacent tooth structure |
| | Bravo | There is a mismatch in color, shade or translucency, but not outside the normal range of tooth color, shade and/or translucency |
| Surface | Charlie | The mismatch is outside the normal range of tooth color, shade and/or translucency |
| | Romeo | Surface is smooth, and the adjacent tissues showed no irritation |
| | Sierra | Surface of the restoration is slightly rough or pitted but can be refinished |
| | Tango | Surface is deeply pitted or shows irregular grooves, which were not related to the natural anatomy and could not be refinished |
| Tooth vitality | Victor | Surface is fractured or flaking |
| | Alpha | Tooth vitality positive |
| | Bravo | Tooth vitality negative |
| Integrity of tooth | Alpha 1 | No damage of tooth structure at all |
| | Alpha 2 | Minor splinters of enamel or enamel cracks; repolishable; no need for therapy |
| | Bravo | larger enamel cracks, where an explorer will catch, not recontourable splinters |
| | Charlie | Enamel splinters with exposure of dentin |
| Sensitivity | Delta | Fracture of cusp/tooth |
| | Alpha 1 | Clinically well, no postoperative sensitivities at all |
| | Alpha 2 | Clinically well, temporary or minor postoperative sensitivities after placement of the restorations. No treatment necessary |
| | Bravo | Clinically acceptable, distinct postoperative sensitivities over several months; no improvement of the situation meanwhile, but on the other hand no treatment necessary or asked from the patient. |
| | Charlie | Clinically not acceptable: permanent postoperative sensitivities—acceptable in the moment, but treatment is planned |
| | Delta | Clinically not acceptable: permanent, non acceptable postoperative sensitivities treatment is to be carried out immediately (i.e. root canal treatment) |

instruction manuals of both adhesives investigated. Thomsen et al. [34] found that the combination of an adhesive system and a resin composite from the same manufacture did not provide bond strength data superior to those obtained from the combination of an adhesive system and a resin composite from two different manufactures.

Restorations were performed by four experienced dentists. One can discuss the influence of diverse operators, the

operator factors, which Bayne [5] described as the potential differences in skill (not judgment) of different dentists. The author states that their abilities might be influenced by manual dexterity affected by one's natural psychomotor skills [5]. In addition, Miyazaki et al. [25] found significant differences in bond strength of the tested adhesives depending on the different operators in each group. It has to be discussed if the operators' skills might be

Table 4 Results of the clinical evaluation of Hybrid Bond (Hb) and Xeno III (Xe) restorations

| | Marginal integrity | | | | Anatomic form | | | Marginal discoloration | | | Color match | | | Surface | | | Tooth vitality | | | Integrity of tooth | | | | Sensitivity | | | | | | | | | | |
|----------|--------------------|----------------|----------------|----|----------------|----------------|----------------|------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|--------------------|----------------|-----------------|-----------------|-----------------|-----------------|----------------|-----------------|-----------------|-----------------|-----------------|----------------|---|---|---|
| | A ^a | | B ^a | | C | D | A ^a | B ^a | C | A ^a | B ^a | C | O ^a | A ^a | B ^a | C | R ^a | S ^a | T | V | A ^a | B ^a | C | A1 ^a | A2 ^a | B ^a | C | D | A1 ^a | A2 ^a | B ^a | C | D | |
| | A ^a | B ^a | C | D | A ^a | B ^a | C | A ^a | B ^a | C | O ^a | A ^a | B ^a | C | R ^a | S ^a | T | V | A ^a | B ^a | C | A1 ^a | A2 ^a | B ^a | C | D | A1 ^a | A2 ^a | B ^a | C | D | | | |
| Baseline | Hb | 100 | 0 | 0 | 0 | 90 | 10 | 0 | 100 | 0 | 0 | 0 | 50 | 44 | 6 | 0 | 92 | 8 | 0 | 0 | 100 | 0 | 0 | 96 | 4 | 0 | 0 | 0 | 100 | 0 | 0 | 0 | 0 | 0 |
| 6 mo. | Xe | 96 | 4 | 0 | 0 | 88 | 10 | 2 | 100 | 0 | 0 | 45 | 55 | 0 | 0 | 90 | 10 | 0 | 0 | 98 | 2 | 0 | 98 | 2 | 0 | 0 | 0 | 98 | 2 | 0 | 0 | 0 | 0 | 0 |
| | Hb | 96 | 4 | 0 | 0 | 92 | 8 | 0 | 90 | 0 | 10 | 44 | 50 | 6 | 0 | 87 | 13 | 0 | 0 | 100 | 0 | 0 | 96 | 4 | 0 | 0 | 0 | 100 | 0 | 0 | 0 | 0 | 0 | |
| 12 mo. | Xe | 94 | 6 | 0 | 0 | 90 | 8 | 2 | 96 | 4 | 0 | 59 | 39 | 2 | 0 | 84 | 16 | 0 | 0 | 96 | 4 | 0 | 98 | 2 | 0 | 0 | 0 | 98 | 0 | 0 | 2 | 0 | 0 | |
| | Hb | 94 | 6 | 0 | 0 | 92 | 8 | 0 | 90 | 0 | 10 | 39 | 53 | 8 | 0 | 82 | 18 | 0 | 0 | 98 | 2 | 0 | 96 | 4 | 0 | 0 | 0 | 100 | 0 | 0 | 0 | 0 | 0 | |
| 24 mo. | Xe | 78 | 12 | 10 | 0 | 82 | 8 | 10 | 88 | 8 | 0 | 49 | 45 | 2 | 0 | 72 | 18 | 0 | 10 | 94 | 6 | 0 | 96 | 4 | 0 | 0 | 0 | 98 | 0 | 0 | 2 | 0 | 0 | |
| | Hb | 92 | 8 | 0 | 0 | 92 | 8 | 0 | 80 | 20 | 0 | 39 | 51 | 10 | 0 | 78 | 22 | 0 | 0 | 98 | 2 | 0 | 96 | 4 | 0 | 0 | 0 | 100 | 0 | 0 | 0 | 0 | 0 | |
| | Xe | 78 | 12 | 0 | 10 | 82 | 8 | 10 | 84 | 16 | 0 | 47 | 45 | 4 | 0 | 69 | 22 | 0 | 10 | 94 | 6 | 0 | 96 | 4 | 0 | 0 | 0 | 100 | 0 | 0 | 0 | 0 | 0 | |

The Ryge and CDA-scores are shown as documented at baseline, after 6, 12 and 24 months.

A Alpha, B Bravo, C Charlie, D Delta, O Oscar, R Romeo, S Sierra, T Tango, V Victor

^a Values in this column are clinically acceptable results.

responsible for the loss of five restorations. Due to the fact that the lost restorations were attributed to four different operators, it can be assumed that there was no clear operator effect responsible for the losses.

The ADA requires non-carious lesions as the bond substrate for a cervical investigation [3]. In contrast to that requirement, in the present study, all other indications for cervical restorations as restoration of primary caries or renewal of existing restorations were included, too. This was done to allow the investigation to become more clinically related to the daily routine work in a dental office, where non-carious cervical lesions are not the only indication for a cervical restoration. To ensure comparability, the non-carious cervical lesions received a distinct surface preparation in terms of a superficial roughening but without altering the cavity form.

All restorations were scored according to the Ryge criteria and to extended criteria according to Pelka et al. [26]. Meanwhile, it was addressed that the evaluation of the clinical performance according to Ryge is not precise enough since there are many clinical variables simultaneously involved [36]. They state that, specifically, the clinical evaluation of resin-based restorations requires a more sensitive interpretation, which can easily be compared to other studies, including the habits of patients (such as bruxism) and the existing damage or location and size of the cavity [21]. This was the reason why new criteria were developed and recently published [21]. The present study was finalised before the time the new criteria were published. Therefore, the traditional Ryge criteria were utilised in this study. Nevertheless, the recommendations of Hickel et al. [21] seem to be proficient for further clinical studies.

There were no obvious secondary caries after a period of 2 years in both groups tested. This could be confirmed by other authors, which found comparable results with different self-etching adhesives as Clearfil Protect Bond, Prompt-L-Pop and Xeno III, too. They stated that the likelihood of developing secondary caries as a consequence of bacterial micro-leakage may not be affected by the use of the above named adhesive systems [15].

It is difficult to speculate about a possible reason for the loss of retention in five of the Xeno III restorations. The influence of the adhesive system in a clinical study might be seen in the outcome of the marginal integrity and the marginal discoloration [11]. In the present investigation, Xeno III showed obvious but, after the Bonferroni adjustment, non-significant (Table 3) differences in terms of marginal integrity, anatomic form and surface compared to Hybrid Bond after a period of 2 years. The scores anatomic form and surface are closely related in terms of the best (Alpha) and worst (Charlie) score. From that standpoint of view, both criteria could be summarised in a single criterion. But in cases of the Bravo scores, the

evaluation criteria are different. Therefore, it is still useful to evaluate both criteria.

It was stated that differences in shear bond strength to dentin exist between the different self-etching systems [4]. In the cited study [4], Xeno III showed significantly lower bond strength data to dentin than Clearfil SE Bond but higher bond strength than Adper Prompt L Pop. This was confirmed by Thomsen et al. who found significantly lower bond strength data to dentin for Xeno III compared to the other adhesive systems tested (Clearfil SE Bond, AdheSE, Optibond Solo Plus) [34]. In contrast, in another paper, the highest bond strength was determined with Xeno III compared to Prompt L-Pop and Prime&Bond NT for both substrates, enamel and dentin [8]. In the present study, Xeno III apparently might not have shown demanding bond strength since 10% of the Xeno III /Filtek Supreme restorations lost retention.

In the Hybrid Bond group, 20% of the restorations showed discoloration at the margins (Bravo scores). This finding is supported by other studies, where Hybrid Bond restorations showed significant deterioration in marginal adaptation and marginal discoloration after 2 years compared to other adhesives tested (Admira Bond, Clearfil SE Bond) [1].

In the present study, Xeno III showed Bravo-score discolorations from 4% at the 6 month recall to 12% after 2 years. Nevertheless, the difference in marginal discoloration between both groups was not of statistical significance.

It has been reported that the amount of marginal deterioration or cavomarginal discoloration can be related to postoperative sensitivities [21]. Restorations (class II cavities) with either marginal deterioration or cavomarginal discoloration failed 8.7 times more frequently within a period of 5 years than restorations without it [20]. That copes with the results of the present study, where some sensitivity in the Xeno III group (2%) was observed but no postoperative sensitivities after a period of 2 years in both groups. However, 10% of the Xeno III/ Filtek Supreme fillings were lost after 2 years; they showed a lower percentage of B scores marginal discoloration and a higher percentage of B scores in marginal integrity compared to the Hybrid Bond group. These results were not statistically significant after the Bonferroni adjustment was applied. These data thus indicate a trend, which could be verified only through a higher number (about $n=200$) of fillings.

Kersten et al. [24] stated that in class II cavities, a continuous margin in enamel of at least 90% and of at least 80% in dentine can be considered a good performance, whereas the ADA for submission of dentin and enamel adhesive materials [3] requires for provisional acceptance that no more than 5% of the restorations may show microleakage at the 6-month recall. As Bravo scored restorations are considered to be clinically acceptable, which were 8% of the Hybrid Bond and 12% of the Xeno

III group, the marginal adaptation did fulfill the ADA acceptance criteria for restorative materials at the 6-month recall. Nevertheless, a recall protocol extended to 24 months [11, 12, 29] allows a better evaluation of the clinical performance of restorative materials compared to the shorter evaluation protocol recommended by the ADA [3].

In accordance to the literature, failures of the adhesive are mostly mixed failures (adhesive and cohesive failures within the adhesive resin) [19, 33]. Differences in bond strength might vary according to the tooth substrate luted to. Generally, the bond strength is higher in enamel than in dentin [4], but this is mainly for etch-and-rinse systems. In self-etch adhesives, the enamel and dentin bond strength data can be similar [18], whereas others report insufficient bonding in dentinal areas [13]. In further investigations, self-etch adhesives bond well to smear-layer-covered dentin [40]. Therefore, this seems to be an individual influence of the particular adhesive and the investigation method.

Other authors conclude that, based on the relationship between degree of conversion and shear bond strength, the percentage of the degree of conversion is the main parameter influencing an adhesives bonding efficacy to ground enamel [23]. However, Atash et al. [4] found statistically significant differences concerning the shear bond strength between enamel and dentin, except for Xeno III vs. Prompt-L-Pop.

The overall clinical success rate after 2 years was 90% for the Xeno III group and 100% for the Hybrid Bond group; no significant difference between the two groups could be pointed out. The success rate obtained from this investigation in short term (2 years) can be compared to the “golden standard” of three-step etch-and-rinse [38]. According to Akimoto et al., self-etching systems can show excellent performance rate even after a period of 10 years [2].

Conclusions

Within the limits of the current investigation, the following may be concluded. At the 24 month recall, both adhesive systems investigated showed acceptable clinical performance in cervical cavities even if five Xeno III restorations had been lost. The null hypothesis had to be accepted, because the differences in both adhesives—mainly loss of retention—did not prove statistically significant and is proved acceptable within the ADA guidelines.

Therefore, both one-step self-etching adhesives can be stated as acceptable for the use in cervical cavities. However, further long-term recalls are needed for a final evaluation.

Acknowledgement This study was supported financially and by supplying the Hybrid Bond test material from Sun Medical Co, Ltd., Japan.

References

- Abdalla AI, Garcia-Godoy F (2006) Clinical evaluation of self-etch adhesives in Class V non-caries lesions. *Am J Dent* 5:289–292
- Akimoto N, Takamizu M, Momoi Y (2007) 10-year clinical evaluation of a self-etching adhesive system. *Oper Dent* 1:3–10
- American Dental Association–Council on Dental Materials, Instruments and Equipment (2001) Revised American Dental Association acceptance program guidelines for dentin and enamel adhesive materials. American Dental Association, Chicago. http://www.adafoundation.org/ada/seal/standards/guide_materials_adhesive.pdf
- Atash R, Vanden Abbeele A (2005) Sealing ability and bond strength of four contemporary adhesives to enamel and to dentine. *Eur J Paediatr Dent* 4:185–190
- Bayne SC (2007) Dental restorations for oral rehabilitation-testing of laboratory properties versus clinical performance for clinical decision making. *J Oral Rehabil* 12:921–932
- De Munck J, Vargas M, Iracki J, Van Landuyt K, Poitevin A, Lambrechts P, Van Meerbeek B (2005) One-day bonding effectiveness of new self-etch adhesives to bur-cut enamel and dentin. *Oper Dent* 1:39–49
- Delfino CS, Duarte S Jr (2007) Effect of the composite surface sealant application moment on marginal sealing of compactable composite resin restoration. *J Mater Sci Mater Med* 12:2257–2261
- El-Araby AM, Talic YF, El-Araby AM (2007) The effect of thermocycling on the adhesion of self-etching adhesives on dental enamel and dentin. *J Contemp Dent Pract* 2:17–24
- Ernst CP (2004) Positioning self etching adhesives: “versus” or “in addition to” phosphoric acid etching? *J Esthet Restor Dent* 16:57–69
- Ernst CP (2006) Options for dentin bonding. *J Esthet Restor Dent* 2:61–67
- Ernst C-P, Brandenbusch M, Meyer G, Canbek K, Gottschalk F, Willershausen B (2006) Two-year clinical performance of a nanofiller vs a fine-particle hybrid resin composite. *Clin Oral Invest* 10:119–125
- Fagundes TC, Barata TJ, Bresciani E, Cefaly DF, Jorge MF, Navarro MF (2006) Clinical evaluation of two packable posterior composites: 2-year follow-up. *Clin Oral Invest* 10:197–203
- Frankenberger R, Perdigão J, Rosa BT, Lopes M (2001) “No-bottle” vs “multi-bottle” dentin adhesives—a microtensile bond strength and morphological study. *Dent Mater* 5:373–380
- Frankenberger R, Tay F (2005) Self-etch vs etch-and-rinse adhesives: effect of thermo-mechanical fatigue loading on marginal quality of bonded resin composite restoration. *Dent Mater* 21:397–412
- Feuerstein O, Matalon S, Slutsky H, Weiss EI (2007) Antibacterial properties of self-etching dental adhesive systems. *J Am Dent Assoc* 3:349–354
- Hannig M, Bott B (2000) Randschlussverhalten von plastischen zahnfarbenen Füllungen in dentinbegrenzten Klasse-II-Kavitäten. *Dtsch Zahnärztl Z* 55:134–138
- Hannig M, Grafe A, Atalay S, Bott B (2004) Microleakage and SEM evaluation of fissure sealants placed by use of self-etching priming agents. *J Dent* 1:75–81
- Hanning M, Reinhardt KH, Bott B (2001) Composite-to-dentin bond strength, micromorphology of the bonded dentin interface and marginal adaptation of class II composite resin restorations using self-etching primers. *Oper Dent* 26:157–165
- Hasegawa T, Itoh K, Koike T, Yukitani W, Hisamitsu H, Wakumoto S, Fujishima A (1999) Effect of mechanical properties of resin composites on the efficacy of the dentin bonding system. *Oper Dent* 24:323–330
- Hayashi M, Wilson NH (2003) Failure risk of posterior composites with post-operative sensitivity. *Oper Dent* 6:681–688
- Hickel R, Roulet JF, Bayne S, Heintze S, Mjör I, Peters M, Rousson V, Randall R, Schmalz G, Tyas M, Vanherle G (2007) Recommendations for conducting controlled clinical studies of dental restorative materials. Science Committee Project 2/98–FDI World Dental Federation Study Design (Part 1) and Criteria for Evaluation (Part 2) of direct and indirect restorations including onlays and partial crowns. *Clin Oral Invest* 11:5–33
- Kaaden C, Powers JM, Friedl KH, Schmalz G (2002) Bond strength of self-etching adhesives to dental hard tissues. *Clin Oral Invest* 3:155–160
- Kanehira M, Finger WJ, Hoffmann M, Endo T, Komatsu M (2006) Relationship between degree of polymerization and enamel bonding strength with self-etching adhesives. *J Adhes Dent* 4:211–216
- Kersten S, Lutz F, Besek M (1999) Zahnfarbene adhäsive Füllungen im Seitenzahnbereich. Zürich Eigenverlag PPK
- Miyazaki M, Onose H, Moore K (2000) Effect of operator variability on dentin bond strength of two-step bonding systems. *Am J Dent* 13:101–104
- Pelka M, Dettenhofer G, Reinelt C, Krämer N, Petschelt A (1994) Validität und Reliabilität klinischer Kriterien für adhäsive Inlay-systeme. *Dtsch Zahnärztl Z* 49:921–925
- Ryge G, Snyder M (1973) Evaluation of the clinical quality of restorations. *J Am Dent Assoc* 87:369–377
- Ryge G (1980) Clinical criteria. *Int Dent J* 30:347–358
- Schirmeister JF, Huber K, Hellwig E, Hahn P (2006) Two-year evaluation of a new nano-ceramic restorative material. *Clin Oral Invest* 10:18–186
- Stansbury JW (2000) Curing dental resins and composites by photopolymerization. *J Esthet Dent* 12:300–308
- Strydom C (2005) Self-etching adhesives: review of adhesion to tooth structure part II. *SADJ* 60(8):10–13
- Swift EJ, Perdigão J, Wilder AD, Heymann HO, Sturdevant JR, Bayne SC (2001) Clinical evaluation of two one-bottle dentin adhesives at three years. *J Am Dent Assoc* 8:1117–1123
- Takahashi A, Sato Y, Uno S, Pereira PN, Sano H (2002) Effects of mechanical properties of adhesive resins on bond strength to dentin. *Dent Mater* 18:263–268
- Thomsen KB, Peutzfeldt A (2007) Resin composites: strength of the bond to dentin versus mechanical properties. *Clin Oral Invest* 1:45–49
- Van Landuyt KL, De Munck J, Snauwaert J, Coutinho E, Poitevin A, Yoshida Y, Inoue S, Peumans M, Suzuki K, Lambrechts P, Van Meerbeek B (2005) Monomer-solvent phase separation in one-step self-etch adhesives. *J Dent Res* 84:183–188
- Van Meerbeek B, Perdigão J, Lambrechts P, Vanherle G (1998) The clinical performance of adhesives. *J Dent* 26:1–20
- Van Meerbeek B, de Munck J, Yoshida Y, Inoue M, Vargas P, Vijay P, van Landuyt K, Lambrechts P, Vanherle G (2004) Adhäsion an Schmelz und Dentin. Aktueller Stand und zukünftige Aufgaben, Teil 2. *Ästhetische Zahnmedizin* 7:95
- Van Meerbeek B, Kanumilli P, De Munck J, Van Landuyt K, Lambrechts P, Peumans M (2005) A randomized controlled study evaluating the effectiveness of a two-step self-etch adhesive with and without selective phosphoric-acid etching of enamel. *Dent Mater* 4:375–83
- Van Meerbeek B, Van Landuyt K, De Munck J, Hashimoto M, Peumans M, Lambrechts P, Yoshida Y, Inoue S, Suzuki K (2005) Technique-sensitivity of contemporary adhesives. *Dent Mater J* 24:1–13
- Yoshiyama M, Matsuo T, Ebisu S, Pashley D (1998) Regional bond strengths of self-etching/self-priming adhesive systems. *J Dent* 26:609–616

Copyright of Clinical Oral Investigations is the property of Springer Science & Business Media B.V. and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.