Clinical performance of resin composite restorations: the value of accelerated in-vitro testing
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Link to publication

Citation for published version (APA):

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CHAPTER 1

Introduction
Tooth-colored materials such as resin-based composites are today the treatment option of choice for the majority of patients. This is mainly attributed to esthetic reasons and not primarily related to lifetime-expectancy of individual restorative approaches. Amalgam was a successful dental restorative material for over 200 years. However, on one hand it was repeatedly alleged to be toxic, and on the other hand it is dark or at best argentic and therefore simply not invisible nor tooth-colored. Today we also know that amalgam, among all toxicologic issues, also has clinical disadvantages: missing adhesive stabilization of remaining tooth hard tissues, cracked teeth after long service times, and mandatory cement linings are not desirable in today's restorative therapy of carious lesions. Resin composites are invisible, adhesively stabilizing to both enamel and dentin, and appropriately sealing. Nevertheless, is the distinct change towards resin composites really better in terms of overall clinical performance? What are resin composite restorations able to perform, especially compared to amalgam in larger stress-bearing posterior cavities? Today it is well-proven that adhesive restorations are successful, having been repeatedly reported for pit and fissure sealings, direct and indirect resin composites, and bonded indirect ceramic restorations. In the focus of the present thesis only directly applied resin composite restorations were investigated, especially as posterior restorations for amalgam replacement.

It is well-known from several studies in the field of adhesive dentistry that durable adhesion to enamel and dentin is a fundamental prerequisite for successful adhesive dentistry because polymerization shrinkage of resin-based composites is still a major issue. Bonding to phosphoric acid etched enamel is generally accepted as clinically successful. The same is true for dentin, however, it is not completely understood whether the etch-and-rinse or the self-etch approach may represent the ultimate way of durable bonding to dentin. And technique sensitivity with bonded restorations still is problematic facing a 1:12 failure rate ratio in a clinical trial with identical materials but different clinical operators. In the literature, many short term evaluations are published, but medium to long-term investigations are still needed. Therefore, bonding degradation over time is an important aspect. In dentin, the last decade revealed an array of innovative findings with regards to bond
degradation, especially in dentin. Both water treeing and enzymatic degradation investigations clearly showed that there is a long way to go for durable dentin bonding also in the nanoscale aspect. Results up to three years are presented here, giving some more aspects of longevity in vitro (Chapter 2).

Moreover, adhesion to enamel is even more important because the main retention is provided by appropriate bonding to enamel margins, and the absence of marginal staining is primarily provided by a tight enamel seal. When cavities get larger and larger, dentin support of the biomechanical tooth-restoration complex gets lost and restoration margins in enamel receive even more stress besides residual shrinkage stress and intraoral chewing forces. Therefore, long-term evaluations over six years also were carried out (Chapter 3). In this chapter, in vitro results were not thought to stand alone. When the setups for a clinical study were designed, it was an aim of the author to simultaneously start both in vivo and in vitro studies; i.e. in vitro evaluations regarding marginal quality were started with the same materials at the same time like the prospective randomized clinical trial dealing with posterior resin composite restorations. So after several years of clinical service, one should be able to directly compare in vitro results with in vivo outcomes.

Resin-dentin and resin-enamel bonding behavior is important for clinical success, but resin composite research is not adhesion alone. Adhesion is certainly an important issue as described above, but restorative material properties such as wear, flexural strength, and flexural fatigue behavior are important as well. In former times (being represented by older studies in the literature of the field), the predominant failure mechanism of resin composite restorations was gap formation and subsequent recurrent caries. Residual stresses led to gap formation over time, supported by different coefficients of thermal expansion. Gaps are colonized by biofilms consequently resulting in secondary caries. This scenario was believed to be the major failure reason for decades and is still in the back of dentists’ minds all over the world. However, facing more recent prospective clinical trials dealing with modern resin composite materials for posterior use, it becomes evident that more material-dependent issues like bulk fractures and chipping have displaced secondary caries as the No. 1 failure scenario with this class of materials. This may be due to the better understanding of long-term bonding to both enamel and dentin,
but it may also be attributed to enhanced materials properties in terms of shrinkage and shrinkage stress.\textsuperscript{2,5;23;25;32}

Randomized prospective clinical trials are still the ultimate instrument for evaluating dental restoratives such as resin composites, ceramics, cements, and prosthodontic restorations.\textsuperscript{4;15;16;46-49} However, the predominant problem with these clinical trials is that once valuable results are available after several years of clinical service, the material under investigation may not be in the market anymore. This is a frustrating situation which often occurred with many research groups. Another problem is when publishable results are obtained, the peer review periods and publication backlog of top dental journals add considerable time and actual publication is postponed significantly. Legislation in the field of medical products also contributes negatively here; it becomes harder and harder to get ethical permission to carry out clinical trials, costs for clinical centers have to be readjusted, and finally the manufacturer may not have enough budget for the study anymore. Due to this considerable number of reasons, preclinical \textit{in vitro} investigations are more important than ever, but it is still not fully understood whether these tests are able to reliably predict clinical behavior.

As already mentioned, the performance of bulky resin composites is of importance to counteract bulk fractures over time.\textsuperscript{17;32;40-42;50;51} Therefore, a thorough \textit{in vitro} vs. \textit{in vivo} comparison of flexural fatigue characteristics of resin composites must be addressed here (Chapter 4). In this case, the strategy was the same as in bonding investigations of Chapter 3. Again, we simultaneously started both in vitro and in vivo branches of the overall investigation plan. However, compared to the informative value of thermomechanical loading for marginal quality estimation, loading of resin composite beams is controversially discussed. On one hand, any fatigue loading design is superior to pure initial loading alone.\textsuperscript{17;32;40-42;50;51} Initially, high loading forces seldomly lead to clinical failures in real life.\textsuperscript{13;20;43} It is more the subcritical, repeated load that degrades dental restorations over several years of clinical service. Loading of beams - with fatigue or not - may not be very close to the clinical situation, because in the oral cavity no resin composite beam may be found to be loaded. Intraorally, resin composites are always bonded more or less successfully to dental hard tissues, i.e. bending forces such as those observed in a classical three- or four-point flexural strength evaluation may not occur similarly.\textsuperscript{13;20;43} Nevertheless, the practical advantage of the presented four-point flexural fatigue evaluation design
is of a very thoroughly standardized quality and moreover, a sound database of many restoratives exists for comparison. So we decided to include this particular way of stressing resin composite specimens in order to simulate bulk fatigue over time. And finally, again we were able to correlate the results to clinical outcome directly.

The ultimate instrument is still the randomized clinical trial. Therefore, a prospective clinical long-term trial was set up and reported (Chapter 5). As mentioned above, both materials under investigation are no longer on the market. On the other hand, a certain amount of valuable information results from the present long-term evaluation of Grandio and Tetric Ceram. The longitudinal approach allows for the correlation of initial cavity size with marginal degradation over time. It is possible to measure wear in both areas, occlusal contact area and contact-free area, and distinct differences among materials can be worked out. Chapter 5 is the heart and center of the present thesis, because it allows a clear view on what is happening with adhesively bonded resin composites in stress-bearing areas of posterior teeth. It is possible to distinguish between smaller, minimally invasive resin composite restorations, and larger restorations with considerable occlusal contacts in resin composite instead of being underpinned by more wear resistant enamel cusps. Last but not least, a prospective clinical long-term trial offers the possibility of getting hints about the ultimate question of how resin composite restorations behave over time and what failure scenarios are really in the center of interest. This is the clear advantage compared to cross-sectional studies offering important observation, but unfortunately in a clearly retrospective nature.

The final question remains and should be addressed with the last issue of the present thesis, i.e. what is this all about or in different words: Is clinical performance of bonded restoratives predictable in the lab (Chapter 6)? It was extensively discussed previously, and it has to be the final statement of the present thesis. The key idea forvaluably estimating this particular and ultimate question was to start with in vitro and in vivo research simultaneously. Only in this way was it possible to truly compare preclinical outcome and clinical observations. And only when evaluated parameters in both branches approximately match, the predictive quality of the chosen in vitro setup is appropriate. This is the simple truth regarding the major question of the present thesis, before smart materials avoiding classical material disadvantages are considered as alternative.
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