Clinical performance of resin composite restorations: the value of accelerated in-vitro testing
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CHAPTER 3

Long-term degradation of enamel and dentin bonds:
6-year results *in vitro* vs. *in vivo*.
**Introduction**

Tooth-colored materials such as resin-based composites are today the treatment option of choice for the majority of patients, primarily due to esthetic demands. It is well-proven that adhesive restorations are successful e.g. pit and fissure sealings, direct and indirect resin composites, and bonded indirect ceramic restorations. Durable adhesion to enamel and dentin still represents the fundamental prerequisite due to polymerization shrinkage of resin-based composites. Bonding to phosphoric acid etched enamel is widely accepted as clinically viable, however, in dentin it is not completely clear whether the etch-and-rinse or the self-etch approach may be more successful in getting durable bonds. Irrespectively, technique sensitivity with bonded restorations remains problematic facing a 1:12 failure rate ratio in clinical trials with identical materials but different clinical operators.

The primary goal of preclinical screening of dental materials should be to mimic the clinical situation in order to predict clinical behavior. Therefore, researchers try to predict clinical behavior of restoratives with laboratory *in vitro* investigations. Of course, randomized clinical trials remain the ultimate instrument for evaluating dental restoratives, however, a major problem with clinical trials is that when they give valuable results after several years of clinical service, the material under investigation may no longer be available in the market. Thus, preclinical *in vitro* investigations are more important than ever, however, it is still not fully understood whether these tests are able to reliably predict clinical behavior. So the aim of this investigation was to compare preclinical results of a large marginal quality *in vitro* database with clinically recorded marginal qualities of the same materials.

**Materials and Methods**

In vitro study: Thirty-two intact, non-carious, unrestored human third molars, extracted for therapeutic reasons with patients’ approval, were stored in an aqueous solution of 0.5% chloramine T at 4°C for up to 30 days. The teeth were debrided of residual plaque and calculus, and examined to ensure that they were free of defects under a light microscope at x20 magnification. Standardized class II cavity preparation (MO, 4mm in width bucco-lingually, 2mm in depth at the bottom of the proximal box) with proximal margins located 1-2 mm below the cementoenamel
junction were performed. The cavities were cut using coarse diamond burs under profuse water cooling (80 µm diamond, Komet, Lemgo, Germany), and finished with a 25 µm finishing diamond (one pair of diamonds per four cavities). Inner angles of the cavities were rounded and the margins were not bevelled to deliver comparable results to previous experiments.11,15

The prepared cavities (n=8) were treated with two different adhesives according to the manufacturers’ instructions (n=16 with Syntac, Ivoclar Vivadent, Schaan, Principality of Liechtenstein, and n=16 with Solobond M, Voco, Cuxhaven, Germany; Table 3.1). The dentin adhesives and resin composite were polymerized with a Translux CL light-curing unit (Elipar Trilight, 3M Espe, Seefeld, Germany). The intensity of the light was checked periodically with a radiometer (Demetron Research Corp, Danbury, CT, USA) to ensure that 600 mW/cm² was always delivered during the experiments. The adhesive was polymerized for 40 s prior to application of the resin composite in all cases. The resin composites Tetric Ceram (Ivoclar Vivadent; shade A2) and Grandio (Voco; shade A2) were used for all experimental restorations. Each cavity preparation was bonded with the respective adhesive and restored incrementally with the resin composite in layers up to 2 mm thickness. The increments were separately light-cured for 40 s each with the light source in contact with the edge of the cavity. Prior to the finishing process, visible overhangs were removed using a posterior scaler (A8 S204S, Hu-Friedy, Leimen, Germany). Margins were finished with flexible disks (SofLex Pop-on, 3M ESPE, St. Paul, USA).

After storage in distilled water at 37°C for 21 days, impressions (Provil Novo, Heraeus Kulzer, Hanau, Germany) of the teeth were taken and a first set of epoxy resin replicas (Alpha Die, Schuetz Dental, Rosbach, Germany) was made for SEM evaluation. One pair of groups was subjected to storage in distilled water at 37°C for 2190 days.14 After storage, impressions were taken and thermo-mechanical loading of specimens was performed in an artificial oral environment (“Quasimodo” chewing simulator, University of Erlangen, Germany).
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In vitro specimens (n=32)

<table>
<thead>
<tr>
<th>Syntac/Tetric Ceram (n=16)</th>
<th>Solobond M/Grandio (n=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>replicas after 21 days water storage (baseline / n=16)</td>
<td>replicas after 21 days water storage (baseline / n=16)</td>
</tr>
<tr>
<td>TML 100,000 x 50 N</td>
<td>TML 100,000 x 50 N</td>
</tr>
<tr>
<td>2,500 x 5°C/55°C</td>
<td>2,500 x 5°C/55°C</td>
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<tr>
<td>replicas (n=8)</td>
<td>replicas (n=8)</td>
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<td>replicas (n=8)</td>
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</tbody>
</table>

Table 3.1: Experimental setup in laboratory groups (TML: thermomechanical loading / WS: water storage).

Two specimens were arranged in one simulator chamber in proximal contact, similar to the oral situation with the two restored marginal ridges in a normal intercuspation. The two adjacent lateral ridges were occluded against a steatite (a multi-component semi-porous crystalline ceramic material) antagonist (6 mm in diameter) for 100,000 cycles at 50 N at a frequency of 0.5 Hz. The specimens were subjected to 2,500 thermal cycles between +5°C and +55°C by restoration the chambers with water in each temperature for 30 s. The mechanical action and the water temperature within the chewing chambers were checked periodically to ensure a reliable thermo-mechanical loading (TML) effect. After completion of TML, a second set of replicas was manufactured for later SEM analysis. The other pair of groups was subjected to TML only.

In vivo study: In the course of a randomized clinical study with approval of a local ethics committee, 30 subjects (23 female, 7 male, mean age 32.9 (24-59) years) with a minimum of two restorations to be replaced in different quadrants received at least two different Class II restorations (52 MO/OD, 16 MOD or more surfaces, no cusp replacements) in a random decision. Thirty six Grandio restorations were bonded with Solobond M (Voco) and 32 Tetric Ceram restorations were bonded with Syntac
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(Ivoclar Vivadent). The cavities were cut using coarse diamond burs under profuse water cooling (80 µm diamond, Komet, Lemgo, Germany), and finished with a 25 µm finishing diamond. Inner angles of the cavities were rounded and the margins were not bevelled. After cleaning and drying under rubber dam isolation (Coltene/Whaledent Inc., Altstätten, Switzerland), adhesive procedures were performed with Solobond M (2-step etch-and-rinse adhesive) and Syntac (4-step etch-and-rinse adhesive). The resin composite materials were applied into the cavity in layers of approximately 2 mm thickness and adapted to the cavity walls with a plunger. Each layer was light cured for 40 s (Elipar Trilight, 3M Espe, Seefeld, Germany). The occlusal region was modeled as exactly as possible under intraoral conditions, avoiding visible overhangs. The light-emission window was placed as close as possible to the cavity margins. The intensity of the light was checked periodically with a radiometer (Demetron Research Corp., Danburg, CT, USA) and was found to be consistently above 650 mW/cm².

As soon as polymerization was completed, the surface of the restoration was checked for defects and corrected when necessary. Visible overhangs were removed with a scaler and the rubber dam was removed. Contacts in centric and eccentric occlusion were checked with foils (Roeko, Langenau, Germany) and adjusted with finishing diamonds (Komet Dental, Lemgo, Germany), shaped with flexible discs (3M Dental, St. Paul, USA), super-fine discs (3M Dental, St. Paul, USA) and polishing brushes (Hawe-Neos Dental, Bioggio, Switzerland). A fluoride varnish (Elmex Fluid, GABA, Lörrach, Germany) was used to complete the treatment. Impressions were used to make epoxy replicas (Alpha Die, Schütz Dental, Germany); 22 of them (n=11 per group) were subjected to scanning electron microscopic (SEM) analysis (Table 3.2). The replicas with the longest evaluable margins were selected randomly.

<table>
<thead>
<tr>
<th>In vivo specimens (n=22)</th>
<th>Solobond M/Grandio (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syntac/Tetric Ceram (n=11)</td>
<td>replicas at initial recall (baseline / n=11)</td>
</tr>
<tr>
<td>replicas (n=11)</td>
<td>replicas at initial recall (baseline / n=11)</td>
</tr>
<tr>
<td>6 years of clinical function</td>
<td>replicas (n=11)</td>
</tr>
</tbody>
</table>

Table 3.2: Procedure for in vivo groups.
All in vitro and in vivo replicas were mounted on aluminum stubs, sputter-coated with gold and examined under a SEM (Leitz ISI 50, Akashi, Tokyo, Japan) at x200 magnification. SEM examination was performed by one operator having experience with quantitative margin analysis who was blinded to the restorative procedures. The marginal integrity between resin composite and enamel was expressed as a percentage of the entire judgeable margin length. Marginal qualities were classified according to the criteria “continuous/gap-free margin” and “gap/irregularity”, non-judgeable parts and artifacts were excluded. Afterwards the percentage “gap-free margins” in relation to the individual judgeable margins was calculated as marginal integrity. For in vivo specimens, all non-judgeable parts such as overhangs were excluded with the remaining criteria having been either “continuous margin” or “gap/irregularity” (crevice, negative step formation, or marginal fracture in enamel or resin composite). For better comparison with in vitro results, gap-free margins were added whether there was a crevice or not. Marginal quality in dentin was not recordable with the impression/replica technique. However, clinical criteria such as secondary caries were evaluated.

Statistical analysis was performed using SPSS 14.0 (SPSS Inc., Chicago, IL, USA). As the majority of groups in each of the two investigations did not exhibit normal data distribution (Kolmogorov-Smirnov test), non-parametric tests were used (Wilcoxon matched-pairs signed-ranks test, Mann-Whitney-U test) for pairwise comparisons at the 95% significance level.

Results
An overview of the results is shown in Table 3.3. In both the in vitro and in vivo scenario, marginal quality of resin composite restorations was significantly deteriorated over time (p<0.05; Wilcoxon test).

In the laboratory processed specimens, all restorations initially revealed nearly 100% gap-free margins (p>0.05; Mann-Whitney U-test). After TML alone, continuous margins dropped to 87-90% in enamel and 55-66% in dentin (p<0.05; Wilcoxon test; in dentin with a significantly higher portion of gap-free margins for Syntac/Tetric Ceram; p<0.05; Mann-Whitney U-test). After water storage for 6 years alone, gap-free margins dropped to 97-99% in enamel and 67-75% in dentin (p<0.05; Wilcoxon test; in dentin with a significantly higher portion of gap-free margins for Syntac/Tetric Ceram; p<0.05; Mann-Whitney U-test). After water storage and TML,
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marginal quality in enamel ranged from 85-87%, and in dentin 42-52% (p<0.05; Wilcoxon test; in dentin with a significantly higher portion of gap-free margins for Syntac/Tetric Ceram; p<0.05; Mann-Whitney U-test). Thermomechanical loading had a more detrimental effect on marginal quality than 6 years water storage alone (p<0.05).

<table>
<thead>
<tr>
<th>Materials</th>
<th>Substrate</th>
<th>Initial</th>
<th>TML</th>
<th>WS</th>
<th>WS + TML</th>
<th>Initial</th>
<th>6 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syntac +</td>
<td>Enamel</td>
<td>100</td>
<td>90(3)</td>
<td>99(2)</td>
<td>87(8)</td>
<td>90(9)</td>
<td>80(18)</td>
</tr>
<tr>
<td>Tetric Ceram</td>
<td>Dentine</td>
<td>100</td>
<td>66(11)</td>
<td>75(10)</td>
<td>52(16)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
<tr>
<td>Solobond M +</td>
<td>Enamel</td>
<td>100</td>
<td>87(4)</td>
<td>97(2)</td>
<td>85(9)</td>
<td>86(10)</td>
<td>74(19)</td>
</tr>
<tr>
<td>Grandio</td>
<td>Dentine</td>
<td>98(2)</td>
<td>55(14)</td>
<td>67(11)</td>
<td>42(14)</td>
<td>n.a.</td>
<td>n.a.</td>
</tr>
</tbody>
</table>

Table 3.3 Overview of results with percentages of gap-free margins in % (SD). TML: Thermomechanical loading; WS: Water storage for 2190 days.

For the in vivo replicas, only marginal quality in enamel was recordable by the impression/replica technique. In enamel, continuous margins were initially at 86-90% and after 6 years of clinical service at 74-80%, however, whether initially (1-3%) nor after 6 years (4-5%) severe gap formation was found. Non-continuous margins were attributed to clinical wear and consecutive negative step/crevice formation/marginal fractures having been slightly more pronounced for Grandio (p<0.05; Mann-Whitney U-test). For proximal margins being located in dentin, clinical observations neither revealed severe staining nor secondary caries formation over 6 years, so the absence of enamel at the bottom of the proximal box did not affect results.
Discussion
The idea to compare in vitro and in vivo outcome of resin-based composite restorations is not new. As first approach in the history of the field, Abdalla and Davidson published their “comparison of the marginal integrity of in vitro and in vivo Class II composite restorations” in 1993, dealing with microleakage scores in both laboratory and ex vivo specimens. In this paper, microleakage was substantially more severe in the in vivo group, so the unanimous conclusion was that it may not be possible to reliably predict clinical behavior of bonded restorations in the lab. In this context, Peumans et al. reported the clinical outcome of different adhesives in non-carious cervical lesions, because Class V setups do not provide macromechanical retention but considerable amounts of dentin margins. However, Class V trials completely fail to prove whether bonded resin-based composites may compete with amalgam in posterior cavities under occlusal load. Although in Class II setups macro-retention is normal, at least in replacement cavities and considerably less dentin margins are routinely found, there are also advantages. Recording of postoperative hypersensitivities is a valid instrument to estimate dentin seal, and secondary caries is a well-suited indicator of loss of bonding performance, especially in proximal areas of the restorations.

Former publications of our workgroup already dealt with resin composites and their corresponding adhesives in both aspects, in vitro and in vivo. The first one aimed to elucidate in vitro performance of resin composites focusing on microtensile bond strengths to enamel and dentin, flexural fatigue behavior, and wear behavior. Ariston pHc and Solitaire showed some differences compared to other contemporary resin composites, Ariston provided significantly less adhesion to enamel and dentin, Solitaire provided inferior flexural fatigue behavior. The corresponding part showed clinical findings of the previously described resin composites being completely unacceptable. So in both cases, clinical performance of resin composites in Class II cavities was predictable from laboratory results.

However, the literature in the field of adhesive dentistry still requires some evidence given from in vitro – in vivo comparisons. Based on the previously described prospective clinical trial, also in vitro experiments with the identical materials were performed. As artificial aging protocol six years water storage was chosen with and without thermomechanical loading. TML setups are frequently used to mimic the clinical situation, however, it is unclear how many cycles mean how much lifetime in
the mouth of the patient. Therefore, setups and cycle numbers are subjected to a wide variation from 4,000 to 1.2 million cycles combined with separate or simultaneous thermocycling. Derived from Swiss data from the 1980’s, it was widely accepted that in vitro fatiguing of resin-tooth interfaces for 1.2 million cycles may be somewhat equivalent to 5 years of clinical service.\textsuperscript{3,7,20,21} Even for fatigue simulations on core build-up restorations as postendodontic restorations, this benchmark was used from time to time.\textsuperscript{25,26} However, the basis of this approach was just counting chewing cycles and not a true in vitro – in vivo comparisons of dental restoratives under simulated and clinical load.

A previous study of our workgroup demonstrated that 100,000 load cycles combined with 2,500 thermocycles was able to simulate clinical behavior of a 2-year period for Class I cavities restored with bonded resin composites.\textsuperscript{11} A distinct advantage for etch-and-rinse adhesives compared to self-etch adhesives was also shown.\textsuperscript{11}

Also the results of the present \textit{in vitro} – \textit{in vivo} comparison revealed a certain relationship between preclinical and clinical observations. Percentage of gap-free margins was chosen as a main criterion, because this way it was possible also to include clinical crevices without detectable gap formations. The present results indicate that TML alone led to a higher loss of marginal integrity than 6 years’ water storage (Table 3.3). On the other hand, a combined WS/TML scenario exhibited the most pronounced effect on marginal quality over time. Nevertheless, in vitro and in vivo results show a certain similarity. However, this is also attributed to the fact that gap-free irregularities were also included in “gap-free” margins. Otherwise, completely perfect margins in vivo (i.e. without any crevice or negative step formation were \textasciitilde 55\% initially and 20-30\% after 6 years of clinical service.

Thus, marginal quality prediction is possible from laboratory findings, however, marginal integrity is only one among several crucial factors responsible for clinical success or clinical failure over time, meaning that more interfacial gaps after thermal and mechanical stressing in vitro raise the probability of the same scenario to occur under clinical circumstances in the oral cavity. However, some important publications about secondary caries clearly demonstrated that the presence of marginal gaps \textit{in vivo} do not necessarily have to be accompanied with secondary caries.\textsuperscript{16,17}
Altogether, a particular problem with adhesive restorations remains in general: A given combination of adhesive and resin composite may obtain high percentages of gap-free margins in vitro, so it may consequently have also a promising clinical behavior related to marginal quality. The residual question is: What percentage of marginal quality may be promising or below what borderline is there no guarantee for clinical success? In the present case, in both groups (Syntac/Tetric Ceram vs. Solobond M/Grandio) the in vitro results were promising, so also clinical outcome was sufficient. For inferior materials, not enough data are collected and furthermore ethically doubtful.

Facing the ultimate question, it has to be taken into account that several studies dealing with evaluated marginal quality of restorations in vitro were designed in order to elucidate primarily experimental questions where clinical trials would never pass an ethics committee. In these cases only in vitro studies are possible, showing appropriate ways for clinical application of dental materials. Facing different laboratory approaches to predict clinical behavior such as bond strength testing or microleakage assessment, thermomechanical loading with a SEM marginal analysis still is the setup being closest to the clinical situation, however, it is still the most extensive and time-consuming way of evaluating restorative materials.
References


32. Tay FR, Frankenberger R, Carvalho RM, Pashley DH. Pit and fissure sealing.
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