



ORIGINAL ARTICLE

Survival rate of indirectly bonded brackets using single vs. two-component orthodontic adhesive: A 12-month split-mouth clinical trial

Federica Pellitteri ^{*}, Francesca Cremonini ¹, Marco Bellavia ¹, Mario Palone ¹, Luca Lombardo ¹

Postgraduate School of Orthodontics, University of Ferrara, Ferrara, Italy

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Abstract Objective: Compare the bonding survival rate of two distinct bonding materials: Ortho Solo + Gradia LoFlo Resin and single component GC Ortho Connect.

Materials and Methods: Indirect bonding fixed appliance treatment was required for 26 consecutive patients, 8 males and 18 females, with a mean age of 22.1 +/- 4.2 years. All patients were treated with SWM (Straight-Wire Mirabella) technique (Sweden and Martina, Due Carrare, Padova, Italy). Each patient's bonding process followed a contralateral pattern. Firstly, a 37 % orthophosphoric acid etching gel was used for 20 s, subsequently the single or two components light-cured adhesives were applied through a split-mouth cross-arch procedure. The patients underwent a 12-month follow-up period and brackets failures were rebounded, but not further included in the study. Statistical analysis was performed to analyse the survival rate of the bonding materials and the influence of the variables, with a significant level of $\alpha = 0.05$.

Results: The GC Connect group was used on 349 teeth, while the Ortho Solo + Gradia group was used on 351 teeth, and the indirect debonding rate was respectively 17.5% and 12.8%. With respect to the total sample, statistically significant values were found for both sex and dental arch. The bracket's survival rate for incisors, canines, premolars and molars was not significant. However, a higher debonding rate was clinically appreciable in upper and lower molars.

* Corresponding author at: Via Luigi Borsari, 46, Ferrara 44121, Italy.

E-mail addresses: federica.pellitteri@hotmail.it (F. Pellitteri), francesca.cremonini@edu.unife.it (F. Cremonini), marcobellavia.ss@gmail.com (M. Bellavia), mario.palone88@gmail.com (M. Palone), dott.lulombardo@gmail.com (L. Lombardo).

¹ Via Luigi Borsari 46, 44121, Ferrara, Italy.

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Conclusion: In a 12-months observation period, considering all maxillary and mandibular teeth the indirect survival rate for the group GC Ortho Connect and Ortho Solo + Gradia was respectively 82.5% and 87.2%. Although the difference was not significant, a pronounced tendency to debonding for the single component group was appreciable from a clinically point of view.

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1. Introduction

Composite resin used for brackets bonding was first proposed by Newman et al. (1965) and represents nowadays the standard bracket of bonding. However, bond failure still represents a common concern in fixed orthodontics.

The bonding procedure is extremely important for the outcome of orthodontic therapy. Manufacturers propose the use of fluid primers to physically adhere to the etched enamel prisms and to establish orthodontic bonding.

However, it's uncertain how primers improve the adhesion of orthodontic brackets to the enamel surface (O'Brien, 1991). Indeed, various researchers pointed out that a chemically cured/light-cured composite could provide sufficient bonding strength for orthodontic bracket adhesion (Lou, 2009; Ok, 2021; Tang, 2000).

In a recent systematic review, a 0.6–28.3 percent of bracket failure was recorded (Almosa, 2018). However, in daily orthodontic clinical practice should not exceed 6% (Brown, 2009; Cal-Neto, 2009; Grünheid, 2018; Khan, 2022; Mavropoulos, 2003).

The different bond strengths of the adhesives employed, in addition to the presence/absence of primers coated on the tooth surface, could be reasons for brackets debonding (Northrup, 2007).

Primers, according to prior studies in the literature, can improve bond strength (Ok, 2021). However, any bonding agent that is less moisture sensitive under clinical conditions, may significantly lower the bond failure's rate. As a result, chairside time, overall treatment duration and its economic impact for the clinician can be significantly reduced (Ok, 2021; Wenger, 2008). Moreover, multiple patient factors generally affect the incidence of bond failure, which include oral hygiene, jaw (maxilla or mandible) (Hammad, 2013; Khan, 2022; Ok, 2021; Sukhia, 2019), group of teeth (incisors, canines, premolars, and molars) (Grünheid, 2018; Hammad, 2013; Khan, 2022) and gender (Grünheid, 2018; Hammad, 2013; Khan, 2022).

Due to the large number of bonding materials on the market and controversy in the literature according to the use of primer to promote adhesion, the current study's goal was to compare the bonding survival rate of two distinct bonding materials: Ortho Solo (Ormco, Orange, CA, USA) + Gradia LoFlo Resin (GC orthodontics, Breckerfeld, Germany) and single component GC Ortho Connect (GC orthodontics, Breckerfeld, Germany).

The null hypothesis is that there is a difference in survival rate between bonding material GC and Orthosol + Gradia. Moreover, any difference between the dental arches, group of teeth, males and females was analyzed.

2. Materials and methods

The study design was a single blinded, split-mouth, cross-arch prospective trial in a single center.

After the approval of the scientific ethics committee of the University of Ferrara (approval number 7/2021), 26 consecutive patients of the orthodontics department were recruited from 30 October 2019 to 8 May 2021.

As regards the sample size, the following the formula was applied:

$$z^2xp(1-p)/e^2/1 + (z^2xp(1-p)/e^2N$$

where z is the z-score confidence interval, e is the margin error, p is the expected proportion (0.05) and N is the population size. It is possible to use a 90% confidence interval for the total sample with an 11% margin of error.

Patients who received upper and lower fixed appliances as part of their treatment and agreed to participate in the trial were considered eligible. Patients undergoing orthognathic and/or extractive orthodontic treatment were included in the study. On the other hand, Patients with congenital enamel defects, multiple buccal restorations with hypomineralization, temporo-mandibular disorder were excluded from the study.

All patients were treated with SWM (Straight-Wire Mirabella) technique with a 0.022×0.028 -inch metallic slot dimensions in a modified MBT prescription.

To eliminate operator's bias, each patient's bonding process followed a contralateral pattern in a split mouth modality: quadrants 1 and 4 were selected to receive the Orthosolo universal bonding primer with Gradia LoFlo resin composite, while the contralateral quadrants (2–3) received the single component GC Ortho Connect composite.

Firstly, isolation of the arches takes place by placement of the Nola dry-field system (Micerium S.p.a, Avegno, Germany). All teeth were cleaned with coarse, oil-free pumice for 10 s with a manual handheld rubber prophylaxis cup, then washed and dried with an air–water syringe for 5–10 s before bonding. A 37 % orthophosphoric acid etching gel was used for 20 s, followed by a thorough rinsing for another 15 s and dried for another 20 s with the air–water syringe before being evaluated for a frosty appearance.

The brackets were positioned by the same operator (L.L.) with medium–soft, transparent, broad-coverage transfer trays fabricated using CAD-CAM (Fig. 1) (Palone, 2023). In Orthosolo + Gradia group, Orthosolo primer was placed in a very thin layer to the enamel's surface and pushed along it for 5 s before being syringed into the etched prisms and light-cured for 5 s with an LED polymerization lamp (VALO, Ultradent, South Jordan, USA). Gradia resin composite was then placed directly to the bracket mesh and light-cured for



Fig. 1 The isolation of the operative field and insertion of CAD-CAM transfer trays in the correct position.

a total of 10 s. The techniques for single-component orthodontic adhesives were identical in the GC group, with the exception that no primer was used and the GC Ortho Connect composite was used instead of Gradia. The transfer trays are inserted into the mouth by the use of tweezers. Once the composite is cured, the transfer trays are removed, applying pressure from the palatal side of the tray to avoid the bracket debonding.

The same clinician tied a 0.016-inch CuNiti archwire with a metallic 0.010-inch ligature for all patients. Following the placement of the appliances, the patient was given verbal and written instructions on diet and care. The absence of pre-contact was verified and occlusal bite raisers were used on the first upper molars when needed.

The patients underwent monthly recalls for a 12-month follow-up period and all events related to bracket failure were recorded in patient reports and collected. Brackets failures were rebonded, but not further included in the study.

2.1. Statistical analysis

A univariate descriptive analysis was carried out.

A Mann-Whitney test was performed to see if there was a statistically significant difference in survival rate with respect to the variables sex and dental arch.

The non-parametric Kruskal-Wallis test was used to analyze the survival rate between groups of teeth.

The survival curves of Kaplan Meir of the tooth survival rate were created and the Logrank test was used to evaluate any statistically significant difference between the two.

Finally, a Cox regression was performed using as a dependent variable the bracket debonding and as independent variables the sex, bonding material, the dental arch and the group of the tooth.

An alpha significance level of 0,05 has been used in all these analyses.

The IBM SPSS Statistics software in version 28 was used for statistical data analysis.

3. Results

In total, 26 patients, 8 males and 18 females with a mean age of 22.1 +/- 4.2 years participated to the study. The follow-up term was 12 months for all patients, with a 1-month period between the appointments.

The descriptive analysis of the sample is given in [Table 1](#). A total of 700 teeth were evaluated. The GC Connect group was used on 349 of them, while the Ortho Solo + Gradia group was used on 351, considered respectively the 49,9% and 50,1% of the total sample ([Table 1](#)).

With respect to the total sample, the p-value of the Mann-Whitney test is statistically significant for both sex ($p < ,001$) and dental arch ($p = ,002$) variable. From [Fig. 2A](#) and [2B](#) it is assumed that, respectively, the survival rate is greater in women and for the teeth belonging to the upper arch. The p-value of the Kruskal Wallis test ($p = ,114$) that describes the bracket's survival rate in the groups of teeth was not significant, indicating the average survival rate is equal for all groups of teeth. The total sample's size survival rate was analyzed through the Kaplan Meier test ([Table 2](#)), being slightly longer for the Ortho Solo + Gradia group. However, the Logrank test revealed this difference was statistically not significant ($p = ,076$).

Cox's regression analysis showed that at least one of the variables taken into account affects the survival rate of the brackets ([Table 3](#)). Indeed, sex ($p = < ,001$), dental arch ($p = ,001$) and group of teeth ($p = ,021$) were statistically significant. Specifically, if the patient is a male, the probability of debonding increases by 109%; if the tooth belongs to the upper arch compared to the lower one, the probability of debonding is reduced by 63,9%; if the tooth is a molar compared to a canine, this increases by 117,5% ([Fig. 3A, B, C](#)).

4. Discussion

Today, some one-step orthodontic adhesives, such as GC Ortho Connect, do not require the use of a primer, because this bonding paste contains phosphoric ester monomer, which adds stable bond.

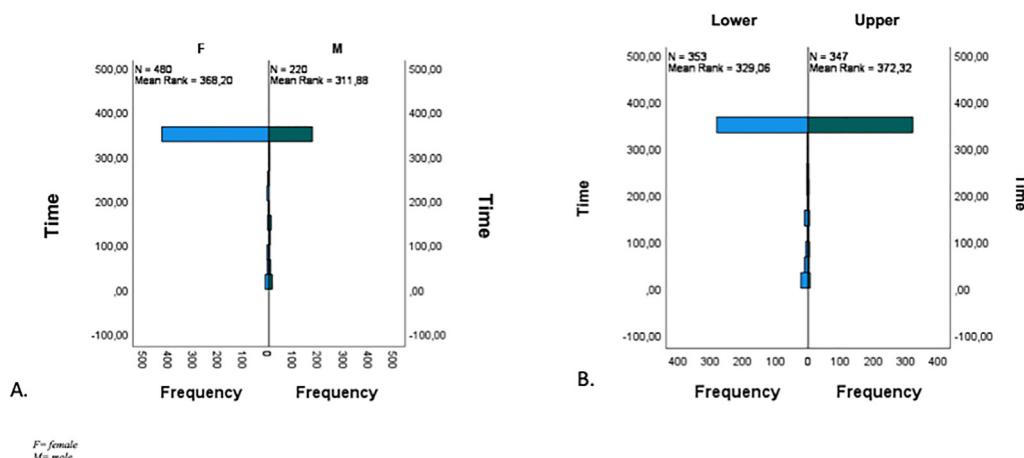
The reduction of chair time is also achieved by using indirect bonding with digital planning. Indeed, the literature demonstrates that the advantage of indirect bonding is not only the reduction of bracket bonding procedure, but also reduces total treatment duration as it minimizes the need for rebracketing reducing the finishing phase and making the orthodontic treatment more efficient. On the other hand, indirect bonding has some disadvantages. If total time is considered, the clinical and digital programming time is significantly greater than traditional direct bonding, which in turn leads to increased costs ([Brown, 2009](#); [Palone, 2023](#)).

The employment of primers remains a controversial issue in the literature. In vitro studies have shown that employing Ortho Solo as a primer improves bond strength, lowering in vivo bond failure rates in clinical practice ([Wenger, 2008](#)). Ortho Solo was also found to be more successful than a standard primer in an in vitro bond strength investigation that evaluated the effect of moisture contamination ([Wenger, 2008](#)).

The bond survival rates obtained in this study were 82.5 % for the GC Connect group and 87.2 % for the Ortho Solo + Gradia group, for a total average of 84.9 % of the total population. Although the GC group has a higher detachment rate, the difference between the two groups is not statistically significant or clinically relevant. Bond failure rates of less than 10% are typically regarded clinically acceptable ([O'Brien, 1991](#)); however, due to the different bonding materials, research designs and follow up durations, it is harder to

Table 1 Descriptive analysis of the two study groups analyzed.

	N Total	Percent (%)	N Debonded	Percent (%)	N Not Debonded	Percent (%)
GC Connect	349	49,9	61	17,5	288	82,5
Ortho Solo + Gradia	351	50,1	45	12,8	306	87,2
Total	700	100,0	106	15,1	594	84,9%

**Fig. 2** A. The Mann - Whitney graph of the survival rate of bracket with respect to sex. B. The Mann - Whitney graph of the survival rate of bracket with respect to the dental arch.**Table 2** Kaplan Meier survival rates (days) for the two study groups.

	Total N	Mean			
		Estimate	Std. Error	95 % Confidence Interval	
				Lower Bound	Upper bound
GC Connect	349	322,424	5,565	311,516	333,332
Ortho Solo + Gradia	351	337,291	4,441	328,586	345,995
Overall	700	329,879	3,569	322,883	336,874

Table 3 Cox's regression analysis.

Variable	Significance
Sex (females vs males)	< ,001*
Bonding material (Gc vs Orthosolo + Gradia)	,074
Arch (lower vs upper)	< ,001*
Teeth groups (canines)	,003*
Incisors	,763
Molars	,021
Premolars	,386

*p less than 0,05.

identify a direct comparison between trials (Bayar, 2020; Krishnan, 2017; Littlewood, 2000; Mandall, 2002).

Ok et al. found that, excluding the first permanent molars, the control group had a 9.0% failure rate and the single component experimental groups had 8.0% and 10.3% failure rates

in the 12-month follow-up period. According to the findings of the current investigation, using single-component orthodontic adhesives to bond brackets had no effect on bracket failure. Furthermore, Nandhra et al. reported an 11.2% debonding rate with primer and a 15.8% single component debonding rate. Our findings, on the other hand, invalidated the findings of Wenger et al. in an in-vivo study, who found that using primers resulted in significantly lower bonding rates, with an overall bond failure rate of 12%.

Although the debonding rate of this study is slightly deviates from the values reported in the literature, this can be explained in the selection of inclusion criteria. Initial malocclusion severity may have increased bracket failure, as extractive and orthognatic cases were also included.

Although previous studies (Hitmi, 2001; Nandhra, 2015; Sukhia, 2019) confirmed that the patient's gender did not influence failure rates, the survival rate was higher for females in the current study. Specifically, if the patient is a man, the debonding rate increases the 109%. These results are in line with the study of Hammad et al. who reported a statistically

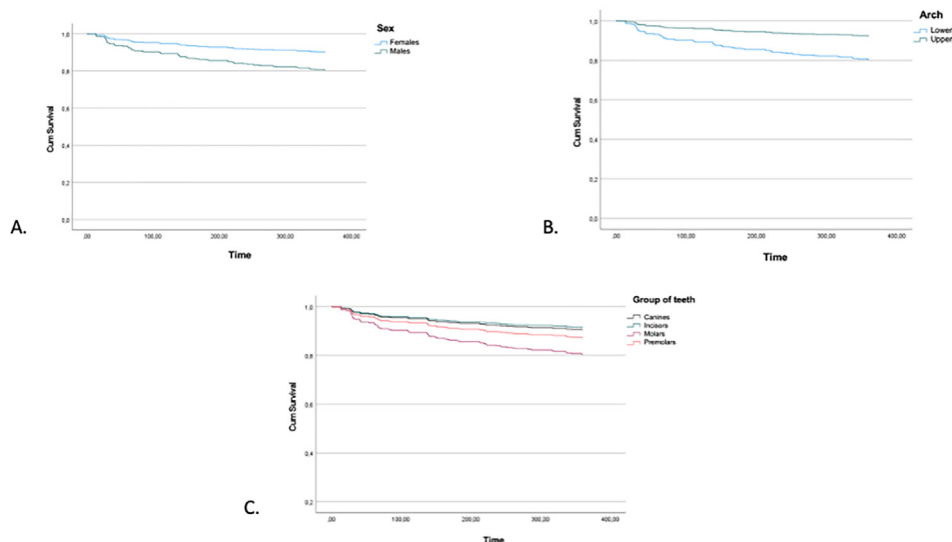


Fig. 3 A. Kaplan Meier curve of the bracket's survival rate with respect to sex. B. Kaplan Meier curve of the bracket's survival rate with respect to the dental arches. C. Kaplan Meier curve of the bracket's survival rate with respect to the groups of teeth.

significant differences between sexes, with a failure rate of 6,4% for males and 1,4% for females; and the study of Khan et al. that confirms that more than 50% of the debondings occurred in his study are of male patients. The difference between males and females could be attributed to various factors, including oral hygiene, the attention in avoiding food that causes debonding and the strength of the chewing mixtures that is generally greater in males (Khan, 2022).

The impact of dental arch on orthodontic bracket survival rate was also investigated, with statistically significant higher failure rates in the mandibular arch than in the maxillary arch. This finding is in line with other researches published in the literature (Khan, 2022; Koupis, 2008; Menini, 2014; Bherwani, 2008). This could be attributed to the lower arch receiving increased masticatory forces related to possible precontact, impact from the upper teeth cusps, and worse bonding due to saliva contamination. In addition, for the same reason, it is explained why among different groups of teeth (incisors, canines, premolars and molars), molars are the ones which underwent the greatest number of debondings. Indeed, although the Kruskal Wallis test claims that the debonding occurred uniformly for the group of teeth during the 12 months of study, the Cox's regression test yielded an increase in the probability of debonding of 117,5% if the tooth is a molar compared to a canine. Bherwani et al. found a statistically significant increase in failure rates in the posterior region compared to the anterior area, which is consistent with our findings. On the other hand, Khan et al. found that the majority of failures occurred two times more frequently in the posterior teeth than in the anteriors, particularly in the lower second premolars.

Since this study was conducted at a single center by a single clinician who was familiar with both adhesives and just one bracket system, the results' generalizability may be restricted. Because the materials were bonded and handled by the same operator, interoperator variability was eliminated.

Furthermore, split-mouth experiments are that the data acquired is not completely unbiased; since all brackets are inserted in the same archwire, what happens to a half arch can reasonably affect what happens in the opposite half.

Future directions of this study could evaluate the bracket survival rate using single vs. two-component orthodontic adhesive in different malocclusions, such as differences between hypodivergent or hyperdivergent patients, Class II or Class III malocclusions. In addition, another future study could evaluate the debonding rate in a split mouth study between digital indirect bonding and direct bonding, with the aim of assessing whether the procedure may affect the brackets survival rate.

5. Conclusions

1. The null hypothesis was rejected. No significant differences were shown between the two bonding materials analyzed.
2. Considering all maxillary and mandibular teeth in a 12 months observation period, the indirect survival rate for the group GC Ortho Connect and Ortho Solo + Gradia was respectively 82.5% and 87.2%. The variables sex and dental significantly affected the debonding rate. Indeed, an increased percentage was observed in males and in lower arches.

CRedit authorship contribution statement

Federica Pellitteri: Conceptualization, Software, Investigation, Resources, Data curation, Writing – original draft, Writing – review & editing. **Francesca Cremonini:** Conceptualization, Methodology, Investigation, Data curation, Writing – review & editing, Visualization, Supervision, Project administration. **Marco Bellavia:** Conceptualization, Methodology, Validation,

Project administration. **Mario Palone:** Conceptualization, Methodology, Validation, Investigation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration. **Luca Lombardo:** Conceptualization, Methodology, Validation, Investigation, Writing – original draft, Writing – review & editing, Visualization, Supervision, Project administration.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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