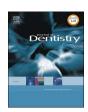
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Journal of Dentistry

journal homepage: www.elsevier.com/locate/jdent





Aesthetic caries infiltration – Long-term masking efficacy after 6 years

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ARTICLE INFO

Keywords: Caries infiltration Infiltrant Post-orthodontic treatment Enamel lesions Aesthetics Resin White spot lesion

ABSTRACT

Objectives: This study aimed to evaluate the masking efficacy of caries infiltration technique of initial caries lesions (ICL) six years after debonding and single treatment.

Methods: In 10 adolescents, 74 ICL (ICDAS 2) in 74 teeth were treated by resin infiltration (Icon, DMG) at a mean (SD) of 1.2 (1.2) months after bracket removal. The etching procedure was performed up to 3 times. Standardized digital images were taken before treatment (T_0), seven days (T_7) and 6 years (T_{2190}) after treatment. Outcomes included the evaluation of the color differences between carious and healthy enamel at T_0 , T_7 and T_{2190} by quantitative colorimetric analysis (ΔΕ), ICDAS scores, quantitative light-induced fluorescence (QLF; $\Delta F_1 \Delta P_2 \Delta P_3 \Delta P_4 \Delta P_4 \Delta P_5 \Delta P_$

Conclusion: Aesthetic caries infiltration can effectively mask post-orthodontic initial caries lesions for at least 6 years. These results for most of the teeth could not only be observed by quantitative but also by qualitative analysis.

Clinical significance: Resin infiltration efficaciously masks post-orthodontic initial carious lesions. The optical improvement can be observed directly after treatment and remains stable for at least six years.

1. Introduction

In adolescence one negative side effect of orthodontic treatment with fixed appliances are initial caries lesions (ICL). ICL can be observed in up to 68.4% of orthodontically treated patients [1]; especially in patients with higher cariogenic diet and impaired oral hygiene [2], since fixed elements (e.g. brackets) may yield to an increased biofilm accumulation. Consequently, avoiding the initiation, arresting the progression, reversing or masking ICL during [3,4] and after [5,6] treatment with fixed appliances have been analyzed in several studies. However, in most cases, the aesthetic appearance remains impaired [6] or no long-term results have been presented yet [5].

Within the first six months after bracket removal ICL may

superficially remineralize, since proper oral hygiene can be performed more effectively again [7]. However, even when caries-preventive supplements (e.g. fluorides) are utilized ICL are likely to remain an aesthetic burden even years after removal of the orthodontic appliances [8]. In contrast, a recent meta-analysis indicated that optically satisfying results may be achieved by resin infiltration [5]. This technique is based on the refractive indices (RI) of sound enamel (RI = 1.63), demineralized enamel filled with air (RI = 1.00) or water (RI = 1.30) and the infiltrant (RI = 1.53). By infiltrating the demineralized areas, the lesion's RI of the infiltrated parts increase up to values closer to the RI of sound enamel. Thus, light scattering is reduced, and the lesion optically resembles the surrounding healthy enamel and also increases microhardness of the enamel [9].

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(Post-orthodontic) ICL can effectively be masked with resin infiltration immediately after its application. However, long-term color stability is still a major concern [5,10]. Extrinsic discoloration and staining were observed *in vitro* [11,12] and *in vivo* (Paris et al. 2010). In some studies, color differences of infiltrated lesions increased relatively to non-infiltrated demineralized or healthy surfaces after subsequent staining [12,13]. Contrastingly, stable masking results could be observed in other *in vivo* studies [5,14,15]. However, the follow-up period in most *in vivo* studies was only 6 months; only one study evaluated the masking effect after up to 2 years [14].

Therefore, the present study aimed to qualitatively and quantitatively assess the masking efficacy and color stability of resin infiltration of post-orthodontic ICL after six years. The primary hypothesis was that no significant difference in the quantitative colorimetric analysis (ΔE), ICDAS scores, quantitative light-induced fluorescence (ΔF , ΔQ ,WS

Arear) and qualitative visual evaluation would be observed between seven days and six years after resin infiltration, but for both time points compared with before the resin infiltration.

2. Materials and methods

2.1. Study design and patient selection

The study was a clinical, single-center, prospective study (EK 110/13, DRKS00005067). The study design has previously been described in detail [16-18]. Reporting follows the STROBE guideline for cohort studies [19]. All participants as well as their guardians provided their informed written consent. Based on the same cohort and cases 10 Patients with 74 non-cavitated Initial caries lesions [ICDAS 2 (International Caries Detection and Assessment System)] after removal of a fixed

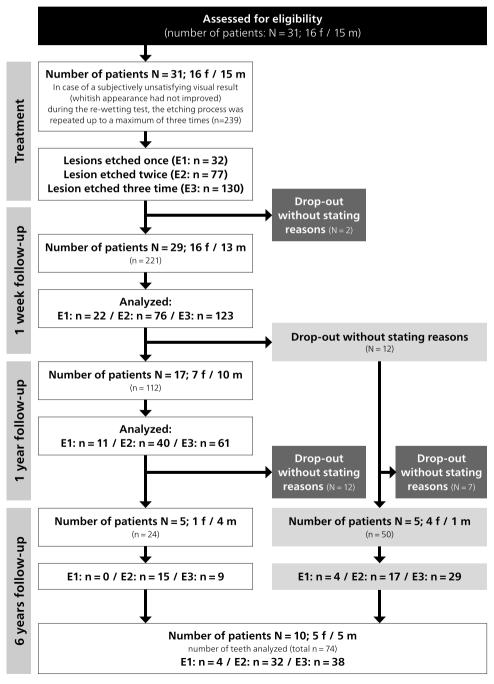


Fig. 1. Participant flow diagram of the cohort for the 6 years follow-up study

orthodontic appliance could be included in this six-year follow-up (Fig. 1). Since the cohorts of the 1-year and 6-year evaluations differed considerably (Fig. 1), no comparison between the 1-year and 6-years results was possible. All inspections and treatments were performed in the Department of Orthodontics, RWTH Aachen University, Germany. Baseline examination and treatment were performed no longer than twelve months after debonding of the fixed elements.

3. Infiltration

Affected teeth were cleaned with a fluoride-free polishing paste (Cleanic; Kerr, Bioggio, Switzerland) and isolated with a liquid rubber dam (OpalDam; Ultradent, South Jordan, USA) to ensure gingival protection and reduce moisture [18]. ICL were etched with 15% HCl gel (Icon etch; DMG, Hamburg, Germany) for 120 seconds. After rinsing with oil-free water for 30 seconds, the lesions were dried and re-wetted with alcohol (Icon dry; DMG, Hamburg, Germany). The dentist then assessed the temporary masking effect of the lesion. In case of a subjectively unsatisfying result, the etching process was repeated. The lesions were then again etched, dried, and re-wetted up to a maximum of three times. Either after achieving a satisfying result or after the third and last etching process, the lesions were infiltrated according to the manufacturer's recommendations. All treatments were performed by one operator (C. K.).

3.1. Photo documentation

Digital, standardized single tooth and overall frontal photos were taken with a SLR camera (Nikon D7000; Nikon, Chiyoda, Japan), a ring flash (Sigma EM-140 DG;Sigma, Kawasaki, Japan) and a macro lens (AF S Micro Nikkor 105mm 1:2.8;Nikon, Chiyosa, Japan) before [T0] (baseline evaluation), one week $[T_7]$ and six years $[T_{2190}]$ after the treatment [16]. The photos were taken by two trained operators (T_0 and T_7 by C. K. and T_{2190} by F. L.)

3.2. Colorimetric analysis

For digital color analysis and processing photoshop (Photoshop Adobe CS6; Adobe, San Jose, USA) was utilized. Color deviations in the photos were equalized by referring to the adjacent grey card. Four different measuring points (11 \times 11 pixels) each were then set in carious [c] and adjacent healthy [h] enamel. Identical measuring points were chosen for the three different time points T0, T_7 and T_{2190} . The $L^*a^*b^*$ -values of all measuring points were then documented in an excel sheet. The color differences between carious and healthy enamel (ΔE) as well as between different time points (ΔE) were calculated with the formula $\Delta E_{c\cdot h} = ((L_c - L_h)^2 + (a_c - a_h)^2 + (b_{c^-} b_h)^2)^{1/2}$ [20] and e.g. $\Delta E_{T1-T7} = \Delta E_{T1}$ - ΔE_{T7} [12,18].

3.3. Quantitative light-induced fluorescence (QLF) documentation

Quantitative light-induced fluorescence (QLF) images were also taken before [T0] (baseline evaluation), one week $[T_7]$ and six years $[T_{2190}]$ after the treatment. The images were recorded using the Inspector Pro system, consisting of the QLF handpiece with an integrated lightguide, camera and ambient light shield and the Inspector Pro Software (version 2.0.0.49, Inspector Research System BV, Amsterdam, Netherlands) [17].

The QLF measurements were performed by two trained operators (T_0 and T_7 by E. E. E. and T_{2190} by F. L.)

3.4. QLF analysis

To quantify location, extent and severity of demineralization all affected teeth were analyzed by the QLF software. In brief: suspicious demineralized areas and nearby healthy enamel were manually marked

to define a region of interest [17]. As done previously the automatic WSL detection mode of the software was not used as in a considerable number of teeth new initial caries lesions were observed six years after debonding (Fig. 2). These lesions were detected in the automatic WSL detection mode and would, of course, have falsified the results of the present study. Afterwards, the QLF software computed the difference (ΔF) between the intensity of the green fluorescence in a point of the image and the intensity of a virtual reconstruction of the sound tooth surface at that same point [21,22].

3.5. Qualitative visual analysis

The digital images of the three time points (T0, T7 and T₂₁₉₀) were also used for visual assessment. Four trained operators (H.M-L.,R.J.W., M.E.-O.,B.A.-A.), with experiences in minimal-invasive and aesthetic treatments, performed a visual evaluation on tooth level (using teeth portraits). As in the QLF analysis, only the area of the original ICL was evaluated, in case of a new ICL this area was excluded from evaluation. Prior to evaluation, all operators were calibrated by discussing clinical cases and agreeing on the degree of ICL expression and masking effect.

Using a 11-point Likert-scale from 0 (no lesions visible on any tooth) to 10 (all teeth affected on the entire vestibular surface) the expression, extension, and contrast of the ICL on tooth level was evaluated [17,18]. The success of treatment was also assessed by five categories: deteriorated (1), unchanged (2), improved, but not satisfying (3), improved and no further treatment required (4), completely masked (5) [18].

3.6. Blinding

Due to the nature of the treatment procedure neither the operator nor the patient could be blinded. However, outcome assessors and the statistician were blinded.

3.7. Statistics

For statistical analysis SPSS (SPSS Statistics 28; IBM, Armonk, USA) was utilized. A prospective power and sample size analysis were performed previously [16]. Furthermore, the retrospective power analysis for the smallest difference (difference between T0 and T_{2190} for teeth being etched once) with 4 teeth still provided a power of at least 99% for ΔE (mean difference (SD): -6.64 (1.73)).

The factors under evaluation were:

- Time at three levels: (T0) situation before treatment, (T₇) one week after treatment, (T₂₁₉₀) six years (≈2190 days) after treatment
- Number of etching procedures: (E1) lesions etched once, (E2) lesions etched twice, (E3) lesions etched three times

Normal distribution was tested using the Shapiro-Wilk-test. Differences of ΔE , ΔF , ΔQ and WS Area in the different groups (E1, E2 and E3) were compared with the Kruskall-Wallis test with Bonferroni adjustment. Differences in ΔE , ΔF , ΔQ and WS Area between different time points (T0, T₇ and T₂₁₉₀) were analyzed using the Friedman-test with Bonferroni adjustments. Differences in ICDAS values between different groups and between different time points were evaluated using chisquare tests. For qualitative visual scores mean values and standard deviations (SD) were used to describe the results of the 11-point Likert-scale and the absolute number of scores were used to describe the results of the 5-point Likert-scale [23]. The correlation between the qualitative and the quantitative evaluation (ΔE) were assessed using Spearman's rank correlation [23]. Intra- and inter-observer reliability were analyzed using Cohens kappa and Fleiss-Kappa, respectively. The level of significance was set at 0.05.



Fig. 2. Digital photographs of an upper second incisor before (A) treatment, (B) 7 days, (C) 1 year and (D) 6 years after resin infiltration. The initial lesion is highlighted by the dotted line. Six years after infiltration new lesions can be seen at the gingival margin that also shows signs of inflammation (indicated by *).

4. Results

4.1. Study design and patient selection

Between November 2013 to December 2014, 31 (16 females, 15 male) patients with 221 lesions were included in this study. Due to nonappearance in the follow-ups, 21 patients had to be excluded after six years, resulting in a drop-out rate of 68%. Ten patients (5 females, 5 males) with a mean (SD) age of 15.6 (± 3.8) years at the first examination participated in this study. The six-years follow-up examination took place between July 2020 and October 2020. Since only 5 of the 10 patients attended the one year and the six year follow-up it was not possible to compare the results at one year and at six years. In total 74 lesions (ICDAS 2) were treated in 74 teeth, of which 13 were upper premolars, 11 upper canines, 17 upper lateral incisors, 12 upper central incisors, 9 were lower premolars, 6 lower canines, 4 lower lateral incisors and 5 lower central incisors.

4.2. Color differences (ΔE)

The median (25th /75th percentiles) color difference between carious and healthy enamel at baseline (ΔE_0) was 10.9 (8.2/13.2) regarding all 221 lesions ($\Delta E_{0;221}$) and 10.3 (8.56/13.0) regarding the 74 lesions ($\Delta E_{0;74}$) (Table 1). A significant decrease to $\Delta E_{7;221}$ =4.0 (2.1/5.8) and $\Delta E_{7;74}$ =3.7 (2.0/5.8),respectively, was observed seven days after treatment (T₇) (p<0.001; Friedmann-test). The six-years follow-up

yielded stable values, no significant differences between $\Delta E_{7;74}$ and $\Delta E_{2190;74}$ (2.9 (1.8/4.2)) (p=0.972), but between $\Delta E_{0;74}$ and $\Delta E_{2190;74}$ (p<0.001) were observed.

The results did not change when analysis of different time points was done separately for the different number of etching procedures (Table 1).

4.3. ICDAS scores

At baseline (T0) all lesions were scored as ICDAS 2 (Table 2). The ICDAS scores significantly decreased seven days after resin infiltration (p<0.001; Chi-square test). Six years after treatment ICDAS scores showed no further change compared to T_7 (p=0.511; Chi-square test). Lesions still ranged from ICDAS 0 to 2.Fifteen lesions were scored as ICDAS 0, 15 as ICDAS 1 and 44 as ICDAS 2.

4.4. QLF differences (ΔF , ΔQ , WS Aera)

The median (25th /75th percentiles) ΔF difference between carious and healthy enamel at baseline ($\Delta F_{0;74}$) was -7.61 (-10.7/-7.6) (Table 1). A significant increase to $\Delta F_{7;74}$ =-6.9 (-7.4/-6.5) was observed seven days after treatment (T₇) (p<0.001; Friedmann-test). The six-years follow-up did not yield constant values. A significant differences between $\Delta F_{7;74}$ and $\Delta F_{2190;74}$ (-7.2 (-8.4/-6.6)) (p=0.025), but not between $\Delta F_{0;74}$ and $\Delta F_{2190;74}$ (p=0.520) were observed.

When analysis of different time points was done separately for the

Table 1 Median (25^{th} /75th percentiles) ΔE, ΔF and ΔQ between carious and healthy enamel at baseline (T_0), seven days (T_7) and six years (T_{2190}).

			ΔΕ			ΔF [%]			ΔQ [% m	m ²]	
Echings	time	n	median	25th and 75th	p-value	median	25 th and 75 th	p-value	median	25 th and 75 th	p-value
frequency				percentiles			percentiles			percentiles	
overall	T_0	74	10.3	8.5; 13.0	reference	-7.6	-10.7; -6.6	reference	-1.0	-7.0; -0.1	reference
	T_7	74	3.7	2.0; 5.8	< 0.001	-6.9	-7.4; -6.5	< 0.001	-0.1	-0.5; -0.1	< 0.001
	T_{2190}	74	2.9	1.8; 4.4	< 0.001	-7-2	-8.4; -6.6	0.520	-0.6	-3.5; -0.2	1.000
once	T_0	4	9.8	9.4; 13.1	reference	-6.8	-8.3; -6.5	reference	-0.1	-0.3; -0.1	reference
	T_7	4	3.9	2.8; 4.5	0.034	-6.7	-7.9; -6.0	1.000	-0.1	-0.9; 0.0	0.368
	T_{2190}	4	4.3	2.3; 6.8	0.034	-8.0	-8.6; -7.3	1.000	-1.8	-3.5; -0.2	0.368
twice	T_0	32	9.8	8.4; 12.3	reference	-6.9	-7.7; -6.5	reference	-0.2	-1.6; -0.1	reference
	T_7	32	2.8	1.7; 4.9	< 0.001	-6.8	-7.3; -6.5	0.202	-0.1	-0.4; -0.1	0.364
	T_{2190}	32	2.6	1.7; 3.7	< 0.001	-6.9	-7.5; -6.5	0.202	-0.4	-2.0; -0.2	0.364
three times	T_0	38	11.6	8.3; 14.3	reference	-10.3	-13.1; -7.4	reference	-3.8	-36.6; -0.5	reference
	T_7	38	4.2	2.3; 6.7	< 0.001	-7.0	-7.8; -6.5	< 0.001	-0.1	-1.1; 0.0	< 0.001
	T_{2190}	38	3.0	2.0; 5.7	< 0.001	-7.7	-9.3;-6.8	0.189	-1.1	-5.6; -0.3	0.244

Median (25th /75th percentiles) ΔE , ΔF and ΔQ between carious and healthy enamel at baseline (T0), seven days (T7)and six years (T2190). P-values indicate (statistically) significant differences in outcomes between T0 and T7 as well as T0 and T2190 (Friedman-test with Bonferroni adjustments). (No) significant differences could be observed between T7 and T2190 (ΔE : p=0.972; ΔF : p=0.025; ΔQ : p<0.001).

Table 2 ICDAS scores and WS area with different etching frequencies at baseline (T_0) , seven days (T_7) and six years (T_{2190}) .

			ICDAS	scores			White Spot	Area	
etching frequency	time	n	0	1	2	p-value	median	25th and 75th percentiles	p-value
overall	T_0	74	0	0	74	reference	0.18	0.02; 0.86	reference
	T ₇	74	20	11	43	< 0.001	0.02	0.01; 0.13	< 0.001
	T ₂₁₉₀	74	15	15	44	< 0.001	0.07	0.03; 0.39	0.520
once	T_0	4	0	0	4	reference	0.02	0.01; 0.04	reference
	T ₇	4	2	1	1	0.091	0.01	0.01; 0.10	1.000
	T ₂₁₉₀	4	1	0	3	0.285	0.22	0.02; 0.41	1.000
twice	T_0	32	0	0	32	reference	0.04	0.01; 0.25	reference
	T ₇	32	15	8	9	< 0.001	0.02	0.01; 0.05	0.202
	T ₂₁₉₀	32	11	11	10	< 0.001	0.05	0.03; 0.21	0.202
three times	T_0	38	0	0	38	reference	0.53	0.07; 2.91	reference
	T ₇	38	3	2	33	0.101	0.03	0.01; 0.17	< 0.001
	T ₂₁₉₀	38	3	4	31	0.036	0.15	0.04; 0.69	0.189

P-values indicate (statistically) significant differences in ICDAS scores (chi-square tests) and WS areas (Friedman-test with Bonferroni adjustments) between T_0 and T_7 as well as T_0 and T_{2190} . (No) significant difference could be observed between T_7 and T_{2190} (ICDAS scores: p=0.511; WS area: p=0.001)..

different number of etching procedures significant difference could only be observed for ICLs being etched three times (Table 1). The corresponding ΔQ and WS area values can be seen in Tables 1 and 2.

4.5. Qualitative visual analysis

The severity of aesthetic impairment due to ICL was rated using the 11-point Likert scale. At baseline (T0) the ICL were rated with an average of 3.8 points (SD 1.4), indicating that mild to moderate cases have been included in the present study. Seven days after treatment (T_7) and six years after treatment (T_{2190}) the ICL were rated with an average of 1.1 (SD 1.0) and 0.9 points (SD 0.9), respectively (inter-observer reliability; Fleiss kappa: T_0 : 0.450 (moderate agreement); T_7 : 0.680 (substantial agreement); T_{2190} : 0.626 (substantial agreement)).

The optical improvement could also be seen in the 5-point Likert scale. At T_{2190} the results of only one tooth were classified as unchanged, whereas 50% (n=37) and 37% (n=27) of the results were classified as improved and no further treatment required and completely masked, respectively (Fleiss kappa: T_{2190} : 0.782 (substantial perfect)).

4.6. Adverse effects

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

5. Discussion

The present study investigated the masking efficacy of resin infiltration qualitatively and quantitatively six years after its application. We confirmed that resin infiltration efficaciously masks post-orthodontic initial carious lesions for at least six years. A significant reduction of the colorimetric values, ICDAS scores and visual impairment could be observed directly after treatment. Results remained stable at the six-years follow-up. However, this reduction could not be observed for all QLF readings. Thus, the hypothesis that no significant change in the colorimetric values would be observed between the seven days and the six-years follow-up had to be partially rejected.

Long-term color stability was assessed by using different methods: colorimetric analysis by using the L*a*b*-values, ICDAS score, qualitative visual assessment and by quantitative light-induced fluorescence. For all outcomes except QLF readings no statistically significant differences between the values seven days and six years after infiltration could be observed. On the one hand this is in line with recent studies presenting follow-up periods of six [6], twelve [15] and 24 months [14]. The latter study even showing stable results up to 45 months [14]. Consequently, resin infiltration seems to be a suitable method for a long-term aesthetical improvement of ICL.

Several issues about the long-term masking efficacy of vestibular

caries infiltration have been discussed in previous studies [14,15,17,18] since follow-up periods were relatively short [6,14,15]. In the present study with a considerably longer observation time than all previous studies, the use of resin infiltration resulted not only in a significant reduction in ΔE -values one week after treatment but also in post-treatment results that remained stable over 6 years. However, newly formed initial caries lesions were observed in non-infiltrated areas in some teeth 6 year after debonding. This, firstly, might be used as indicator for a high caries risk in the included patients and, secondly, indicates that patients have to be instructed that they have to maintain to proper individual oral hygiene standards since resin infiltration does not prevent against new lesions. Otherwise, they might develop a false sense of security.

General methodical issues have been discussed in our previous studies; e.g. the primary aim of the present study (Kobbe et al. 2019), the low inter-operator agreement for baseline overall aesthetic impairment [17], the influence of the time between debonding of the brackets and infiltration of the ICL [18] and the high drop-out rate after 1 year (45%) [17]. As it could be expected the drop-out rate after 6 years (68%) increased compared with the 1-year evaluation of this cohort. This of course resulted in an attrition bias; Although, the retrospective power analysis for the smallest difference with 4 teeth still provided a power of at least 99% for ΔE [T₀ and T₂₁₉₀ for teeth being etched once], this can presumably be seen in the prevalence rates of affected teeth. In the present study the upper premolar was the most effect tooth, whereas previous studies [24-26] and the 7-day and 1- year evaluations [16,18] of the present study reported the lateral incisors and canines as the most affected teeth. However, as in the recent studies upper frontal teeth were more prone to ICL than lower ones. The high drop-out rate (only 10 patients attended the 6-year evaluation) might be explained by the heterogeneous socioeconomic background of the patients in a university hospital and lower awareness of their caregivers. Furthermore, due to the high masking success of the infiltration technique, patients might not understand the need for further participation in the study. Since the aesthetic improvement could be seen directly, most of the patients were satisfied with the result achieved.

To quantify location, extent and severity of demineralization all affected teeth were analyzed using QLF images. As done in the previous publication [17] it could be shown that DeltaF-, DeltaQ-values and White Spot Areas significantly decreased 7 days after treatment and that slight differences between the varying number of etching procedures could be observed. However, in contrast to the 1-year results, in which QLF outcomes remained stable, a significant decrease in all QLF outcomes could be observed after 6 years. It might, firstly, be speculated that QLF analysis is a sensitive tool to asses changes in porosity (progression or regression) of a lesion [27,28] but not for alteration of the porosity due to (low viscosity) resins. However, this would not explain

why the results were reduced 7 days and 1 year after treatment. Secondly, it might be speculated that new ICL in non-infiltrated areas falsified the QLF readings. However, the automatic WSL detection mode of the software was not used and the original demineralized areas and nearby healthy enamel were manually marked to define the regions of interest. Thirdly, teeth alter physiologically and/or unphysiologically (e. g. due to erosive tooth wear, staining) over the years. This might change OLF values of (sound) enamel, resulting in decreased OLF values [29, 30]. However, this difference might become significant after longer time periods. Since QLF outcomes have only been used in two studies with a follow-up period of 2 years [29,31] and in two studies with a follow-up period of 4 years [32,33], this is the first study using QLF outcomes with an observation time of six years or more. Consequently, further long-term studies are needed to investigate the influence of tooth alteration on QLF readings. Nevertheless, based on the present study the used QLF reader was not able to quantify the masking efficacy after 6 years which has been confirmed by colorimetric values, ICDAS scores and subjective aesthetic impairment.

Qualitatively 50% and 37% of the lesions were classified as "improved and no further treatment required" and "completely masked", respectively. This is in line with a recent study on enamel hypomineralization in which a significant and strong correlation between quantitative and qualitative results before and directly after infiltration could be observed [34].

Based on our results it can be corroborated that resin infiltration efficaciously masks post-orthodontic initial caries lesions. Moreover, six years after the significant reduction ΔE remained just slightly below the threshold for perception. Color stability could also be confirmed by significantly decreased ICDAS scores that also remained unchanged during the follow-up period. Quantitative and qualitative assessment showed good to substantial correlations. Furthermore, the used QLF reader was not able to quantify these stable results over time.

6. Author contributions

Richard Johannes Wierichs contributed to conception, contributed to acquisition, analysis, and interpretation, drafted manuscript, gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy

Franzisker Langer contributed to acquisition and interpretation, critically revised the manuscript, gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy

Céline Kobbe contributed to conception and design, contributed to acquisition and interpretation, critically revised the manuscript, gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy

Bedram Abou-Ayash contributed to acquisition, critically revised the manuscript, gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy

Marcella Esteves-Oliveira contributed to acquisition, critically revised the manuscript, gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy

Michael Wolf contributed to acquisition, critically revised the manuscript, gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy

Isabel Knaup contributed to acquisition, critically revised the manuscript, gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy

Hendrik Meyer-Lueckel contributed to conception and design, contributed to acquisition, analysis, and interpretation, drafted manuscript, gave final approval and agrees to be accountable for all aspects of work ensuring integrity and accuracy

Funding statement

This study was funded by the authors and their institution.

Ethical approval

The study was a clinical, single-center, prospective study (DRKS00005067). Approval was given by the ethical committee of the RWTH Aachen (EK 110/13).

Informed consent

All participants respectively their guardians provided their informed written consent.

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Declaration of Competing 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.

Data availability

All data generated or analyzed during this study are included in this article [and/or] its supplementary material files. Further enquiries can be directed to the corresponding author.

Acknowledgments

The authors thank Eva E. Ehrlich for taking the QLF images before and 7 days after treatment.

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