SCIENTIFIC SECTION

An *ex vivo* assessment of gingivally offset lower premolar brackets

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Objectives: *To compare the force to failure of standard premolar brackets to that of gingivally offset brackets and evaluate the site of bond failure between the two bracket types through the use of the Adhesive Remnant Index (ARI).*

Design: *An* ex vivo *study.*

Setting: *Dental Materials Science Laboratory, Dundee Dental School, Dundee.*

Materials and methods: *Forty extracted lower premolar teeth (caries free, extracted as part of orthodontic treatment, all donors living in a non-fluoridated area), divided into two equal size sample groups, as follows: Group 1: Victory Series™ (3M Unitek, Monrovia CA, USA) lower premolar brackets bonded to buccal surfaces with Transbond XT (3M Unitek, Monrovia CA). Group 2: Victory Series™ Gingivally Offset Bicuspid Brackets (3M Unitek, Monrovia CA) bonded to buccal surfaces with Transbond XT (3M Unitek, Monrovia CA). Force was applied in the occluso-gingival direction using an Instron Model 4469 Universal Testing Machine (Instron Ltd, High Wycombe, UK) operating at a cross-head speed of 0.5 mm/min and its value at failure determined. Following debond, the site of bond failure and ARI were recorded.*

Outcome: *Force to failure, site of bond failure and adhesive remnant index.*

Results: *The Weibull analysis gave higher values for the force to failure at 5% level (200* v. *159 N) and at all other levels of probability of failure for the gingivally offset bracket. The non-parametric survival analysis using Gehan–Wilcoxon tests with Breslow's algorithm ($p < 0.0001$) showed significant difference in force to failure between bracket types. Chi-square tests showed no significant ($p = 0.55$) relationship between the site of bond failure and the bracket types.*

Conclusion: Ex vivo *testing suggests that there is a significant difference in the force to failure between gingivally offset and standard lower premolar brackets when force application is from an occluso-gingival direction. The site of failure (as given by the ARI) is insensitive to bracket types and force to failure.*

Key words: *Dentistry, orthodontics, orthodontic bracket bonding, gingival offset brackets*

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Introduction

The debonding of orthodontic brackets is a common problem in orthodontic practice. Ideally, a bracket should remain bonded to a tooth until the end of treatment and resist complex occlusal forces whilst in service. Bond failure rates between 2.7% and 6% have been reported.[1,2]

Various reasons for this bond failure have been cited. These include the bonding agent applied,[3] bonding technique used,[4] design of the bracket base,[5] etch time and concentration of etchant.[6,7]

Another important factor is occlusal trauma. This may stem from the type of malocclusion, e.g. cusp to cusp occlusion where brackets may fail when the patient brings the posterior teeth into contact, or from excessive occlusal forces when the patient fails to follow the instructions provided. Previous studies[8] have shown that lower premolar brackets are the most vulnerable to occlusal forces and most likely to debond during treatment. In order to reduce this problem a redesigned lower premolar bracket is now available, on which the wings of the bracket are offset gingivally to provide a greater bracket base area, occlusal to bracket wings. The manufacturer (3M Unitek, Monrovia CA, USA) claims that this arrangement should provide greater resistance to debonding, thus reducing the incidence of bond failure.

Aims

The main aim of this *ex vivo* study was to compare the force to failure of the gingivally offset brackets lower premolar with that of standard brackets, by means of

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probabilistic approach (Weibull analysis). The null hypothesis is that there are no differences between gingivally offset brackets and standard brackets with respect to:

- force to failure;
- site of failure.

The second aim was to evaluate the site of bond failure between two bracket types. It is of interest to determine whether any change in the force to failure that results from bracket selection is accompanied by change in the site at which failure occurs. The ARI was selected as a simple, but informative semi-quantitative method to provide this evidence. The null hypothesis is that there is no difference in the distribution of ARI scores between bracket types or force to failure levels.

Material and methods

Forty sound lower premolar teeth, extracted for orthodontic purposes from patients under the age of 18 years living in an area with a non-fluoridated water supply, were collected and stored in distilled water. They were mounted in resin blocks with the long axis of each tooth set vertically. These specimens were divided randomly into two equal size groups. This sample size complies with the recommendation of Fox *et al.*[9] that at least 20 teeth per test be used for *ex vivo* bond strength testing:

Group 1. Standard pre-adjusted edgewise lower premolar brackets (Victory Series™, 3M Unitek, Monrovia CA, USA). Bonding product — Transbond XT (3M Unitek, Monrovia CA, USA). This group served as the control. Sample size = 20.

Group 2. Gingivally offset brackets lower premolar brackets (Victory Series™ Gingivally Offset Bicuspid Bracket, 3M Unitek, Monrovia CA, USA). Bonding product — Transbond XT (3M Unitek, Monrovia CA, USA). Sample size = 20.

A single operator carried out all bonding. The materials were used according to the manufacturer's instructions: The teeth were pumiced using fluoride-free pumice and water for 15 seconds with a rubber cup, then rinsed with water and dried in a stream of oil-free compressed air. The teeth were then etched for 30 seconds with orthophosphoric acid etchant (37%) provided by the manufacturer, washed for 60 seconds then dried using oil-free compressed air. A thin layer of primer was applied to each tooth with a microbrush. The bracket was loaded with adhesive paste and placed on the buccal surface with light pressure exerted to extrude any excess adhesive paste. This excess was removed with a probe. The composite was cured with a 60-second light exposure (Visilux 2™, 3M-ESPE, St Paul, MN, USA). The application of light was 15 seconds each from occlusal, gingival, mesial and distal direction. The bonded specimens were stored in distilled water at 37 °C for 1 week before determining the force to failure.

An Instron Model 4469 Universal Testing Machine (Instron Ltd, High Wycombe, UK) was used to measure the force to debond. To simulate the intra-oral failure of brackets due to occlusal trauma, they were debonded with the force applied in an occluso-gingival direction using a flat-ended steel rod. One end of the rod was fixed rigidly to the moving cross-head. The test jig by which the specimen was attached to the stationary anvil allowed the specimen position to be adjusted in the *x–y* plane and then locked into position. This enabled the other end of the rod to be placed precisely and consistently over the bracket between the occlusal tie wings of each bracket, to ensure the distance between the surface of the tooth and point of application of force was same for each specimen (Figure 1). A cross-head speed of 0.5 mm/min was used and the force required to dislodge the bracket measured to a resolution of 0.1 N. Debonding tests were conducted in air at ambient laboratory temperature.

Following debond, each tooth was examined by a single operator at ×10 magnification. The site of bond

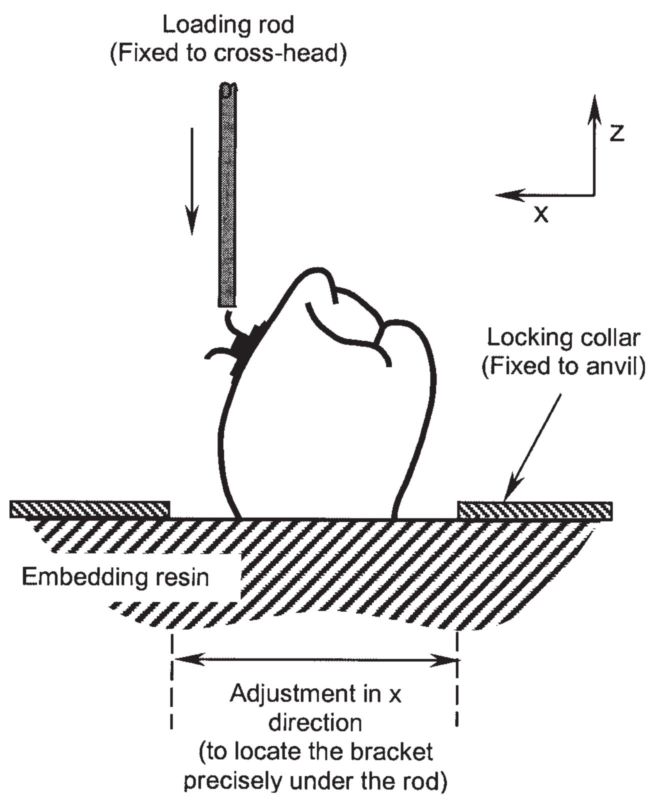

Figure 1 The specimen and its positioning in the loading apparatus, viewed in the mesial direction. This shows the adjustment in the *x* direction to position the bracket under the loading rod. A similar adjustment exists in the *y* direction, for the same purpose

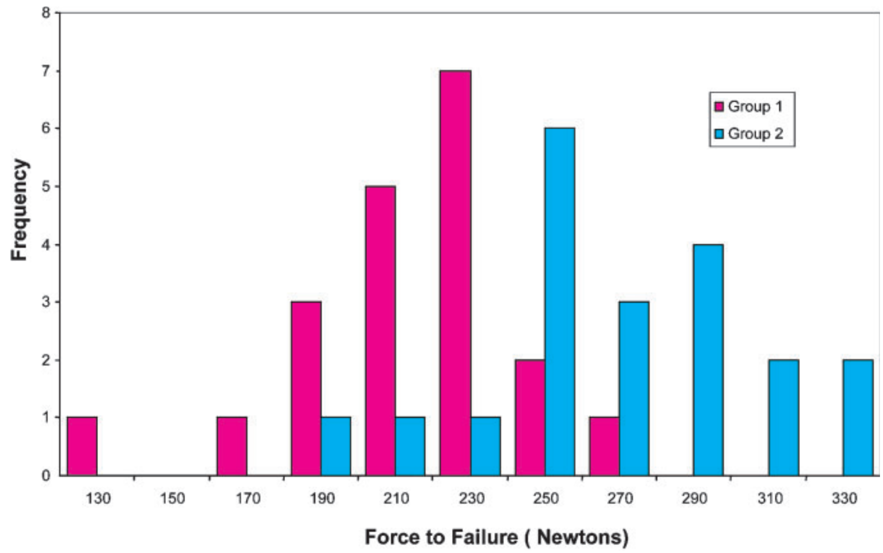

Figure 2 Histogram showing the frequency distribution of force to failure of the two bracket types

failure was recorded along with the Adhesive Remnant Index. (ARI).[10] In order to check the reliability of ARI scoring 20 random samples were scored by the first and the second authors independently on two separate occasions to calculate the inter- and intra-rater reliability. There was 100% agreement on both occasions by the first author and a single disagreement between occasions by the second author giving his intra-rater kappa of 0.77 indicating substantial agreement.[11] In regard to inter-rater reliability, on the first occasion a single disagreement between authors gave a kappa value of 0.77. However, on the second occasion, there was 100% agreement between the two authors.

The statistical analyses were carried out using Unistat 5.0 (Unistat Ltd, London, UK). Weibull analysis was carried out to relate the probability of bond failure to the applied force. This analysis has been advocated previously.[9] Non-parametric survival analysis was carried out. The ARI data were analysed with chi-squared tests.

Results

The results of the study are presented graphically in Figure 2. The histogram shows the distribution of force to failure values of both bracket types in Newtons. The standard brackets debonded consistently at lower force level than gingivally offset brackets.

The Shapiro–Wilk test[12] of normality was carried out on both groups of force to failure data. As Table 1 shows, Group 2 has results compatible with a normal distribution. Group 1 did not and further examination of the data revealed one extreme outlier. (A check of the original machine output confirmed this value and excluded a data entry error). Group 1 was only just non-significant for non-normality, but Tiku[13] has shown that Shapiro–Wilk test is not particularly powerful. It is therefore unsafe to assume normality when the test produces marginally non-significant results.[14]

Re-application of the Shapiro–Wilk test of normality with the exclusion of this single value shows compatibility with normal distribution. However, it was an abnormally low value and the authors feel that it is inappropriate to exclude this 'inconvenient' data point from further analysis.

Weibull analyses[15] were carried out and Weibull plots for the two groups are shown in Figure 3 and the statistics in Table 2. Group 1 has a slightly lower Weibull modulus. Given the non-normality of some of the data, median and

Table 1 Shapiro–Wilk test for normality

Group number	Sample size	Mean force, N	Standard deviation, N	Shapiro–Wilk statistic	Probability
1	20	216	30	0.91	0.055
1 without outlier	19	221	21	0.98	0.98
2	20	267	37	0.96	0.50

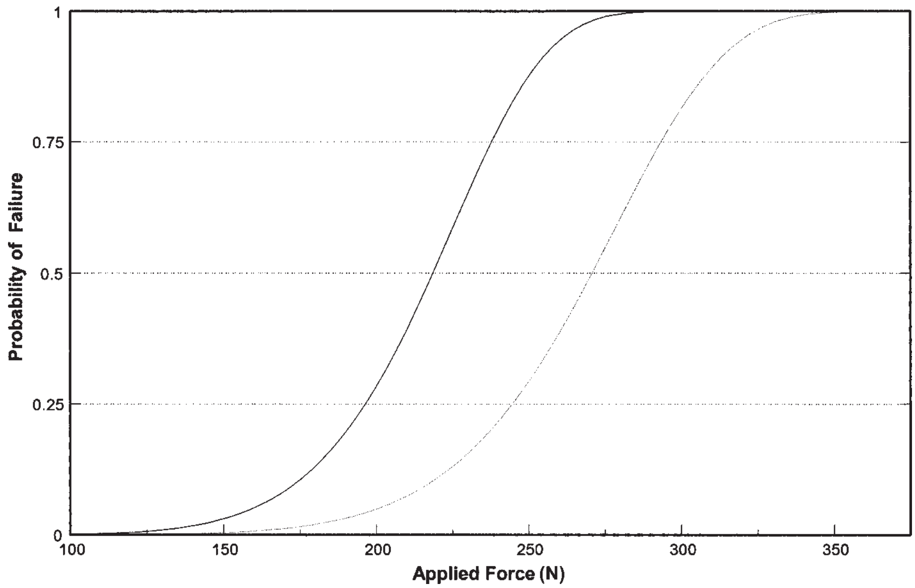

Figure 3 The Weibull plots for the force to failure for the two bracket types. — offset bracket, — normal bracket

Table 2 Weibull analysis

Group number	Median force to failure , N	95% lower CI, N	95% upper CI, N	Weibull modulus	Normalizing parameter (characteristic force), N
1	220	205	232	8.2	229
2	270	249	282	8.7	282

Table 3 Force required for specific probabilities of failure

Group number	Force for 1% chance of failure, N	Force for 5% chance of failure, N	Force for 90% chance of failure, N
Group 1	131	159	253
Group 2	166	200	311

95% CI exact conservative intervals about the median are provided in preference to the mean and normal distribution-based confidence intervals. Examination of these confidence intervals shows that they do not overlap for Groups 1 and 2. Thus, Groups 1 and 2 differ from each other with respect to the applied force to failure. The force to failure required for various probabilities of failure are in Table 3.

Non-parametric survival analysis was carried out using Gehan–Wilcoxon tests with Breslow's algorithm[16] to confirm the deductions from the confidence intervals. Tests were carried out comparing Groups 1 and 2. The results are in Table 4. Additionally, the test was repeated for Groups 1 and 2 excluding the Group 1 outlier. This shows that excluding the outlier does not significantly affect the result and that the outlier is not responsible for most of the differences found. The null hypothesis that the force to failure at 5% level of probability of failure is same for both bracket types is rejected.

The bracket resin interface was the more common site of bond failure for both the groups. Thirty-seven specimens failed at the bracket resin interface and remaining three failed at enamel resin interface (Table 5). Table 6 shows the Chi-square test results for bracket types and ARI scores, indicating no significant difference. The null hypothesis that there is no difference in the distribution of ARI scores between bracket types is accepted.

Further investigation was carried out in order to determine whether there is a relationship between ARI scores and the amount of force required to debond brackets. The specimens were redistributed into ARI score groups. The number of specimens in one group was too small

Table 4 Survival analysis

	χ^2 Statistic	Degrees of freedom	Right tailed probability
Groups 1 and 2	19.73	1	<0.0001
Groups 1 and 2 excluding outlier in 1	18.82	1	<0.0001

Table 5 Site of bond failure of each group

Group number	Sample size	Enamel/resin (%)	Bracket/resin (%)
Group 1	20	2 (10%)	18 (90%)
Group 2	20	1 (5%)	1 (95%)

Table 6 Chi-square test for bracket type and ARI scores

Group number	ARI score 0	ARI score 1	ARI score 2
Group 1	2	13	5
Group 2	1	11	8

Chi-squared, 1.19; df = 2; $p = 0.55$.

Table 7 ARI scores and related force to failure for all specimens

	Specimens with ARI score 0	Specimens with ARI score 1	Specimens with ARI score 2
Number of specimens	3	24	13
Median, N	228	236	249
Lower quartile (25%)	208	199	230
Upper quartile (75%)	254	270	278

for statistical testing. Therefore, it was not possible to test the null hypothesis. The median and inter quartile intervals for the ARI score groups are shown in Table 7.

Discussion

The experiment

The gingivally offset lower premolar bracket has been designed by the manufacturer to reduce bracket failure from occlusal forces. The results of this *ex vivo* study suggest that a gingivally offset lower premolar bracket has a significantly higher force to failure than conventional lower premolar brackets. This difference could be due the greater bracket base area; this bracket has 25% greater bracket base area than the standard bracket. (According to the manufacturer, the bracket base area of the standard bracket is 10.57 mm^2 and that of the gingivally offset bracket is 13.96 mm^2). Previous studies[17] have reported that the bracket base area has minimal effect on bond strength, but this conclusion is based upon the stress at failure and not the force to failure. While failure is initiated when the stress experienced by the bond reaches a critical value, this stress is the result of the trauma force being distributed over the bracket base area. It is the maximum trauma force that can be withstood before failure that is clinically relevant and any comparison of brackets that have different designs should be made using the force to failure as the criterion.

Reynolds[18] has suggested that a minimum bond stress of 5.9 to 7.8 Nmm^{-2} would be adequate for most clinical orthodontic needs. Arguably, it is inappropriate to use stress instead of force to quantify failure that takes place at the resin/bracket interface since this interface is convoluted. Nevertheless, the force is transmitted through the resin to the resin/enamel interface that is considered planar and at which stress to cause failure is the accepted criterion (as, for example, in restorative dentistry).[19,20] Reynolds' stress range is equivalent to a force to failure range of 63–109 N for the brackets used in the present study. The results presented here show that when the debonding force applied in occluso-gingival direction, the force to failure is much higher than this 'recommended' level. When the site of failure is considered, the majority of these were at the bracket/resin interface. This is consistent with other studies[21,22] that have shown that brackets bonded with adhesive resins systems cured with visible light tend to fail at the bracket/resin interface. Though the force to failure showed variability (pooled data — minimum force 125 N, maximum 328 N), overall no relationship was found when the force failure was compared with the site of failure for the two groups, as evident from Table 7. The tensile bond stress has been recommended[23] not exceed 14.5 Nmm^{-2} to prevent enamel fracture. This can be translated to a force to failure of 153 and 202 N for the standard and gingivally offset brackets, respectively. Though such values would result in a low chance of failure (5%), no enamel fractures were seen and the bracket/resin interface was the predominant failure site.

Conclusions drawn from any laboratory test must be applied with caution since it is normal to minimize the number variables through the design of the *ex vivo* experiment to allow the effect of change in a specific variable to be studied. Often, it is possible to simulate conditions that are close to those in clinical use, but the potential for unrecognized factors to modify the outcome should always be borne in mind. Thus, the results of this *ex vivo* force to failure study should be treated as a first positive indication of a superior performance by gingival offset brackets. In the clinical situation, the forces that act on the bracket are more complex.[24] A clinical trial is the logical next step and, in progress, to compare *in vivo* failure rates.

Statistical methods

The statistical methods used were determined by the need to avoid tests that depend upon the normal distribution of the data. A single extreme outlier in one group was on the low side of force required to produce failure. Since a low force for failure would be clinically significant its exclusion could have biased the results towards better performance. In fact, as the subsequent analysis showed, its inclusion or exclusion did not significantly affect the outcome. Medians and distribution-free exact estimates of 95% CI were used to avoid the problems of non-normal distribution for conventional means and parametric confidence intervals. The use of confidence intervals is preferable to statistical testing, since inspection shows whether overlapping intervals exist and, hence, if differences are likely. Certainly, they usefully pointed the way for subsequent analysis.

Failure time and survival analysis statistical techniques are directly applicable to this study, as the force to failure can be treated in the same way as time to failure. The parametric method of the Weibull analysis is preferred in the absence of missing or censored data, but is still to a degree dependent on the goodness of fit of the data to a Weibull distribution. Goodness of fit tests showed adequate, but as is usual with small samples, not great fit. Therefore, a non-parametric survival analysis, Gehan–Wilcoxon tests with Breslow's algorithm was used as well. The Weibull moduli suggest little scattering of the results in the groups not withstanding the outlier. The normalizing parameter (or characteristic force) is a measure of central tendency used in Weibull analysis, instead of the mean and is a more reliable indicator of expected force to failure. Breslow's algorithm was chosen as it is more robust than that originally used by Gehan. All the statistical methods used, confidence intervals, Weibull analysis and survival analysis produced consistent conclusions.

Conclusions

1. There was a significant lower force required to debond conventional brackets when compared with gingivally offset brackets.
2. There was no significant relationship between the ARI scores and the bracket types.

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Contributors

Bikram Singh Thind was responsible for study design, conducting the experiment, data interpretation, drafting of the article and final approval of the article. Colin J. Larmour assisted with protocol of the study and was responsible for preparation of the specimens and proofreading of the article before submission. David R. Stirrups was responsible for the data interpretation, statistical analysis and contributed to the writing of the article. Charles Lloyd was responsible for design of the apparatus and test procedures, supervising the production/commissioning of equipment and contributed to the writing of the article. Bikram Singh Thind and David R. Stirrups are the guarantors.

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