Commentary

Do we need a randomized controlled trial to assess trivial, albeit standard used, clinical steps in bonding? The answer is yes, but there are some interpretation issues

Theodore Eliades

Summary

The feasibility of generalizing and extrapolating the results of the RCT assessing the necessity of a bonding stage to the routine clinical situation is discussed in this commentary. The lack of difference in failure rate between the two procedures followed may not receive the dimensions of a directive to alter a step of the bonding process, before other factors related to the performance of the materials are considered.

The randomized controlled trial published in this issue (1) is perhaps the most effective response to the clinical question raised on the appropriateness and necessity of a clinical procedure, namely the use of primer or bonding agent as it is usually known among practitioners, in orthodontic bonding. Laboratory approaches to investigating this issue most often arrive to clinically irrelevant conclusions because of a number of factors, which cannot be simulated in vitro and include the effect of fatigue of the bond due to load development during mastication (2); the ageing of the materials, particularly that of adhesives (3), due to the temperature fluctuations, enzymatic degradation, salivary exposure, and pH changes; and various methodological problems related to experimental procedures, ranging from selection and maintenance of teeth to load alignment during testing (4). The foregoing variables preclude a reliable inference to the clinical situation and therefore, much of the in vitro work confines its applicability within the premises of preliminary testing.

This void can only be filled by long-term clinical trials of the sort of the one published in this issue, which are designed to provide a definitive response to this matter. Therefore, with a decent degree of certainty and for a treatment duration within the order of that utilized in this study, the significance of the outcome clinically is pretty clear. Some limitations pertinent to use of specific bracket type (adhesive pre-coated), which is different from the conventional bracket-adhesive complex used in routine practice, should not have any measurable effect on the outcome. The critical finding, however, is that there was no difference (marginal lack of significance) in the duration of bonding between the two schemes tested, and this, in essence, negates the potential time gains by omitting the primer step. On the other hand, the Adhesive Remnant Index distribution among debonded enamel surfaces of the experimental group showed a favourable outcome implying that, perhaps, the debonding process might be easier and shorter. The assumption that the 12 months employed in this study as a monitoring period, may be a representative time frame of the actual average orthodontic treatment duration, should also be tested.

Nonetheless, caution should be exercised in suggesting that a failure rate trial with a limited set of objectives, related solely to the performance of an adhesive system in keeping the bond intact, may constitute sufficient ground to formulate a general guideline for the use of adhesives in orthodontic bonding.

In general, the use of primers facilitates sealing and not bonding. Owing to their lower viscosity, primers can penetrate at higher velocity and considerably deeper into the enamel following acid etching; the difference in viscosity between the widely used primer and the composite paste orthodontic adhesive reaches orders of magnitude of 10^4 Pa s (5). Although the length of resin tags per se is not associated with the bond strength (6), sealing of the surface with a resin of thinner viscosity may present a benefit in protecting the enamel surface from subsurface lesion from leakage and demineralization (7). Even though these materials may present more polymerization shrinkage because of the lack of fillers, which maximizes the quantity of the available organic matrix subjected to shrinkage, their small thickness allows for higher degree of cure relative to composite resins, provided that the uncured (oxygen-inhibited) is removed before applying the paste.

On the other hand, the complexity of primer application is enhanced when these are used without polymerization prior to composite adhesive placement; this may result in the displacement of a large amount of primer by the thicker and heavier composite
adhesive paste upon pressing firmly of the bracket–paste complex onto the tooth. This pressure pushes the primer to the margins of the bonding area (corresponding to bracket periphery of bracket base), which results in a dissolution-susceptible margin, assigned to the higher water sorption of these unfilled resins (8).

The aforementioned complex effects related to the structure of the enamel–adhesive interface might reflect on two key parameters of clinical performance of the adhesive, which have not been assessed in this study: the potential for demineralization, and the release of monomers and composite by-products. Currently no clear answer can be given on the difference between primer-mediated and paste-only bonding with respect to those two parameters. Therefore, more research using the same concept and materials but with a different outcome (white spot lesions/demineralization in situ, and monomer release) conducted for a longer period than 12 months, may be necessary before certain clinical procedures are adopted or abandoned at large scale. But is this worth the effort of eliminating a step, which might decrease the bonding time by a minute—at the most?

On a different level, this reveals the core challenge of the cost-effective character of orthodontic clinical trials and their often disproportionally demanding nature relative to the impact of the information furnished to clinical practice. Therefore, the effort of investigators, including the authors of this trial, who devote considerable resources to trials seeking answers to clinical questions, should be heartily praised as they cannot be sufficiently rewarded.

References