Commentary: Basic concepts concerning bracket failure research

James R. Miller, DDS, MSD

Laboratory studies have been designed to evaluate the bond strength of adhesives as an indication of the risk of clinical bracket failure. Several characteristics make a laboratory study a good choice for a preliminary investigation of an adhesive.[1] The researcher can select a reliable measurement of bond strength, and it is relatively easy to incorporate an appropriate control group for comparison and to reduce the potentially distorting influence of extraneous variables (confounders) through randomization. Therefore, the measurements obtained from laboratory studies are quite useful as a first step. Unfortunately, no one variable or combination of variables that can be measured in the laboratory is perfectly predictive of what might occur when the bonding adhesive is used in the demanding environment of the oral cavity. Therefore, even when laboratory results are promising, clinical research is still advisable.[2] This commentary will discuss some of the relevant issues concerning the design and analysis of clinical bracket failure research.

Confronting potential confounders

When research moves out of the laboratory and into the clinical setting, the selection of an appropriate control group becomes important and is generally appreciated by both researchers and clinicians. However, equally important and probably less understood are the necessity to recognize the potential for distortion of the results by confounding and the steps that are necessary to reduce the probability of this occurring. Confounding is the mixing of the effects between the exposure (type of adhesive) and the outcome (bracket failure) and a third factor (confounder) that is associated with the exposure and independently affects the risk of developing the outcome.[3] Confounders can be known or unknown. An example of a known confounder might be gender. Let's assume that boys have a higher risk of bracket failure than girls. If one of the adhesive groups being tested has more boys than girls, this might distort the results. Two common clinical research designs for studying clinical bracket failure are cohort studies and randomized clinical trials. Controls are used in both of these designs. However, they differ in important ways with respect to the issue of confounding.

In cohort studies, groups are determined by exposure status. Individuals (or teeth) in which the experimental adhesive is used to bond the brackets are placed in one group. Those in which the comparison adhesive is used are placed in the control group. The ability of the researcher to handle confounding varies according to the specific research design. In prospective cohort studies the researcher has the option of compensating for known confounders in the design phase or to measure the known confounders and adjust for them in the analysis. In retrospective cohort studies, if known confounders aren't measured at the time the bracket failure data is recorded, then it is difficult for the researcher to compensate for known confounders. One characteristic

of a cohort study is lack of random exposure. Without randomization, unknown confounders may distort the results. This is a major limitation of cohort studies.

In randomized clinical trials individuals (or their teeth) are randomly assigned to the various experimental groups. A different adhesive is used to bond the brackets in each group. One reason this design is so powerful is that it helps address the issue of confounding. Randomization tends to produce a similar distribution of all known and unknown confounders. Therefore, in a randomized clinical trial the effects of both known and unknown confounders are reduced. A randomized clinical trial is a powerful research design and in clinical research approaches what would be equivalent to a laboratory experiment.

Complications with data analysis

Analysis of clinical bracket failure research presents several challenges. If a set of bracketed teeth are observed, a certain number of brackets will have failed at any time. Bracket failure is often reported in terms of the cumulative percentage of bracket failure that has occurred by the end of the total observation period.[4] However, using this measurement is problematic if not all individuals are observed for the same period of time. Another potential problem is that calculating the percentage of bracket failure at the end of the study doesn't provide information about when the brackets actually failed.

A more sophisticated approach is to use survival analysis to calculate the cumulative probability of bracket failure at various points of time during the study for each adhesive group.[4,5] If a set of teeth is followed over time and bracket failure is recorded when it occurs (or at least monthly), then a cumulative probability of failure curve can be generated. At any point in time along that curve there will be a cumulative probability of bracket failure for each adhesive group.

Survival analysis has not been used much in the orthodontic literature.[6-9] However, even if survival analysis hasn't been used, meaningful information can be gained from most reports. If an article reports a certain measurement of bracket failure, at the minimum, try to determine the average observation period for all patients (i.e., average treatment time during which bracket failure is counted). This will give an indication of the average time the teeth were at risk to experience a bracket failure. It is more difficult to get meaningful information from articles that simply report the range of observation periods.

Other complicating issues must also be considered when analyzing bracket failure data. Bracket failures on teeth within an individual may be related; different types of teeth have different cumulative percentages (probabilities) of bracket failure; and the probability of a tooth experiencing a second bracket failure may be different than the probability of a first bracket failure. Special analytic methods are available to address these issues.[9,10]

Research on orthodontic bonding adhesives—and the clinical bracket failure associated with these adhesives—is complicated. The concepts presented in this commentary will, it is hoped, help readers evaluate the research in this field.

Author Address

James R. Miller, DDS, MSD
Department of Dental Public Health Sciences
University of Washington
Box 357475
Seattle, WA 98195-7475
Phone: (206)543-2034
Fax: (206) 685-4258
E-mail: jrmill@u.washington.edu

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