

Is in vitro research in restorative dentistry useless?

It started with a few doubts.

- In 1989, a paper was published in the Journal of Dentistry criticizing bond strength measurements (van Noort et al, 1989).
- A couple of years ago, a prominent member of a Dental Materials department told everyone at the IADR meeting that the microtensile test was very problematic, due to inhomogeneous load distribution in the sample. His conclusion: Microtensile testing is bad.
- A meta-analysis on the reliability of dye penetration tests came to the conclusion that the results cannot be compared due to the huge variability of different test parameters (Raskin et al, 2001).
- Clinical studies that placed fillings in teeth that were extracted after some months and subjected to dye penetration revealed no correlation of dye penetration to post-operative sensitivity or other clinical parameters (Opdam et al, 1998).
- I recall endless discussions with my group of researchers as to which tests should be performed to offer good prediction of clinical behavior of dental restorative materials.

In other words, the value of in vitro research on restorative dental materials is being questioned. This trend has increased dramatically within the last years. In 2010, the Academy of Dental Materials devoted their annual meeting to the question of how to best test for adhesion. Söderholm et al (2012) have just published a paper in which finite element analysis (FEA) showed that the main stress does not occur at the interface in a microtensile bond strength test. They thus concluded that the “bond strength” values determined with the microtensile test do not represent the true situation. In an editorial, Söderholm reinforced his view that microtensile bond strength tests should not be performed (Söderholm, 2012). Kelly et al (2012) have recently published an article critically questioning shear bond tests, wear testing, and load to failure testing, based on analyses of published data. Their conclusion is that the actual tests do not represent the clinical reality at all, and they even recommend that “editors of dental materials and prosthodontics journals should take a

similar ethical stand against the publication of studies using ‘crunch the crown’ protocols in particular and take a more critical look at the value of publishing bond strength research.” The trigger for this recommendation is not only the data presented in the paper, but the information that the Journal of Endodontics has stopped accepting papers using microleakage protocols.

This, of course, has prompted me to write an editorial myself. First, just a comment on the endodontic problem: Years ago we were well aware of the fact that dye tracers do not represent the truth when it comes to looking at the functionality of root canal sealers. Therefore, my co-workers at the time decided to examine whether a root canal filling is able to prevent bacterial penetration (Barthel et al, 2000). This makes sense, since bacteria are supposed to be the main reason for failure of root canal treatment. Therefore, a bacterial penetration test was designed and used. To our astonishment, it was just a matter of time until the bacteria had reached the chamber beyond the apex. Out of curiosity, my co-workers applied the test to a solid bar of dentin without a root canal at all, and ... surprise surprise, the bacteria found their way to the test chamber as well. This anecdote underlines that reality is much more complex than we want to believe.

Now back to adhesion, wear and strength tests. The common line in all papers that criticize this type of in vitro research is that there is no reproducibility within and among different methods, that the results are contradictory, the results do not represent the reality of the failure mechanism (eg, if looked at with FEA), and that there is no correlation to clinical behavior. It's easy to criticize. I can go on: Most of these in vitro tests are very difficult and complex, and the outcome is often “operator sensitive”. In the clinical correlations, usually only material classes are compared, but never the same material (product), similar wear procedures are used for all materials, and the authors usually do not consider batch to batch differences. Do the authors who conduct meta analyses or use data from the literature know whether the data used are reliable? In other words, were the machines used in these publications suitable and the processes validated according to GLP (good laboratory practice)? How sound were the clinical

outcome data used for correlations? Then I must ask: Have the new methods used to explain what is really going on been validated? How do you know that the FEA models used really represent reality? Are you sure you were able to model the very complex interface dentin/adhesive/composite accordingly and in sufficient resolution? Or provocatively asked: are the models used representative or just an assumption as well (of course much better than what we had in the past)? Besides a better understanding of the failure mechanism, do FEA or fracture mechanics tests predict the clinical behavior of restorations in order to predict their longevity? And if yes, is this prediction validated with clinical data? Here is another anecdote (I know its value): The only in vitro wear method praised as clinically relevant in the Kelly et al (2012) paper was never able to yield reproducible results when we applied it.

So one could conclude that we must employ clinical testing only. But then we end up with the same dilemma of having to decide what is better: randomized controlled prospective clinical studies or practice-based research? How can the dentist be standardized? Are patients ever standardizable? We know from the “battles of the bonds” of my late colleague Michel Degrange that the influence of the dentist is far greater than the influence of the material (maybe this is related to the wrong test). When it comes to patients, my common sense tells me that patients change their behavior (diet, stress, medication, oral hygiene etc.) over time and therefore results of clinical tests necessarily vary considerably. Furthermore, consider the time involved. Today’s restorative materials are excellent, which means that in the hands of good dentists, it takes a long time (years) until differences between different materials can be observed in clinical application. Moreover, clinical failure is not limited to fractures of the restorations. There are many other factors that can lead to a clinical problem.

Criticism is the motor of progress, but this is only half of the truth. Criticism is just the initiator of the process of progress. Therefore, my plea to my fellow researchers is to not just say no, no, no, but to come up with some yes, yes, yes! In other words, your critique is much more valid if you also formulate positive recommendations for in vitro testing. I know, this is a great challenge, but we definitely need valid in vitro data before we initiate clinical studies. This is an ethical requirement we are obliged to fulfill.



Sincerely yours,
Jean-François Roulet

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