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# The inappropriateness of conventional orthodontic bond strength assessment protocols

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SUMMARY The purpose of this article is to examine the soundness of conventional orthodontic bonding assessment methods. A classification of bond strength studies is proposed with the testing environment (*in vivo, in vitro,* and *ex vivo*), loading mode (shear, tensile, and torsion), and bonding substrate (enamel, restorative, and prosthetic materials) serving as discriminating variables. Inconsistencies throughout the various stages of research protocols are analysed. These include the following: tooth selection, storage, and preparation; bonding; testing; and data analysis with regard to the clinical applicability of the reported information, as well as the scientific integrity of the testing procedure.

Contradictory models may partially account for the considerable variability noted for reported bond strength values of different orthodontic bonding systems. Such discrepancies may also explain the conflicting evidence reported on the failure characteristics of the components of the bonding system in different trials examining the efficacy of nominally identical materials.

A novel approach to study the fatigue life of materials is proposed to understand the processes occurring prior to bond failure. Mock research data manipulation is also utilized to illustrate the correct statistical treatment of findings, and recommendations for future research are made to ensure scientific soundness and clinical applicability of data.

## Introduction

Bonding of brackets to enamel has been a critical issue in orthodontics since the introduction of direct bonding, because of the biomechanical importance of a stable bracket–adhesive interface to transfer the loads generated from the engagement of an activated archwire to the tooth. As new bonding agents were introduced, research focused on this area and the resultant publication rate of papers on bonding increased considerably. This is illustrated in the steadily increasing number of bonding papers appearing in the leading orthodontic journals.

In spite of the vast amount of information presented in hundreds of articles during the last decade, there is a remarkable lack of consensus regarding clinical bond strength values. Moreover, no reliable protocol for estimating the *in vitro* strength provided by orthodontic bonding systems has been described. The necessity for such a fundamental reference in restorative dentistry led to the establishment of the ASC MD156 (Accredited Standards Committee 156 for Medical Devices) Task Group in 1990 sponsored by the American Dental Association Council on Dental Materials, Instruments, and Equipment. The main purpose of that task group was to examine the clinical significance of *in vitro* bond strength tests of composite resin restorative materials bonded to tooth structure, including enamel and dentine. The report (Söderholm, 1991) published from this collaborative project emphasized the clinical inapplicability of most research methodologies employed in this area. Suggestions were made for overcoming problems associated with the standardization of various *in vitro* screening tests, thereby facilitating proper comparison among studies published from different research groups.

The purpose of this paper is to provide an overview of the protocols currently available on orthodontic bonding assessment, examine their scientific integrity, and reveal their underlying clinical importance and impact on the extrapolation of conclusions to *in vivo* conditions. Each of the important variables at the different stages of the experimental procedures will be considered.

## Classification of studies on orthodontic bonding evaluation

In general, orthodontic bond strength assessment and the associated study of failure patterns may first be classified according to the test environment (Table 1) as:

(1) *in vitro* tests, usually performed with the aid of a mechanical testing machine or by simulation of clinically applied debonding procedures in the laboratory, where the failure mode of the systems evaluated are determined by microscopic examination;
(2) measurements of the failure rates of brackets *in vivo*, usually during the full course of treatment, with the bracket type and failure site frequency being the parameters examined;
(3) *ex vivo* studies utilizing finite element analysis modelling of the stress distributions in the components of the enamel-adhesive-bracket system.

A second characterization of bond strength tests can be made according to whether the mode of load application is shear, tension, or torsion. Use of shear loading has been very popular due to the relative simplicity of the experimental configuration and the presumably increased reliability of simulating debonding that occurs during treatment. The tension or torsion loading modes have been considered by many investigators as less relevant to clinical practice and have attracted much less interest.

A third classification of bond strength tests is based upon the bonding surface of the substrate; enamel (Eliades *et al.*, 1991), composite resin veneers (Kao *et al.*, 1995), porcelain (Winchester, 1991), and amalgam surfaces (Gross *et al.*, 1997) have been employed. The emergence of the latter three categories arises from the increased emphasis on adult orthodontics during the last two decades, which led to the necessity of bonding aesthetic orthodontic attachments to restored teeth.

## Orthodontic bond strength assessment: protocol stages

### *Tooth selection, storage, and preparation*

A variety of teeth have been used in orthodontic bonding experiments, including upper central incisors, premolars, and lower incisors; this has

**Table 1** Classification of orthodontic bond strength tests.

| Environment | Loading mode | Substrate |
|---|---|---|
| *In vitro*<br>Mechanical testing machine; debonding with pliers, simulating clinical debonding procedures | Shear<br>Movement of bar against mounted rig (testing machine) | Enamel<br>Fluoridated, normal |
| *In vivo*<br>Analysis of rate and site of bracket failure during the course of treatment | Tensile<br>Wire dislodging loop (testing machine) | Composite resin veneers<br>Conventional orthophosphoric acid-etching using various concentration gradients and times<br>Fluoric acid treatment |
| *Ex vivo*<br>Finite element analysis modelling | Torsion<br>Customized wrenches (testing machine) | Porcelain<br>Roughened or unaltered<br>Silane-treated |
| | | Amalgam |

contributed to the lack of comparable results among trials performed in different laboratories. While premolar extraction may be an integral part of orthodontic therapy, facilitating the collection of those teeth, premolar crown contour variations (Taylor, 1978) may complicate the effort to have substrate surface consistency.

On the other hand, upper and lower incisors are mostly retrieved from periodontally involved dentitions. The use of such teeth introduces the complicating factor of the age of the average periodontal patient, since the fluoride content in the outermost surface layers has been documented to change with age (Weatherell *et al.*, 1972); perhaps etching patterns vary accordingly, although no evidence regarding this parameter has been presented. In addition, possible adsorption of inorganic or proteinaceous species, as well as the consequences of various therapeutic procedures and pharmaceutical agents administered to these patients, may modify the reactivity of the enamel surface layers with an undetermined impact on etching patterns.

An overview of bond strength experimental protocols reveals a wide range of storage time periods extending from 24 hours to 5 years (Williams and Svare, 1985). When these varying storage times are combined with the use of miscellaneous storage media (Rueggeberg, 1990) that have employed different concentrations of thymol, saline, aqueous chloramine, and formalin, it becomes very difficult to draw conclusions from such studies. The variability in results has prompted examination of the influence of post-extraction time and storage conditions on bond strength. The majority of the investigations were not able to demonstrate any additional significant effect when teeth were stored for time periods greater than 20 minutes (Söderholm, 1991). However, bond strength values provided by teeth stored in formalin were reported to be twice as much as those of their saline-stored counterparts (Kimura *et al.*, 1985), although no information was provided about the statistical analysis used in that study. In one of the few articles published on the effect of storage medium on enamel, Mühlemann (1964) showed that enamel specimens stored in physiologic saline were softer than corresponding specimens stored in water. Linden (1968) subsequently examined the structure of enamel in extracted teeth following miscellaneous storage conditions and found only minor colour differences. Silverstone (1967) suggested the avoidance of formaldehyde, because its strong acidity following oxidation to formic acid may affect the pH of storage media. Even though an animal model (Pashley *et al.*, 1988) has reproduced *in vitro* bond strength values acquired from *in vivo* tests, other *in vitro* studies (Jemt *et al.*, 1986), that examined the bond strength between glass ionomers and enamel, yielded values twice as high as *in vivo* measurements under nominally identical experimental conditions.

The fact that most of the more recently published research on adhesion in the dental scientific literature deals with dentinal bond strength, which is critical for the survival of restorations, emphasizes the lack of data on modelling of orthodontic bonding conditions *in vitro*. Extrapolation of the results of dentinal bonding studies to enamel bonding must be viewed with scepticism because of the highly organic content of dentine, which might be altered by ionic or enzymatic storage environments, in contrast to the highly inorganic enamel, which seems to be unaffected (Rueggeberg, 1990). Thus, it is plausible that extraction time and storage media have little, if any, influence on adhesive bond strength to enamel. Most critical reviews (Rueggeberg, 1990; Söderholm, 1991) suggest that a storage time of 6 months may be used for normalization purposes among miscellaneous experimental protocols.

Often, experimental treatment of collected teeth include levelling of the prospective enamel surfaces by grinding in an attempt to standardize the topographic variants of the substrate (Eliades *et al.*, 1991). The argument supporting this notion relates to the incongruities found in the profile contour and convexity of the labial enamel surface, particularly those of premolars; the latter induces a variable pertinent to adaptation of the adhesive layer to the tooth crown, inevitably modifying the composite resin thickness. Although this procedure is obviously inappropriate to clinical conditions, its major flaw is the profound alteration of the substratum.

Apparently, surface layers of enamel possess properties dissimilar to those found in deeper zones, due to the higher fluoride content of the outermost 10 μm layer (Jenkins, 1978). In addition, grinding of the enamel surfaces is performed *ad libitum*, using stones or silica discs of varying roughness, while the duration of this process is determined by visual inspection, being thus highly subjective (Schneider *et al.*, 1981). Therefore, not only is there failure in constructing a simulated clinical analogue, but this method also introduces a variability in enamel condition that precludes comparing results from different studies.

An interesting aspect associated with the routine practice of examining the bond strength of various materials bonded to extracted teeth received attention during the 1980s. While alarming levels of bacterial contamination in the dental operatory during cavity preparation had previously been noted (Larato *et al.*, 1966), 20 years elapsed before the potentially hazardous nature of manual utilization and especially grinding of extracted teeth was documented (Pagniano *et al.*, 1985). Rueggeberg (1990) indicated that extracted teeth stored in alcohol or formalin disinfectants contain substantial numbers of micro-organisms that are capable of colonizing the surroundings of the laboratory via aerosol spreading induced by the preparation of teeth with air turbines. *Staphylococci*, *Pseudomonas*, *Shingella*, *Enterobacter*, *Klebsiella*, and *Proteus* were found to be the prevailing species. However, qualitative aspects of bacterial colonies detected varied considerably, depending upon the microflora of the oral cavity from which the teeth were collected, and cross-contamination eventually occurred from specimen storage in groups. Investigations concluded that it is doubtful that commonly-used storage media possess any bactericidal activity, thus necessitating autoclaving of extracted teeth.

Use of this procedure gave rise to studies focusing on the impact of sterilization on the bond strength and enamel structure alterations. The consensus from the limited data available is that autoclaving at 127°C for 20 minutes, followed by storage in 1 per cent sodium hypochloride, does not seem to alter measured values of bond strength or the enamel morphology observed with the scanning electron microscope (Shaffer *et al.*, 1985). Nonetheless, the ASC MD 156 Task Group report (Söderholm, 1991) suggested that minimal guidelines, including the use of gloves, masks, and protective eyewear must be applied whenever animal or human body parts are handled.

### *Bonding*

In general, orthodontic bonding to enamel may involve a combination of the following:

(1) penetration of the initially fluid material into the etched enamel and formation of resin tags after polymerization;
(2) development of strongly bonded surface precipitates, which serve as a substrate to which a resin can be mechanically retained or chemically bonded (Causton and Johnson, 1982);
(3) chemical bonding to the calcium ion of the hydroxyapatite principal constituent of enamel, which is employed in many approaches involving polycarboxylate or polyphosphate ionic binding (Smith and Cartz, 1973).

Evidence obtained in the last decade suggests that both phosphoric acid concentration and etching time may be significantly reduced without notable effects on bond strength (Barkmeier *et al.*, 1987; Wang *et al.*, 1994).

The procedure of adhesive application to the bracket base has raised the issues of the quantitative aspects of adhesive and force utilization during bonding. The methods in published studies (Eliades *et al.*, 1991) involve either the application of a standardized quantity of adhesive or the use of an undetermined amount of composite resin. Even though the first approach may normalize variables related to adhesive paste application, allowing for the estimation of reference material properties such as degree of conversion and monomer leaching, it lacks the essential element of simulating the typical clinical procedure employed by orthodontists. A method proposed to overcome this deficiency (Eliades *et al.*, 1995)

combines components from both approaches by having multiple pilot trials involving application of an adhesive to bracket bases for bonding by a trained orthodontist. This approach allows an estimate of the weight range of the adhesive used, which represents a standardized baseline amount for application to the bracket bases.

A similar concern has been expressed about force application during bracket–adhesive attachment to enamel. In the majority of protocols this is achieved by manual, free-handed application of an undetermined amount of pressure to the bracket. Efforts to adjust the pressure by applying a fixed load to the bracket will yield more consistent results (Kao *et al.*, 1995). However, a serious problem will arise if the amount of force utilized results in significantly thinner adhesive layers, with unknown effects on the material properties.

In spite of the presumed appropriateness of simulating the *in vivo* milieu in laboratory testing, it is worth noting that the oral environment contains a number of parameters that are impossible to reconstruct in an *ex vivo* model. Some of these factors are the stresses arising from an activated archwire coupled with occlusal loads, extreme pH and temperature variations, and the presence of complex oral microflora and their by-products. This latter factor has been found capable of inducing substantial alterations in the structure and surface properties of restorative materials, orthodontic adhesives (Matasa, 1995), and archwires exposed in the oral cavity (Oshida *et al.*, 1992). In particular, orthodontic adhesive degradation induced by microbial attack during treatment has been recently described by Matasa (1995), who examined retrieved brackets intended for recycling.

### *Testing*

The mode of load application and the instrumental configuration for bond strength testing have been investigated by Katona and colleagues (Katona and Chen, 1994; Katona and Moore, 1994; Katona, 1997). Finite element analysis has established that the stress distribution within the adhesive layer, and the stresses generated in the brackets and enamel during testing are inhomogeneous, contradicting the uniform stress assumption that has been prevalent in the majority of *in vitro* experimental protocols. Evidence emphasizing the inappropriateness of comparing results derived from different loading modes (shear, tension, and torsion) was presented, and it was shown that the maximum stresses developed in the orthodontic bonding system under tensile loading may be five times greater than the reported average stress (Katona, 1997). Hence, traditional bond strength studies substantially under-estimate the probability of system failure. Moreover, failure analyses that are intended to provide inferences about the strength of individual components of the bonding system based on their prospective interfacial fracture characteristics, should be questioned (Eliades *et al.*, 1993). This is because the site of failure may arise from crack initiation caused by higher stresses compared with other areas, which is not taken into consideration in the traditional assumption of homogeneous stress.

The validity of comparing results of similar studies is affected by the experimental test configuration, as analysed by Fox *et al.* (1994). The applied force may generate moments of various magnitudes, depending upon the distance of the point of force application from the bracket base surface. This parameter may complicate the extrapolation of conclusions regarding the anticipated failure events (Van Noort *et al.*, 1989).

In summary, some critical aspects of orthodontic bond strength protocols that affect the outcome of research trials may include the following:

1. The cross-head speed of the loading plate in shear testing is usually set at 0.5 mm/min for consistency (Eliades *et al.*, 1991; Kao *et al.*, 1995), although this value lacks correspondence to clinical conditions. *In vivo* debonding incidents are expected to occur at much higher impact velocity, where viscoelastic behaviour of the adhesive, which may be important at low cross-head speeds, is largely absent.
2. In debonding procedures where the bracket is pulled with the use of a wire loop, the loop harness adaptation and frictional resistance

may complicate interpretation of the results. Katona and Chen (1994) proposed that long, thin wires should be used in such an experimental model.

3. Bracket design may contribute to misalignment of load application, making the bonding system prone to failure, depending on the stress gradients generated. It has also been found that variability exists among manufacturers with respect to wing design or dimensions for brackets with a nominally identical prescription (Katona, 1997). This variability poses a substantial problem for the comparison of studies evaluating bracket bond strength.

Another previously unstudied factor affecting the survival of orthodontic bonding may be the propagation of fatigue damage in the adhesive component of the enamel-adhesive-bracket system. The five major stages of fatigue failure (Suresh, 1991) include:

(1) microstructural changes initiating nucleation of permanent damage;
(2) microscopic crack formation;
(3) growth of flaws to yield macroscopic cracks;
(4) stable propagation of macrocracks;
(5) structural instability leading to failure.

A number of variables relevant to the environmental conditions, as well as the mechanical properties and structural configuration of the bonding system members, have a dominant role in determining the rate of crack propagation and the progression of failure. In general, research in this field employs two major approaches in studying fatigue phenomena (Suresh, 1991):

(1) total-life approach where the objective is to characterize the cyclic stress or strain range required for initiation of a dominant crack in an initially uncracked specimen and propagation of this flaw until failure is reached;
(2) defect-tolerant approach that is based upon the premise that all engineering components are inherently flawed. Therefore, if the extent of microdefects present in an as-received specimen can be characterized, the number of fatigue cycles or time to propagate the dominant crack from its initial size to a critical dimension leading to failure can be determined, thereby yielding the fatigue life.

In new research studies on fatigue in orthodontic bonding systems, *post-mortem* analyses would be required to provide evidence about the potentially complex interactions among the components of the system. The scarcity of such evidence may be attributed to the multiplicity of the materials in the system, the complex mechanical behaviour at the diverse interfaces, and the anticipated subtle microscopic character of the fatigue process.

The crack nucleation and propagation that determine fatigue life have been found to depend upon the testing environment (Hertzberg and Manson, 1980). For polymers, the rate and mode of microscopic failure progression are affected by the molecular structure, the nature of the cyclic loading conditions and the type of deformation (elastic, linear, or non-linear viscoelastic). Since it is probable that the detailed stages of the fatigue response cannot be detected in the laboratory for an orthodontic bonding system, the location, and description of flaws will probably be confined to the site of terminal or catastrophic failure.

The clinical implications of these conjectured fatigue processes in orthodontic bonding systems also remain to be elucidated and it is doubtful that the sensitive methods required to investigate these phenomena will be developed in the near future. The necessity of introducing a bracket for testing applications may partially lift the burden of hypothetical inferences and approximations existing within some models (Katona, 1997) currently employed to study orthodontic bond strength. These models generally limit the applicability of the research findings for clinically orientated orthodontists, who will disregard reported observations unless they have evident practical significance.

Fox *et al.* (1994) recently presented an extensive critique of 60 publications on orthodontic bond strength testing. Upon reviewing 22 articles investigating the bond strength of a well-known commercial product, they found that variations

**Table 2** Results (mean ± SD) from the shear bond strength test of three brackets bonded to enamel ($n = 10$)*.

| Measured variable | Bracket X | Bracket Y | Bracket Z |
|---|---|---|---|
| Debonding force (N) | 17.9 ± 0.9 [A] | 15.2 ± 1.0 [B] | 14.1 ± 0.6 [B] |
| Surface area of base ($m^2$) | $1.6 \times 10^{-6}$ | $1.4 \times 10^{-6}$ | $1.8 \times 10^{-6}$ |
| Mean bond strength (MPa) | 11.4 [A] | 10.9 [A] | 7.8 [B] |

*Hypothetical model using arbitrarily defined force values. The bracket base area was calculated from the dimensions of representative upper incisor ceramic brackets, assuming a simple rectangular geometry.
Means with same letters are not significantly different at the $\alpha = 0.05$ level, using the Tukey multiple range test.

in tooth type, storage conditions, method of debonding, analysis of the results, and the selection of other products for comparison resulted in none of the studies having the same methodology. Consequently, despite the large number of previous publications, Fox *et al.* (1994) concluded that the bond strength of this commercial product had not been properly studied and they proposed a detailed protocol for bond strength evaluation.

*Data analysis and presentation*

A review of the literature on orthodontic bond strength testing reveals some basic inconsistencies in the use of units and the statistical analysis of data. A hypothetical research project to investigate the shear bond strength for three brands of ceramic brackets to upper enamel incisor surfaces, using a chemically-cured orthodontic adhesive, may serve to elucidate some aspects of these issues. The data used in this example are based upon a previously published study (Eliades *et al.*, 1991). The sample size for each group of brackets tested was 10. The mean and standard deviation of the debonding force (measured in Newtons) for each bracket type is listed in the first row of Table 2. Assuming rectangular bracket bases, the calculated surface areas in $m^2$ (using the SI system of units) are provided in the second row. The third row presents the resultant mean bond strength values expressed in the stress units of $N/m^2$ or MPa (ignoring the previously discussed effects of stress concentrations). A scanning electron microscopic investigation of the bracket base surfaces was also performed to seek correlation of the bond strength values with the morphological and structural features of the bases. Representative photomicrographs are provided in Figures 1–3 for brackets X, Z and Y, respectively.

Table 2 reveals an interesting discrepancy between the statistically significant differences found for debonding forces and mean bond strengths. One source of this discrepancy is that the effective surface area of the bracket base in contact with the adhesive is far from rectangular (Figures 1–3). Furthermore, substantial variations in the load distribution patterns are expected among the three bracket types because of differences in overall morphology, as well as in the interfacial characteristics of the bracket–adhesive complex. The previous assumption of a uniform load distribution among the interfaces involved must be rejected. Moreover, significant fluctuations in adhesive thickness have been

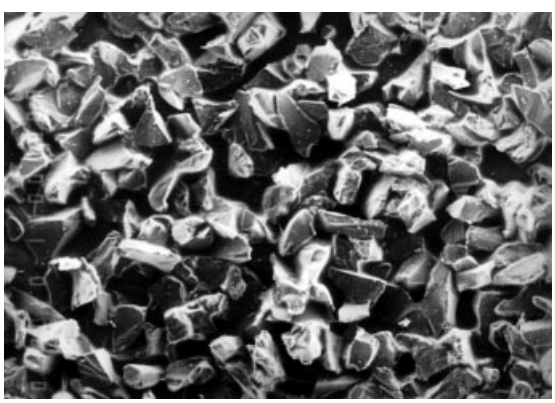

**Figure 1** SEM photomicrograph of the base of a polycrystalline ceramic bracket (X). Note the dramatic increase of surface area through the projection of crystal-like formations. (Original magnification ×100.)

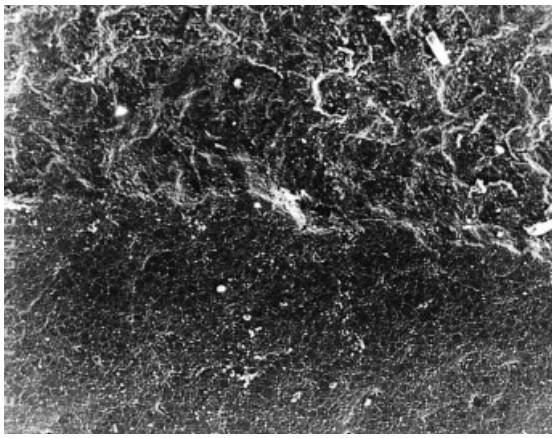

**Figure 2** SEM photomicrograph of the base of a polycrystalline ceramic bracket (Y) presenting less morphological variability compared with bracket X. (Original magnification ×100.)

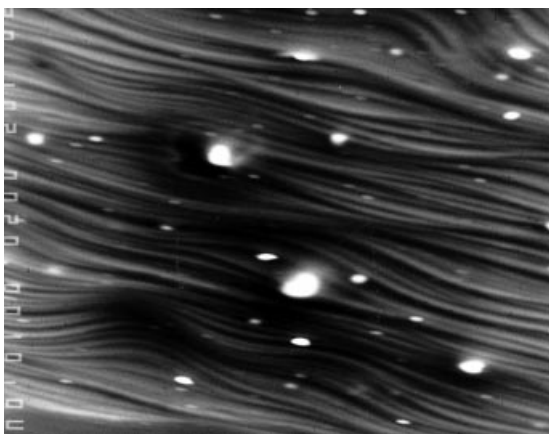

**Figure 3** SEM photomicrograph of the base of a single-crystal ceramic bracket (Z) showing a uniform, relatively smooth surface. (Original magnification ×100.)

noted between smooth bracket bases that contribute to a homogeneous load application and rough bracket bases, where crystal-like formation results in the retention of the adhesive (Eliades *et al*., 1991). This effect may depend upon the rheological properties of the adhesive, and the size of the pores or grooves formed in the bracket base. The presence of these variables may validate the argument that clinicians should not be concerned with the expression of bond strength values in terms of stress, because this may be irrelevant to the actual force at which the system fails *in vivo*. Moreover, some authors have provided evidence supporting the independence of bond strength variations from the nominal area and mesh size for 14 types of bracket bases (Dickinson and Powers, 1980). Thus, in the foregoing example, which represents the average style of papers published in this field, the actual contact area of the bracket base cannot be accurately estimated to allow for the proper transformation of units from force to stress, and there is little reliability in projecting laboratory results to clinical conditions.

An important final consideration about the use of units has been described by Katona (1997), who pointed out the potential confusion in reporting torsional strength, which is expressed in N/m as the quotient of torque (Nm) and area ($m^2$). The confusion arises because the units for shear strength are $N/m^2$, and torsion corresponds to a state of shear stress (Popov, 1968). When torsional loading is involved, the polar moment of inertia must be considered, which describes the distribution of the cross-section area about the axis of twisting.

The statistical treatment of data in Table 2 employed one-way analysis of variance (ANOVA), followed by the Tukey multiple range test. The data for the debonding force and mean bond strength were subjected to separate statistical analyses and the results are provided in Table 3. Assuming that all other testing variables have the same effect upon all three samples and that these groups are normally distributed, it is shown that two different pairwise multiple comparison tests (Tukey, Duncan) can yield different results about which specific groups are significantly different. The discrepancy noted in Table 3 may not be limited to simply stating the differences between the two methods of statistical analysis, since authors often feel that they should provide substantiation of the reported information. In this example, the researcher who used the multiple range test (Duncan) showing more significant differences between the three groups would probably attempt to correlate differences in mean debonding force to bracket base features observed in the SEM photomicrographs, making inferences about the effect of the

**Table 3** Significant differences among results (mean ± SD) of the debonding forces (N) in Table 2, using two different multiple pairwise comparison tests.

| Bracket type | Mean ± SD | Tukey grouping | Duncan grouping |
|---|---|---|---|
| X | 17.9 ± 0.9 | A | A |
| Y | 15.2 ± 1.0 | B | B |
| Z | 14.1 ± 0.6 | B | C |

ANOVA *F* value: 42.9.
Means with same letters are not significantly different at the $\alpha = 0.05$ level.

specific base design. Thus, a series of arguments pertinent to microstructural and morphological features of the bracket base surfaces may be formed in accordance with the results observed; in this case, the proposed theoretical justification may lack a scientific basis.

The appropriate sample size has been a matter of dispute and has served as a criterion of the soundness of research. This is attributed to the likelihood that sample sizes of less than 10 specimens per group may not follow a normal distribution. Normally distributed samples, randomness of individual sampling and homogeneity of variances are fundamental assumptions for the use of ANOVA (Sokal and Rohlf, 1995). The publication of studies reporting mean bond strength values derived from groups containing less than 10 specimens has resulted in strong criticism (Fox *et al.*, 1994) and some authors advocated that the minimum sample size per group should be of the order of 30. Rather than set a specific sample size *a priori*, the appropriate statistical approach is to perform a power analysis (Sokal and Rohlf, 1995) on the results of pilot experiments to establish the correct sample size that meets $\alpha$ and $\beta$ levels previously established in the research protocol.

Finally, the use of a Weibull survival analysis has been proposed (Fox *et al.*, 1994) for bond strength studies. This analysis does not require normally distributed samples and also focuses on the tail of the distribution that contains the smaller values, thereby providing more emphasis on the safety of the bonding system performance.

## Future research directions

As the state of our current knowledge on bonding advances rapidly, the clarification of the purpose of the bond strength research protocols and the precise definition of the objectives of relevant research may assist investigators in the field to arrive at clinically meaningful conclusions. This will help orthodontists to efficiently handle this clinical stage, while, at the same time, provoke the manufacturing of materials that will meet the clinical demands.

The simulation of clinical conditions is a task that is not seen to be attainable in the near future. The fact that the failure pattern of controlled debonding procedures occurring in a set up involving the use of a testing machine bears little comparison with the topography of failure occurring *in vivo* (Katona, 1997), distorts the applicability of the information provided. A potential solution might be the construction of debonding pliers for testing purposes, which will presumably direct the applied loads according to the manufacturers' suggestion, while providing, through a strain gauge mechanism, a quantitative scale of the magnitude of the force applied. This will facilitate a reference that may serve as a discriminating variable for comparison purposes among various adhesive–bracket systems. However, this approach limits the effectiveness of the trial to the debonding incidents occurring under the given loading pattern, and cannot provide an insight of the wide array of tensile or torque loads transferred to the system, emanating from mastication or engagement of heavy rectangular archwires on fully prescribed, pre-adjusted brackets.

Additional approaches in resolving the issue of soundness of *in vitro* derived data, may involve the challenging area of fatigue of the adhesive-bracket system. This may be accomplished through protocols aimed at exploring the total-life tolerance of the system to a low-magnitude, cyclic, mechanical stress, rather than measuring its strength to a sudden, powerful impact, such as that occurring during standard strength tests. This is because the system may fail at considerably lower values, as it was not constructed to resist high impact loading, which is supposedly absent *in vivo*.

Another route, currently followed by some investigators, is the finite element analysis, which has already clarified some issues pertaining to research methodology and interpretation of findings relevant to bond strength experimental configuration. The introduction of a bracket for strictly testing applications proposed by Katona (1997), points at the direction of standardization of research and elimination of the exceedingly increased variability of the findings noted among different studies investigating identical materials.

While it is true that certain aspects of physical and chemical adhesive properties may be clarified by *in vitro* approaches, the actual performance of the system can only be illustrated in the environment where it was intended to function. Therefore, clinical studies focusing on the failure rate of appliances in a controlled environment under identical conditions with respect to malocclusion, appliance prescription and slot dimensions, status of patients, as well as applied mechanics, may target the examined variable. However, these trials are laborious, requiring extended monitoring, which may be problematic in a private office. On the other hand, the multiplicity of variables existing in an academic environment pertaining to the educational scope of the programme involving the exposure of students to a wide variety of appliances and mechanics, as well as the treatment of a range of malocclusions, make the construction of similar research protocols nearly infeasible.

The clear definition of research objectives implemented by the construction of a standardized bracket analogue is intended for solely testing applications. The controlled testing environment with respect to the application of forces imposing measurable biomechanical effects on the bracket–adhesive system, and the appropriate statistical design, may enhance the integrity and repeatability of research findings. This might be an integral part of conducting sound investigations.

Finally, it seems that the underlying difficulty in carrying out these tests relates to the challenge of defining the goals of research; an essential stage of this is the elimination of some apparent deficiencies existing in research protocol design. Performing investigations with vaguely defined objectives and employing obviously erroneous methodologies indiscriminately, inevitably confines the purpose of our research efforts.

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## References

Barkmeier W W, Gwinnett A J, Shaffer S E 1987 Effects of reduced acid concentration and etching time on bond strength and enamel morphology. Journal of Clinical Orthodontics 21: 395–398

Causton B E, Johnson N W 1982 Improvement of polycarboxylate adhesion to dentine by the use of a new calcifying solution. An *in vitro* study. British Dental Journal 152: 9–11

Dickinson P T, Powers J M 1980 Evaluation of fourteen direct-bonding orthodontic bases. American Journal of Orthodontics 78: 630–639

Eliades T, Viazis A D, Eliades G 1991 Bonding of ceramic brackets to enamel: morphologic and structural considerations. American Journal of Orthodontics and Dentofacial Orthopedics 99: 369–375

Eliades T, Viazis A D, Lekka M 1993 Failure mode analysis of ceramic brackets bonded to enamel. American Journal of Orthodontics and Dentofacial Orthopedics 104: 21–26

Eliades T, Eliades G, Brantley W A, Johnston W M 1995 Polymerization efficiency of chemically cured and visible light-cured orthodontic adhesives: degree of cure. American Journal of Orthodontics and Dentofacial Orthopedics 108: 294–301

Fox N A, McCabe J F, Buckley J G 1994 A critique of bond strength testing in orthodontics. British Journal of Orthodontics 21: 33–43

Gross M W, Foley T F, Mamandras A H 1997 Direct bonding to Adlloy-treated amalgam. American Journal of Orthodontics and Dentofacial Orthopedics 112: 252–258

Hertzberg R W, Manson J A 1980 Fatigue of engineering plastics. Academic Press, New York

Jemt T, Stålblad P A, Øilo G 1986 Adhesion of polycarboxylate-based dental cements on enamel: an *in vivo* study. Journal of Dental Research 65: 885–887

Jenkins G N 1978 The physiology of the mouth. Blackwell Scientific Publications, Oxford

Kao E C, Eliades T, Rezvan E, Johnston W M 1995 Torsional bond strength and failure pattern of ceramic brackets bonded to composite resin laminate veneers. European Journal of Orthodontics 17: 533–540

Katona T R 1997 A comparison of the stresses developed in tension, shear peel, and torsion strength testing of direct bonded orthodontic brackets. American Journal of Orthodontics and Dentofacial Orthopedics 112: 244–251

Katona T R, Chen J 1994 Engineering and experimental analyses of the tensile loads applied during strength testing of direct bonded orthodontic brackets. American Journal of Orthodontics and Dentofacial Orthopedics 106: 167–174

Katona T R, Moore B K 1994 The effects of load misalignment on tensile load testing of direct bonded orthodontic brackets—a finite element model. American Journal of Orthodontics and Dentofacial Orthopedics 105: 543–551

Kimura S, Shimizu T, Fujii B 1985 Influence of dentin on bonding of composite resin, Part 1—effect of fresh dentin and storage conditions. Dental Materials Journal 4: 68–80

Larato D C, Ruskin P F, Martin A, Delanko R 1966 Effect of a dental air turbine drill on the bacterial counts in air. Journal of Prosthetic Dentistry 16: 758–765

Linden L A 1968 Microscopic observations of fluid flow through enamel *in vitro*. Odontologisk Revy 19: 349–365

Matasa C G 1995 Microbial attack of orthodontic adhesives. American Journal of Orthodontics and Dentofacial Orthopedics 108: 132–141

Mühlemann H R 1964 Storage medium and enamel hardness. Helvetica Odontologica Acta 8: 112–117

Oshida Y, Sachdeva R C, Miyazaki S 1992 Microanalytical characterization and surface modification of TiNi orthodontic archwires. Biomedical Materials and Engineering 2: 51–69

Pagniano R P, Scheid R C, Rosen S, Beck F M 1985 Reducing airborne microbes in the preclinical dental laboratory. Journal of Dental Education 50: 234–235

Pashley E L, Tao L, Mackert J R, Pashley D H 1988 Comparison of *in vivo* vs. *in vitro* bonding of composite resin to the dentin of canine teeth. Journal of Dental Research 67: 467–470

Popov E P 1968 Introduction to mechanics of solids. Prentice-Hall, Englewood Cliffs, NJ, USA

Rueggeberg F A 1990 Substrate for adhesion testing to tooth structure—review of the literature. Dental Materials 7: 2–10

Schneider P M, Messer L B, Douglas W H 1981 The effect of enamel surface reduction *in vitro* on the bonding of composite resin to permanent human enamel. Journal of Dental Research 60: 895–900

Shaffer S E, Barkmeier W W, Gwinnett A J 1985 Effect of disinfection/sterilization on *in vitro* enamel bonding. Journal of Dental Education 49: 658–659

Silverstone L 1967 The histopathology of enamel lesions produced *in vitro* and their relation to enamel caries, Vol.1. PhD Thesis, University of Bristol, UK

Smith D C, Cartz L 1973 Crystalline interface formed by polyacrylic acid and tooth enamel. Journal of Dental Research 52: 1155 (Abstract)

Söderholm K-J M 1991 Correlation of *in vivo* and *in vitro* performance of adhesive restorative materials: a report of the ASC MD 156 task group on test methods for the adhesion of restorative materials. Dental Materials 7: 74–83

Sokal R R, Rohlf F J 1981 Biometry. The principles and practice of statistics in biological research, 3rd edn. Freeman, New York

Suresh S 1991 Fatigue of materials. Cambridge Solid State Science Series, Cambridge

Taylor R M S 1978 Variation in morphology of teeth. Anthropologic and forensic aspects. Thomas Springfield, IL, USA

Van Noort R, Noroozi S, Howard I C, Cardew G 1989 A critique of bond strength measurements. Journal of Dentistry 17: 61–67

Wang W N, Yeh C L, Fang B D, Sun K T, Arvystas M G 1994 Effect of $H_3PO_4$ concentration on bond strength. Angle Orthodontist 64: 377–382

Weatherell J A, Robinson C, Hallsworth A S 1972 Changes in the fluoride concentration of the labial enamel surface with age. Caries Research 6: 312–324

Williams V D, Svare C W 1985 The effect of five-year storage prior to bonding on enamel/composite bond strength. Journal of Dental Research 64: 151–154

Winchester L 1991 Direct orthodontic bonding to porcelain: an *in vitro* study. British Journal of Orthodontics 18: 299–308