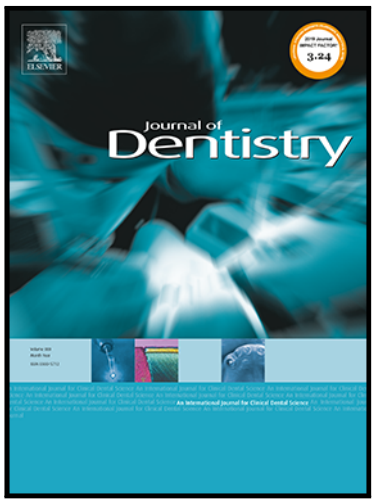

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PII: S0300-5712(23)00299-3
DOI: https://doi.org/10.1016/j.jdent.2023.104713
Reference: JJOD 104713

To appear in: *Journal of Dentistry*

Received date: 4 August 2023
Revised date: 14 September 2023
Accepted date: 17 September 2023

Please cite this article as: Richard Johannes Wierichs , Hannah Selzner , Sotiria Bourouni , Elena Kalimeri , Kyriaki Seremidi , Hendrik Meyer-Lückel , Dimitrios Kloukos , Masking-efficacy and caries arrestment after resin infiltration or fluoridation of initial caries lesions in adolescents during orthodontic treatment - a randomised controlled trial, *Journal of Dentistry* (2023), doi: https://doi.org/10.1016/j.jdent.2023.104713

Masking-efficacy and caries arrestment after resin infiltration or fluoridation of initial caries lesions in adolescents during orthodontic treatment - a randomised controlled trial

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Short title: Resin infiltration during orthodontic treatment

Keywords: Caries infiltration; Orthodontic treatment; Enamel lesions; Aesthetics; White spot lesion; Initial caries lesion; Micro-invasive treatment

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Abstract

Objectives: The aim of this randomised, controlled, split-mouth trial was to assess the masking results in initial caries lesions (ICL) that were either resin infiltrated or fluoridated during treatment with fixed orthodontic appliances.

Methods: Adolescent patients (age range:12-18years) with fixed orthodontic appliances who had developed ICL [ICDAS 1 or 2 (International Caries Detection and Assessment System)] during orthodontic treatment were consecutively recruited and randomly assigned to either resin infiltration with up to 3 etching procedures (Group:Inf) or to 3-monthly application of a fluoride varnish (Group:FV). Both interventions were performed according to the manufacturer's recommendations. Primary and secondary outcomes (ΔE, ICDAS, DIAGNOdent) included the evaluation of the appearance of the ICL before (T_0), 1 week after (T_1) treatment and at the last appointment before debonding (T_2).

Results: Fifteen patients (8females, 7males) with 57ICL were included. Mean (SD) observation time at the last appointment before debonding was 0.5 (0.3) years. At T_0 FV and Inf did not differ significantly in ΔE (median $\Delta E_{0,FV}$(25^{th}/75^{th} percentiles):11.6 (8.7/20.3): $\Delta E_{0,Inf}$:15.1 (11.4/19.5); p_{T0}=0.135), ICDAS (p_{T0}=0.920) and DD (p_{T0}=0.367). At T_1 and T_2 ΔE values (p_{T1}<0.001,p_{T2}<0.001), ICDAS scores (p_{T1}<0.001,p_{T2}<0.001) and DIAGNOdent values (p_{T1}=<0.001,p_{T2}=<0.001) for Inf were significantly reduced whereas ΔE values (p_{T1}=0.382,p_{T2}=0.072) and ICDAS scores (p_{T1}=0.268,p_{T2}<0.001) for FV remained unchanged.

Conclusions: Resin infiltration effectively masked ICL during treatment with fixed orthodontic appliances both immediately after application and at the last appointment before debonding. Furthermore, the visual appearance of fluoridated lesions was not as satisfactory as that of the infiltrated ones at both T_1 and T_2.

Clinical Significance: Resin infiltration effectively masked ICL during treatment with fixed orthodontic appliances both immediately after application and at the last appointment before debonding. Furthermore, the visual appearance of fluoridated lesions was not as satisfactory as that of the infiltrated ones immediately after first application as well as half a year after application.

Trial registration: German Clinical Trials Register (DRKS-ID: DRKS00011797)

Introduction

Contemporary orthodontics still extensively relies on the use of fixed orthodontic appliances irrespective of the type of the bracket. This is fully recognised despite the widespread use of

removable transparent aligners, especially in the case of limited cooperation or of limited clinical effectiveness of aligners. In any case, fixed orthodontic appliances have revolutionised modern orthodontics, despite the fact that treatment may last for several months or years [1]. Nevertheless, fixed orthodontic appliances represent a potential factor for additional biofilm accumulation, as it can interfere with standard oral hygiene procedures [2, 3]. The risk for the development of initial caries lesions (ICL) increases with the intake of carbohydrates as this causes an ecological shift in the plaque microflora and establishes caries-conducive conditions in the oral cavity [4]. The typical white opaque appearance of ICL is attributed to the stronger light scattering within lesion's body as a result of air and saliva insertion in comparison to the surrounding healthy enamel [3]. It has been reported that ICL can persist for more than 10 years after removal of the orthodontic appliances [5].

The prevalence of post-orthodontic ICL is reported to vary between 23% and even 97% [6, 7]. ICL often represent a major aesthetic burden for orthodontic patients [8] especially when anterior teeth are involved. After bracket removal, proper oral hygiene is typically performed more effectively and ICL may superficially remineralise. As an adjunct, fluoride containing agents are recommended to enhance remineralizing effects; nevertheless, the appearance in the majority of cases remains aesthetically insufficient [9].

Various interventions have been recommended to avoid initiation, arrest or reverse the progression, or mask the ICL during treatment with orthodontic appliances [10]. Additionally, several approaches with fluoride containing agents [9], CPP-ACP-containing pastes [11] or bioactive glasses [12] seem to enhance remineralization post-treatment. However, as none of these approaches seem to completely prevent the development or completely reverse ICL [13], the aesthetic result usually remains impaired [11]. Two minimally invasive treatments have been advocated to treat orthodontically induced ICL: micro-abrasion, which has been mainly proposed to mask superficial lesions, and resin infiltration [14]. In several studies, a positive masking effect after the infiltration has been observed; with ICL being treated with resin infiltration showing a significantly higher optical improvement than those without any treatment or with fluoride varnish application [14]. Interestingly, it was also reported that the time interval between debonding of appliances and resin infiltration appears to play an important role for the successful masking of ICL [15]: the masking effect was more successful as the time interval between bracket removal and resin infiltration was shorter. This observation was also supported in a non-controlled study [16], in which the masking effect of caries infiltration was examined during orthodontic treatment. Immediately after the detection of an ICL the bracket was removed. Subsequently, the ICL was infiltrated and the

bracket was bonded again. During the 10-month follow-up, 92.5 % of the infiltrated ICL showed no further progression. The success to arrest and mask ICL, thus, depends on the time between detection and infiltration. This has raised the clinical inquiry if the aesthetic outcome might further be optimised by infiltrating ICL during the orthodontic treatment but more importantly, if caries progression might be hampered.

Thus, the aim of the present study was to evaluate and quantify the masking results in ICL that were infiltrated in the course of treatment with fixed orthodontic appliances, without removing the brackets of the affected teeth. The primary hypothesis was that infiltration of ICL immediately after their appearance during orthodontic treatment leads to a significant reduction in the colour difference between the carious and healthy enamel (ΔE) compared with baseline. The secondary hypothesis was that no significant difference in the reduction of colorimetric (ΔE) and laser fluorescence values (ΔD) in ICL being infiltrated can be observed when compared to ICL being fluoridated 3-monthly.

Materials and Methods

Study design and ethical aspects

The study was designed as a single-center, randomized, controlled split-mouth trial (RCT) (DRKS-ID: DRKS00011797). Ethical approval was given by the Ethics Committee of the 251 Hellenic Air Force General Hospital, Athens, Greece (Approval Nr. 076/ 15518/ 4628/ 18.10.2018). The study design has previously been described in detail [17]. Reporting followed the CONSORT statement for RCTs [18]. All participants or their guardians gave their written informed consent before participating in this study.

Sample selection – inclusion and exclusion criteria

This study has enrolled adolescent orthodontic patients (age range: 12 - 18 years old) being treated with fixed orthodontic appliances in the Department of Orthodontics and Dentofacial Orthopedics, 251 Hellenic Air Force General Hospital, Athens, Greece. The participants who had developed ICL [ICDAS 1 or 2 (International Caries Detection and Assessment System)] on buccal surfaces of the first premolars, canines and the front teeth of the upper and lower jaw during treatment were consecutively recruited. Recruitment took place between January 2021 and May 2022. The natural fluoride concentration in tap water of the area of Athens is 0.1 mg F^-/l.

Inclusion criteria:

Written informed consent by the patient or his/her guardians; patient being resident in the area of Athens since birth; patient at age between 12 and 18 years; patient with two or more non-cavitated ICL (ICDAS 1 or 2) on buccal surfaces of the first premolars, canines and the front teeth of the upper and lower jaw; patient with ongoing treatment with fixed orthodontic appliances.

Exclusion criteria:

Participants with allergies to the used materials; patients with ICL classified as ICDAS ≥3; pregnant patients or patients in the lactation period; patients with fluorosis; patients with enamel developmental defects; patients under orthodontic treatment with removable appliances.

Interventions

Information on the orthodontic treatment has been previously described [17]. Baseline assessment of the ICL was performed by one of two experienced operators (DK, EK). Without removing the brackets, teeth in the test group were infiltrated with a low-viscosity polymer (Icon, DMG, Hamburg) (Group Inf). Teeth in the standard interventional control group were treated with a fluoride varnish (Tiefenfluorid®, Humanchemie, Alfeld/Leine) (Group FV). Fluoride application was repeated 3-monthly. Both interventions were performed according to the manufacturer's recommendations. Full intervention details have been previously described [17]. All treatments were performed by one of the two operators (DK, EK). Before the start of the study, both operators were trained in assessment and treatment and they were calibrated in 10 teeth to ensure standardization of the procedures.

Oral Health instructions

In addition to the oral health instructions given at bonding of orthodontic appliances, all participants underwent a mechanical plaque removal which involved supragingival debridement two weeks before the first treatment session. Patients were then given oral hygiene instructions for home care and received a general simplified explanation of related pathologies. They were all recommended to brush their teeth 3 times daily according to the modified Bass technique using a fluoride toothpaste (1450 ppm F). Interdental cleaning of teeth using interdental brushes was also recommended and demonstrated and all participants were advised to avoid the use of an antimicrobial mouthwash during the study period. The

correct usage of the toothbrush around braces was demonstrated on a plastic model and all information were also given to patients in written form.

Randomization and allocation concealment

Since resin of the infiltrated teeth cannot carry-across and infiltrated surfaces cannot be fluoridated anymore, no carry-across effect from either the infiltrant group to the fluoride group or vice versa was expected. To account for any clustering effects, teeth, as per quadrant units, were chosen as the randomization segments. Split-mouth allocation was, thus, performed tooth-wise. This implies that a certain patient could have one intervention per side or both interventions per side. Teeth with ICL were randomly divided into the two groups under investigation. Restricted randomization was performed by a random table (https://www.sealedenvelope.com; block of 4) and assignment to treatment arms was allocated with sealed opaque envelopes. To conceal the allocation sequence until participants were enrolled and assigned to intervention an investigator, who was not directly involved in performing the interventions, notified the operator of the respective treatment after lesion detection by the two operators (DK, EK), which was also photographically documented by the treatment providers.

Blinding

Due to the treatment nature, neither the operators nor the patients could be blinded. However, outcome assessors and the statistician were blinded.

Outcome Measurement

Outcomes were analysed before treatment (baseline, T_0), 1 week after initial application of interventions (T_1) and every three months (T_2-T_5, for better readability hereinafter referred to as T_2) until the orthodontic treatment plan called for debonding (figure 1). As the interventions were applied simultaneously, period effects that could confound the association between interventions and outcomes were not expected.

Thus, the factors under evaluation were:

- Time points: (T_0) before treatment, (T_1) 1-week after first treatment, (T_2) last appointment immediately before debonding

- Intervention: (Inf) application of caries infiltration, (FV) 3-monthly application of a fluoride varnish

Primary outcome

Photo documentation

Digital, standardized photos were taken as described previously [19]. Photos of 2 patients can be found in the supplementary material. For this, a SLR camera (Nikon D7000; Nikon, Chiyoda, Japan), a ringflash (Sigma EM-140 DG; Sigma, Kawasaki, Japan) and a macro lens (AF S Micro-Nikkor 105 mm 1:2.8; Nikon, Chiyosa, Japan) were used. All camera settings (1/250, aperture F29, iso-sensitivity 100 and a fixed white balance of 6250 K, ¼ left and right flash intensity) and the tooth-lens distances (20 cm) were standardized by one operator (EK).

Colorimetric analyses

Digital photographs were analysed as described previously [17, 19] with one exception: Photoshop 2021 (Photoshop Adobe 2021; Adobe, San Jose, USA) instead of Photoshop CS6 was used. The CIE L*a*b* colour space was used for colour determination. Four different measuring points (11 x 11 pixels) in carious and in healthy enamel were used for the pre- (T_0) and post- treatment (T_1 and T_2). The measuring points were chosen in the area of the most obvious opaque and white lesion and in the adjacent healthy enamel. The same measuring points were used in the pre- and post-treatment analysis. Then, the formula $\Delta E_{T0} = ((L_c - L_h)^2 + (a_c - a_h)^2 + (b_c - b_h)^2)^{1/2}$ [20] and e.g. $\Delta\Delta E_{T0\text{-}T1} = \Delta E_{T0} - \Delta E_{T1}$ [21, 22] was used to calculate the colour differences between the carious (index c: e.g. L_c) and adjacent healthy (index h: e.g. L_h) enamel (ΔE) plus between different time points ($\Delta\Delta E_{T0\text{-}T1}$ as well as $\Delta\Delta E_{T0\text{-}T2}$). All colorimetric analyses were performed by RJW and HS.Secondary outcomes

ICDAS

Caries lesions were recorded at tooth level using the ICDAS (International Caries Detection and Assessment System) by two out of three operators (DK, KS, EK), when not involved in the intervention administration. [23].

Laser fluorescence readings

The laser fluorescence readings were performed with DIAGNOdent 2190 (Kavo; Biberach, Germany) as described previously [17]. Prior to measurements, teeth were professionally

cleaned with a soft cup rotating at 500 rpm using a fluoride-free polishing paste (Cleanic; Kerr, Bioggio, Switzerland). The device was calibrated using a ceramic standard provided by the manufacturer. The flat tip (occlusal tip probe tip 2) was used and the peak value of each site was identified. All sites were measured in quintuplicate. The mean value of the measurements was recorded. Again, two out of three operators (DK, KS, EK), when not involved in the intervention administration, performed the evaluation.

Statistical analyses

For statistical analysis SPSS (SPSS Statistics 26; IBM, Armonk, USA) was used. A prospective power and sample size analysis was performed as reported previously [17]. Normal distribution of the data was tested using the Shapiro-Wilk-test. The ΔE values and DIAGNOdent readings (DD) in both groups within each time point were compared with Wilcoxon signed rank tests. To compare differences between ΔE values and DIAGNOdent readings of the different time points (T_0, T_1, T_2) within one group, the Wilcoxon signed rank tests were used. Differences in ICDAS values between groups and at different time points were evaluated utilizing Chi-square tests. Results, unless otherwise specified, were noted as median (25^{th}/75^{th} percentiles). The level of significance was set at 5%.

Results

Between January 2021 and July 2022, 17 patients with 76 initial lesions were included in this study. However, due to drop outs the final analysis was performed with 15 patients (8 females, 7 males) with 57 initial lesions (figure 1). The mean number of teeth (standard deviation [SD]) per patient was 3.8 (1.4). Thirteen of these lesions were scored as ICDAS 1 and 44 as ICDAS 2. All patients appeared at the last appointment before debonding (T_2). Mean age of patients at T_0 was 14,3 years (range: 12-18 years). Mean treatment duration at the time of the first assessment was 19.87 months (range 4-36 months). Caries score by mean DMFT values (25^{th}/75^{th} percentiles) (sum of the number of Decayed, Missing due to caries, and Filled Teeth in the permanent teeth) was 26,02% (7.28/28) and ranged between 7.14% - 42.86% (2/28- 12/28) among included participants.

At T_0, 76 lesions (ICDAS 1-2) were treated in 76 teeth of which 18 (24%) were upper central incisors, 18 (24%) upper lateral incisors, 16 (21%) were upper canines, 7 (9%) lower first premolars, 7 (9%) upper first premolars, 6 (8%) lower canines, 2 (2.5%) lower central incisors and 2 (2.5%) lower lateral incisors.

Colour differences ΔE

At baseline (T_0) FV and Inf did not differ significantly in ΔE (median $\Delta E_{0,FV}$ (25^{th}/75^{th} percentiles): 11.6 (8.7/ 20.3); median $\Delta E_{0,Inf}$ (25^{th}/75^{th} percentiles): 15.1 (11.4/ 19.5); p_{T0}=0.135, table 1). One week after treatment (T_1), ΔE values for Inf were significantly smaller than for FV (median $\Delta E_{T1,Inf}$: 5.3 (3.3/ 10.9)); median $\Delta E_{T1,FV}$: 13.3 (9.5/ 21.1); p_{T1}<0.001; Wilcoxon signed rank tests). At the last appointment before debonding (T_2), which took place after a mean (standard deviation) follow-up period of 0.5 (0.3) months, ΔE values for Inf were still significantly smaller than for FV (median $\Delta E_{T2,Inf}$: 5.2 (3.3/ 8.6); median $\Delta E_{T2,FV}$: 10.1 (7.0/ 14.5; p_{T2}<0.001; Wilcoxon signed rank tests). Furthermore, at T_1 and T_2 ΔE values for Inf were significantly reduced compared to T_0 ($p_{T1\text{-}T0,Inf}$<0.001; $p_{T2\text{-}T0,Inf}$<0.001; Wilcoxon signed rank tests) and ΔE values for FV remained unchanged compared to T_0 ($p_{T1\text{-}T0,FV}$=0.382; $p_{T2\text{-}T0,FV}$=0.072; Wilcoxon signed rank tests)

Consequently, the change in colorimetric values ($\Delta\Delta E_{T0\text{-}T1}$ as well as $\Delta\Delta E_{T0\text{-}T2}$) for Inf was significantly higher than that for FV ($p_{T0\text{-}T1}$ <0.001; $p_{T0\text{-}T2}$ <0.001; Wilcoxon signed rank tests).

ICDAS scores

At T_0, 13 lesions were scored as ICDAS 1 and 44 as ICDAS 2 and did not differ significantly between groups (p=0.920, Chi-square test, Table 1). One week after treatment (T_1), ICDAS scores in group Inf were significantly reduced (p_{Inf}<0.001; Chi-square test), whereas ICDAS scores in group FV remained unchanged (p_{FV}=0.268; Chi-square test). However, at the last appointment before debonding (T_2) ICDAS scores in both groups were significantly reduced (p_{FV}<0.001; p_{Inf}<0.001; Chi-square test).

DIAGNOdent values

At T_0 both groups did not differ significantly in DIAGNOdent values (median $DD_{0,FV}$ (25^{th}/75^{th} percentiles): 11 (8; 12): median $DD_{0,Inf}$ (25^{th}/75^{th} percentiles): 11 (8/14); p_{T0}=0.367, table 1). One week after the treatment (T_1) and at the last appointment before debonding (T_2) DD values for Inf were significantly lower than for FV (p_{T1}=0.007; p_{T2}=0.003; Wilcoxon signed rank tests; table 1). However, at T_1 and T_2 DD values in both groups were significantly reduced (p_{T1}<0.001; p_{T2}<0.001; Wilcoxon signed rank test).

Adverse effects

No adverse or side effects were recorded during the follow-up period.

Discussion

The present study evaluated the masking efficacy in initial caries lesions that were either infiltrated or fluoridated during treatment with fixed orthodontic appliances. Based on the data of the follow-up period up to the appointment before debonding, a significantly higher reduction of colorimetric and laser fluorescence values in ICL being infiltrated immediately after their appearance could be observed than in ICL being fluoridated. Therefore, the first hypothesis (immediate significant reduction of ΔE after infiltration) could be confirmed, whereas the second (no significant difference in the reduction of ΔE and ΔD between infiltration and fluoridation) had to be rejected.

In this follow-up study ICL were infiltrated immediately after the initial diagnosis. This is in contrast to previous studies, in which orthodontically induced ICL were infiltrated immediately after debonding [14]. In our study, the natural reminalisation/regression of the lesions in the Inf group, which typically takes place after appliances' removal was omitted. ICL were infiltrated in an earlier, more initial state, though. This was done since it was expected that lesions would progress during further orthodontic treatment. Thus, a thicker surface layer was assumed, impeding penetration of the infiltrant and consequently resulting in large numbers of unfavorable aesthetic results. The present results confirm that even these early lesions can successfully be masked by infiltration.

In the first publication of this research project about short-term effectiveness of resin infiltration, it was highlighted that reversal or progression of the lesions in the standard interventional control group (fluoride varnish) could not be observed after 7 days, since up to 6 months are needed to naturally remineralize ICL [24]. Furthermore, as observed in a recent RCT, in patients with multi-bracketed fixed orthodontic appliances [25], we expected that lesions will progress in FV over time, since fixed appliances, and, in turn, biofilm formation, remain. Interestingly, this was not observed in the present stduy. In contrast, colorimetric values remained unchanged after a mean follow-up period of 6 months and ICDAS scores as well as DD values significantly decreased indicating a significant reversal of the lesions. Due to ethical reasons no negative control group (no oral health instruction, no additional fluoridation) was included in the present study. Therefore, it remains unclear if this finding is a result of the intensive preventive program including a) frequent fluoride application, b) detailed oral hygiene instructions, c) a regular follow-up program or e) a result of the Hawthorn effect[26]. Positive, though transient, results can be observed when patients or their

parents/caregivers in case of children are aware that they are being observed, graded, or measured, resulting in intentional changes in their behavior.

In the present study infiltrated lesions showed a significantly higher optical improvement in all three outcomes compared with lesions being only fluoridated. This is in line with DIAGNOdent readings of previous studies [27-30] in which ICL were diagnosed and treated after debonding. Only in one study fluoride varnish provided optical results comparable to resin infiltration [30]. However, in that study inconsistencies of the inclusion criteria of the lesions were reported. Furthermore, after fluoride application the optical improvement required up to 6 months, whereas a subsequent post treatment colour-change could be observed after resin infiltration.

In a recent meta-analysis, serious doubts regarding the reliability of laser fluorescence readings for assessing demineralization or remineralization have been raised [31]. Up until now, research has primarily focused on the reproducibility, calibration procedures, and sensitivity of DIAGNOdent readings in primary occlusal caries lesions, both in vitro [32, 33] and in vivo [34]. In cases of secondary caries adjacent to amalgam or composite restorations t has also been explored in one study [35]. Furthermore, there is conflicting information regarding the reliability and sensitivity of DIAGNOdent readings when used under restorative materials like composite or infiltrant [36, 37]. Consequently, it remains uncertain whether DIAGNOdent readings are influenced by low-viscosity resin and whether there is a connection between DIAGNOdent values and optical results, such as ΔE. Two in vitro studies found that, despite a significant improvement in the visual appearance of artificial lesions following infiltration, there was no difference in DIAGNOdent values before and after the procedure [38, 39]. This observation aligns with unpublished data from the authors, indicating no correlation between changes in DIAGNOdent values and colorimetric values (ΔE) or subjective assessments during infiltration. As a result, although recent studies on post-orthodontic interproximal caries lesions have employed DIAGNOdent readings as a primary or additional outcome measure for assessing remineralization processes [28-30], it is essential to interpret the results of DIAGNOdent readings from both previous and the current study with caution. In the present study, DIAGNOdent measurements were included as a secondary outcome to investigate whether there is a correlation between DIAGNOdent readings and optical outcomes (e.g., ΔE), as DIAGNOdent readings were planned for all follow-up examinations.

Previous studies reported that after infiltration of ICL a reduction of the colorimetric value ΔE below 3.7 – the threshold for perception from a common social distance [40] – could be achieved [19, 41]. This is in contrast to the present study; although a significant reduction in colorimetric values could also be observed, the absolute values remained above 3.7. However, the higher ΔE values can be explained by gradients in teeth color from the cervical region, which is the most saturated, to the incisal region [42] and the slightly different study designs. When colorimetric analyses were done after bracket removal [19, 41], measurement points for healthy enamel were chosen next to the area of the measurement points for carious enamel. Thus, color gradients of the tooth did not influence colorimetric differences between healthy and carious enamel. In contrast, when brackets have not been removed, most of the teeth are covered by the brackets, the ligatures, or the archwire, so that the measurement points for healthy enamel must be chosen further away from the measurement points for carious enamel. In the present study, for instance, the carious area was mostly cervical and the healthy area incisal. Consequently, color gradients of the teeth influence colorimetric differences between healthy and carious enamel. Nonetheless, since the same measuring points were used in the pre- and post-treatment analysis, masking success/failure can still be analyzed - albeit with higher absolute ΔE values.

As discussed recently [43], the success to arrest and to mask ICL seems to depend on the time between detection of the ICL, debonding and infiltration [15, 16]. Shorter time periods between debonding and infiltration seem to be advantageous in order to allow a more effective masking of ICL. This has raised the inquiry if the aesthetic outcome might be optimised by infiltrating ICL during the orthodontic treatment but more importantly, if caries progression would be hampered. Moreover, infiltration treatment while the bracket is not temporarily removed seems to be more efficient. With the present results it is demonstrated that resin infiltration can efficaciously be used during orthodontic treatment with fixed appliances. However, it will still be interesting to compare these results with the results of ICL that were initially fluoridated and that will be infiltrated – if necessary – after fixed appliances removal.

Conclusion

Based on the present data resin infiltration efficaciously masked initial caries lesions during orthodontic treatment with fixed appliances immediately after material application. Moreover, half a year after application aesthetic results for all outcomes remained consistently improved.

In contrast, fluoride varnish was not able to immediately improve the visual appearance of initial caries lesions. Only after regular application fluoridation improved the visual appearance of ICL during orthodontic treatment in two of the three outcomes assessed. However, the visual appearance of fluoridated lesions was still not as satisfactory as that of the infiltrated ones.

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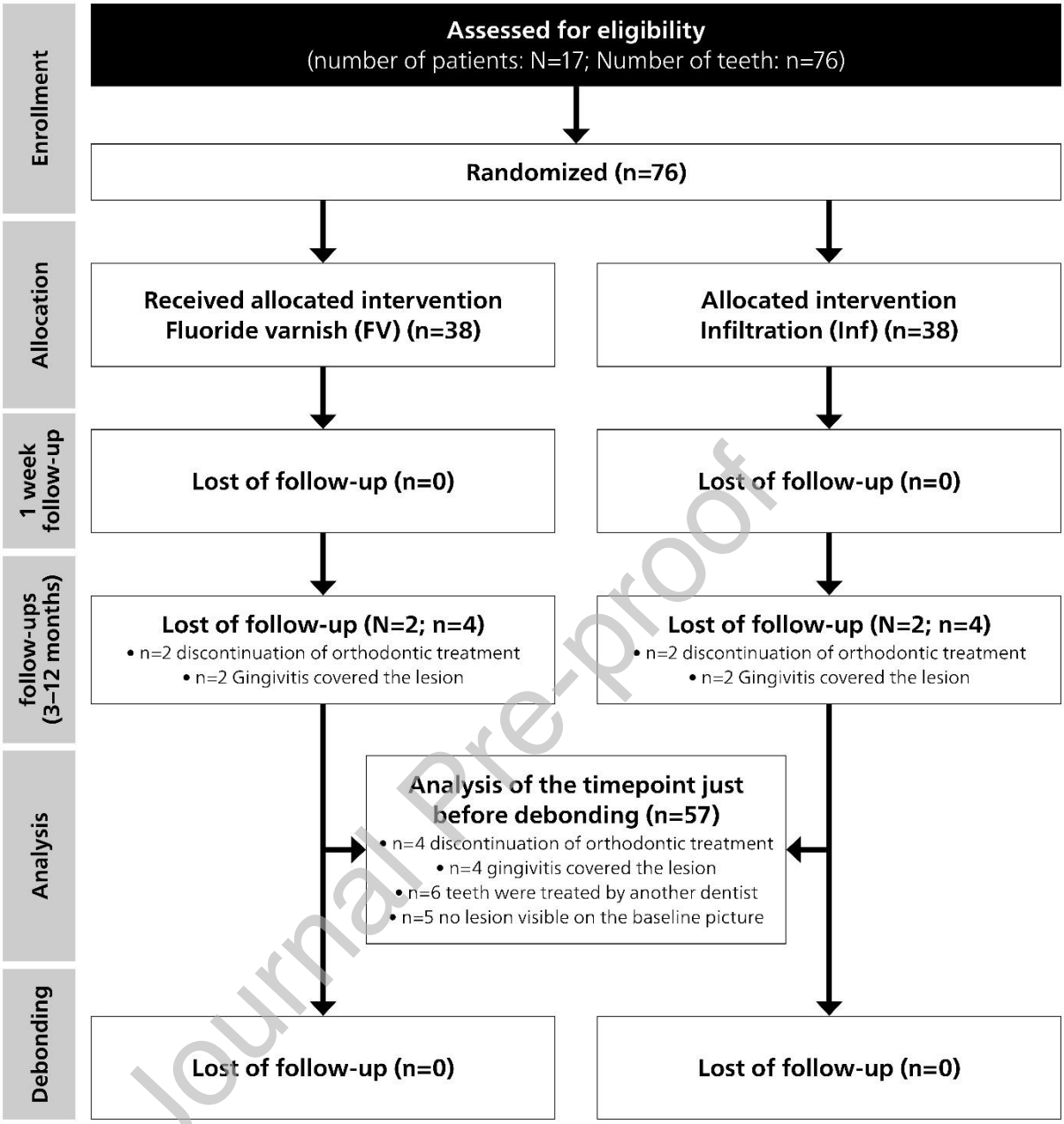
Table 1

A: Colorimetric analysis (ΔE)						
		n	**median**	**25th**	**75th**	
FV	T_0	30	11.6	8.7	20.3	AB
	T_1	30	13.3	9.5	21.1	A*
	T_2	30	10.1	7.0	14.5	B*
Inf	T_0	27	15.1	11.4	19.5	a
	T_1	27	5.3	3.3	10.9	b*
	T_2	27	5.2	3.3	8.6	b*
B: ICDAS						
			ICDAS score			
		n	**0 (number)**	**1 (number)**	**2 (number)**	
FV	T_0	30	0	7	23	A
	T_1	30	2	9	19	A*
	T_2	30	13	9	8	B
Inf	T_0	27	0	6	21	A
	T_1	27	4	15	8	B*
	T_2	27	20	3	4	C
C: Laser fluorescence readings (DIAGNOdent)						
		n	**median**	**25th**	**75th**	
FV	T_0	30	11	8	12	A
	T_1	30	8	6	10	B*
	T_2	30	7	5	9	B*
Inf	T_0	27	11	8	14	a
	T_1	27	6	5	8	b*
	T_2	27	5	4	8	b*

A: Median (25^{th} /75^{th} percentiles) colour difference (ΔE) between carious and healthy enamel; B: ICDAS scores: C: Median (25^{th} /75^{th} percentiles) DIAGNOdent values before (T_0), one week after (T_1) treatment and at the last appointment before debonding (T_2). Different letters indicate significant differences between the different time points ($p<0.001$; Wilcoxon signed rank tests for ΔE and DIAGNOdent values; Chi-Square test for ICDAS scores). Asterisks indicate significant differences between the groups ($p<0.001$; Wilcoxon signed rank tests for ΔE and DIAGNOdent values; Chi-Square test for ICDAS scores).

Figure 1: CONSORT flow-chart of study follow up.



CRediT author statement

Masking-efficacy and caries arrestment after resin infiltration or fluoridation of initial caries lesions in adolescents during orthodontic treatment - a randomised controlled trial

Richard Johannes Wierichs: contributed to conception, design, acquisition, analysis and interpretation, drafted and critically revised the manuscript

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All authors gave their final approval and agree to be accountable for all aspects of the work.

Declaration of interests

☐ 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.

☒The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

H.M.-L is appointed as inventor for patents of an infiltration technique for dental caries lesions, held by Charité-Universitätsmedizin Berlin, and receives royalties from DMG, the manufacturer of Icon.

All other authors declare no conflicts of interests.