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OCT for early quality evaluation of tooth–composite bond in clinical trials

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ABSTRACT

Objectives: To evaluate early quality of composite restorations with a universal adhesive in different application modes clinically and with optical coherence tomography (OCT).

Methods: 22 patients with four non-carious cervical lesions each received composite restorations (Filtek Supreme™ XTE, 3 M). The universal adhesive Scotchbond Universal™(SBU, 3 M) was applied with three etching protocols: self-etch (SE), selective-enamel-etch (SEE) and etch-and-rinse (ER). The etch-and-rinse adhesive OptiBond™ FL (OFL, Kerr) served as a control. Restorations were imaged by OCT (Thorlabs) directly after application (t_0). After 14 days (t_1) and 6 month (t_2) OCT imaging (interfacial adhesive defects) was repeated combined with clinical assessment (FDI criteria). Groups were compared by Friedman-/Wilcoxon- and McNemar-Test.

Results: No differences were seen clinically between groups ($p_i \geq 0.500$). OCT assessment revealed more adhesive defects at the enamel interface with SBU/SE at t_0.t_2 compared to all groups ($p_i \leq 0.016$). OFL showed more defects than SBU/ER (t_1: $p = 0.01$; t_2: $p = 0.083$). At dentin/cementum interface OFL exhibited more adhesive defects than SBU with all conditioning modes (t_0, t_1, $p_i \leq 0.003$) and at t_2 to SBU/SE and SBU/ER ($p < 0.001$). Since t_1 defects with SBU were detected more frequently in the SE and SEE modes compared to ER ($p_i \leq 0.037$). In contrast to SBU defects increased with OFL up to t_2 ($p_i \leq 0.007$).

Conclusions: In contrast to clinical evaluation, OCT revealed subtle adhesive defects directly after application that might interfere with clinical success. It was demonstrated that ER does not decrease initial adhesion of SBU to dentin.

1. Introduction

Clinical success of adhesive restorations is considered to be influenced by a variety of factors including material, clinical and operator variables as well as socioeconomic, demographic and further individual patient parameters [1,2]. All these factors have a combined impact on the microstructural level of the interface between composite and adhesive system on the one hand and the tooth substrate on the other [3]. Breakdown of the tight adhesive bond poses a challenge for the clinical longevity of adhesive restorationsn [4].

The difficulties in establishing and pertaining a durable bond need to be well-understood to identify strategies to overcome degradation of the adhesive bond. Whereas bonding to enamel is generally regarded as reliable [5], dentin-bonded interfaces are more prone to integrity loss due to collagenolytic activity and hydrolysis of the resin-impregnated hybrid interface [6]. This is one of the reasons for a continuous drive to further developments in adhesive dentistry.

However, these potential innovations have to be assessed regarding its clinical outcome. Since clinical studies are expensive and relevant information is mostly available only after longer observation periods there is a need for performance information available at earlier stages of product development. Therefore, one frequently relies on results from laboratory tests or fatigue testing of the tooth-composite bond in vitro, which always raises the question how good these results can predict clinical outcome [7]. Furthermore, the commonly used clinical evaluation criteria are less sensitive to distinct changes of the adhesive bond [8,9] making it necessary in principle to evaluate for many years to see the clinical consequences of adhesive defects that have been developed already some time ago.

Against this background, it would be worth considering whether clinical studies as the ultimate success indicator could be supported by more sensitive outcome parameters allowing an earlier outlook on the

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clinical success of material developments in adhesive technology. Moreover, it would be desirable that a more reliable link between early experimental and clinical results could be established [10], as well as more early in vivo evaluations compared to elaborate clinical studies. In authors' opinion, optical coherence tomography (OCT) could create this connection. This is a non-invasive imaging method with high spatial resolution that is routinely used in ophthalmology for retina assessment and is now attracting more attention in dental research [11–13]. Quick 3D-image stack acquisition allowing near real-time imaging up to a penetration depth of 2–2.5 mm into tooth surface [14–17].

The primary aim of this randomized clinical trial (RCT) was to evaluate early OCT findings of interfacial bond failure at the cavity-restoration interface of adhesive restorations compared to clinical performance. This should be studied with the first and meanwhile well-established universal adhesive Scotchbond™Universal under the influence of different application modes compared to an etch-and-rinse reference adhesive. We tested the hypotheses that (1) in contrast to clinical evaluation OCT would early reveal differences in interfacial adhesive defects and (2) that OCT could demonstrate differences compared to control and between application modes of a universal adhesive.

2. Materials and methods

2.1. Study design

In this randomized controlled trial adult participants were recruited at the Department of Cariology, Endodontology and Periodontology of University of Leipzig. The prospective study was approved by the Ethics Committee of the University of Leipzig with reference number 196-14 140420114. The trial was registered at German Clinical Trials Register # DRKS00011084 (http://www.drks.de/DRKS00011084). All participants were informed about the study and signed the consent declaration. Restorative treatments were carried out from July 2014 to December 2014. Four dental fillings were placed per participant following a four–arm parallel design with the non-carious cervical lesions (NCCL) as unit of randomization. The decision to restore as well as the check of the inclusion and exclusion criteria were made by calibrated dentists of the department not involved in this trial.

2.2. Study population

Based on a pilot study a calculation of the sample size was carried out (G*Power 3.1.9.2), which resulted in a number of necessary pairs of 18–20 for enamel and 18–19 for dentin (power: 80%, $\alpha = 0.05$). On this basis, 22 patients with four non-carious cervical lesions (NCCLs) each in incisors, canines and premolars were selected. Qualification for inclusion needed participants to be a least 18 years old without any removable dentures and with trial teeth being vital and possessing natural antagonists. Subjects were excluded if they had less than 20 teeth, contamination control during restoration was impossible and a lesion communicated with pre-existing restorations. Moreover, periodontal probing depth above 4 mm at the trial teeth, alcohol and drug-dependence, pregnancy, bruxism, habits and known allergies to materials used led to exclusion.

The lesions to be restored in each study participant were equally allocated to the intervention groups using a computer-generated list of random numbers created by a member of the dental clinic not involved in this project. Whereas the operator applying the restorations was aware of the allocation to the adhesive materials, all test subjects, the clinical and OCT examiner were kept blinded to the allocation.

2.3. Restorative procedure

Universal adhesive Scotchbond™Universal (3 M Deutschland GmbH, Seefeld, Germany) in combination with the composite Filtek Supreme™XTE (3 M Deutschland GmbH, Seefeld, Germany) was used. The adhesive was applied in the three different conditioning modes self-etch, selective-enamel-etch and etch-and-rinse (Table 1). The adhesive system Optibond™FL (Kerr GmbH, Rastatt, Germany) together with Filtek Supreme™XTE served as reference standard.

Table 1
Study groups.

group	SBU/SE	SBU/SEE	SBU/ER	OFL
adhesive	Scotchbond Universal (SBU)			OptiBond FL (OFL)
application mode	self-etch (SE)	selective-enamel-etch (SEE)	etch-and-rinse (ER)	etch-and-rinse (ER)
composite	Filtek Supreme XTE			

Table 2
Selection of teeth and lesions.

	Number of restorations (n)			
Group	SBU/SE	SBU/SEE	SBU/ER	OFL
Location				
- *maxilla*	10	11	14	10
- *mandibula*	12	11	8	12
Lesion extension (enamel/dentin/mixed)	-/2/20	-/4/18	-/2/20	-/4/18
Lesion depth				
- *shallow (< 1 mm deep)*	–	1	–	2
- *medium (1-2 mm deep)*	22	21	21	19
- *deep (> 2 mm deep)*	–	–	1	1
Pre-operative hypersensitivity (yes/no)	19/3	20/2	20/2	21/1
Primary treatment (yes/no)	21/1	20/2	22/0	22/0

The sizes of the 88 lesions were assessed prior to restoration placement and varied from shallow (depth ≤ 1 mm) and medium (depth ≤ 2 mm) to deep (depth > 2 mm) equivalent to scores 2 to 4 on Smith and Knight's tooth wear index [18]. The characteristics of the teeth and lesions are shown in Table 2. The same calibrated operator (P. S.) restored all teeth after the calibration process included placement of 12 NCCL restorations in vitro and OCT evaluation of marginal application quality under supervision of the primary investigator.

The restorations were placed according to the following protocol using a dental loupe (2.5x): All lesions and surrounding tooth surfaces were cleaned with an oil-and fluoride-free cleaning paste prior to shade selection. After placing a retraction cord the cervical cavity margins, the hypermineralized dentin and the enamel margins were carefully prepared using a 15 µm diamond bur (Intensiv SA, Grancia, Switzerland). Safeguarding contamination control, the adhesives and the filling material were applied according to the manufacturing instructions. The restorations were finished immediately with fine diamond burs (15 µm) and polished with rubber points (Shofu Dental GmbH, Ratingen, Germany).

2.4. Study outcomes

2.4.1. Clinical

At all appointments (t_0- t_2) study teeth were photographed. After 14 days (t_1) and 6 months (t_2) the principal investigator (M. H.) assessed the restorations clinically according to the FDI criteria [8,9]. The aesthetic, functional and biological criteria were evaluated visually with a dental loupe (2.5x), by explorer, by CO_2-snow, by use of a visual analogue scale and by a periodontal probe. If restorations were rated clinically unacceptable in one of the criteria, they had to be excluded from further assessment, and were repaired or replaced.

2.4.2. OCT imaging

All restorations were 3-dimensionally imaged by the principal