Survival of bonded lingual retainers with chemical or photo polymerization in orthodontic patients over a 2-year period: A single-center, randomized controlled clinical trial

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Abstract *[Please consult CONSORT for abstracts]*

Introduction: The objective of this "2-arm parallel" trial was to compare the survival rates of mandibular lingual retainers bonded with either chemically cured or light-cured adhesive after orthodontic treatment. **Methods:** Patients having undergone orthodontic treatment at a private orthodontic office were randomly allocated to fixed retainers placed with chemically cured composite or light-cured composite. Eligibility criteria included no active caries, restorations, or fractures on the mandibular anterior teeth, and adequate oral hygiene. The main outcome was any type of first-time lingual retainer breakage; pattern of failure (adapted adhesive remnant index scores) was a secondary outcome. Randomization was accomplished with random permuted blocks of 20 patients with allocation concealed in sequentially numbered, opaque, sealed envelopes. Blinding was applicable for outcome assessment only. Patients were reviewed at 1, 3, and 6 months and then every 6 months after placement of the retainer until completion of the study. Data were analyzed using survival analysis including Cox regression; analysis was carried out after data imputation for subjects lost to follow-up. **Results:** Two hundred twenty patients (median age, 16 years; interquartile range, 2; range, 12-47 years) were randomized in a 1:1 ratio to either chemical or light curing. Baseline characteristics were similar between groups, the median follow-up period was 2.19 years (range, 0.003-3.64 years), and 16 patients were lost to follow-up. At a minimum follow-up of 2 years, 47 of 110 (42.7%) and 55 of 110 (50.0%) retainers had some type of failure with chemically cured and light-cured adhesive, respectively (log-rank test, $P = 0.35$). Data were analyzed on an intention-to-treat basis, and the hazard ratio (HR) was 1.15 (95% confidence interval [CI], 0.88-1.70; $P = 0.47$). There was weak evidence that age is a significant predictor for lingual retainer failures (HR, 0.96; 95% CI, 0.93-1.00; $P = 0.08$). Adhesive remnant index scoring was possible for only 66 of the 102 (64.7%) failures and did not differ between composites (Fisher exact test, $P = 0.16$). No serious harm was observed other than gingivitis associated with plaque accumulation. **Conclusions:** The results of this study indicated no evidence that survival of mandibular lingual retainers differs between chemically and light-cured adhesives. The overall failure rate was 46.4%; however, this included any type of failure, which may have exaggerated the overall failure rate. (Am J Orthod Dentofacial Orthop 2013;■:169-76)

Registration: This trial was not registered.

Protocol: The protocol was not published before trial commencement.

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The guarantee of long-term stability after orthodontic treatment has been a fruitless quest since the specialty began. Posttreatment changes appear to be due to a combination of maturational changes and relapse.[1] Acclaimed research has demonstrated that changes after orthodontics are unpredictable[2,3]; if stability is to ensue, only perfect retention can guarantee this. In view of variable compliance with removable retention regimens, fixed retention has become paramount since its inception in the 1970s,[4] with up to one third of practitioners in the United States and 97% in The Netherlands[5] routinely using mandibular fixed retainers.[6]

Fixed retainers have proven fallible, however, with problems stemming from distortion or residual activity of the wire[7] and the potential for periodontal consequences related to plaque stagnation,[8] although fixed retainers have also shown compatibility with periodontal health.[9] A significant problem continues to relate to bond failures, estimated at 6% to 25%, depending on the placement technique and the observation period.[9-11]

Fixed retainers have evolved from preliminary designs typically involving large-diameter stainless steel round wires (0.030-0.032 in) bonded to the canines, to narrower, braided, or coaxial round wires, or reduced cross-section rectangular wires of various compositions and resilience, bonded to all mandibular anterior teeth.[12,13] More recently, alternatives including fiber-reinforced materials[14-16] and alumina ceramic retainers[17] have been tested. A transition from the routine use of chemically cured composites to placement with light-cured polymerization has taken place over the past 2 decades. Although light-cured materials offer longer working times and improved moisture control, no randomized controlled trial has been published investigating the importance of these theoretical advantages.

Specific objectives or hypotheses

In this study, we aimed to compare the survival of mandibular lingual retainers placed using either chemical or photo polymerization after orthodontic treatment.

METHODS

Trial design and any changes after trial commencement

This was a parallel-group, randomized, active-controlled trial with a 1:1 allocation ratio.

Participants, eligibility criteria, and settings

Consecutive patients who had completed orthodontic treatment with fixed appliances were recruited at the private practice of the first author (N.P.) from April 2009 to November 2010. The following selection criteria were applied: no active caries, restorations, fractures on the mandibular anterior teeth, or periodontal disease; and adequate oral hygiene. Subjects were excluded if they were unwilling to be assigned to any of the approaches or had any abnormal oral or medical condition contraindicating fixed retention. Consent was obtained from the patients (and the parents if the patients were adolescents) before their recruitment. *[No changes to methods after trial commencement occurred.]*

Interventions

After their orthodontic treatment, the patients were seen by their general dentist for supragingival debridement, and the appointment for the lingual retainer was confirmed. All patients received a soft bonded lingual retainer of 0.022-in (Tru-Chrome multi-stranded wire; Rocky Mountain Orthodontics, Denver, Colo) that was fabricated intraorally. A cheek retractor was placed; the lingual surfaces of the 6 mandibular anterior teeth from canine to canine were pumiced, rinsed, dried, and acid-etched with 37% phosphoric acid. The etched surfaces were subsequently rinsed and carefully dried, a cotton roll was placed in the vestibule, and 3 pieces of waxed dental floss were passed through the interproximal surfaces between the canines and the lateral incisors, and between the central incisors, forming loops to stabilize the retainer wire. The wire was passed through the loops; gentle labial traction was applied to the dental floss to secure the wire passively in place. Every effort was made to position the wire passively across the lingual surfaces of the teeth. The enamel surfaces were checked for moisture and redried as required, and small amounts of liquid and paste adhesives were placed on each tooth covering the wire.

In the chemical polymerization group, Maximum Cure 2-part liquid adhesive (Reliance Orthodontic Products, Itasca, Ill) was mixed and applied on the wire and the teeth, and Excel 2-part paste (Reliance Orthodontic Products) was mixed, loaded on a syringe dispenser, and applied. The dental floss was removed after 7 minutes. In the photo polymerization group, a light-cured liquid (Assure; Reliance Orthodontic Products) and paste in 2 layers (Flow-Tain; Reliance Orthodontic Products) were placed on the wire and adjacent enamel and were light cured for 9 seconds per tooth with a plasma light (Ortholite; 3M Unitek, Monrovia, Calif). After placement of the bonded wire, all patients were instructed to maintain meticulous dental hygiene and to visit their dentist every 6 months for monitoring of the periodontal conditions.

Outcomes (primary and secondary) and any changes after trial commencement

The main outcome was any first-time failure of the lingual retainer. The secondary outcome was the pattern

of failure based on the adhesive remnant index (0, no retained resin on tooth surface; 1, <50% retained resin on tooth surface; 2, >50% retained resin on tooth surface; and 3, all resin retained on tooth surface).[18]

The patients were advised to visit the orthodontist initially at 1, 3, and 6 months after retainer placement, followed by scheduled appointments at 12, 18, and 24 months after the initial placement of the bonded retainer to evaluate its integrity. In case of breakage, the patients were instructed to call and visit the office immediately. The subsequent appointment to review the retainer was scheduled in advance to ensure regular follow-up; reminders were sent in case of appointment failures. When scheduled appointments were unfeasible, particularly approaching the end of the trial, an assessment of retainer integrity was made over the telephone. During the telephone interview, the patient was asked to the best of his or her knowledge whether the lingual retainer was intact and bonded on all teeth, loose on any tooth, or completely lost. When breakages were reported, it was not possible to assess the adhesive remnant index score. There were no outcome changes after trial commencement.

Sample size calculation

Calculation of sample size was based on the ability to detect a clinically relevant difference in the risk of first-time failure (primary outcome) of 20% between the 2 trial arms (15% vs 35% with $\alpha = 0.05$ and power of 85%). Foek et al[19] found a 35% failure rate for light-cured lingual retainers; we used this value as our reference for the sample calculation. This calculation indicated that 93 participants were required in each arm; this was rounded up to 110 to account for losses to follow-up.

Interim analyses and stopping guidelines

Not applicable.

Randomization (random number generation, allocation concealment, implementation)

Randomization was accomplished using the "*-ralloc-*"[20] command in Stata software (StataCorp, College Station, Tex) in random permuted blocks of 20 patients, ensuring equal distribution in the 2 groups. Allocation concealment was achieved with sequentially numbered, opaque, sealed envelopes containing the treatment allocation cards, which were prepared before the trial. Baseline information was written on the outside before opening the envelope. The practice manager was responsible for opening the next envelope in sequence and implementing the randomization process.

Blinding

Blinding of either patient or operator was not possible; however, assessment was blind because it was not possible to distinguish between the treatment groups.

Statistical analysis (primary and secondary outcomes, subgroup analyses)

Comparisons of the survival of lingual retainers bonded with the 2 techniques were carried out with statistical methods for survival analysis. The log-rank test was used and Kaplan-Meier plots were produced. Hazard ratios (HR) and associated 95% confidence intervals (CI) were calculated using Cox regression modeling. The Nelson-Aalen plot was used to assess the proportional hazards assumption. Missing outcome data were imputed using the variables intervention type, sex, and age. Imputation was performed under the Missing At Random (MAR) assumption, ie, assuming that given intervention type, sex, and age, the distribution of outcome was the same whether or not we were able to observe it. Imputations were implemented using the "*-mi-*" family of commands adapted for Cox regression. Adhesive remnant index scoring between composites was compared using Fisher exact test. All analyses were conducted with Stata software (version 12.01; StataCorp).

RESULTS

Participant flow (include flow diagram, early stopping and time periods)

Two hundred twenty patients (median age, 16 years; interquartile range, 2 years; range, 12-47 years) were randomized in a 1:1 ratio to either chemical or light curing; 16 patients were lost to follow-up (Fig 1). Patient recruitment commenced in April 2009 and ended in November 2010.

Baseline data (include baseline table)

At baseline, information regarding age, sex, Angle classification, and gingival index was collected,[21] and a subjective 3-level score of cooperation (poor, average, or good) was assigned to each patient based on the practitioner's impressions during the orthodontic therapy.

Baseline characteristics were similar in both groups (Table I) with a median follow-up period of 2.19 years (range, 0.003-3.64 years; Table II).

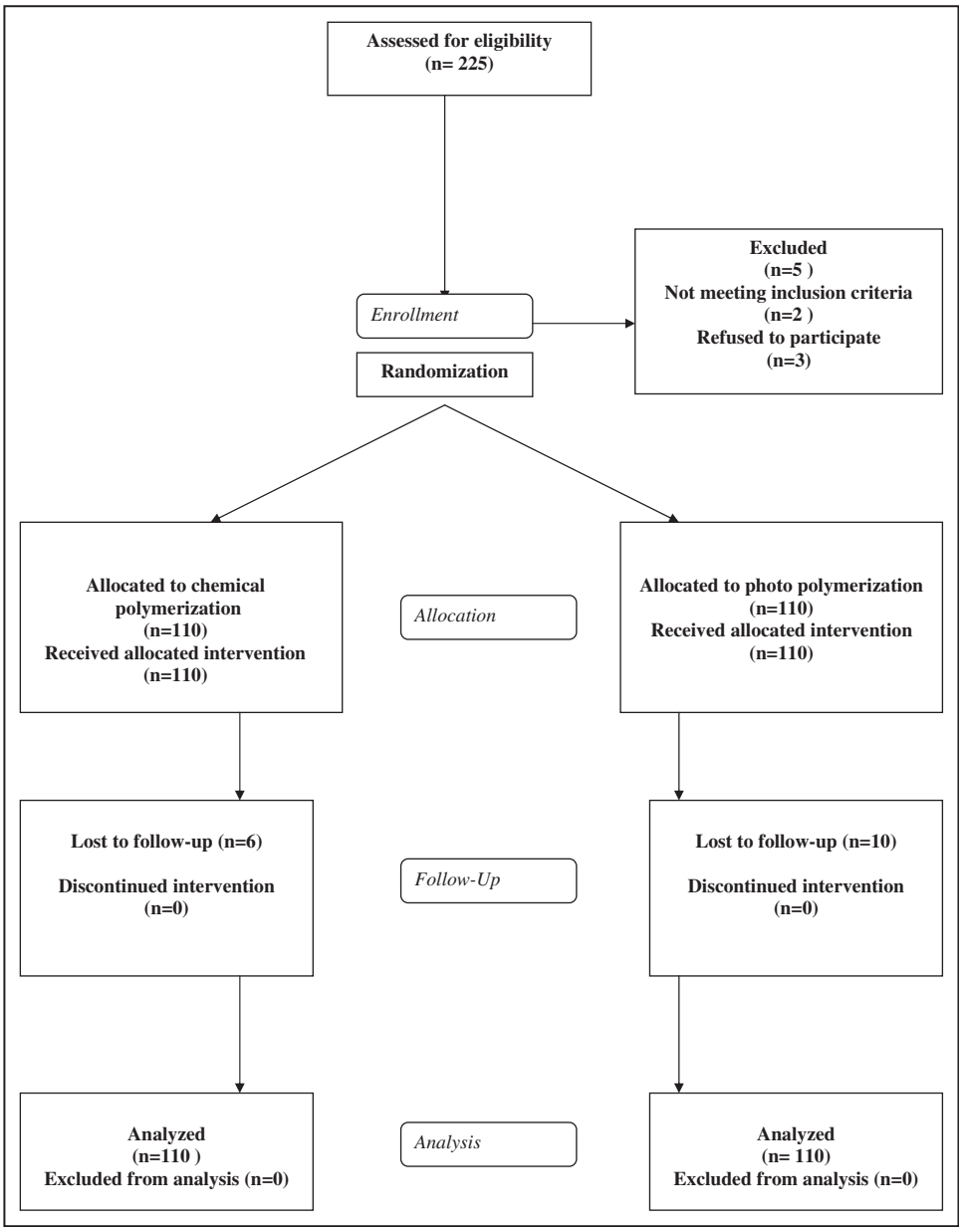

Fig 1. CONSORT flow chart showing patient flow during the trial.

Numbers analyzed for each outcome, estimation and precision, subgroup analyses

Two years after entry of the final patient, 47 of 110 (42.7%) and 55 of 110 (50.0%) retainers bonded with chemically cured and light-cured adhesive, respectively, had failed (risk difference, 7.3%; 95% CI, −5.9% to 20.5%). The primary analysis was carried out on an intention-to-treat basis involving all patients randomized after imputation of missing data.

The proportional hazards assumption was satisfied; the Kaplan-Meier survival plots with patients at risk as a function of time for chemically and light-cured lingual retainers are shown in Figure 2. No statistical difference in failures was observed between treatment groups (log-rank test, $P = 0.35$). The HR with the imputed data was 1.15 (95% CI, 0.88-1.70; $P = 0.47$). There was weak evidence indicating that age might be a significant predictor of lingual retainer failure (HR, 0.96; 95% CI, 0.93-1.00; $P = 0.08$;

Table I. Baseline characteristics of patients in each treatment group

	Total n = 220 *Median or %*	*IQR*	*Excel n = 110* *Median or %*	*IQR*	*Flow-Tain n = 110* *Median or %*	*IQR*
Demographic characteristics						
Age (y)	16.0	15-17	16.0	15-17	15.0	15-17
Sex						
Female	72.7		71.8		73.6	
Male	27.3		28.2		26.4	
Clinical characteristics						
Gingival index	1.5	1-2	1.3	1-2	1.5	1-2
Cooperation						
Bad	26.4		27.3		25.5	
Average	55.9		59		52.7	
Excellent	17.7		13.7		21.8	
Angle Class						
I	59.2		56.4		62	
II	39		40.9		37	
III	1.8		2.7		1	

IQR, Interquartile range; *Excel*, chemically cured adhesive; *Flow-Tain*, light-cured adhesive.

Table II. Number of failures (%), total follow-up periods in person-years per treatment group, median follow-up periods, and ranges

Risk factor	*Total number (%)*	*No. of failures observed (%)*	*Follow-up period in person years*	*Median (y)*	*Range (y)*
Adhesive					
Excel	110 (50)	47 (42.7)	206.30	2.22	0.003-3.64
Flow-Tain	110 (50)	55 (50.0)	201.68	2.16	0.005-3.58

Excel, Chemically cured adhesive; *Flow-Tain*, light-cured adhesive.

Table III). Imputed analysis gave similar HRs with both analyses (Table III); the data with no imputations assumed that all missing observations were censored. Adhesive remnant index scoring was possible for only 66 of the 102 (64.7%) failures and did not differ between composites (Fisher exact test, $P = 0.16$); most confirmed failures occurred at the enamel-adhesive level (Table IV).

Harms

No serious harm was observed other than gingivitis associated with plaque accumulation.

DISCUSSION

Main findings in the context of the existing evidence, interpretation

This trial attempted to compare the survival of mandibular lingual retainers bonded with either chemically cured or light-cured adhesive in patients after orthodontic treatment by randomizing 220 patients equally between the 2 adhesive groups. Although no significant difference in retainer failure rates was noted, the numbers of recorded failures were considerable, ranging from 43% to 50% over a 2-year period after debonding. This preponderance of failures is compatible with a recent prospective study investigating failure rates of fixed retainers, with 38% reported over a 6-month period.[22] However, lower failure rates have also been demonstrated in other prospective studies.[23-25] A recent long-term retrospective study with a large group of patients (n = 221) showed that 24% had at least 1 failure over a 2-year retention period, whereas 14% had at least 1 failure during the next 3 years.[26] The retrospective nature of this study, however, might have underestimated the failures. Nevertheless, it appears that fixed retainers are not a panacea; further work is required to make the process more predictable.

The absence of a significant difference in bond failure rates between chemical and light-cured materials ensures that extraneous factors should be considered when deciding which material to use. Certainly, light-cured materials have the advantage of controlled working and setting times; it would be intuitive to expect this to lead to a reduction in breakages because of the enhanced control and the reduced risk of moisture contamination, but this was not confirmed in our investigation. Although the setting time of the

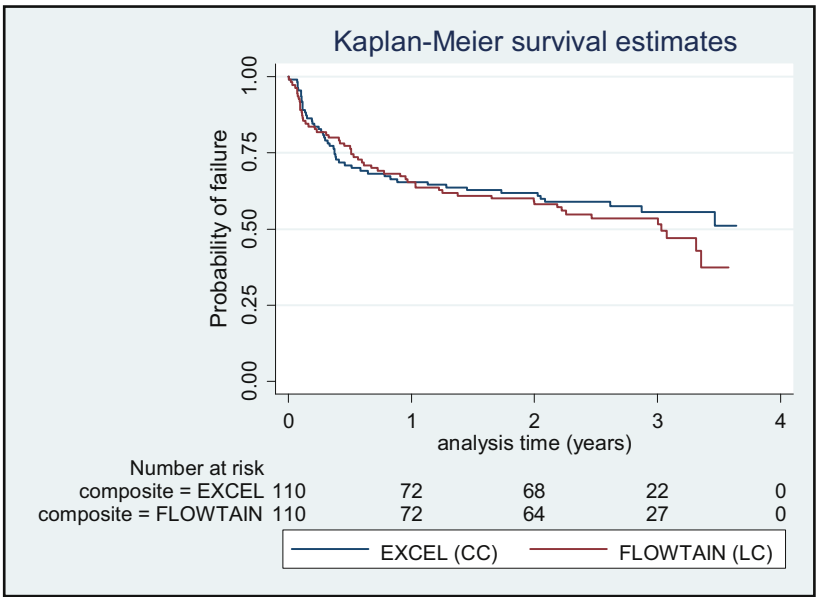

Fig 2. Kaplan-Meier survival plots by type of adhesive.

Table III. Hazard ratios from Cox regression for type of adhesive adjusted for age using imputed data for unobserved failures from losses to follow-up and censoring for unobserved failures

Risk factor	*Hazard ratio imputed (95% CI)*	P *value**	*Hazard ratio observed (95% CI)*	P *value**
Adhesive				
Excel	Referent		Referent	
Flow-Tain	1.15 (0.88-1.70)	0.47	1.16 (0.78-1.72)	0.44
Age (per year)	0.96 (0.93-1.00)	0.08	0.97 (0.93-1.01)	0.09

Excel, Chemically cured adhesive; *Flow-Tain,* light-cured adhesive.
*Wald test.

Table IV. Adhesive remnant index (ARI) scores for the 66 failures

	Adhesive		
ARI score	*Excel n (%)*	*Flow-Tain n (%)*	P *value (Fisher exact test)*
0	27 (64.3)	18 (75.0)	
1	15 (35.7)	5 (20.8)	
2	0 (0.0)	1 (4.2)	
Overall	42 (100.0)	24 (100.0)	0.16

Excel, Chemically cured adhesive; *Flow-Tain,* light-cured adhesive.

chemically cured material is longer, there is no requirement to wait for a complete set as is the case before engaging a wire after bonding the brackets. Therefore, from an office-management perspective, the longer setting time of the chemical-cure material is less important for bonded retainers than for bonding fixed appliances. In these instances, the cure might even be more efficient, considering the relatively long photo-irradiation times.

It was possible to ascertain the mode of failure of the bonded retainer in only 65% of the failures; however, a predilection for failure at the enamel-adhesive junction was noted. Failure at this boundary could indicate problems relating to moisture control and contamination of enamel during the bonding procedures. This pattern of failure is, however, common to most retainer bonding regimens.[27,28] No significant difference in failure mode was found between the bonding regimens. In this study, only first-time failures were included. This approach circumvented statistical issues pertaining to clustering of failures within subjects. However, no differentiation was made between catastrophic and relatively minor failures, with all breakages and detachments considered to be overall failures. This universal approach was chosen because even minor failures or small breakages can promote plaque accumulation or discoloration, therefore needing repair. Hence, we considered all types of material deterioration as failures. This is a major difference between this

study and previous ones, in which only complete detachments were regarded as failures. Consequently, it is possible that the effects of trivial breakages might be overstated in our study. The incisor irregularity developing in both groups as a consequence of retainer breakages was not considered in this study. However, it is inevitable that breakages will result in a degree of irregularity at some point, during either the short term or the long term, irrespective of the mode or magnitude of the failure.[26]

Our relatively high failure rate is difficult to explain. It might be related to the prospective design and the relatively lengthy follow-up. Similarly, any breakage was recorded as such; therefore, even minor fractures of little consequence, which might have been overlooked in other retrospective studies, were recorded as failures in this study. Of the 66 failures clinically confirmed, 28 involved 1 tooth; minor breakages of this nature are likely to be undetected in other study designs. In relation to the bonding technique, plasma curing lights were used in this study; a recent systematic review concluded that there is no statistical difference in bond failure risk with plasma, light-emitting diode, or halogen lights.[29] Consequently, this is unlikely to have been influential. It could be speculated that residual stress might be associated with single-tooth failures, since wire fabrication was performed intraorally and might have precluded placement of a wire in an entirely passive configuration. Previous research has indicated that retainer failures are related to operator experience; it is therefore reasonable to assume higher failure rates for less experienced operators.[30] Nevertheless, we believed that the selection criteria were strict, yet our subjects represented typical orthodontic patients in a specialist's practice setting.

The advantages of this study include the randomized treatment allocation accounting for balanced baseline characteristics between treatment groups and thus a low risk of selection bias.

Limitations

Although blinding of the operator was not feasible at the intervention stage, outcome assessment was blind; therefore, the risks of observation and detection biases can be considered low. Additionally, the prospective nature of the study allowed for better examination of the frequency and patterns of failure compared with retrospective studies for which data are likely to be less accurate because the data are often collected from patient files. Our study's limitation might be that it was not possible to examine all patients to inspect the failures, particularly near the end of the study. This issue is particularly problematic in studies of retention procedures because patients consider active treatment completed and are often reluctant to return for appointments. This shortcoming risks causing information bias because minor failures might have been undetected by patients who were interviewed over the telephone. This inability of patients to correctly determine failures might underestimate the risk of minor failures of bonded lingual retainers. Only 16 patients were lost to follow-up, and potential attrition biases were counteracted by analyzing data on an intention-to-treat basis, which incorporated missing data imputations. The losses to follow-up highlight a problem associated with randomized controlled trials and, in general, prospective studies with long follow-up periods, and should be seriously considered at the design stage of the trial.

Generalizability

The generalizability of these results might be limited because this research was undertaken in a single center by 1 clinician (N.P.) experienced in both chemically cured and light-cured bonding.

CONCLUSIONS

Based on this randomized trial, there is no evidence that the use of either chemical or light-cured composite is associated with a difference in failure rate or failure mode of bonded lingual retainers.

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