Prevention of white spot lesion formation during treatment with fixed orthodontic appliances

The efficacy of using a fluoride rinse and repeated oral hygiene instructions

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CHAPTER 2

A PROSPECTIVE, RANDOMIZED PLACEBO-CONTROLLED CLINICAL TRIAL ON THE EFFECTS OF A FLUORIDE RINSE ON WHITE SPOT LESION DEVELOPMENT AND BLEEDING IN ORTHODONTIC PATIENTS

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ABSTRACT

Demineralizations around orthodontic brackets are a main disadvantage of orthodontic treatment. To prevent their development several methods have been advocated, such as fluoride rinses or varnishes. In this randomized clinical trial a fluoride rinse (combination of sodium-fluoride and amine-fluoride) was compared with a placebo rinse, to be used every evening after tooth brushing. A total of 81 participants (mean age 13.3 years) completed the study (mean treatment period 24.5 months). Demineralizations, measured using Quantitative Light-Induced Fluorescence, and Decayed, Missing and Filled Surfaces (DMFS) were assessed before treatment (baseline) and around six weeks after debonding (post treatment). Bleeding scores were measured at baseline, during and post treatment. The Incidence Rate Ratio for demineralizations was 2.6 (95% CI 1.1-6.3) in the placebo group versus the fluoride group. In the fluoride group 31% of the participants developed at least one demineralization, compared to 47% in the placebo group. Relative to baseline, gingival bleeding increased significantly in the placebo group one year after start of treatment and onwards. For the fluoride group bleeding scores during treatment were not different from those at baseline. In conclusion, using a fluoride rinse helps to maintain better oral health during fixed appliance treatment, resulting in fewer demineralizations.
INTRODUCTION

Most orthodontic patients are treated because of aesthetic reasons with only a minor part of patients receiving orthodontic treatment due to medical or dental indications (Ackerman, 2010). Any potential disadvantages, such as demineralizations, must therefore be taken into account before a treatment starts. The environment in the adolescent oral cavity will be affected by the placement of fixed orthodontic appliances, changing the microbial composition and increasing the number of retention sites and thus plaque formation (Naranjo et al., 2006, Gastel J et al., 2008). This disturbance of a balanced microbial ecology may in turn contribute to oral diseases such as caries (Crielaard et al., 2011) and periodontitis (Socransky, 1977, Loesche, 1996). Because clinical investigations have shown that generalized gingivitis develops within one or two months of placement of fixed appliances (Zachrisson and Zachrisson, 1972), good oral hygiene is an important prerequisite for sustaining oral health during orthodontic treatment (Kloehn and Pfeifer, 1974, Atack et al., 1996) and also for preventing the formation of white spot lesions (WSL) in enamel (Øgaard et al., 1988). According to the literature the prevalence of WSL ranges between 50-97% (Gorelick et al., 1982, Boersma et al., 2005, Al Maaitah et al., 2011, Julien et al., 2013), depending on the examination technique used and the duration of treatment.

Clinical studies have used several methods to detect and measure WSL, based either on clinical indices (Gorelick et al., 1982), on photographic examinations (Millett et al., 1999), or on other optical methods such as quantitative light-induced fluorescence (QLF) (Boersma et al., 2005, Mattousch et al., 2007). QLF is an optical, visible light-based system that can be used to detect and quantify early demineralization of enamel.

Various methods of reducing the formation of WSL have been described, including the improvement of oral hygiene and the use of additional fluoride such as in varnishes or rinses. The most common oral hygiene protocol recommended by orthodontists is probably a daily 0.05% sodium-fluoride rinse in conjunction with fluoridated toothpaste (Derks et al., 2007). But although this recommendation is based on research showing that the use of sodium-fluoride rinse significantly reduces caries rates in non-orthodontic patients, the evidence with regard to its efficacy in preventing WSL in orthodontic patients is inconclusive (Benson et al., 2013). Some moderate evidence is found that fluoride varnish applied every six weeks during orthodontic treatment is effective (Stecksen-Blicks et al., 2007, Benson et al., 2013).

In this randomized clinical trial (RCT), we compared a fluoride rinse (combination of sodium-fluoride and amine-fluoride) with a placebo rinse in preventing WSL in patients undergoing orthodontic treatment with fixed appliances. WSL incidence was assessed by QLF.
METHODS

Study population and clinical procedures

An RCT was performed, under normal practice settings, on the efficacy of a fluoride rinse during orthodontic treatment with fixed appliances. Approval of the Medical Ethical Committee of the VU Medical Centre of the VU University of Amsterdam was obtained for this study (VU-METc 2009/026 and Dutch trial register: NTR1817).

The study was conducted at the Department of Orthodontics of the Academic Centre for Dentistry Amsterdam (ACTA). Patients who were scheduled for full fixed orthodontic appliances at ACTA were eligible to participate after written informed consent. Patients needed to fulfill the following criteria: (1) age between 10-18 years, (2) good general health, (3) no use of medication, and (4) no demineralizations in need of restorative present at a buccal surface. All patients selected for this study received fixed appliances in both jaws. The brackets used were Roth Ovation Brackets (Dentsply GAC international, Bohemia, New York, USA). After placement of the fixed appliances the participants were randomly assigned to rinse A or B, which contained either 250 ppm fluoride (100 ppm amine-fluoride and 150 ppm sodium-fluoride) (Elmex caries protection, Colgate-Palmolive Europe, Therwil, Switzerland) or was a fluoride-free placebo rinse (also provided by Colgate-Palmolive Europe), further mentioned as fluoride respectively placebo. The bottles with rinse were identical in appearance, consistency, taste and smell. This was tested and regulated by Colgate-Palmolive Europe. Allocation of study id was determined by order of inclusion and appointment scheduled by reception persons. Assignment occurred at the first appointment by using a pre-defined randomization list (made in Microsoft Office Excel 2003). Participants were informed that they could receive either a rinse containing fluoride or a placebo rinse. Participants, examiners, statistician and treating orthodontic postgraduates were blinded for test and placebo product type. During the study period participants were instructed not to use any other fluoride containing products other than fluoride toothpaste. The participants’ dentist was informed about the ongoing study and instructed not to apply extra fluoride during the study period. All examinations were done, mainly by the researcher (NK) and by trained dental students. Approximately one week before the placement of the fixed appliances (T0) QLF images were made and an intra-oral examination was performed. QLF images of buccal surfaces of all teeth in upper and lower jaw from second premolar to second premolar were captured. Participants were clinically examined using the Decayed, Missing, and Filled Surface (DMFS) Index (World Health Organisation, 1997) and the International Caries Detection and Assessment System (ICDAS) (Pitts, 2004, Ismail et al., 2007, Topping and Pitts, 2009) followed by assessment of gingival bleeding. Participants were assessed, at regular intervals (approximately 6 weeks (T1), 3 months (T2) and every 6th month after the placement (T3 and further)) during the orthodontic treatment to stimulate optimal oral hygiene, to supply the rinse and to look for unwanted signs of developing
caries. At these intervals bleeding was also recorded. At the day of debonding (TD) and around 6 (TD1) and 12 (TD2) weeks after debonding DMFS, ICDAS and bleeding scores were assessed and QLF images were made to quantify the WSL. The caries assessments of TD1 were used for data analyses. Figure 1 shows a flowchart with the different time points and measurements. The end of data-collection was set at January 2013. After analysing all data obtained the code regarding the rinse was broken.

**Primary study parameter**

The main study parameter was the number of caries white spot lesions as found by QLF, developed during the treatment with fixed orthodontic treatment.

**Secondary study parameters**

Secondary study parameters were the ICDAS-score and DMFS measured before and after fixed appliance treatment; the bleeding scores per participant measured at different time points during the fixed orthodontic appliance treatment; and the lesion extent of the WSL as determined by QLF (fluorescence loss and lesion area) after debonding.
Power analysis
No earlier performed studies are known. A power analysis was performed for an effect of 0.25 (with a power of 0.8 and a significance level of 0.05). This results in a total of 94 participants or 47 participants per study group. To compensate for participant attrition, we aimed to include 120 patients in total.

QLF imaging; WSL measurements
Fluorescence images of the (to be) bonded buccal surfaces were captured using an intra-oral fluorescence camera (QLF/Clin; Inspektor Research Systems, Amsterdam, the Netherlands) (Angmar-Mansson and ten Bosch, 2001, de Josselin de Jong et al., 2009). Dedicated software (Inspector-Pro version 2.0.0.48; Inspektor Research Systems) was used to assess the QLF images after debonding (fluorescence loss i.e. white spots). QLF images were analysed for fluorescence loss (ΔF) and size of lesion area (A) using a threshold of 5%, at TD1 in comparison with the QLF images made at T0. If caries was present at T0, the results were subtracted from TD1, using the method described by Mattousch (Mattousch et al., 2007). The number of lesions per participant was calculated and for every participant having at least one lesion mean ΔF and area were calculated. The measurements were done by the same examiner (NK). The examiner (NK) was trained and calibrated for QLF assessments against experienced examiner (MV) prior to study start. Inter- and intra-observer reliability were established at a random sample of 10% of the participants with an interval of two weeks. The inter-examiner ICC scores for QLF were 0.92 for the ΔF and 0.96 for the lesion area. The intra-examiner ICC was 0.94 for ΔF and 0.98 for the lesion area.

DMFS
DMFS of all participants was scored by examining all teeth with the use of a mouth mirror, an explorer and optimal light (World Health Organisation, 1997). Also, radiographs (orthopantomographs and when available bitewings or solo-images) were checked carefully. The D-portion comprised all surfaces with signs of decay diagnosed clinically as caries lesion with enamel breakdown. To determine the M-portion of the DMFS, only surfaces missing due to caries were counted. Teeth extracted for orthodontic purposes were not included. Restorations made because of trauma were excluded from the F-portion.

ICDAS
Before placement (T0) and after removal of the appliances (TD, TD1 and TD2) the buccal surfaces from all bonded teeth were examined using the ICDAS assessment system (Pitts, 2004, Ismail et al., 2007, Topping and Pitts, 2009). Each buccal surface received a code from 0 to 6 to express the degree of caries.
Code 0 depicts sound surface without change after air-drying except for stain, hypoplasia, wear, erosion and other non-caries phenomena.

Code 1 is given for first visual change in enamel, seen after air-drying.

Code 2 is given if a distinct visual change (white or colored) is seen on wet enamel surface.

Code 3 is given when local enamel breakdown is present, but without visible dentine.

Codes 4 to 6 are given to cavitated lesions with increasing severity.

Average ICDAS-scores were calculated for each participant.

**Bleeding score**

During each visit, a gingival bleeding score was determined by probing each (to be bonded or bonded) tooth mesiobuccal and distobuccal with a periodontal probe. Based on the percentage of the bleeding sites, bleeding scores 1 to 5 were given for the whole mouth (thus per participant).

- Score 1 (good) - if none to 5% of the sites were bleeding.
- Score 2 (medium/good) – if 6 to 10% of the sites were bleeding.
- Score 3 (medium) – 11 to 20% of the sites bleeding.
- Score 4 (medium/poor) – 21 to 35% of the sites bleeding.
- Score 5 (poor) – if more than 35% of the sites were bleeding.

**Statistical analyses**

The statistical analyses were performed using IBM SPSS 20.0 and Stata (Intercooled Stata 10.0; Stata Corporation, College Station TX, USA).

We estimated the difference in number of WSL (primary end point) and DMFS score between participants with fluoride and placebo rinses, using a regression model. Because both number of WSL and DMFS are count variables and our data were over-dispersed (variance much greater than mean), we used negative binomial regression (Grainger and Reid, 1954, Bohning et al., 1999). Likelihood ratio tests comparing our negative binomial models to Poisson regression models were used to evaluate our decision. Because caries lesion data often exhibit an excess number of zeroes (Preisser et al., 2012), we also compared our negative binomial models to zero inflated negative binomial regression models using the Vuong test. Both tests indicated a negative binomial regression model offered the best possible fit. Results were expressed using the estimated Incidence Rate Ratio (IRR) and 95% Confidence Intervals (95% CI) were constructed.

To investigate possible confounding by treatment duration, bleeding, DFMS or ICDAS scores at T0 we added these parameters to the model. None of them induced a change of more than 10% in the estimated IRR, so no confounding was present.
Differences in ICDAS, fluorescence loss and lesion area were tested by means of a Mann-Whitney U test. A Wilcoxon signed ranks test was used to compare the bleeding score at different time points, with a Bonferroni correction for multiple comparisons.

RESULTS

Descriptive results

A total of 120 participants were entered into the study between April 2009 and January 2011. Nine participants declined further participation immediately after T0 (approximately one week before bonding), at placement of the fixed appliances, thus not receiving the allocated rinse. Eleven further participants declined to participate later during the study, in addition to one participant who moved away and one who failed to show up for appointments. Eighty-one of the 98 remaining participants were debonded before January 2013. This point was chosen to end the study according to protocol. At the study end point 17 participants were expected to continue treatment with fixed appliances for more than three months, exceeding the study period due to unforeseen treatment complications or non-compliance. The mean treatment time was 24.5 (SD 5.5) months. A flowchart for all different analyses is shown in Figure 2.

Table 1. Characteristics of the study group at baseline (T0).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Fluoride (n = 36)</th>
<th>Placebo (n = 45)</th>
<th>All (n = 81)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)*</td>
<td>13.1 (10.0-16.6)</td>
<td>13.6 (11.7-16.5)</td>
<td>13.3 (10.0-16.6)</td>
</tr>
<tr>
<td>Male gender, (n) (%)</td>
<td>14 (38.9)</td>
<td>21 (46.7)</td>
<td>35 (43.2)</td>
</tr>
<tr>
<td>Treatment duration (months)*</td>
<td>25.0 (12.0-36.3)</td>
<td>24.1 (13.3-37.6)</td>
<td>24.5 (12.0-37.6)</td>
</tr>
<tr>
<td>DMFS score ***</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>67</td>
<td>58</td>
<td>62</td>
</tr>
<tr>
<td>1-2</td>
<td>11</td>
<td>24</td>
<td>19</td>
</tr>
<tr>
<td>3-4</td>
<td>19</td>
<td>7</td>
<td>12</td>
</tr>
<tr>
<td>(\geq 5)</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>DMFS score overall**</td>
<td>0 (14)</td>
<td>0 (13)</td>
<td>0 (14)</td>
</tr>
<tr>
<td>ICDAS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.00</td>
<td>47</td>
<td>53</td>
<td>51</td>
</tr>
<tr>
<td>0.01-0.05</td>
<td>17</td>
<td>11</td>
<td>14</td>
</tr>
<tr>
<td>0.06-0.15</td>
<td>17</td>
<td>18</td>
<td>17</td>
</tr>
<tr>
<td>(\geq 0.16)</td>
<td>20</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>ICDAS score overall**</td>
<td>0.05 (0.8)</td>
<td>0 (0.7)</td>
<td>0 (0.8)</td>
</tr>
<tr>
<td>Bleeding*</td>
<td>2 (1-4)</td>
<td>1 (1-3)</td>
<td>1 (1-4)</td>
</tr>
</tbody>
</table>

Data are expressed as *mean (range), **median (maximum), or ***percentage.
Table 1 contains baseline data; there were no significant differences between groups. There were no WSL present at baseline. Caries data of 6 weeks after debonding (TD1) were used for 77 participants. For three, who missed appointment TD1, the WSL assessments (QLF, DMFS and ICDAS) from immediately post-debond (TD) were used, and for one the QLF pictures, due to malfunction of the QLF-device were only made at TD2. The WSL assessments were made at an average of 52 days after debonding (with a range from 0-156 days).

![Flowchart](image-url)
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Given the difference in treatment duration between participants and taking account of the loss to follow-up, the bleeding data were assessed in two separate steps: complete dataset from baseline until T6 and complete dataset from baseline until T5, TD1 and TD2. A total of 66 participants (31 fluoride group, 35 placebo) were analysed who had a complete dataset regarding bleeding from start (T0) until two years after placement of fixed appliances (T6; mean 727 days). Of these participants, 25 fluoride and 31 placebo participants were also analysed for WSL after debonding. 56 participants (26 fluoride group, 30 placebo) were analysed with a complete dataset regarding bleeding from start (T0) until one year and six months after placement of fixed appliances (T5; mean 555 days) and TD1, 6 weeks after debonding (mean 50 days) and TD2 3 months after debonding (mean 99 days). Since many appliances were removed between T5 and T6, T6 was excluded from this analysis.

QLF-results

WSL counts

Out of 81 participants, 32 participants had developed at least one WSL (39.5%). In the fluoride group, 11 out of 36 participants developed at least one WSL (30.6%), ranging from one to five WSL per participant (fig. 3). In the placebo group, 21 out of 45 participants had at least one WSL (46.7%), with a range of one to 15 WSL per participant. Participants in the placebo group had an IRR of 2.6 (95% CI 1.1-6.3) compared to fluoride rinse (P=0.038). DMFS, ICDAS, and bleeding at T0 and treatment duration were no confounders.

Figure 3. Percentage of total participants and their white spot lesion counts, 52 days after debonding. In the fluoride group 69.4% of the participants were WSL-free, compared to 53.3% in the placebo group after treatment with fixed orthodontic appliances.

Fluorescence loss; ΔF [%] and lesion area [mm²]

The mean ΔF and mean area was calculated for each participant with at least one WSL (fluoride group n= 11 and placebo group n =21). The mean ΔF was 10.3% (SD 3.0) for placebo
participants and 11.6% (SD 5.0) for fluoride participants. Mean area was 1.3mm$^2$ (SD 1.6) for placebo participants and 0.9mm$^2$ (SD 0.6) for fluoride participants. At a mean of 52 days after debonding there were no statistically significant differences in mean ΔF and mean area of the lesions per participant between both groups (table 2).

**DMFS-results**

DFMS scores at TD1 ranged from 0 to 13 in the placebo group and from 0 to 26 in the fluoride group (table 2). In the fluoride group there was one outlier, this subject started with a DMFS of 14 and after debonding had a DMFS of 26. Both groups showed a significant increase in DMFS between T0 and TD1. A negative binominal regression analysis showed that there were no differences in the DMFS between both groups.

**ICDAS-results**

There were no significant differences between the placebo and fluoride rinse regarding the ICDAS scores after debonding. Also no significant difference between T0 and TD1 were found regarding the ICDAS scores (fluoride: $P=0.88$ and placebo: $P=0.06$) (table 2).

**Bleeding**

**Bleeding T0-T6**

Gingival bleeding scores of the individuals receiving the placebo rinse were significantly higher at three points: visit T4, one year since start of treatment (mean 373 days) ($P=0.02$); visit T5, one year and six months (mean 546 days) since start of the treatment ($P=0.00$); and visit T6, 2 years (mean 718 days) since the start of the treatment ($P=0.00$) compared with the respective baseline visit scores. For the group receiving the fluoride rinse, this difference did not reach statistical significance (fig. 4). A Mann-Whitney U test showed that there were no differences between the groups at the different time points.

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**Table 2. Results, 6 weeks post debonding (TD1), according to study group and for the total group.**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Fluoride</th>
<th>Placebo</th>
<th>All</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>TD1</td>
<td>n</td>
</tr>
<tr>
<td>WSL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td>36</td>
<td>0 (5)*</td>
<td>45</td>
</tr>
<tr>
<td>Mean ΔF (%)</td>
<td>11</td>
<td>11.6 ± 5.0</td>
<td>21</td>
</tr>
<tr>
<td>Mean A (mm$^2$)</td>
<td>11</td>
<td>0.9 ± 0.6</td>
<td>21</td>
</tr>
<tr>
<td>DMFS</td>
<td>36</td>
<td>0 (26)</td>
<td>45</td>
</tr>
<tr>
<td>ICDAS</td>
<td>36</td>
<td>0.05 (0.6)</td>
<td>45</td>
</tr>
</tbody>
</table>

Data are expressed as the median (maximum), or as mean ± SD.
* Significant difference ($P < 0.05$) between the fluoride and placebo groups.
Figure 4. Bleeding scores during visit T0- T6, for the fluoride (left panel) and placebo rinse (right panel). At visit T4 and at subsequent visits the placebo group differs significantly compared to baseline. The fluoride group did not show a difference.
Bleeding T0-T5 and TD1, TD2
Comparison of participants in the two groups indicated that there were no differences after removal of the fixed appliances.

**DISCUSSION**

This is the first randomized, triple-blind, placebo-controlled study showing that a fluoride rinse reduces the formation of WSL during fixed orthodontic appliance treatments. Participants using placebo developed 2.6 times more WSL during the study period than participants using a daily fluoride rinse containing 100 ppm amine-fluoride and 150 ppm sodium-fluoride. In the fluoride group 31% of participants developed at least one WSL. A previous study showed that 33.5% of the patients developed WSL after using a 0.05% sodium-fluoride rinse, no placebo was used in that study (Geiger et al., 1992). In our study 47% of the participants developed at least one WSL, while using a placebo rinse. This figure is comparable with the literature, showing around 50% of WSL development without a preventive method or after using a placebo foam (Gorelick et al., 1982, Jiang et al., 2013). We could not demonstrate a reduction in overall lesion size and depth using a fluoride rinse if WSL developed. Our finding of considerably fewer WSL than observed in the QLF study of Boersma (Boersma et al., 2005) might be due to the fact that the ACTA orthodontic department has introduced a stringent oral hygiene protocol since Boersma’s study.

In this study we measured WSL (QLF, DMFS and ICDAS) at 6 weeks after debonding, since it is known that the gingival swelling immediately after debonding obscures part of the buccal surfaces, but recedes six weeks later and thus showing a higher number of WSL at TD1 (Boersma et al., 2005).

WSL are not only an aesthetic problem, after debond an overall improvement is seen in only 16% of the lesions, a large portion (49%) of the caries lesions remains stable over time and 15% of lesions are in need of or received restorative care two years after debonding (Mattousch et al., 2007).

Compliance is often mentioned as a shortcoming of prescribing a rinse. It has been reported that the more compliant a patient is, the fewer WSL are formed (Geiger et al., 1992). The latter colleagues also found that those patients who exhibited poor oral hygiene, but were strict in their rinsing, showed a reduction in the incidence of WSL. Since both groups in our study used a rinse, we assume compliance was similar in both groups. Compliance was not checked, thus mimicking normal practice settings. Thus, we demonstrated that a rinse is an effective method for WSL prevention during treatment with fixed orthodontic appliances, even if participants may be non- or partially compliant.

Even though we showed a difference in WSL development between groups, we did not meet the goal of our power analysis. This was firstly due to the overall load of the appoint-
ments, although mostly scheduled in combination with regular visits, resulting in a higher attrition. Secondly, extensions of treatment duration in combination with the end-point of January 2013 resulted in fewer participants in our analyses than planned.

Our study showed that rinsing with fluoride helped to maintain good oral health during fixed appliance treatment, as evidenced by a lower bleeding score over time. For non-orthodontic populations it is known that use of a Meridol (amine/stannous fluoride) rinse retards the development of gingivitis, resulting in a lower bleeding score as well as a lower plaque gingival bleeding indices (Brecx et al., 1993, Madléna et al., 2012). In an orthodontic population one study reported the effect of Meridol on bleeding (Øgaard et al., 2006), indicating that bleeding increased significantly between bonding and debonding for the group only using a fluoride toothpaste, whereas in the group using Meridol bleeding did not change between bonding and debonding. No other studies are known that show a positive effect on bleeding using a fluoride rinse during fixed appliance treatment.

Based on this study, we conclude that the prescription of a fluoride rinse, to be used at home, has a measurable positive preventive effect on the overall oral health. It helps to prevent WSL formation and to slow down the number of WSL and to maintain a better gingival health (measured as bleeding).
REFERENCES


