Resin-modified glass ionomer cement vs composite for orthodontic bonding: A multicenter, single-blind, randomized controlled trial

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Introduction: In this study, we aimed to compare the incidence of new demineralized lesions and bond failures between 2 groups of participants wearing fixed orthodontic appliances bonded with either light-cured resin-modified glass ionomer cement or light-cured composite. **Methods:** This trial was a multicenter (6 centers: 2 teaching hospitals, 4 specialist orthodontic practices), single-blinded, randomized controlled trial with 2 parallel groups. Patients aged 11 years or older, in the permanent dentition, and about to start fixed orthodontic treatment in these 6 centers were randomly allocated to have either resin-modified glass ionomer cement or light-cured composite for bonding brackets, forward of the first molars. Pretreatment and day-of-debond digital photographic images were taken of the teeth and assessed by up to 5 clinical and 3 lay assessors for the presence or absence of new demineralized lesions and the esthetic impact. The assessors were masked as to group allocation. **Results:** We randomized 210 participants, and 197 completed the trial. There were 173 with complete before-and after-digital images of the teeth. The incidence of new demineralized lesions was 24%; but when the esthetic impact was taken into account, this was considerably lower (9%). There was no statistically significant difference between the bracket adhesives in the numbers with at least 1 new demineralized lesion (risk ratio,1.25; 95% confidence interval, 0.74-2.13; $P = 0.403$) or first-time bracket failure (risk ratio,0.88; 95% confidence interval, 0.67-1.16; $P = 0.35$). There were no adverse effects. **Conclusions:** There is no evidence that the use of resin modified glass ionomer cement over light-cured composite for bonding brackets reduces the incidence of new demineralized lesions or bond failures. There might be other reasons for using resin modified glass ionomer cement. **Registration:** This trial was registered at ClinicalTrials.gov NCT01925924. **Protocol:** The protocol is available from the corresponding author on request. (Am J Orthod Dentofacial Orthop 2019;155:10-8)

Enamel demineralized lesions (DLs) are a common adverse effect of fixed orthodontic appliance treatment. In addition to good oral hygiene and limiting the consumption of fermentable carbohydrates, fluoride has been shown to reduce the prevalence of demineralization, mainly by promoting remineralization.[1] Unfortunately, there is limited evidence about the most effective means of delivering fluoride to the orthodontic patient to prevent new DLs.[2] Regular professional applications of fluoride varnish at each appliance adjustment visit have been shown to work,[3] as well as regular use of high-concentration fluoride toothpaste by patients.[4] However, achieving a sustained, low concentration of fluoride in the mouth, without reliance on patient adherence, would be ideal.

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The development of fluoride-releasing glass ionomer cement (GIC) for dental restorations was first reported in 1972.[5] Conventional GIC was found to be too weak for orthodontic bonding,[6] but use of a stronger, resin-reinforced or modified GIC (RM-GIC) was reported in 1995.[7] RM-GIC has not been widely adopted in clinical orthodontic practices, despite some promising laboratory data on the release, recharge, and further release of fluoride,[8] but clinical evidence for the effectiveness in the prevention of DLs is weak.[9]

The aim of this study was to compare the use of light-cured RM-GIC with a light-cured composite (LCC) resin when bonding orthodontic brackets.

Specific objectives

Our objectives were to answer 2 main research questions. Does the use of RM-GIC for bonding orthodontic brackets reduce the incidence and severity of DLs during fixed orthodontic appliance treatment? Is there a higher failure rate of orthodontic brackets when using RM-GIC compared with composite resin?

Some weaknesses of trial designs in this area of research have been identified in the orthodontic literature to date.[2] This clinical trial addresses these inadequacies in the following ways.

1. We used a randomized design, with outcomes that are relevant to clinicians and patients.
2. We used parallel groups to reduce the possibility of crossover of fluoride between different parts of the mouth.
3. This was a real-world study, undertaken in several clinical settings, to increase the generalizability of the findings.
4. The patients were followed to the end of their orthodontic treatment.

MATERIAL AND METHODS

Trial design and any changes after trial commencement

This was a multicenter, randomized controlled trial, with 2 parallel groups, examining the superiority of light-cured RM-GIC for bonding orthodontic brackets compared with LCC. Ethical approval was obtained from the National Research Ethics Service Committee of Yorkshire and the Humber (Leeds West) Ethics Research Committee (reference number 07/H1307/153; October 24, 2007) in the United Kingdom and the Clinical Research Ethics Committee of Cork Teaching Hospitals (reference number ECM5(2)5208; February 6, 2008) in the Republic of Ireland. After substantial delays, research governance approvals were obtained for each site under its own local arrangements. The trial was registered in a clinical trials registration database (ClinicalTrials.gov; NCT01925924). There were no changes to the protocol after trial commencement.

Participants, eligibility criteria, and setting

Participants about to start orthodontic treatment with fixed orthodontic appliances were recruited. The inclusion criteria were (1) age 11 years and older; (2) full permanent dentition, requiring maxillary and mandibular fixed appliances; (3) good general health; and (4) oral hygiene considered by the operator to be sufficient for fixed appliance treatment.

The exclusion criteria were patients with cleft lip and palate and those who required combined orthodontic and orthognathic surgery.

Eight centers were initially involved in the study (6 specialist orthodontic practices and 2 teaching hospitals); however, 1 center recruited only 2 participants and 1 recruited 7; data collection from these centers was incomplete, and they were withdrawn from the study. Six qualified orthodontists treated the patients through the whole course of treatment to minimize performance bias.

Written consent was obtained from all participants and their parents or guardians, but participants were free to withdraw consent at any stage.

Interventions

Brackets were bonded with either light-cured RM-GIC (Fuji Ortho LC; GC; Tokyo, Japan) or LCC resin (Transbond XT Light Cure Adhesive; 3M Unitek, Diegem, Belgium). It was left to each operator to decide whether to clean the teeth with prophylaxis paste before bonding. Participants' teeth in both groups were etched with 37% phosphoric acid for 10 seconds. A thin layer of unfilled resin was applied before placing the brackets bonded with composite. Since this was a real-world trial, different fixed appliance systems were used between the centers; however, the randomization process was stratified, so that each operator was allocated an equal number of participants in the RM-GIC and LCC groups. This stratification would help to account for confounding factors, such as bracket make, size, and method of ligation that might influence the outcome. Molars were banded with GIC. To prevent performance bias, each operator was required to have used each bonding adhesive for least 5 patients before starting recruitment to the trial.

The patients were reviewed every 4 to 6 weeks and instructed to brush their teeth 2 or 3 times a day with a fluoridated toothpaste. No standard protocol was used

Fig 1. Example of 1 slide in the presentation for assessment of new DLs.

for fluoride mouth rinses, because problems with compliance have been reported in the literature; therefore, each clinician was asked to give his or her normal instructions in regard to mouth rinses. Operators also used their standard debonding procedure when removing the appliances.

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

The primary outcome was the presence or absence of new DLs on any teeth from the right second premolar to the left second premolar in both arches, assessed using the pretreatment and day-of-debond clinical photographic images. The secondary outcomes were a judgment about the esthetic appearance of new DLs and the number of first-time bond failures (any bracket anterior to the first molars) during treatment, taken from the clinical record.

The intraoral photographs were taken by the operator treating the patient, using a digital camera, in normal room lighting conditions. All operators had received teaching and experience for taking clinical images during their specialist studies and continued to routinely take clinical photographs; therefore, no extra training was provided for the study. Three views were used in the assessment: right buccal segment, left buccal segment, and frontal view. The clinical photographic images were arranged in a PowerPoint presentation (Microsoft, Redmond, Wash). The 3 start images and the 3 day-of-debond images from the same patient were arranged side by side (Fig 1) with the question "can you see any new white lesions that you think might be due to demineralization during the brace treatment?" The arrangement of the images and background color of the presentation, as well as the data collection sheet were piloted by 3 expert specialist orthodontists initially, using 20 images. When the formatting was agreed, the 3 expert assessors undertook the remaining evaluations independently. If these initial experts unanimously agreed on the presence or absence of new DLs, then this assessment was considered final, and these images were excluded from further assessment. Images with at least 1 disagreement were shown to a fourth expert specialist orthodontist assessor and, if necessary, a fifth expert assessor. A consensus was deemed to have been achieved, when at least 3 experts agreed on the presence or absence of new DLs. All data were combined and transferred to an Excel spreadsheet (Microsoft). The

images with consensus on new DLs by at least 3 expert assessors were then shown to 6 assessors, 3 specialist orthodontists and 3 laypeople, who were asked whether the DLs were an esthetic concern. Consensus was achieved using a simple majority of judgments.

There were no changes to the outcomes after trial commencement.

Sample size calculation

The sample size was calculated according to the method of Altman[10] for comparing the proportions of binary data. It was determined that a sample size of 200 patients (100 in each group) would be required to detect a 20% reduction in the prevalence of new DLs between those bonded with RM-GIC and those bonded with LCC (significance level of 0.05 and power of 0.85). To account for an estimated potential withdrawal or dropout rate of 20%, a total of 240 participants would need to be recruited.

Interim analyses and stopping guidelines

No interim analyses were planned. No adverse events were encountered, so the stopping guidelines (excessive bond failures) were not introduced.

Randomization (random number generation, allocation concealment, implementation)

Randomization was carried out using a computer-generated random number sequence to produce a random sample stratified on the operator. This ensured that each operator was allocated the same number of participants in the 2 groups. Blocked randomization was used to keep the 2 groups equal. Subjects were allocated using sequentially numbered opaque envelopes at each center.

Blinding

The trial was single-blinded, because it was not possible to mask either the clinician carrying out the treatment or the participants to the type of bonding adhesive used; however, the examiners assessing the clinical photographic images were masked to group allocation.

Statistical analysis (primary and secondary outcomes, subgroup analyses)

The demineralization data were binary (yes, the participant had at least 1 new DL; no, the participant had no new DL) and independent of each other; therefore the relative risk ratio was used to test whether there was a difference in the incidence of demineralization between the 2 groups. A 2×2 table was constructed according to the method of Altman.[10] According to the null hypothesis, the expected risk ratio value was equal to 1. The 95% confidence interval was constructed to assess the accuracy of the results, and the significance level alpha was set at 0.05. Descriptive analyses for commonly affected teeth and esthetic judgments of the new DLs are presented.

The bracket failure rate was analyzed descriptively as the percentage of first-time bracket failures from the maxillary and mandibular right second premolars to the maxillary and mandibular left second premolars. The binary data (yes, the participant had at least 1 first-time bracket failure; no, the participant had no first-time bracket failures) were used to calculate the relative risk ratio, the 95% confidence intervals, and P values for the bond failures between the 2 adhesives using the same method as the demineralization data. All participants were analyzed in the group to which they were originally allocated.

RESULTS

Participant flow

Recruitment began in February 2009 and was completed by March 2012. The first patient was debonded in September 2010 and the last in December 2014. A total of 210 patients were randomized, and the flow of participants through the trial is shown in Figure 2.

Baseline data

The baseline demographic and treatment data are shown in Table I.

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

For the incidence of demineralization, although 197 participants were followed to the end of their orthodontic treatment, 23 had missing day-of-debond clinical photographic images, and 1 set of images could not be analyzed due to poor quality; therefore, there were complete sets of baseline and day-of-debond images for 173 participants that were independently assessed by up to 5 expert assessors. The agreed evaluations of the assessors after each round of evaluations is shown in Table II.

A total of 131 participants (RM-GIC, 62; LCC, 69) were judged to have no evidence of new DLs by at least 3 judges. The total number of participants who were judged by at least 3 judges independently to have developed new DLs after treatment was 42 (RM-GIC, 23; LCC, 19); this was an overall incidence of 24% of all

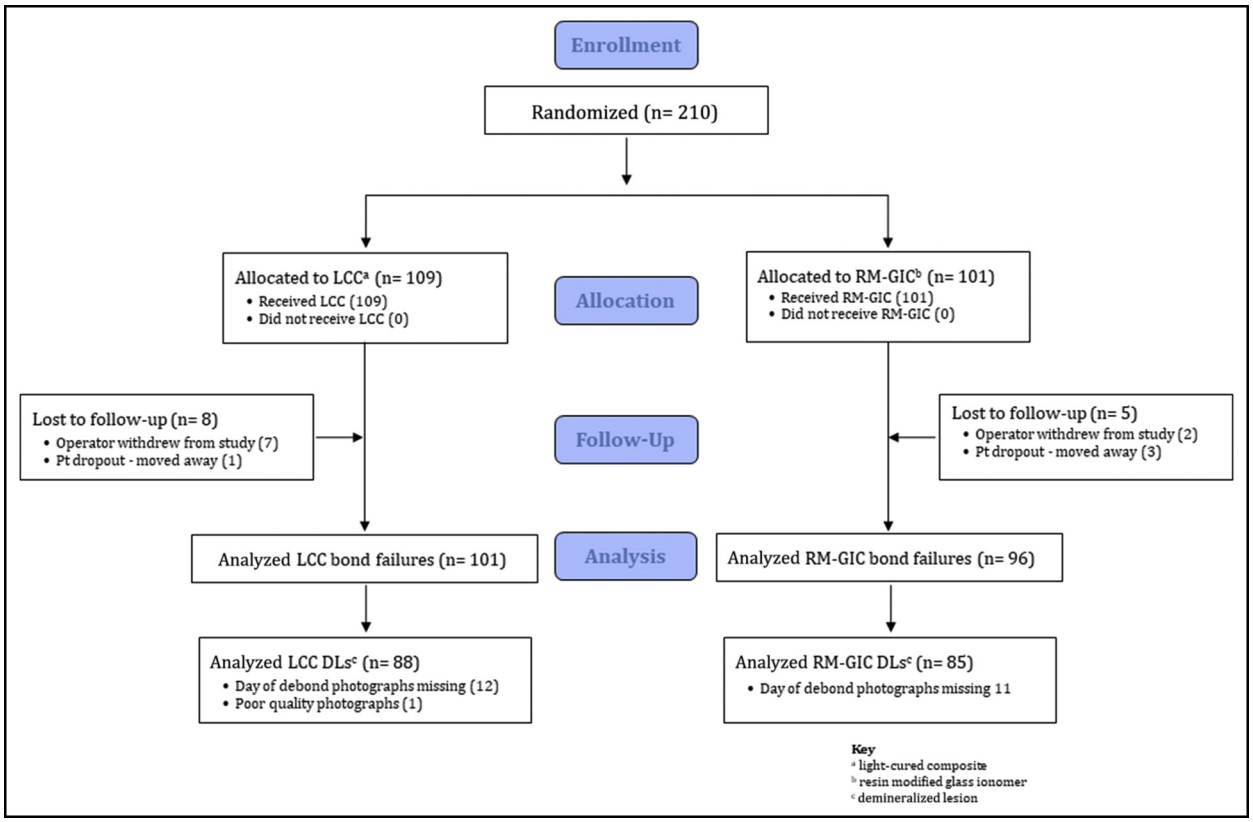

Fig 2. Flow of participants through the trial.

Table I. Baseline demographics and treatment data for participants in bond failure analysis

	LCC n = 101			*RM-GIC n = 96*			*All n = 197*		
Male:female ratio (%)	*39:62 (39%/61%)*			*41:55 (43%:57%)*			*80:117 (41%:59%)*		
	n	*Mean*	*SD*	*n*	*Mean*	*SD*	*n*	*Mean*	*SD*
Age (y)	99	15.4	3.3	96	15.5	3.3	195	15.5	3.3
Mean treatment duration (mo)	100	17.9	7.0	93	17.3	7.3	193	17.6	7.1
Mean of routine visits (n)	101	12.4	4.0	96	12.3	4.5	197	12.4	4.2
Mean of extra visits (n)	84	1.1	1.4	80	1.3	1.7	164	1.2	1.6

participants whose images were assessed. The relative risk ratio for new DLs between the 2 groups was 1.25 (95% CI, 0.74-2.13), which was not statistically significant ($P = 0.403$). The number of teeth affected with new DLs was 113. The distribution of the teeth affected is shown in Table III.

For the esthetic assessment of the lesions, the images of 15 of the 42 participants with new DLs were judged to have an esthetic concern by a majority of the expert and lay assessors; therefore, the overall incidence of esthetically displeasing new DLs at the end of orthodontic treatment was 9% (15 of 173). Agreement between the assessors about the esthetic impact of the new DLs was good, with over 80% agreement for 27 images and over 60% agreement for the remaining 15. There was no difference in the proportion of new DLs on the teeth bonded with RM-GIC (8 of 23; 35%) that were judged to have esthetic concerns compared with those bonded with lCC (7 of 19; 37%) ($P = 0.572$, Fisher exact test).

For the bracket failure rate, a total of 3588 brackets were bonded during the study (RM-GIC, 1727; LCC, 1861). There were 246 first-time bracket failures (second premolar to second premolar), which is an overall incidence of 6.9% (RM-GIC, 110, 6.4%; LCC, 136, 7.3%).

Table II. Agreed judgments after 3, 4, and 5 independent, expert evaluations

		New DLs	
	n	*No*	*Yes*
3 Assessors	173	31	64
4 Assessors	78	4	34
5 Assessors	40	7	33
n		42	131

Table III. Teeth judged to have new DLs (n = 113)

Tooth	*Number*	*%*
Maxillary central incisor	23	20
Maxillary lateral incisor	28	24
Maxillary canine	21	19
Maxillary first premolar	10	9
Maxillary second premolar	6	5
Mandibular central incisor	2	2
Mandibular lateral incisor	4	4
Mandibular canine	9	8
Mandibular first premolar	4	4
Mandibular second premolar	6	5

Table IV. First-time bond failure rates for each operator, as a proportion of brackets bonded and proportion of participants with at least 1 first-time bond failure

	First-time bond failures	
Operator	*Brackets*	*Participants*
1	4.7%	29%
2	5.3%	54%
3	14.3%	85%
4	1.7%	18%
5	6.7%	49%
6	9.5%	71%

Table V. Proportion of images when consensus was obtained for the presence or absence of new DLs after 3, 4, and 5 assessments

		Agreement		
	n	*Yes*	*No*	*%*
3 assessors	173	95	78	55
4 assessors	78	38	40	76
5 assessors	40	40	0	100

The numbers of participants who had at least 1 first-time bracket failure were RM-GIC, 44 of 96 (46%), and LCC, 53 of 101 (52%). The relative risk of at least 1 first-time bond failure was 0.88 (95% CI, 0.67-1.16; $P = 0.35$). There were large differences in the incidences of first-time bond failures between operators (Table IV).

Harms

There were no adverse events during the trial.

DISCUSSION

Main findings

In this multicenter, single-blinded, randomized clinical trial, we found no differences in either the proportions of patients with new DLs or first-time bracket failures, when participants were bonded with either LCC or RM-GIC. We followed the design advocated in a recent Cochrane review.[2]

There was a wide range of reported incidences and prevalences of DLs during fixed orthodontic treatment. This is because various methods have been used to determine demineralization, including clinical examinations, assessments from photographs, and fluorescent techniques. Fluorescent techniques, such as quantitative light-induced fluorescence have been validated against destructive methods of measuring demineralization (usually transverse microradiography); however, they are sensitive to small changes in enamel mineral content and are likely to detect demineralization before it can be seen. Consequently, we believe that the recently reported high proportions of patients with DLs after orthodontic treatment (many of which might remineralize before becoming an esthetic or restorative problem) are an overestimate of the true extent of the problem.[11]

The use of clinical photographic images has the advantage of allowing clinically relevant assessments of before-and-after images at the same time, by several masked assessors, without the problems of ensuring and maintaining calibration of clinical judges, throughout a clinical trial, which in orthodontics is usually lengthy. The use of multiple assessors is important because we found unanimous agreement between 3 assessors for the presence or absence of new DLs for only 55% of the participant images (Table V). A minimum consensus of agreement between 3 assessors was achieved for 77% of participant images after 4 assessments, with a fifth assessor involved to achieve a final consensus. No special filters were used to reduce reflection from the flash that would complicate the photographic equipment required. It was decided that by using images of the same teeth, taken at different angles, the assessor could determine whether there was a DL.

The overall incidences of participants in our study with new DLs after orthodontic treatment (24%), as well as the teeth affected, were similar to those reported in 2 recent large-scale randomized controlled trials involving fluoride products.[3,4] These studies also used before-and-after

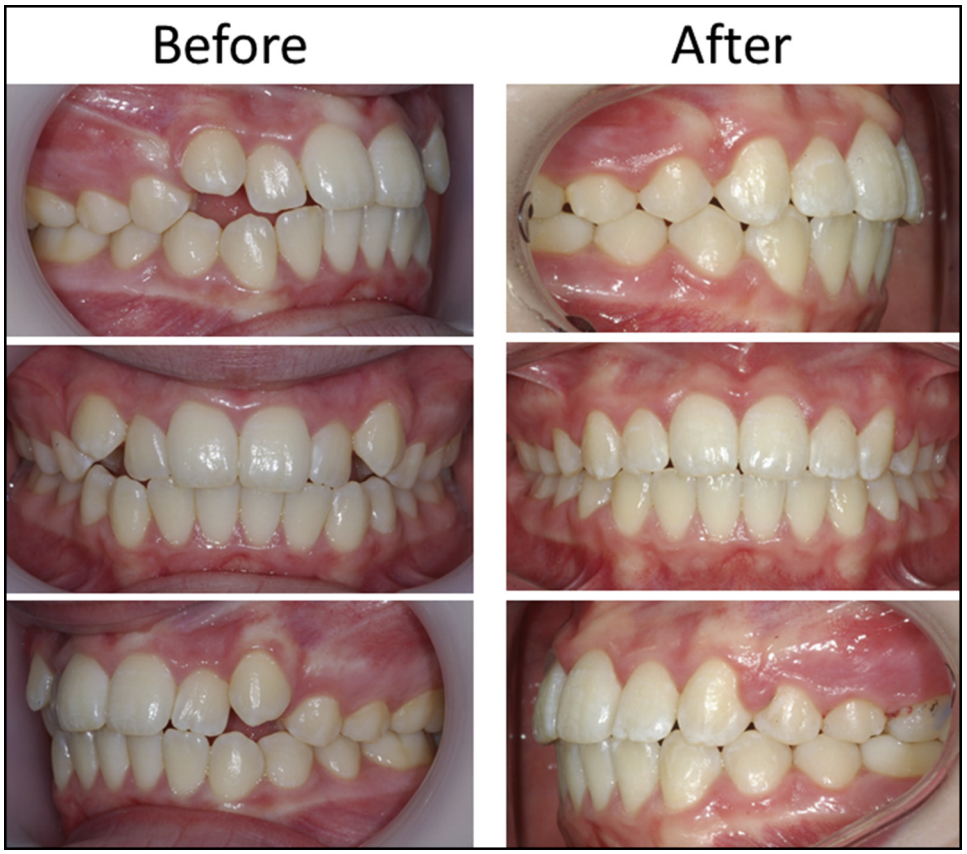

Fig 3. Baseline and day-of-debond clinical photographic images of a participant judged to have new DLs that were unanimously considered to not be unesthetic.

clinical photographs to record the presence or absence of new DLs and masked the judges to undertake the assessments. Although these studies did not report on the esthetic impact of the DLs, they both used the same index to assess the DLs. They found that a large majority of lesions were classified as "slight white spot formation (thin rim)" and, therefore, likely to have minimal esthetic consequences. We believe that our finding of a 9% overall incidence of esthetically displeasing DLs after orthodontic treatment is closer to most clinicians' experiences of this adverse event. To illustrate the difference between images that were considered esthetically displeasing or not, the images of 1 patient are presented, judged to have new DLs after orthodontic treatment, but unanimously considered not to have an esthetic impact on the outcome of treatment (Fig 3). These images can be contrasted with those of another participant with new DLs that were unanimously considered to be esthetically displeasing (Fig 4). It is possible that although the incidence of new DLs was not reduced when using RM-GIC, there might be a reduction in the severity of DLs when present; however, there was no evidence for this with the proportions of new DLs considered esthetically displeasing similar between the 2 groups.

In addition to assessing demineralizations after orthodontic treatment, this study was designed to address some shortcomings in the literature in studies investigating the effectiveness of different bonding adhesives in regard to failure rates.[12] The finding that there were no differences in the failure rates between the 2 adhesives is contrary to the implied results of many laboratory studies that indicate that GIC has a lower bond strength than conventional composite resin. This again calls into question the applicability and validity of findings from laboratory studies. Clinicians were advised to only briefly etch (10 seconds) the enamel with 37% phosphoric acid, thoroughly wash the teeth, and leave them wet before bracket placement. This method has been shown to increase the bond strength to enamel.[13] Although there were no significant differences between bonding agents, there were large differences between operators; this suggests that care during the bonding procedure is more important in reducing bond failures than choice of bonding agent. It also indicates that bonding agents

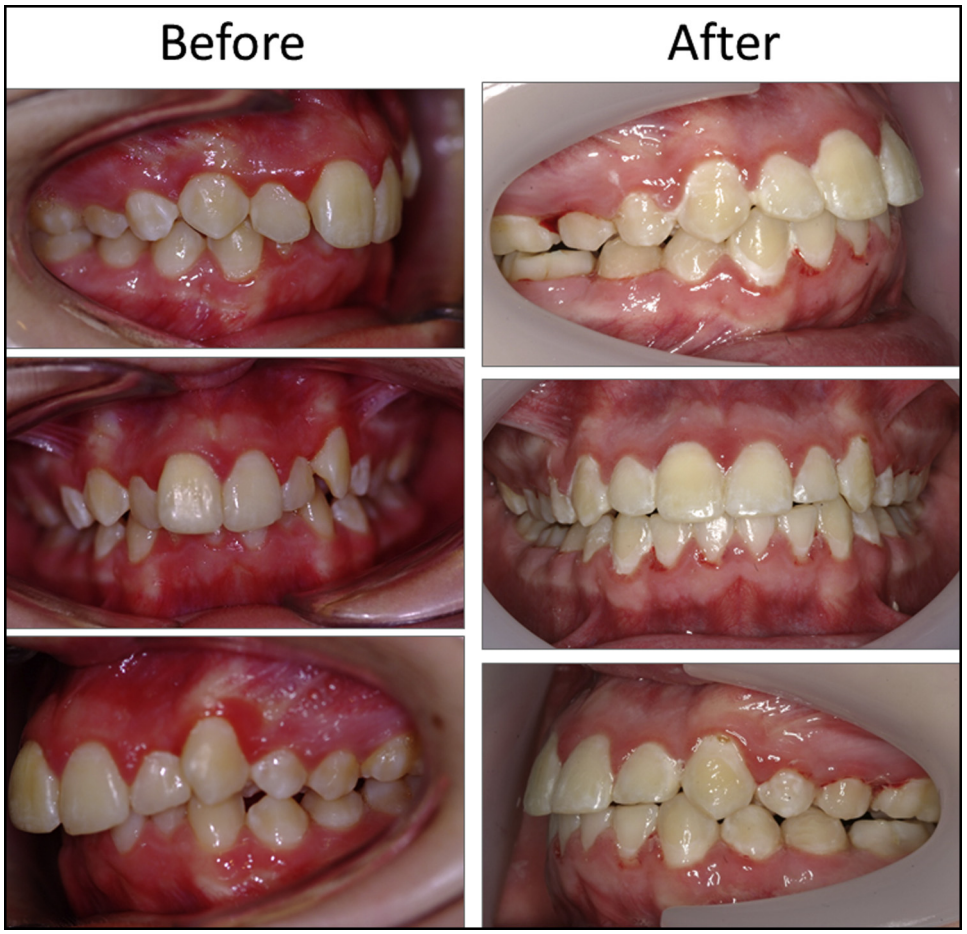

Fig 4. Baseline and day-of-debond clinical photographic images of participant judged to have new DLs that were unanimously considered to be unesthetic.

need to be tested in a number of settings and with many operators to assess how they perform in the real world.

Although the use of RM-GIC was shown not to reduce the incidence of demineralization in this study there might be other advantages for its use. GICs are hydrophilic materials, and bond strength has been shown to be greater when the enamel is left wet; therefore, it is a useful bonding adhesive for conditions where strict moisture control is difficult. GIC has also been shown to chemically bond to the enamel surface and not simply rely on micromechanical attachment after etching. This might make it a useful bonding adhesive where there is an altered enamel structure, such as amelogenesis imperfecta.

The biocompatibility and environmental effects of dental materials are important. Composite resins are considered reasonably safe to use in the oral environment; however, there are several reports regarding cytotoxicity, allergic reactions, and estrogenic effects, particularly to the monomer component.[14-16] RM-GIC is not as biocompatible as conventional GIC, because it still contains monomers, but the proportions are much lower than in acrylic resin adhesives (10%-20% vs 50%, depending on the brand).[17] There is also the issue of cost. Although it is difficult to directly compare the prices of the 2 products, the GC Fuji Ortho LC capsules are more expensive than a tube of Transbond XT Light Cure Adhesive; however, there is a relatively new application system for RM-GIC, an alternative to the capsules, that will reduce the cost of this adhesive. A final potential advantage of RM-GIC is the distinct clinical impression of those who routinely use this bonding adhesive—that it is much easier and quicker to remove than composite—making the cleaning of cement from the teeth after debond less unpleasant for the patient and a potential saving of chair-side time for the clinician. This might be a useful avenue for research in future studies.

Limitations

The main weakness of this study was that 37 of the 210 (18%) participants recruited did not have day-of-

debond photographs with which to assess the presence or absence of new DLs. This was disappointing, but is 1 consequence of a study in a busy clinical environment that might not be used (or have time) to collect research data at the times requested. Despite this, we believe that these results are reliable and generalizable; however, further studies, using similar methods and outcomes, are needed to confirm the findings.

Generalizability

The main strength of the study is that it was undertaken in 6 centers, 4 of which were specialist orthodontic practices, where most patients in the United Kingdom are treated. Other strengths include that participants were followed to the end of treatment, and clinically relevant outcomes were collected and analyzed appropriately (with the participant as the unit of analysis, not the tooth).

The mainstay for the prevention of DLs during fixed orthodontic treatment will be the patients' home use of fluoride toothpaste (minimum of 1450 ppm of fluoride) twice a day, as well as daily fluoride mouth rinses (minimum of 250 ppm fluoride). The clinician should consider recommending a high-dose fluoride toothpaste (2800 or 5000 ppm) and regular applications of fluoride varnish (minimum of 10,000 ppm of fluoride) at every visit for those at high risk. The effectiveness of slow-release fluoride devices for patients wearing fixed orthodontic appliances should also be investigated in the future.[18]

CONCLUSIONS

1. There was no difference in the incidence of new DLs in patients who received fixed orthodontic appliances bonded with either a light-cured RM-GIC or LCC.
2. There was no difference in the failure rates between the 2 bonding adhesives.
3. The operator has a greater influence on the failure rate than the choice of bonding adhesive.
4. There are other potential advantages to using RM-GIC, including reduced sensitivity to moisture, reduced cleanup time, as well as lower environmental and cytotoxic impacts.

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SUPPLEMENTARY DATA

Supplementary data related to this article can be found online at https://doi.org/10.1016/j.ajodo.2018.09.005.

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