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SCIENTIFIC SECTION

Bonded versus banded first molar attachments: a randomized controlled clinical trial

Philip Banks
Burnley General Hospital Burnley, Lancashire, UK

Tatiana V. Macfarlane
Department of General Practice and Primary Care, The University of Aberdeen, UK

Objective: To compare the clinical failure rates of bonded first molar tubes with those of cemented bands during fixed appliance therapy.

Design: Prospective randomized controlled clinical trial.

Setting: Two UK hospital orthodontic clinics, February 2001–December 2004.

Participants: Hospital waiting list patients needing fixed appliances (n=110).

Method: Patients were randomly allocated to two groups. Experimental group patients (n=55) received single first molar tubes (n=181) bonded with a no-mix chemically cured composite (Rely-A-Bond) after a 30-second etch. Control group patients (n=55) were treated with bands (n=186) cemented with Intact glass ionomer cement (GIC). First-time failures were recorded together with the time of failure. All patients were followed to the end or discontinuation of treatment.

Results: First-time failures: bands=18.8%; bonds=33.7 %. Bonded tubes were more likely to fail [RR 2.4; 95% CI (1.4, 4.1)] compared with bands. Experimental group patients also had more bracket failures (P=0.009), when analysed at patient level.

Conclusion: First molar tubes bonded with Rely-A-Bond composite showed a significantly higher first-time failure rate than bands cemented with Intact GIC.

Key words: Molar bonds, molar bonded tubes, Rely-A-Bond, Intact, randomized controlled clinical trial, molar attachment failure rates

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Introduction

Orthodontists have traditionally preferred to band molar teeth during fixed appliance therapy. In the early years of direct bonding, bonded molar attachments were found to have a high failure rate (up to 30%) when compared with bonding other teeth.[1] More recently, there has been an increase in the popularity of molar bonding, which is more convenient for both patient and clinician. The need for separators and, therefore, antibiotic prophylaxis in patients at risk from bacteraemia is eliminated. In addition, oral hygiene is facilitated as bonded attachments attract less plaque.

Anecdotal evidence suggests that bonded molar tube retention has been improved by better design features, such as foil-mesh bases,[2] optimal wire mesh size (60–70)[3–5] and brazing of mesh to base.[5,6] Tube bond strength has also been improved by use of a 30-second etch time,[7] since molar buccal enamel microstructure has fewer prisms present.[8] Retention is also affected by the complex interaction between different bracket base designs and different cement types which needs further investigation,[9] although there appears to be no relationship between attachment base size and bond strength.[3] This was supported by an audit performed by the authors where mini-twin and standard size brackets exhibited similar failure rates.[10]

Testing *in vitro* has shown a variation in bond strengths for different tooth types, and unexpectedly, mandibular molars showed the highest value,[11] although the validity of such laboratory testing has been questioned.[12] In addition, clinical bond strengths after lengthy orthodontic treatment are significantly lower than bond strengths recorded *in vitro*.[13] Composite is

Address for correspondence: Mr Philip Banks, Orthodontics Department, Burnley General Hospital, Casterton Avenue, Burnley, Lancashire BB10 2PQ, UK.
Email: philbanks_burnly@yahoo.com

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superior to GIC in bracket retention,[14] and light and chemical-cured composite types produce similar bracket failure rates.[15] Band cementation using GIC has produced clinical failure rates from 0.6 to 20% in different studies,[16–20] although different types (resin-modified, light-activated and conventional) of GIC perform equally well.[21] Micro-etching of the fitting surface of bands has been shown to reduce their failure rate significantly,[22,23] although sandblasting molar tubes had minimal effect on their bond strengths.[24]

Other factors which may influence molar attachment failure rates are patient age,[26] different operators,[17,26] treatment mechanics[17] and occlusal stress,[25] but most authors do not specify whether or not bite planes were used to protect molar attachments from this during clinical trials. In one retrospective evaluation of bonded molar tubes, however, bands were placed instead of bonded attachments where occlusal trauma was likely.[26]

To date, there has been a lack of scientific clinical evidence comparing bonded and banded attachments in a randomly controlled trial. Studies report the success of one type of attachment alone and few use a prospective design. In retrospective analyses, bonded molar attachment failure rates varied from 14.8 to 29.5%.[1,25–27] A systematic review of orthodontic adhesives highlighted the lack of good evidence and demonstrated weaknesses of previous research methodology.[28]

The aim of this study was to investigate whether there is a difference in failure rates between bonded and banded first molar attachments.

Null hypothesis tested

That there is no difference in the first-time clinical failure rates of bonded and banded first molar attachments during pre-adjusted edgewise appliance therapy.

Materials and methods

Sample size calculation

The sample size for each group was estimated by the number of first molar attachments required, as this was the unit of measurement. The study was based on demonstrating a 15% difference in first-time molar attachment failure rates between the two groups, which was thought to be clinically significant. To give 80% power and a 5% significance level using a two-sided, continuity corrected chi-squared test (Elashoff JD. nQuery Advisor® Version 5.0, Los Angeles, CA, 2002), a sample size of 226 attachments (113 attachments per group) was calculated as sufficient to detect a difference between a group 1 rate of failure of 10% and a group 2 rate of failure of 25%. To generate 113 molar attachments per group, approximately 40 patients would be required, as the number of teeth per patient would vary due to extractions, missing teeth and other excluded teeth. To allow for treatment discontinuation, we aimed to recruit a total of 100 patients.

On a patient level, when the sample size in each group is 40, a two-group continuity corrected chi-squared test (Elashoff JD. nQuery Advisor® Version 5.0, Los Angeles, CA, 2002) with a 0.05 two-sided significance level will have 86% power to detect the difference between failure rates (at least one failure per patient) of 20 and 55%.

Clinicians and subjects

Treatment was carried out by three experienced specialist clinicians working in two UK hospital orthodontic clinics (consultant, FTTA, community specialist). Three operators were necessary to achieve sufficient patient numbers in a reasonable time period. Patient selection criteria were as follows:

Inclusion criteria:

- patients requiring (with no previous history of) fixed appliances.

Exclusion criteria:

- orthognathic cases;
- patients needing lingual arches and/or headgear;
- molars with buccal restorations or congenital enamel defects;
- patients with a craniofacial anomaly or a relevant medical history that contraindicated the use of bands.

Study design

Ethical approval for the study was granted by both Burnley Pendle and Rossendale (reference LRECBPR 299), and Bury and Rochdale (reference BRLREC 225) Local Research Ethics Committees. Patients were taken consecutively from the departmental treatment waiting lists and consent was obtained. All the patients needed fixed appliance therapy, and no attempt was made to match the patients for age, sex or malocclusion to ensure a representative sample of patients. They were then randomized to either the control (bands) or experimental (bonds) group. This was achieved by one operator (PAB) preparing opaque numbered sealed envelopes in blocks of 10 in advance using random number tables, which enabled stratification on operator and clinic. Each operator enrolled participants and

assigned them to their group using their sealed envelopes, which blinded the operator and participant to the assignment before enrolment. Once the envelopes were opened the blinding was lost.

Molar attachments used

All attachments used were 0.022-inch Roth prescription. Bonded molar tubes were used in the experimental group patients. These were all single non-convertible type ('Peerless', Ormco (Europe) BV, Amersfoort, Netherlands) bonded using a no-mix chemically-cured adhesive (Rely-a-Bond, Reliance, Illinois, USA) after a 30-second etch. For the control patients, non-sandblasted bands (A-Company, Ormco (Europe) BV, Amersfoort, Netherlands) were used, cemented with a conventional GIC (Intact, Ortho-Care (UK), Bradford, UK). These were materials that we had been using routinely in our clinics for several years. All attachments were placed in their correct anatomical position on the tooth. As a result some attachments produced a direct occlusal interference, which may have increased the risk of bond failure.[25] In such cases, a small quantity of GIC was placed on the occlusal surfaces of the mandibular molars to open the bite. Care was taken to ensure that this did not interfere with the molar attachments.

Molar tube bonding technique

- Prophylaxis with pumice/water slurry and bristle brush at slow speed.
- Thorough wash and dry using oil-free air from a 3-in-1 tip.
- Isolation of the bonding surface using a cheek retractor and saliva ejector.
- Etching the enamel surface for 30 seconds using 37% phosphoric acid gel.
- Thorough wash with water and air syringe.
- Isolation of the bonding surface using cheek retractor, saliva ejector and cotton wool rolls.
- Dry with oil-free air to produce a frosted enamel appearance.
- Application of a thin layer of Rely-A-Bond unfilled resin to enamel surface and molar tube base.
- Application of Rely-A-Bond paste to the molar tube base.
- Firm seating of tube and removal of excess paste with a Mitchell's trimmer.
- Composite allowed to set for seven minutes before placing archwire.
- Bonding was performed one side at a time to ensure good moisture control.

Band cementation technique

- Band selected as the smallest size where correct seating was possible using firm pressure from bite sticks and hand seating instruments.
- Tooth prophylaxis with pumice slurry and bristle brush at slow speed.
- Thorough wash and dry using oil-free air from a 3-in-1 tip.
- Isolation of the tooth using cheek retractor, saliva ejector and cotton wool rolls.
- Mixing intact GIC on provided pad according to the manufacturer's instructions.
- Application of cement to the clean dry fitting surface of the band.
- Full seating of the band using bite sticks and hand seating instruments.
- Removal of excess cement using Mitchell's trimmer.
- Cement allowed to set for five minutes before archwire placement.
- One mix of cement was used to attach two bands—both sides of each arch.

Clinical protocols

All patients received similar straight-wire mechanics and archwire sequences as different mechanics may affect the failure rates of molar attachments. Mini-twin 0.022-inch Roth prescription A-Company brackets (Ormco (Europe) BV, Amersfoort, Netherlands) were bonded to all teeth apart from molars using Rely-A-Bond adhesive. Archwire sequences typically included 0.014 and 0.018×0.025-inch superelastic nickel-titanium then 0.019×0.025-inch steel wires. Occasionally 0.018 or 0.017×0.025-inch steel intermediate wires were used before the final archwires where bite opening was problematic. Only first molars were included in the study as there is some evidence that second molars may etch and bond differently[27] and would be unerupted at the start of treatment in many patients. Second molar attachments were not placed unless they were deemed clinically necessary—for overbite reduction or alignment of the second molars themselves. All patients were given verbal and written instructions about diet and care after fitting of the appliances. Finally, we used the Adhesive Remnant Index (ARI) to record the amount of residual composite attached to enamel after bonded tube failures.[29] All patients were followed to the end or discontinuation of treatment.

Record taking

The following data were collected:

- The patient's date of birth and gender.

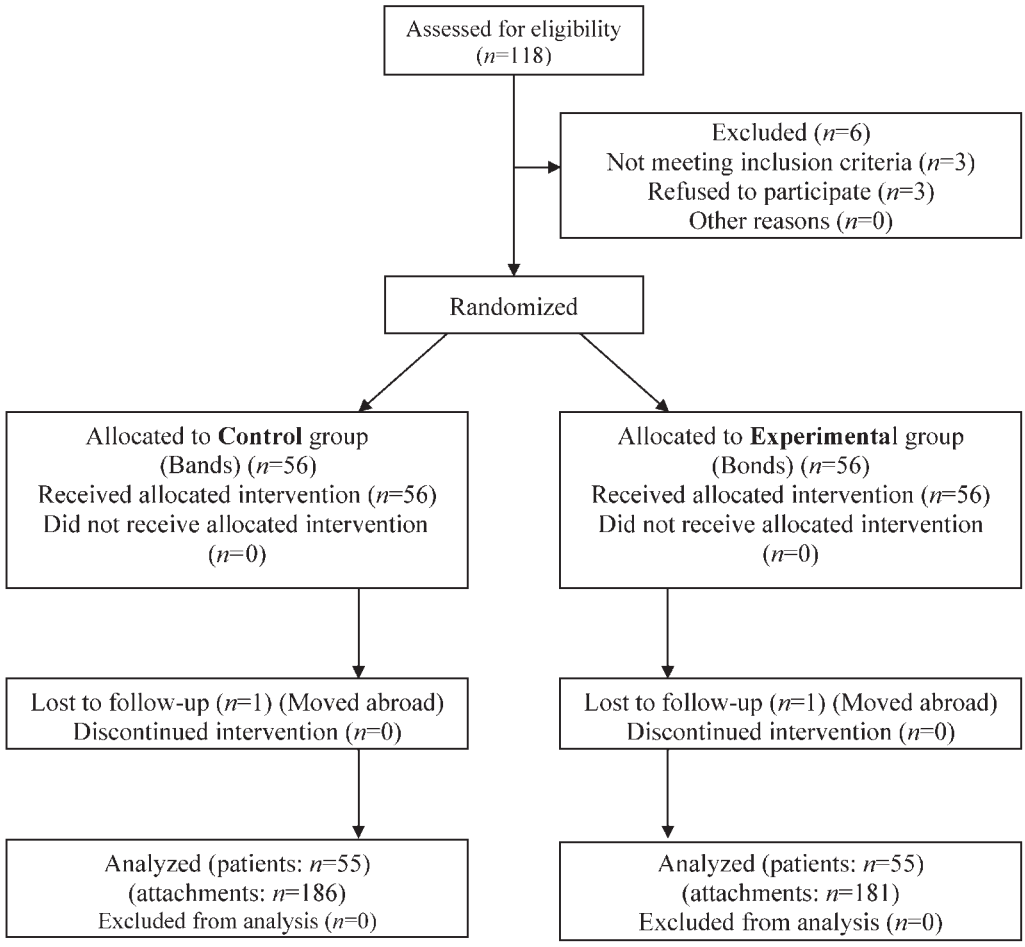

Figure 1 A CONSORT diagram showing the flow of participants through each stage of the trial

- The patient's postcode, to enable assessment of social deprivation using the Townsend deprivation index.[30] From each postcode the corresponding enumeration district was mapped[31] then the following four variables from the 2001 census information[32] for that enumeration district were used: percentage unemployment; percentage overcrowded households, percentage with no car/vans ownership and percentage non home-owners.
- Operator.
- The teeth included in the trial and date of attachment placement.
- Type of malocclusion.
- Date of first-time molar bond or band failures.
- Adhesive Remnant Index (ARI) for bond failures.
- The patient's clinical treatment progress record.
- Date of completion of treatment.
- Date and reason for treatment discontinuation.

Outcome

The first-time failure (detachment or loosening of the attachment) for each tooth was recorded by date and tooth number. Where the patient was unaware of an attachment failure, the date was recorded as the date of the appointment when failure was first noted by the clinician. Subsequent failures for that same tooth were noted but not included in the study.

Primary outcome was attachment failure (tooth level) and secondary outcome was number of failures per patient (patient level).

Statistical data analysis

Statistical data analysis was conducted at both patient and tooth level, and only first-time failures were used in the analysis. Such an approach is useful to permit comparison with previous studies.[28] Analysis of failures

at patient level was made using the Mann–Whitney test. At tooth level the cluster-adjusted chi-square test was performed.[33] The Cox regression proportional hazards model,[34] widely used in survival analysis, was used to estimate relative risk of failure. The Cox's proportional hazards model is defined as:

$$\log_e [h(t)/h_0(t)] = b_1x_1 + b_2x_2 + \ \ldots \ + b_mx_m$$

where $x_1,\ldots,x_m$ are the predictor variables, $b_1,\ldots,b_m$ are the coefficients that are estimated from the data, and t is the time until the event occurred. Hazard function $h(t)$, unknown function of time, is the probability of failure at time t.[34] The hazard function with all the predictor variables equal to zero is $h_0(t)$. The hazard ratio $h(t)/h_0(t)$ is the relative risk of failure occurring at any given time. The assumption that the hazard ratio is proportional over time (the assumption of Cox proportional hazard model) was tested using generalization by Grambsch and Therneau (STATA statistical software Version 9.0., Stata Co., College Station, Texas, USA). To prevent an individual with a high number of failures from having too great an influence on the results, standard errors were adjusted for clustering of teeth within patients.[35]

Results

The flow chart for the trial is presented in Figure 1. One hundred and eighteen patients were identified as suitable (three declined participation), and 115 were randomized and entered the trial. Two patients emigrated during treatment and were lost from the study. Three patients were withdrawn as they did not meet all the inclusion criteria. The number of patients completing treatment was 55, both in the control and in the experimental group (the number of molar attachments placed was 186 and 181, respectively).

The first participant was recruited in February 2001, the last in October 2003 and the study was completed in December 2004.

There were no adverse events or side effects in either treatment group.

Baseline demographic and clinical characteristics of each group are presented in Tables 1 and 2. The participants were between 9 and 33 years of age. The minimum duration of treatment was 7 months and the maximum 41 months.

The overall failure rates for attachments were: bands 18.8%; bonds 33.7% (Table 3), cluster-adjusted chi-square test $P=0.016$, ICC=0.31; 95% CI 0.20, 0.43. Bonded tubes were more likely to fail [RR 2.42; 95% CI (1.41, 4.14)] compared with bands. Figure 2 shows survival functions for the two treatment groups. The

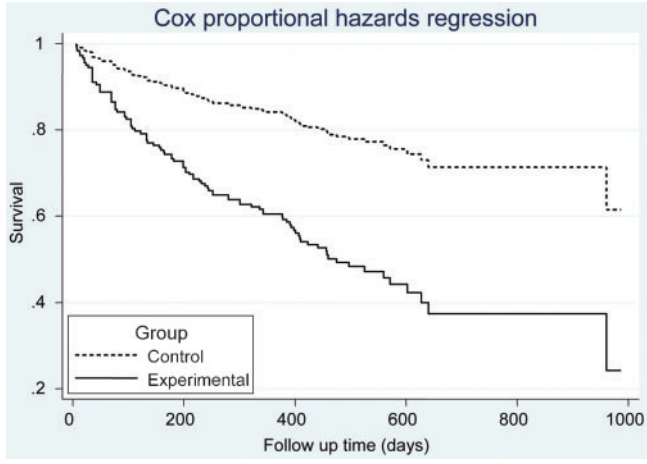

Figure 2 Survival function for each treatment group

Table 1 Distribution of patient characteristics at baseline for each treatment group.

Patient characteristics	Experimental group No. (%) of patients	Control group No. (%) of patients
Total	55	55
Age		
9–12	13 (23.6)	13 (23.6)
13–14	26 (47.3)	25 (45.5)
15–33	16 (29.1)	17 (30.9)
Gender		
Males	23 (41.8)	22 (40.0)
Females	32 (58.2)	33 (60.0)
Deprivation Index (Townsend)		
−4.07; −1.89	15 (27.3)	17 (30.9)
−1.62; 1.03	19 (34.6)	18 (32.7)
1.04; 13.17	18 (32.7)	19 (34.6)
Missing	3 (5.4)	1 (1.8)
Malocclusion		
Class1	23 (41.8)	21 (38.2)
Class II Div 1	21 (38.2)	21 (38.2)
Class II Div 2	3 (5.4)	2 (3.6)
Class III	8 (14.6)	11 (20.0)
Operator		
1	36 (65.5)	39 (70.9)
2	16 (29.1)	12 (21.8)
3	3 (5.4)	4 (7.3)
Duration of follow-up (months)		
7–13	14 (25.5)	14 (25.4)
14–18	22 (40.0)	21 (38.2)
19–41	19 (34.5)	20 (36.4)

Table 2 Distribution of tooth characteristics for each treatment group.

Tooth characteristics	Experimental group No. (%) of bonds	Control group No. (%) of bands
Total	181 (100)	186 (100)
Tooth location		
Upper	109 (60.2)	106 (57.0)
Lower	72 (39.8)	80 (43.0)
Tooth location		
Left	92 (50.8)	94 (50.5)
Right	89 (49.2)	92 (49.5)

experimental group demonstrated a higher rate of failure over the observation period. There was no difference in failure rates between maxillary and mandibular teeth, or between left and right sides. Experimental group patients had more attachment failures (Table 3, $P=0.009$), when analysed on a patient level.

Eighty per cent of the failed bonded attachments had ARI scores of 1 (10% ARI=0; 10% ARI=2). This showed that most failures were a combination of adhesive and cohesive types.

Subgroup analysis was not planned in advance in the protocol although another finding was the evidence of interaction between operator and treatment group ($P<0.05$) at tooth level. Operators 2 and 3 had higher failure rate (48.3%) compared with operator 1 (15.4%), and the effect size was larger for operator 1 [RR 4.22; 95% CI (2.02, 8.86)] compared with operators 2 and 3 ([RR 1.62; 95% CI (0.90, 2.92)].

Attachment failure was influenced by the degree of patient social deprivation (patient level analysis, Kruskal-Wallis test $P=0.0358$) with 64.9% participants from the most deprived backgrounds experiencing at least one failure during the treatment, while only 34.4% of more affluent participants experienced at least one failure. However, statistically there was no evidence of interaction between deprivation and attachment type ($P>0.05$) at tooth level.

Discussion

The main finding of this study was that the failure rate of bonded molar tubes was significantly higher than (almost twice) that seen for bands and the survival time of the bonded tubes was almost half that of the bands. This finding resulted in rejection of the null hypothesis.

Study design

While the study achieved the required sample size, the original sample size calculations did not take into account aggregation of attachments within the participants. The use of clusters (individuals in this case) reduces the power of the trial[33] and multiple testing increases the chance of false positive results, so an increase in sample size is required. Fortunately in this study the number of participants recruited generously exceeded the initial target. Future randomized trials in orthodontics should take these issues into account and increase the required sample size accordingly.

Attachment allocation

Some studies evaluating orthodontic bonding materials have used a 'split-mouth' design where different quadrants are assigned as 'experimental' and 'control' in the same patient. This has the advantage that the patient acts as their own control reducing the influence of compliance. Unfortunately, it is possible that one material may affect the performance of the other and that attachment placement technique will be altered and will not conform to normal clinical practice. In view of

Table 3 Relationship between patient and tooth characteristics and bracket failure.

Outcome	Experimental group	Control group	Effect size and precision
Primary outcome: failure at tooth level	No. (%) of bonds	No. (%) bands	RR (95% CI) #
n (%) of failures	61 (33.7)	35 (18.8)	2.42 (1.41, 4.14)
Secondary outcome: number of failures per patient	No. (%) of patients	No. (%) of patients	
0	21 (38.2)	36 (65.5)	Mann–Whitney test $P=0.009$
1	17 (30.9)	9 (16.4)	
2	8 (14.6)	5 (9.1)	
3	8 (14.6)	4 (7.3)	
4	1 (1.8)	1 (1.8)	

Crude RR here is determined from the Cox regression model taking into account clustering of teeth within each patient. In order to fulfil proportional hazard assumption ($P=0.157$, no evidence to reject the assumption), stratified estimation by age group and operator was performed allowing baseline hazard functions to differ for the groups.

this, patients were randomly allocated to one attachment type only in this study.

Occlusal stress

As discussed above, bonded molar attachments may be more susceptible to failure from direct occlusal stress than bands. To reduce the effect of this, all molar attachments were initially placed out of occlusion by the application of a posterior GIC biteplane when necessary. This is an effective clinical technique, which requires minimal patient compliance. Most authors do not specify if molar attachments were placed out of occlusion, making comparisons with this study difficult. A retrospective assessment of 1190 first molar tubes[26] bonded with Transbond (3M/Unitek, Monrovia, California) revealed a failure rate of 21%, but bands were used on molar teeth if significant occlusal stress was anticipated.

Attachment failure rates

The higher failure rate of the bonded tubes may be related to the much larger surface area available for attachment of bands, and perhaps to the increased difficulty in bonding tubes to molars because of difficult access, moisture control and enamel quality. Previous clinical trials by the authors using the same composite averaged failure rates below 5% for bonding of all teeth excluding molars suggesting that molar bonding is more technique sensitive than bracket bonding. With reference to molar enamel quality, most bond failures in this study were a combination of adhesive and cohesive type and the locations of failure were therefore mixed. The failure rate for bonded tubes in this study was higher than those published earlier.[1,25–27] This may be explained by differences in tubes and adhesives used, different operators, settings and patient samples. The band failure rate seen in this study was within the values in previous reports.[16–20] This may reflect that there is less influence upon band failure rates from these variables.

Patient and operator factors

Attachment failure was influenced by the degree of patient social deprivation in that patients from the most deprived backgrounds experienced over twice as many breakages when compared with those with the least deprivation. Another factor significantly affecting band or bond failure was operator. The difference was surprisingly high since operator 2 had over four-and-a-half times more failures (of all attachments) than operator 1. The reasons for this are not clear, but are probably related to technique and the level of experience. In view of this, personal audit of attachment failures would be a useful exercise for all clinicians. Subgroup analysis, however, should be considered with caution as multiple analyses of the same data create a considerable risk for false-positive findings and analyses that were pre-specified in the trial protocol are much more reliable than those suggested by the data. Additional caution should be applied to the inter-operator comparison as operator 3 recruited significantly fewer patients than operators 1 and 2 therefore reducing the power of the analysis.

Timing of failures

Attachment survival reduced steadily throughout treatment in both groups (Figure 2). This lends support to the recommendations of the Cochrane review that patients should be followed to the end of treatment in trials of orthodontic bonding adhesives.[28]

External validity

The findings of this study have limited external validity and only apply to the attachments and adhesives used—they can only be regarded as baseline evidence using conventional materials. The findings also only apply within our patient inclusion criteria, and to the types of patient typically treated in a district general hospital setting, with treatment which is cost free to the patient. Further randomized trials are to be encouraged using new adhesive materials and attachment designs and in different settings. It is possible that features, such as lower tube profile, hydrophilic primers and latest composite technology would improve molar bonding results.

Clinical implications

The results of this study indicate that the clinical use of Ormco 'Peerless' first molar tubes bonded with Rely-A-Bond cannot be recommended although A-Company bands cemented with Intact provide a satisfactory clinical performance.

Conclusions

- First molar tubes bonded with Rely-A-Bond composite showed failure rates almost double and survival times almost half of those seen for bands cemented with Intact.
- Attachment failure was influenced by attachment type, level of patient social deprivation and operator.
- Personal audit of molar attachment failure rates is recommended for all clinicians. Further clinical trials are indicated to increase the available evidence on this subject.

Contributors

Phil Banks was responsible for the study concept and design, administration, obtaining ethical approval, recruitment and treatment, drafting, critical revision and final approval of the article. Serena Derwent and Yvonne Jones were responsible for recruitment and treatment. Tatiana MacFarlane wrote the section on statistical analysis and was responsible for data analysis, drafting, critical revision and final approval of the article. Jean Wright assisted with the study design. Phil Banks is the guarantor.

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