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Limitations of In Vitro Orthodontic Bond Strength Testing

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Volumes and volumes of in vitro orthodontic bonding studies have been published. Many clinicians may actually base their selection of adhesives on the highest bond strengths reported in these tests or by the manufacturers themselves. Laboratory tests of enamel bonding are so fraught with problems and limitations, however, that much of the data and conclusions in these studies may not be clinically valid.

Standardization of Bond Strength Testing

In 1964, the National Institute of Dental Research (NIDR) let contracts for the development of a resin that would chemically adhere to enamel and dentin in restorative applications. Three laboratories were contracted—3M, Gillette, and Epoxylite—with expertise in the fields of acrylics, urethanes, and epoxy resins, respectively. I was a primary investigator on this project while working at Epoxylite. Although the research, which took more than five years, did not produce the intended product, it provided valuable insight into the difficulties of testing adhesion to tooth structure.

At the beginning of the study, the three laboratories were using different testing methods and then reporting their bond strength data to NIDR. There was no way to correlate the results obtained by the three companies. Standard testing procedures therefore had to be developed, along with standardized fixtures for shear and tensile testing that were disseminated to all three research facilities.[1-3]

It quickly became apparent that human enamel would not suffice as the test substrate. It was not available in large enough quantities, and its variable integrity, composition, and mineralization precluded its use in any but the final stages of product development. After evaluating artificial materials such as porous ceramics, we selected bovine teeth because they were readily available and similar to human teeth, without the variations in structure and composition (Fig. 1). Since the process of amelogenesis in yearling calves is not as likely to be affected by diet, drugs, infections, and fevers as in humans, bovine teeth can be used for internal, controlled comparative testing. It was never our intention that bovine teeth would serve as a definitive test medium, but only for large-scale preliminary screenings, which would be followed by further testing of human teeth before the final in vivo studies. The large bovine incisors used for the research were removed (by me) from the lower jaws of yearling cows, prepared for testing, and sent to the three research laboratories.

The three facilities and NIDR thus had a means of conducting standardized shear and tensile tests, producing results that could be compared among research centers with some degree of validity. Today, no such standardization exists. One study cannot be compared to another if they use different test fixtures, different loading rates, different methodologies, different test substrates, and different brackets.

Eliades has clearly pointed out the problems inherent in laboratory bond strength testing.[4,5] Fox and colleagues, after reviewing 60 in vitro studies of orthodontic bond strength, were unable to make

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Fig. 1 Bovine incisors used for bond strength testing.

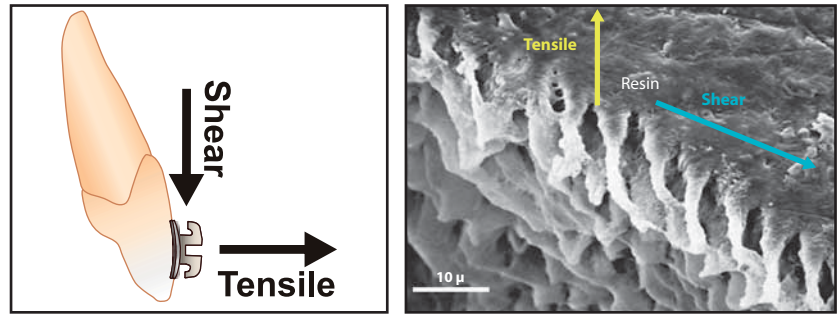

Fig. 2 Difference in direction between shear and tensile loading relative to direction of resin tags.

comparisons because of the variability in testing methods.[6] A recent publication of the ADA Council on Scientific Affairs cautioned, "Can you rely on the bond strength values cited in advertisements, even those quoted from well-designed studies, when selecting a product? Probably not."[7]

Clinical Validity of In Vitro Studies

An ADA Council on Dental Materials task group reported that most laboratory bonding studies could not predict the clinical behavior of the adhesives tested.[8] One of the few studies that have actually attempted to make a direct correlation between in vivo and in vitro results concluded, "Comparisons between the findings of this study and those of a previous ex vivo study by the same authors failed to validate ex vivo bond strength testing as clinically relevant."[9] Pickett and colleagues found intraoral bond strengths at the completion of comprehensive orthodontic treatment to be significantly lower than those found in vitro—5.4 MPa vs. 12.8 MPa.[10]

In 1975, in the early days of orthodontic bonding, Reynolds stated that 6-8 MPa was the clinically acceptable force needed to retain bonded brackets.[11] Since then, more than 100 other publications have cited his conclusion, repeating the 6-8 MPa force level to the point that it has become a de facto standard in laboratory bond strength testing. For example, a recent article stated, "It is a common belief that clinically adequate bond strength for a stainless steel bracket to enamel should be 6-8N/mm^2. In the present investigation the bond strength values of the unfilled and filled adhesives are approximately within this range."[12]

There are many reasons, however, why in vitro bond strengths cannot be correlated with clinical performance, including the variability of enamel, the differences in size and structure among various teeth, the difficulties of intraoral isolation and saliva control, the influence of stresses and saliva over time in the oral environment, and the lack of standardization in testing procedures.

Most in vitro studies are conducted within a short time after bonding, often within 24 hours. This practice does not take into account the potential influence of the oral environment on the bonding material and on the interface between substrate and adhesive. Saliva, in particular, is a powerful surfactant that can percolate between interfaces and force them apart. Some studies have used thermocycling to accelerate the effects of time on their specimens. This is still an inexact procedure, however, because it is unknown whether a certain amount of cycling will have too much effect or not enough effect. In addition, thermocycling cannot replicate the effects of bond degradation by saliva.

Laboratory specimens are typically loaded to failure at relatively slow speeds (the ISO's 2003 "Guidance on Testing of Adhesion to Tooth Structure", TR 11405, specifies a minimum loading rate of .75 ± .30 mm/minute[13]). As loading rates increase, the distribution of the data widens. Bishara and colleagues reported a significant reduction in bracket bond strength as their loading rate increased

from .5mm/minute to 5mm/minute, accompanied by a substantial increase in standard deviations.[14] Yet more rigid materials, such as bonding resins and especially enamel, exhibit significantly lower fracture resistance as the stress loading rate increases. It is unlikely that our patients will be occluding at a rate of only .75mm/minute or that our orthodontic adjustments will be performed at a snail's pace.

Shear vs. Tensile Testing

There are two primary methods of loading a bond to failure: shear and tensile. Shear loading exerts a force perpendicular to the enamel rods and resin tags; tensile loading is parallel to the enamel rods and resin tags (Fig. 2).

The main disadvantage of shear testing is that it may not accurately represent the forces of intraoral stress and orthodontic appliance adjustments. Short resin tags, which can result from inadequate etching, acid-resistant enamel, or other factors, will often test as strong as longer resin tags in shear loading, but are less able to resist higher forces in tensile loading. Furthermore, shear testing may not be sensitive enough to detect variations at the enamel-resin interface that might be revealed by other modes of stress.

Tensile testing is more difficult to conduct, however, without producing some peel forces, which can break a bonding interface at a significantly lower level than either tensile or shear loading. Therefore, tensile tests tend to show much higher standard deviations and coefficients of variation than shear tests.

Although these problems can be minimized by greatly increasing the sample size, human teeth of adequate size and integrity are in short supply. Extracted human bicuspids are used in most studies, with sample sizes of no more than 10-15 specimens per variable. A question that has seldom been raised and never answered is whether a sample of a relatively few extracted teeth is representative of the population at large. On the other hand, bovine teeth are unsuitable for in vitro testing of variables such as acid concentration, etching time, depth of resin penetration, and resin-to-enamel interaction.

Fig. 3 Cohesive bond failure at bracket base, with resin remaining on tooth.

Testing of Bonding Interfaces

There are three possible locations of bond failure: at the enamel-adhesive interface, within the adhesive, and at the adhesive-bracket interface. One cannot simply look at the force necessary to separate a bracket from a tooth without also attempting to identify the interface at which the failure occurred. For example, a study comparing different enamel treatments cannot rightfully conclude that treatment A was any different from treatment B, at any force level, if the majority of bond failures occurred at an interface other than the enamel-adhesive surface. Studies must not only examine and report where the bond failures occurred—as many do, using the Adhesive Remnant Index—but must also correlate the failure mode with the bond strength data.

More than 30 years of clinical experience in bonding brackets to acid-etched enamel have shown that the most common mode of failure, assuming a reasonably good enamel bond and a metal bracket with mechanical base adhesion, is a cohesive failure within the bonding resin, usually at the base of the bracket (Fig. 3). This is as it should be—it prevents a transfer of stress to the enamel-adhesive interface, which could fracture the enamel. That actually occurred in the mid-1980s, when a ceramic bracket was produced with a chemically treated bonding base, yielding extremely high bond strength between the bracket and the

adhesive.

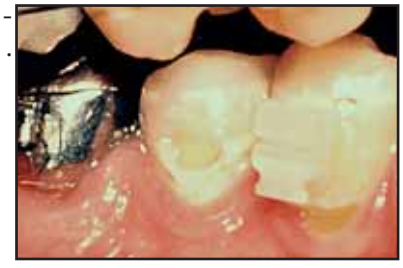

Fig. 4 Enamel fracture from debonding ceramic bracket with chemically treated base.

Thousands of cases of enamel fracture were subsequently reported (Fig. 4). Of course, the manufacturer's in vitro testing did not indicate a potential for enamel fractures. On the contrary, laboratory tests showed that when the manufacturer's special instrument was used, debonding was entirely safe. The simulated debonding, using a relatively few extracted teeth, could not possibly factor in all the variations of human enamel integrity and operator skills. The other lesson that should be learned from this traumatic experience is that it is relatively easy to fracture or craze human enamel, so that it may not always be wise to solve problems of excessive bond failures by searching for the highest possible bond strengths.

Recommendations for Future Testing

A first step toward improving in vitro studies of orthodontic bond strength would be to standardize test protocols and devices. Stanley questioned whether the ISO's 2003 standard for testing adhesion to tooth structure[13] would resolve the problem of clinical relevance. He did argue that "the efforts of the ISO should be supported until an appropriate in vivo test is forthcoming. Nevertheless, I have this uneasy feeling that the dental profession could be misled and that new data should be accepted with a degree of skepticism. The urgency of the problem is obvious."[15]

Perhaps the best we can expect from a well-controlled, statistically valid laboratory study of bond strength is that it serve as a preliminary screening for a controlled clinical investigation. There is no substitute for in vivo testing of bonding variables.

Fortunately for us, the requirements for both in vivo and in vitro testing of orthodontic bonds are significantly less rigorous than those for restorative applications. The criteria for successful bonding of a bracket are readily apparent, and the results of clinical testing can be obtained within a relatively short period.

The orthodontic literature is replete with in vitro bonding studies, many of them conducted as required master's theses. Our profession would be far better served if all this talent and energy were directed toward more meaningful clinical research into orthodontic bonding.

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