Clinical safety, quality and effect of resin infiltration for proximal caries

Abstract

Aim Resin infiltration of proximal lesions is a new approach to stop caries progression. The aim of this clinical trial was to assess its safety and quality, as well as the therapeutic effect.

Materials and methods In 47 children, adolescents and young adults, ten dentists applied the infiltration material ICON® (DMG, Germany) on initial proximal lesions according to the manufacturer’s instruction. One lesion with radiographic extension into enamel or the outer third of dentin per participant was allocated for the treatment. The clinical safety and quality of resin infiltration were assessed 1 week, 6 months and 12 months after the treatment and the evaluation of the therapeutic effect was analysed by pair-wise radiographs.

Results The clinical safety and quality of the infiltration were assessed in 45 individuals after 12 months. The test surfaces showed no relevant changes in clinical status, plaque accumulation or gingival status (p >0.05). A high quality of infiltration was found for the marginal adaptation. In contrast to the improvement of colour at the one-week recall (p = 0.005), the infiltrated surfaces showed a statistically significant increase in the discoloration within the following year (p = 0.014). Out of the 43 lesions which could be assessed radiographically, only two lesions showed progression to a different score (4.7%).

Conclusion Resin infiltration can be considered a safe and effective treatment to reduce progression of initial proximal caries.

Keywords Clinical quality; Efficacy; Initial lesions; Proximal caries; Resin infiltration; Safety.

Introduction

Proximal caries is still a relevant clinical problem in children, adolescents and young adults [Maragakis et al., 2007; Mejäre et al., 2004; Marthaler et al., 1996] in spite of the caries decline in many countries over the last 30 years [Marthaler et al., 1996]. The treatment of proximal lesions, especially initial ones, remains a dilemma for modern dentistry due to the massive loss of tooth structure of all restorative approaches [Vidnes-Kopperud et al., 2011; Gordan et al., 2009]. On the other hand, the efficiency of professional flossing in proximal caries control is questionable [Hujoel et al., 2006], in addition to the questionable compliance of many patients with proximal oral hygiene measures [Buglar et al., 2010; Ashkenazi et al., 2007]. Therefore, many studies tried to transfer the successful concept of sealing pits and fissures to the proximal surfaces, either with glass-ionomer cement [Trairatvorakul et al., 2011], resin [Martignon et al., 2006] or polyurethane patch [Alkilzy et al., 2009]. Nevertheless, proximal sealing requires two appointments within a few days to create an adequate proximal separation, which may prevent adoption of this procedure as an easy routine, minimally invasive procedure. Infiltration of the porous lesion body with low-viscosity resin offers a new approach for initial proximal lesion [Meyer-Lueckel et al., 2007; Meyer-Lueckel et al., 2006; Mueller et al., 2006], and it showed high efficiency in reducing caries progression in adults [Paris et al., 2010] and children [Ekstrand et al., 2010]. Caries infiltration requires only one visit and was perceived as an easy, applicable method by the dentists as well as a high acceptance by the patients [Altarabulsi et al., 2013].

The aim of the present study was to assess the clinical safety and quality of caries infiltration and to evaluate its therapeutic effect radiographically in children, adolescents and young adults.

Materials and methods

Sample

After protocol approval by the Ethics Committee of the University of Greifswald (BB 52/09), the 47 children, adolescents and young adults (21 female, age range 5–35 years, mean age 17.6±6.9) enrolled in the study had to have a proximal lesion in the enamel or in the outer third of the dentine on a deciduous or permanent tooth assessed radiographically. Exclusion criteria were: pregnancy, mental retardation, allergies (especially to resin materials) and presence of visible or detectable cavitation on the tested proximal surface (according to the manufacturer’s instruction). All patients who participated in this investigation received detailed information about the procedure and they or their parents were required to give an informed consent.
Baseline examination

After customization of the holders with silicon impressions (Optosil® P plus, Hanau, Germany), the bitewing radiographs were taken with digital x-ray (Sirona, 60 kV 7 mA; using the software SIDEXIS® Sirona, Bensheim, Germany). The classification of proximal lesions was made according to the following criteria: radiolucency in the outer half of the enamel (E1), radiolucency in the inner half of the enamel (E2), and radiolucency with obvious spread in the outer third of dentin (D1) [Paris et al., 2010]. Radiolucency with obvious spread in the middle third of dentin (D2) or in the inner third of dentin (D3) was not allowed in the study. The medical history and the dental status were assessed during the baseline examination. This included recording of decayed, missing, filled teeth and surfaces (DMFT/S) and thermal vitality testing of the tooth selected for infiltration and the adjacent teeth using cold spray (Pluradent®, Offenbach, Germany). Furthermore, the clinical status, plaque accumulation as well as the gingival status of the tested teeth were recorded descriptively before treatment. The clinical status was scored as healthy (0), initial carious lesion (1), while carious defect (2) were not allowed at baseline. Plaque accumulation was scored as no plaque (1), mild (2), moderate (3), excessive plaque (4) after the use of a plaque detector [Mira-2-Tone, Hager & Werken, Duisburg, Germany]. The gingival status was scored as healthy (1), bleeding after probing with a WHO probe (2), swelling (3), and strongly inflamed with profuse bleeding (4). Moreover, oral hygiene habits such as tooth brushing, flossing, using of fluoride toothpaste and the frequency of visiting the dentist was recorded using a questionnaire filled out by the patient.

Resin infiltration

Under the supervision of two trained investigators (M.B.A. or M.A.) and without previous practical training before the study, ten licensed dentists at the University of Greifswald applied the resin infiltration after reading the instruction manual from the producer and following the steps. After cleaning the tested and adjacent proximal surfaces with dental floss, a rubber dam (Ivory® Heraeus Kulzer, Hanau, Germany) was placed on the affected tooth and adjacent teeth. After separation with the included wedge, the proximal surface of the test tooth was etched with 15% hydrochloric acid for 120 s with obvious spread in dentin (D1) and polished with finishing discs and polishing strips (Soft-Lex, 3M ESPE, MN, USA). The resin infiltration was applied on the test lesion for 180 s using another enclosed proximal applicator which is also permeable only on one side. After removing the excess material using dental floss, the infiltrant was light-cured [Mini L.E.D, Sirona, Bensheim, Germany] from three sides for 40 s according to the manufacturer’s instructions. In order to improve the infiltration, the infiltrant was reapplied for 60 s and light-cured [Robinson et al., 2001]. Finally, the contour of the proximal surface was finished and polished with finishing discs and polishing strips (Soft-Lex, 3M ESPE, MN, USA).

Recall and clinical evaluation

The clinical safety and quality of the resin infiltration were assessed by two trained examiners who had also performed the screening and assessment at baseline. Patients were clinically re-examined after one week, six months and twelve months. At every recall appointment, the changes in the medical or dental status were assessed. The clinical status, plaque accumulation and gingivitis were recorded according to the same criteria used at baseline. In order to assess the quality of the resin infiltration, the discoloration and marginal adaptation were recorded accordingly. The baseline examination. In case of a discrepancy, they discussed on the basis of the evaluation criteria to find an agreement. At the 6- and 12-month recalls, thermal vitality testing of the infiltrated and adjacent teeth was repeated.

Radiographic assessment

The follow-up radiographs were taken at the one-year recall with the same standardised technique employing the customized bitewing holder used at baseline. The clinical effect of resin infiltration on the caries progression (regression, progression or stable lesion) was assessed by comparison of the baseline and follow-up radiographs. A team of two clinical investigators was trained and calibrated for the pair-wise visual reading. The radiographs were coded and randomly organised. The examiners read the radiographs pair-wise and evaluated the bitewing radiographs with the same criteria at the baseline examination. In case of a discrepancy, they discussed on the basis of the evaluation criteria to find an agreement. After 6 weeks, the conventional pair-wise visual of radiographs was repeated to assess the reproducibility.

Statistical analysis

All data were entered into a SPSS software (SPSS16.0}

40
Results

Forty-five patients were followed up clinically. Two patients could not be contacted by telephone or mail and two participants were excluded from the radiographic follow-up examination due to pregnancy and exfoliation of a primary tooth. The majority of the infiltrated lesions were located on permanent molars and premolars (Table 1). The mean DMF-S of the sample was 6.2 ± 8.2 corresponding to a DMF-T of 3.8 ± 4.4. A slight increase in the patients’ caries experience was observed after 12 months (7.4 DMF-S ± 8.9; 4.9 DMF-T ± 4.5). Furthermore, the study sample showed a very good level of home dental care according to the questionnaires. The majority of the patients (n = 37, 78.7%) brushed their teeth more than once per day and all patients used dentifrices with fluoride. Moreover, 21 patients (44.7%) were using dental floss more than two times per week. The vast majority (n = 45, 95.7%) reported semi-annual check-up visits at the dentist.

Clinical safety and quality

No local or systemic effect as well as changes in the medical status due to the infiltration treatment were detected at the follow-up appointments. Furthermore, no changes in the vitality of the infiltrated or adjacent teeth were found during the course of the study. At baseline, the teeth selected for infiltration showed a considerable amount of plaque (63.8%) and little gingival bleeding (36.2%) which both decreased at one week after the treatment (Table 2). During the course of the study, the infiltrated surfaces showed almost consistent scores of plaque accumulation which did not differ significantly between the recall appointments. Despite of the slight, statistically non-significant increase in gingival bleeding (Table 2), no clinically relevant differences were observed at the recalls. Furthermore, no swelling or strong reaction in the adjacent gingiva was recorded in the assessment of gingival status (Table 2). Considering the clinical status of the infiltrated lesion, a statistically significant decrease in discoloration of the tested surfaces was observed.

<table>
<thead>
<tr>
<th>Teeth</th>
<th>Infiltrated teeth</th>
<th>Infiltrated surfaces</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Permanent Molar</td>
<td>Permanent Premolar</td>
</tr>
<tr>
<td>Number (47)</td>
<td>21</td>
<td>19</td>
</tr>
<tr>
<td>Proportion (%)</td>
<td>44.7</td>
<td>40.4</td>
</tr>
</tbody>
</table>

**TABLE 1** Distribution of the infiltrated lesions according to tooth type and surface.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Code</th>
<th>1-week</th>
<th>6-months</th>
<th>12-months</th>
<th>P values for changes from 1 wk to 12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaque accumulation</td>
<td>No Plaque</td>
<td>18 (39.1%)</td>
<td>17 (40.5%)</td>
<td>13 (28.9%)</td>
<td>0.115</td>
</tr>
<tr>
<td></td>
<td>Minor</td>
<td>27 (58.7%)</td>
<td>21 (50%)</td>
<td>29 (64.5%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>1 (2.2%)</td>
<td>4 (9.5%)</td>
<td>2 (4.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Excessive</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>1 (2.2%)</td>
<td></td>
</tr>
<tr>
<td>Gingiva status</td>
<td>Healthy</td>
<td>41 (89.1%)</td>
<td>37 (88.1%)</td>
<td>35 (77.8%)</td>
<td>0.096</td>
</tr>
<tr>
<td></td>
<td>Bleeding on probing</td>
<td>5 (10.9%)</td>
<td>5 (11.9%)</td>
<td>10 (22.2%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Swelling</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strongly inflamed</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>Discoloration</td>
<td>No discoloration</td>
<td>41 (89.1%)</td>
<td>34 (81%)</td>
<td>35 (77.8%)</td>
<td>0.014</td>
</tr>
<tr>
<td></td>
<td>Partial discoloration</td>
<td>5 (10.9%)</td>
<td>7 (16.7%)</td>
<td>9 (20%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>discoloration of whole surface</td>
<td>0 (0%)</td>
<td>1 (2.3%)</td>
<td>1 (2.2%)</td>
<td></td>
</tr>
<tr>
<td>Marginal adaptation</td>
<td>Smooth transition</td>
<td>44 (95.7%)</td>
<td>40 (95.2%)</td>
<td>43 (95.6%)</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>Sharp-edged margins</td>
<td>2 (4.3%)</td>
<td>2 (4.8%)</td>
<td>2 (4.4%)</td>
<td></td>
</tr>
</tbody>
</table>

**TABLE 2** Plaque accumulation, gingival status and clinical quality at the site of the infiltrations at the 1-week, 6- and 12-month recalls.
through the treatment recorded after one week ($p = 0.005$, Wilcoxon Signed Ranks Test), possibly associated with etching and infiltrating the pores of the lesion. This effect was compensated within the following year ($p = 0.014$, Wilcoxon Signed Ranks Test) (Table 2). Thus, the clinical appearance of the infiltrated surfaces did not change significantly during the study ($p = 0.366$, Wilcoxon Signed Ranks Test), as the vast majority of cases ($n = 44/46, 95.7\%$) showed good marginal adaptation with smooth transition and no sharp edged margins (Table 2).

**Clinical effect**

The inter-rater reliability for pair-wise comparison showed substantial agreement and the intra-examiner reproducibility was almost perfect (0.739 and 0.835 kappa values). The radiographic evaluation of the bitewing radiographs showed no progression of $41/43$ lesions (95.3%) from baseline to the 1-year recall (Fig. 1). The data on progression status revealed that only two lesions (4.7%) had progressed from E2 to D1. Furthermore, one lesion (D1) showed a progression, though limited within the same initial score.

**Discussion**

Treatment of proximal caries, especially lesions which do not reach the middle third of the dentine, varies greatly between dentists [Vidnes-Kopperud et al., 2011; Gordan et al., 2009]. Both non-invasive and restorative treatments have their drawbacks. Caries infiltration offers a new approach which could be an effective technique to arrest or reduce the progression of non-cavitated proximal lesions. Several studies revealed that caries infiltration of proximal caries was superior to placebo and fluoride varnish treatment in reducing caries progression [Paris et al., 2010; Ekstrand et al., 2010]. Therefore, this observational field study evaluates the clinical implementation of infiltration as routine technique in health care system without standardising the training of the dentist and regardless of age, type of lesions and preventive regime.

The selection criteria of the lesions in this study, following the manufacturer’s recommendations, aimed to select the initial lesions without visible cavitation. Although the microcavitations of the tested proximal lesions could not completely be excluded, the progression rate of the initial caries lesions which did not show frank cavity to cavitation is very low even in a high-risk population [Ferreira Zandoná et al., 2012]. In addition, visible cavitation was excluded in the present study.

The present investigation was conducted on children, adolescents and young adults due to the high prevalence of initial proximal caries in these age groups [Maragakis et al., 2007; Mejäre et al., 2004; Marthaler et al., 1996]. As operator-related factors can influence some technique-sensitive procedures such as resin restorations [Kubo et al., 2011; Bouillaguet et al., 2002], the study followed a practice-based design by employing ten dentists who had no previous experience with this procedure.

As caries infiltration is a new technique in dentistry, the estimation of its safety was an important purpose assessed in this study. In the study sample, no adverse effects on general or dental health were recorded within one year. The subjects in this study had moderate caries levels, as in the respective age group in Germany and other industrialised countries [Mejàre et al., 2004; Holst and Schuller, 2000; Marthaler et al., 1996]. Throughout the study, caries incidence in the sample was similar to that of other studies on the clinical effect of proximal sealing or infiltrating lesion in young adults in Germany [Alkilzy et al., 2009; Paris et al., 2010].

A reduction in the quality of composite restorations over time was recorded in several studies [Burkeet et al., 2005; Brunthaler et al., 2003]. Marginal integrity and colour match were always considered important factors to assess the quality of posterior composites [Bayne and Schmalz, 2005; Cvar and Ryge, 2005] and, therefore, the widely used USPHS criteria were adapted for the micro-invasive infiltration technique in order to allow a comparison with the infiltration. Employing these criteria in a typical clinical study on the performance of conservative composite restorations, Demarco et al.

---

**FIG. 1** Development of infiltrated proximal lesions from baseline to 1-year recall in pair-wise bitewing radiographs.
[2011; 2007] reported that 15.5% of the fillings showed sharp margins detectable with the explorer after one year. Proximal sealing using a polyurethane patch [Alkilzy et al., 2009] result in an even higher rate of 28.6% sharp margins after 12 months due to the positive step of the patch. The marginal adaptation of the infiltrated surfaces in this study showed a perfect transition and no steps or margins could be detected in 43 out of 45 cases (95.6%) which is superior to composite fillings [Demarco et al., 2011; 2007; Türkün and Aktener, 2001] and proximal patches [Alkilzy et al., 2009]. Moreover, stable results of the marginal adaptation were observed during the follow-up recalls.

Several in vitro and in vivo studies [Paris et al., 2013; Hammad et al., 2012; Kim et al., 2011] revealed that the infiltrant can practically modify the opaque colour of white spot lesions and restore their translucency. This aesthetic property may explain the huge, rapid improvement in the discoloration of infiltrated surfaces one week after the treatment, but it was reduced in the subsequent 12 months. This increase in discoloration (11.1%) is still acceptable in comparison to the standard composite filling, where up to 61.2% showed a mismatch of colour and translucency after one year [Demarco et al., 2011; 2007]. Even if the USPHS criteria were not developed for assessment of the infiltration, the adapted criteria used in this study show clearly that infiltration is superior to resin restoration and patches in all aspects such as perfect adaptation, anatomical outline and no color issue. These results seem normal and self-explanatory taking into consideration that resin infiltration is based on a rapid penetration into the porous lesion driven by capillary forces [Meyer-Lueckel et al., 2007; Meyer-Lueckel et al., 2006; Mueller et al., 2006], which means that the resin coat on top of the lesion is not necessary if the porous lesion was homogeneously infiltrated [Paris et al., 2006]. Therefore, there is no additional risk factor for creating sharp margins which can increase plaque accumulation and gingivitis [Lang et al., 1983]. Increased plaque accumulation and gingivitis are others factors affecting the quality and prognosis of dental restoration, especially of composite fillings [Svanberg et al., 1990]. The gingival status and plaque accumulation at the infiltrated and adjacent surfaces did not differ significantly during the study.

Regarding the therapeutic and protective effect of caries infiltration of proximal caries, the data of the present study showed the great efficacy of resin infiltration in hampering caries progression (95.7%), similarly to the results from Paris et al. [2010] with 93% after 18 months. Moreover, the effect of resin infiltration on caries progression reported in this study is superior to that found in other studies [Martignon et al., 2012; Ekstrand et al., 2010]. This disparity among the studies was ascribed to the varying proportion of the dentin lesion (61.5% to 44%) [Martignon et al., 2012; Meyer-Lueckel et al., 2012]. In contrast to these speculations, the two lesions that progressed in the present study were located in enamel and there was no further progression in the dentin lesions. Moreover, timing of follow-up on progression remains a questionable explanation after observing the varying results from two studies with a 3-year evaluation of resin infiltration [Martignon et al., 2012; Meyer-Lueckel et al., 2012]. Of course, the different level of caries activity, structured prevention and home dental care between the samples can be considered important factors to explain the different results among the various investigations. In this study, the sample showed adequate levels of home dental care, at least according to the patients’ self-report.

Conclusion

Caries infiltration showed no clinical problems and very good results regarding the clinical quality and safety. Furthermore, the current radiographic data confirm the high efficacy of caries infiltration in hampering the progression of initial proximal lesion extending radiographically in the enamel or the outer third of dentin.

Acknowledgments

Innovative Zahnmedizin (Switzerland) is acknowledged for supporting the study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Conflicts of interest

There are no conflicts of interest for any of the authors involved in this study.

References
