### A Comparative Clinical Trial of a Compomer and a Resin Adhesive for Orthodontic Bonding

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Abstract: The study aimed to compare the survival time and cariostatic potential of a compomer to that of a resin adhesive when used to bond stainless steel orthodontic brackets to labial segment teeth only. The effect of the patients' sex, age at the start of treatment and presenting malocclusion on bracket survival time was assessed also. Forty-five consecutive patients who attended for fixed appliance therapy were randomly selected. Four hundred twenty-six brackets were bonded (213 with compomer and 213 with resin adhesive) with a split mouth design; the right or left side allocation of compomer in either arch was alternated. Color transparencies of the maxillary incisors, mandibular incisors, or both, and transparencies of the canines, were taken before treatment. At the debond stage, the transparencies were projected  $(20\times)$ and assessed by an experienced examiner, who used a caries index. The survival time distributions for brackets bonded with each bonding agent were not significantly different (P = .74, paired Prentice-Wilcoxon test; P = .75, Akritas test), with bracket failure rates of 17% and 20% recorded for compomer and resin adhesive, respectively. Neither the patients' sex (P = .85) nor malocclusion (P = .26) appear to affect significantly bracket survival, but patient age was identified as a useful prognostic indicator of bracket survival (P < .001). On average, there was more decalcification related to brackets bonded with resin adhesive than with compomer (P = .0075). Survival time distributions of brackets bonded with compomer or resin adhesive appear comparable, but decalcification was reduced significantly by bonding with compomer. (Angle Orthod 2000;70:233–240.)

Key Words: Clinical trial; Compomer; Resin adhesive; Survival analysis; Decalcification

#### INTRODUCTION

Since the introduction of acid etching of enamel by Buonocore,<sup>1</sup> direct bonding of orthodontic brackets to teeth with resin adhesives<sup>2</sup> has been adopted routinely as part of fixed appliance placement.<sup>3–5</sup> Over the past 3 decades, adhesive formulations have been modified such that currently 2-paste systems<sup>6</sup>, no-mix adhesives<sup>7</sup>, light-activated direct bonding materials, <sup>8,9</sup> and adhesive precoated brackets<sup>10,11</sup> are available for bracket bonding. Enamel loss during prophylaxis,<sup>12</sup> acid etching,<sup>13</sup> and debonding,<sup>14</sup> in addition to

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the caries risk imposed by plaque accumulation around the bracket in individuals with poor oral hygiene,<sup>15,16</sup> have led to a search for alternative bonding agents for bracket attachment.

Glass ionomer cements offer some potential in this regard. These materials have attracted considerable attention as orthodontic bonding agents because they adhere to metal and enamel,<sup>17</sup> often without the need for acid etching<sup>18</sup>; there is less enamel damage at postdebond clean-up<sup>19</sup>; and they have the ability to release<sup>20</sup> and absorb<sup>21</sup> fluoride, thereby preventing decalcification.22 However, because conventional glass ionomer cements have weaker bond strengths compared with resin adhesives, hybrid materials comprising glass ionomer and composite components have been developed more recently, and these appear to offer improved potential for bracket bonding.18 One group of hybrid cements is the polyacid modified composites, or compomers,<sup>23,24</sup> formed by combining composite resin and fluoride silicate glass into a single component composite resin. Compomers are also capable of fluoride release<sup>25</sup> and uptake,<sup>26</sup> but to a lesser degree than that of conventional glass ionomer cements, and they may therefore confer some protection against development of decalcification around bonded attachments.27

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Laboratory<sup>28–30</sup> and short-term clinical<sup>27,31</sup> evaluations have demonstrated the potential of the compomer, Dyract Ortho (DeTrey, Dentsply, Konstanz, Germany) as a bonding agent with cariostatic potential.<sup>27</sup> However, the efficacy of the latter was assessed only after 1 month in conjunction with withdrawal of the major source of extrinsic fluoride through use of a nonfluoride dentrifice.<sup>27</sup> To date, there have been no comparative clinical studies of the performance of brackets bonded with a compomer versus those bonded with a resin adhesive over the entire course of orthodontic treatment. Nor has the cariostatic effect of a compomer been compared with that of a resin adhesive over such a time period.

As decalcification is of greater aesthetic concern if it affects labial segment teeth, the aims of this study were to compare the survival time and cariostatic potential of compomer to that of resin adhesive when used to bond brackets to labial segment teeth only. The effects of patients' sex and age at the start of treatment and the effect of the patients' malocclusions on bracket survival were assessed also. The null hypothesis tested was that there was no difference in bracket survival through treatment or decalcification after treatment for teeth bonded with either bonding agent.

#### MATERIALS AND METHODS

Right-On (T.P., La Porte, Ind), a no-mix resin adhesive, was used as the control material, and Dyract Ortho (DeTrey, Dentsply, Konstanz, Germany), a light-cured 1-component compomer resin, was the test agent. The latter product, formed by combining a composite resin with a glass ionomer cement, is supplied in sealed ampoules from which it is applied to the bracket base. It hardens only through photopolymerization but takes up water after its initial set, which triggers an ionic-acid base reaction and leads to the formation of hydrogels in the resin structure.

Following ethical approval, 45 consecutive patients who required upper, lower, or both upper and lower fixed appliance therapy were randomly selected. Each had a normal complement of teeth in the upper, lower, or both labial segments with a plaque score<sup>32</sup> of  $\leq 10\%$  at initial assessment. Informed written consent to participate in the trial was given by all patients or their parent or guardian. Prior to bracket bonding, the teeth were cleaned with a nonfluoridated prophylaxis paste, washed with water, and dried in a stream of compressed air. Following insertion of 1-piece self-retaining cheek retractors (Dentaurum K.G, Ispringen, Germany), the labial or buccal enamel surface was etched with 37% orthophosphoric acid liquid applied by a sponge pledget for 15 seconds, washed with water for 60 seconds, and then dried with compressed air. Isolation was maintained with cotton rolls and a high-vacuum saliva ejector. All bonding procedures were carried out by 1 clinician with several years' experience. Brackets (0.022 in Mini Twin Roth prescription; 3M Unitek, Monrovia, Calif) were bonded to teeth in the upper, lower, or both labial segments according to a split mouth design, with the right or left side allocation of compomer in either arch made alternately. Four hundred twenty-six brackets were bonded in 45 patients, half with compomer and half with resin adhesive. Brackets were bonded with each bonding agent according to manufacturer's instructions. Once the brackets had been positioned firmly on the tooth, great care was taken to ensure that excess bonding material was removed from around the bracket via a sharp probe. The compomer was then cured for 40 seconds (20 seconds each from the incisal and gingival aspect of the brackets) while the resin adhesive was allowed to cure for 5 to 7 minutes. Elsewhere in each mouth, brackets were bonded to premolars with resin, and bands were cemented to molars with glass ionomer cement (AquaCem, DeTrey, Dentsply, Germany).

Initial aligning archwires (0.012 or 0.014 in Nitonol; 3M Unitek) were tied into the bracket slots following completion of bracket bonding. Verbal and written instructions regarding appliance care were issued to each patient, along with a specific request to return if a bracket became loose or if any problem arose with the appliance. Each patient was instructed to brush with a fluoride-containing dentifrice after each meal for the duration of treatment. Forty-one patients brushed with their right hand, and 4 patients brushed with their left hand. A fluoride mouthwash (Fluorigard; Colgate-Palmolive Ltd., Guildford, UK) was issued after placement of all fixed appliance components, and each patient was instructed to maintain its use throughout treatment. Review visits were scheduled at 4- to 6-week intervals.

A similar archwire sequence and approach to treatment mechanics was adopted for each case. Bond failures were recorded accurately in the patient's case record, with the time of bond failure identified as the date when bond failure was noticed. From the hospital record file of each case, the following information was recorded: date of placement of each bonded bracket in the upper, lower, or both labial segment, including the bonding agent employed for each; date of birth and sex of the patient; and the presenting malocclusion based on the incisor relationship. A code was assigned to each bonded bracket, indicating that it survived the course of treatment (censored, code 1), was lost to follow-up because of patient transfer (withdrawn, code 2), or had debonded (failed, code 3).

To assess decalcification, all 6 upper and lower anterior teeth (canine through canine) were recorded photographically, with 3 separate views for upper and lower labial segment. Photographs were taken before treatment and immediately after debond. On both occasions, the labial enamel was recorded in the wet state since this is the manner in which it is perceived in social interaction. Views were taken in a standardized way on Ectachrome 64 color transparency film with a Nikon F3 camera with a 135-mm lens at full bellows extension with a multiblitz ring flash. Each transparency was coded, arranged randomly, and projected  $(20\times)$  on to a screen for 20 seconds in a darkened room. One examiner, an experienced epidemiologist, made an independent assessment of decalcification on each tooth with a modification of the scoring system of Geiger et al,<sup>33</sup> adopted previously by Marcusson et al<sup>22</sup> as follows: 1 = slight white spot formation; 2 = severe white spot formation; and 3 = excessive white spot formation (cavitation). The examiner was unaware of which teeth had been bonded with either bonding agent. To assess intraexaminer reliability, scoring took place on 2 occasions separated by a 2week interval to eliminate memory bias. The order of projection of the transparencies was changed on the second occasion.

#### Statistical analysis

Where a single bonding agent is used for a patient in a clinical trial, survival analysis may be undertaken conventionally on a single bracket per patient, assuming that all observations are independent of each other. In the present paired study (ie, 2 bonding agents were used in each mouth), any method of analysis which assumes independence (ie, the log-rank test and standard Cox proportional hazards models) may be unsuitable. In order to take account of the possible dependent structure of the data, 2 different paired log-rank tests and 2 extensions to the Cox proportional hazards model<sup>34</sup> were used. The failure time of each bonding agent group was compared initially for the bonding agent alone and finally incorporated all other covariates (ie, age, sex, and presenting malocclusion).

### Comparison of time to bracket failure: the effect of bonding agent alone

An overall subjective impression of the data may be gained by Kaplan-Meier curves, looking separately at the time to first failure of each bonding agent; 2 different paired log-rank tests (the paired Prentice-Wilcoxon test and the Akritas test<sup>34</sup>) were used to formally test for a difference in survival.

#### The separate effects of sex, age, and malocclusion

To gain insight into these factors, the paired survival data were summarized for each individual by looking at the time until first failure (ignoring the bonding agent used). In order to visually assess the separate effect of each categorical covariate (ie, sex and malocclusion) on the time to bracket failure time, Kaplan-Meier curves were presented. One method to assess the effect of a continuous covariate is to recode the continuous covariate into a small number of categories chosen to best display the true effect of the covariate. The categorization process could be based on previous clinical research. If, however, such classification information is not available, a tree-based approach for survival data could be considered. Regression trees for survival data (ie, continuous data with censoring) have been proposed<sup>35</sup> in order to elicit high-risk subgroups. In general, tree-based techniques are used to identify important prognostic groups, but in the application proposed here, the tree-based analysis is used to suggest suitable cut points for recoding the continuous covariate. The log-rank test was used to determine if there was any suggestion of a significant effect on failure time of sex, malocclusion, and the tree-based age categories.

## The combined effects of bonding agent, sex, age, and malocclusion

Extensions to the Cox proportional hazards model,<sup>36</sup> building on the paired nature of the data, were used to assess the joint effects of bonding agents employed, controlling for patient sex, age, and malocclusion type. The marginal model initially fits an independent proportional hazards model and corrects the variance postfit. The stratified model allows each patient to define a separate stratum. The random effects (or frailty model) incorporates a random effect for each pair (assumed to be gamma distributed) into the proportional hazards model that represents the degree of association between measurements of a pair.

#### Assessment of decalcification

Where a bracket bonded with compomer debonded during treatment, the bracket was rebonded with resin adhesive. This practice was adopted to prevent the introduction of a fresh resource of ionic fluoride to the teeth bonded initially with the compomer. Consequently, in view of the paired nature of the study design, the tooth associated with the failed bracket and its opposite number in the same arch were removed from the assessment of decalcification. In total, 294 teeth, half bonded with compomer and half with resin adhesive, were compared. To assess the intraexaminer reliability in caries assessment, a kappa statistic was used; guidelines for its interpretation were suggested by Landis and Koch.<sup>37</sup> Moderate agreement was identified (kappa = 0.59).

For each patient, the average decalcification score was calculated for each bonding agent, and the difference between these taken as a suitable summary of the difference in decalcification produced by the 2 bonding agents for that patient. A sign test was then used to analyze the differences in average decalcification scores and to assess whether the median levels of decalcification differed for the 2 bonding agents tested.

#### RESULTS

#### Comparison of time to bracket failure

Details of the sample, including the number of bracket failures for each malocclusion type, are given in Table 1.

TABLE 1. Sample Characteristics for 426 Bonded Brackets<sup>a</sup>

Number of patients (13 male subjects; 32 female subjects)	45
Median age at start of treatment, y	14.4
(lower quartile, 13.7 years; upper quartile, 15.5 years)	
Number of patients per malocclusion type	
Class I	20
Class II, division 1	16
Class II, division 2	6
Class III	3

<sup>a</sup> Of the 426 bonded brackets, 213 were bonded with compomer and 213 with resin adhesive.



FIGURE 1. Stratified Kaplan-Meier estimates of the survivor function for each bonding agent.

Seventeen patients had no bracket failures for either of the 2 bonding agents, whereas 15 patients had failures with both. Seven patients had bond failure with Right-On but not with Dyract Ortho, and 6 patients had bond failure with Dyract Ortho and not with Right-On. In total, 80 brackets debonded, 37 having been bonded with compomer and 43 with resin adhesive, representing failure rates of 17% and 20% respectively, an overall bond failure rate of 19%.

#### The effect of bonding agent alone

The median time to first failure of brackets bonded with compomer was 546 days compared with 526 days for brackets bonded with resin adhesive, where the median time to first failure is the time when 50% of patients would have had at least 1 bracket failure. There was no significant difference in the failure pattern for brackets bonded with either compomer or resin adhesive (P = .74, paired Prentice-Wilcoxon test; P = .75, Akritas test; Figure 1).

### The effect of patient sex, patient age at start of treatment, and malocclusion type

Stratified Kaplan-Meier plots for each of these factors are shown in Figures 2 through 4. Neither patient sex (P = .85) nor malocclusion (P = .26) appear to have a significant effect on bracket survival, despite male subjects' appearing to have slightly longer survival times than female subjects,



FIGURE 2. Stratified Kaplan-Meier estimates of the survivor function for patient sex.



FIGURE 3. Stratified Kaplan-Meier estimates of the survivor function for patient age (determined with a tree-based analysis).



FIGURE 4. Stratified Kaplan-Meier estimates of the survivor function for patient malocclusion type.

and patients with Class II division 2 malocclusion appearing to have the shortest bracket survival times.

A tree-based analysis that used the log-rank test as a splitting criterion suggested 2 age risk groups—that is, under 15 years and older than 15 years. The effect this categorization of age has on bracket survival is clear from the stratified Kaplan-Meier plot displayed in Figure 3 and has an associated P value of .014.

	Regression		Exp (β) (95% Confidence	
Model	Coefficient β	ese (β)	Interval)	P Value
Marginal PH	0.05	0.27	1.05 (0.6–1.7)	0.86
Stratified PH	0.33	0.36	1.38 (0.7–2.8)	0.37
Gamma frailty	0.11	0.32	1.11 (0.6–2.1)	0.74

TABLE 2. Estimated Bonding Agent Type Effect ( $\beta$ ) While Controlling for Age for Each Model Fitted

## The combined effects of bonding agent, sex, age, and malocclusion

A patient's age was the only useful prognostic factor with respect to bracket survival (P < .001), and there was no strong evidence that the failure time distribution was different for the 2 bonding agents when correcting for age (Table 2), regardless of the analysis technique we used.

#### Decalcification

Before treatment, only 9 teeth, 2% of a total of 408 available, in 4 patients had a score of 1; all other teeth had a score of 0. The overall distribution of posttreatment decalcification scores by tooth position for teeth bonded with compomer or resin adhesive is given in Table 3, and the frequency of difference in average decalcification scores shown in Figure 5. It is important to note, however, that statistical comparisons in decalcification between teeth bonded with each bonding agent were not based on this overall data but on the mean difference in decalcification scores between each bonding agent per patient. There is evidence that on average, there is more decalcification with resin adhesive than with compomer (P = .0075).

#### DISCUSSION

The performance of 426 brackets (213 bonded with compomer and 213 bonded with resin adhesive) has been examined over the entire duration of fixed-appliance therapy.



FIGURE 5. Histogram for difference in average decalcification scores (compomer minus resin adhesive).

Although the influence of bracket-base design4,38 and bracket position in the arch<sup>3-6,9,38,39</sup> have received considerable interest with regard to the clinical performance of orthodontic bonding agents, less attention has been focused on the effects of patient sex and age at the start of treatment and the effect of the presenting malocclusion on bracket failure.7,8,33,36 In addition, few studies have used survival analysis for data evaluation,<sup>5,7,8,39,40</sup> most reporting solely on the failure rate of a specific bonding adhesive without reference to the importance of time to failure afforded by these more sophisticated analyses. The use of a split mouth design to evaluate 2 bonding agents is particularly useful in that both adhesives are subjected to the same environmental insults<sup>22,27,39,41,42</sup> and is therefore especially pertinent in the additional analysis of intraindividual differences in decalcification between the bonding agents tested.<sup>22</sup> This design for the latter purpose may also be justified, as topically applied fluoride has been shown mainly to act locally,43 although slight crossover may occur via saliva.44 The paired nature of the data from a split mouth design, however, requires more incisive statistical handling than traditional survival analysis can offer. No previous study in the ortho-

TABLE 3. Distribution of Posttreatment Decalcification Scores According to Tooth Position and Experimental Group

	Decalcification score, n (%)						
_		Compomer			Resin A	dhesive	
Tooth Position	0	1	2	0	1	2	3
13	14 (87.5)	2 (12.5)	0 (0)	9 (64.3)	3 (21.4)	2 (14.3)	0 (0)
12	8 (72.7)	3 (27.3)	0 (0)	6 (42.9)	3 (21.4)	5 (35.7)	0 (0)
11	12 (100)	0 (0)	0 (0)	10 (83.3)	1 (8.3)	0 (0)	1 (8.3)
21	10 (83.3)	2 (16.7)	0 (0)	12 (100)	0 (0)	0 (0)	0 (0)
22	7 (50)	6 (42.9)	1 (7.1)	6 (54.6)	5 (45.4)	0 (0)	0 (0)
23	9 (64.3)	4 (28.6)	1 (7.1)	15 (93.8)	0 (0)	0 (0)	1 (6.2)
33	13 (86.7)	2 (13.3)	0 (0)	8 (80)	1 (10)	1 (10)	0 (0)
32	12 (92.3)	1 (7.7)	0 (0)	7 (77.8)	2 (22.2)	0 (0)	0 (0)
31	14 (100)	0 (0)	0 (0)	16 (85.7)	1 (14.3)	0 (0)	0 (0)
41	7 (100)	0 (0)	0 (0)	12 (85.7)	2 (14.3)	0 (0)	0 (0)
42	9 (100)	0 (0)	0 (0)	11 (84.6)	2 (15.4)	0 (0)	0 (0)
43	9 (90)	1 (10)	0 (0)	11 (73.3)	4 (26.7)	0 (0)	0 (0)

dontic literature appears to have undertaken paired survival analysis despite available data,<sup>38</sup> presumably in view of the complexities that this poses. Nor have the effects of independent variables on attachment survival been assessed or the predictors of bracket survival been identified by these means.

#### **Bracket survival**

The median first failure time of brackets bonded with a light-cured compomer (Dyract Ortho) was 546 days and was not significantly different from the 526 days recorded for brackets bonded with a chemically cured resin adhesive (Right-On). Interestingly, these results support the claims of an in vitro study,<sup>29</sup> which predicted that these bonding agents would be likely to perform similarly in vivo. The median survival times recorded in this clinical study, however, are longer than the median survival time of 442 days reported in a retrospective study of brackets bonded with the light-cured resin, Transbond<sup>45</sup> (3M Unitek).

As the same operator undertook all the bonding procedures in the study reported here, the only other variable likely to account for the rather high bracket failure rate recorded is the bracket base area. Mini-Twin brackets (3M Unitek) were used, and their smaller bonding base (as compared with standard size bases) with cut grooves may partly explain the increased bracket failure rate, as this base design has previously been shown to exhibit a greater failure rate than a meshed foil base.38 However, there was no significant difference in the failure rate of brackets bonded with compomer (17%) or resin adhesive (20%). The comparable clinical performance of these 2 adhesives mirrors the performance of light-cured, resin-modified glass ionomer cement (Fuji Ortho LC; GC Corp, Tokyo, Japan) and a chemically cured resin adhesive<sup>41</sup> (System 1 and composite bonding resin; Ormco Corp, Glendora, Calif). However, the failure rates reported for these materials in the latter study were 3.3% and 1.6%, respectively, but the observation time was only 12 months. In a study extending over the full course of orthodontic treatment, the bracket failure rates are likely to be greater. In a prospective randomized clinical trial over the full course of orthodontic treatment, Norevall et al<sup>38</sup> reported a bracket failure rate of 36% with a conventional glass ionomer cement and 15% with diacrylate. Miller et al<sup>40</sup> also found bracket failure rates of 55% and 23% with a conventional glass ionomer cement and resin adhesive, respectively. The failure rates reported in these studies for brackets bonded with composite resin compare favorably with the failure rates reported for both bonding agents used in the present study. As compomer is more akin to a resin adhesive than to a glass ionomer cement, it is not surprising that its clinical performance as a bracket bonding agent is similar also.

There was no significant difference in bracket survival between male and female patients, which confirmed the finding of Norevall et al.<sup>38</sup> However, significant differences have been reported by Shammaa et al<sup>39</sup> between bracket survival distributions of male and female subjects for brackets bonded with Fuji Ortho LC (GC Corp), but this trend was not apparent with a chemically cured resin adhesive,<sup>7</sup> supporting the results of the present study.

With respect to malocclusion type, no significant difference was observed for either bonding agent, confirming the findings of other retrospective<sup>45</sup> and prospective<sup>39</sup> studies, although there was a trend for patients with Class II division 2 malocclusion to exhibit a shorter bracket survival time. This trend has been observed previously<sup>45</sup> and may reflect the increased likelihood of bracket failure early in treatment in this malocclusion group because of the increased overbite.

#### Decalcification

The percentage of teeth affected by decalcification at debond was significantly different for compomer (20%) and resin adhesive (26%), indicating the greater efficacy of the compomer in the prevention of white spot lesions than the control material. This difference occurred despite the use of fluoride toothpaste and the recommended use of a fluoride mouthrinse throughout the trial period, both of which will replenish the fluoride reserves of the compomer.<sup>25,26</sup> The findings of the present study appear to confirm the potential of compomer as a cariostatic agent, a property highlighted recently in a 36-month evaluation of its clinical performance in pediatric dental practice.<sup>46</sup>

Marcusson et al<sup>22</sup> also found significantly fewer white spots on teeth bonded with glass ionomer cement (24%) compared with those bonded with diacrylate (40.5%) over an 8- to 39-month treatment period. The higher incidence of white spots in that study compared with the present study may relate to the difference in treatment time (mean treatment time in the present study was 21.3 [SD 6.6] months) and that no additional fluoride treatment other than fluoride toothpaste was prescribed. Studies on fluoride-releasing composites,47,48 which are likely to have behavioral similarities to compomers, have also demonstrated a significant reduction in decalcification with these materials compared with resin adhesives, but the study by Mitchell<sup>49</sup> found no such difference. Variations in treatment times and additional preventive measures are most likely to account for the different findings of these studies. Only 1 study,<sup>50</sup> one in which brackets were bonded with a resin-modified glass ionomer cement (Fuji Ortho LC; GC Corp), reported no decalcification at debond, although in that study, the observation time, the method of assessment of decalcification, and whether or not fluoride supplements were prescribed were not specified.

On the basis of the results presented here, the survival time of brackets bonded with compomer appears comparable to those bonded with a resin adhesive, but compomer has the added benefit of appearing to confer less decalcification at debond.

#### CONCLUSIONS

There was no significant difference in first failure time distribution for brackets bonded with either compomer (Dyract Ortho; median 546 days) or a no-mix resin adhesive (Right-On; median 526 days), with bracket failure rates of 17% and 20% respectively.

Neither patient sex nor presenting malocclusion had any significant effect on the time to first failure of brackets bonded with either bonding agent, but patient age at the start of treatment was identified as a useful predictor of bracket survival for each bonding agent.

Labial segment teeth where brackets were bonded with compomer exhibited significantly less decalcification immediately after debond than those in which brackets had been bonded with resin adhesive.

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