Randomized Controlled Trial

A randomized clinical trial comparing the impact of different oral hygiene protocols and sealant applications on plaque, gingival, and caries index scores

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SUMMARY
OBJECTIVE: This prospective randomized clinical trial investigated the impact of different tooth brushing strategies and sealant application on patients with fixed appliances: plaque, gingival, caries index scores, periodontal parameters, microbial, and molecular biological parameters were assessed.
MATERIALS AND METHODS: Fifty-five male and 63 female patients aged 11–15 years were enrolled in this 12-week, four-arm parallel-group trial. Patients of group 1 used a Sonicare® FlexCare electric brush, patients of group 2 used a manual (elmex® interX short head) plus interdental (Curaprox® CPS 15) brush, and patients of group 3 and 4 used a manual brush only. The teeth of patients in groups 1, 2, and 3 were sealed with a filled resin (ProSeal®). Patients were advised to brush twice daily and measured time spent brushing mornings and evenings [tooth brushing duration (TBD)]. Plaque (PIB, TQHI, MAPI) and gingival index (PBI) as well as caries index (DMFT/DMFS) scores were assessed at baseline and after 4, 8, and 12 weeks.
RESULTS AND CONCLUSIONS: TBD did not differ significantly between patients using the electric or manual brush only (between 197 and 209 seconds) but was longer when using the combination of two manual brushes. TBD was slightly longer in the evenings. There was no gender difference. Although TBD was longer for the combination group, we failed to demonstrate any beneficial effect on outcome parameters for this group. No differences between sealed or unsealed tooth surfaces or for use of a manual or electric brush were observed.

Introduction

Development of incipient carious lesions is one of the most frequently encountered unwanted side effects of orthodontic treatment with fixed appliances. Previous studies have shown that nearly 25 per cent of the patients developed one or more decalcifications during the course of treatment with fixed appliances (Lovrov et al., 2007; Julien et al., 2013). The high incidence has been attributed to the plaque retention of the appliance components that make tooth brushing more difficult and lead to prolonged biofilm accumulation on tooth surfaces (Zachrisson, 1974) and various preventive strategies have been suggested (Derks et al., 2004).

Biofilm removal plays a key role in prevention of gingivitis, periodontal disease, caries, and decalcification and use of fluoride toothpaste is particularly important (Wong et al., 2011). There is conflicting evidence whether an electric or a manual brush is better during fixed appliance treatment (Kossack and Jost-Brinkmann, 2005; Costa et al., 2007; Kaklamanos and Kalfas, 2008). Differences in research design and lack of data on tooth brushing duration (TBD) might explain contradictory study outcomes (Van der Weijden et al., 1993; Robinson et al., 2006). There is little scientific evidence, which conclusively proves that the use of an interdental brush is effective (Arici et al., 2007; Goh, 2007; Bock et al., 2010).

Use of enamel surface sealants is compliance free and is designed to protect the teeth from decalcification. Sealants have recently gained in popularity. Although a number of in vitro studies support the caries protective properties of filled resin sealants (Hu and Featherstone, 2005; Buren et al., 2008), little information is available about the impact of these sealant sealed surfaces in vivo (Fornell et al., 2002; Sobiegalla, 2009). Several studies that investigated the effect of tooth brushing on deterioration of sealants and

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restorative resin materials showed an increase in surface roughness with increasing brushing (Engel et al., 2009; Heintze et al., 2010; Korbmacher-Steiner et al., 2012) and surface roughness is associated with increased bacterial attachment (Mei et al., 2011).

Although various caries preventive strategies can be used in combination, there are few studies involving orthodontic patients investigating two effects, i.e. brushing technique and sealant use.

‘Equipment factors’ such as manual versus electric brush as well as TBD have been shown to be an important variable in comparative tooth brushing studies; biofilm removal efficacy increases with brushing time and may vary depending on the brushing device(s) used (Van der Weijden et al., 1993; Pelka et al., 2011). In the majority of studies investigating oral hygiene, the TBD was standardized at 2 or 3 minutes (Van der Weijden et al., 1993; Van der Weijden, 2002). However, fixed appliances make tooth brushing less effective and these may require longer brushing times to be effective, particularly when recommendations are based on a ‘systematic brushing sequence’. To our knowledge, this is the first investigation on the duration of tooth brushing in patients with fixed orthodontic appliances on the basis of time measurements.

The objective of the present study was to comprehensively describe and compare the impact of different tooth brushing strategies and sealant applications on the oral hygiene status of orthodontic patients during the first 3 months of treatment with fixed appliances. This was by examination of clinical, microbial, and molecular biological oral hygiene parameters. Past investigations have shown that tooth brushing habits can have a profound impact on oral hygiene parameters (Poyato-Ferrera et al., 2003; Creeth et al., 2009; Peros et al., 2012) and part of our study was to provide detailed information what impact group-specific brushing techniques and sequences had on the time spent brushing. This study also compared the effect of different dental cleaning devices and a resin-based sealer on plaque, gingival, and caries index scores. Periodontal, microbial, and molecular biological differences between the groups will be reported in part 2 of this investigation.

**Aims of the study**

1. To describe tooth brushing habits when using an electric sonic toothbrush, manual toothbrush alone or a manual brush in combination with an interdental brush.
2. To compare the TBD between the three tested brushing strategies.
3. To investigate cleaning outcomes of the three cleaning devices in cohorts of patients with 1. initially either lower or higher plaque values, 2. males or females, and 3. anterior or posterior teeth that occurred longitudinally in the first 3 months of fixed appliance treatment. We also investigated whether TBD is longer in the morning or evening.
4. To compare the impact of a sealant on the above parameters. A manual brush only group was used as a control group on teeth without sealant.
5. To investigate group differences with respect to changes of 1. plaque, gingival, and caries index scores, 2. periodontal, 3. microbial, and 4. molecular biological parameters from baseline to week 12.

**Materials and methods**

**Study design and treatment groups**

This study was a 12-week, blinded, single-centre, stratified, four-arm, parallel-group randomized clinical trial with an equal patient allocation to the four groups (Figures 1–3):

- Group 1: sonic toothbrush and surface sealant
- Group 2: manual toothbrush, interdental brush, and surface sealant
- Group 3: manual toothbrush and surface sealant
- Group 4: manual toothbrush

**Ethical approval**

The study protocol was approved by the ethics committee of the medical faculty of the University of Jena (approval no. 2210-01/08) and the trial was registered before commencement using the US National Institutes of Health clinical trial registration system (registry number NCT00681135). The study conformed to the Declaration of Helsinki and was performed according to the guidelines of Good Clinical Practice. Before participation, all the participants and their parents/guardian(s) received full oral and written information on the aims of the study and signed a written form of consent.

**Study setting and eligibility criteria**

Patients were recruited from an orthodontic practice in Herford, Germany. The inclusion criteria were 1. age 11–15 years, 2. no relevant medical history, 3. treatment with fixed orthodontic appliances indicated and with at least 10 fully erupted permanent teeth per arch, and 4. consent. Participants were excluded if they had 1. a carious lesion or defective filling(s), 2. past history of treatment with antibiotics or antibacterial rinses within 6 months of entering the study, or 3. a diagnosis of

**Figure 1** The three dental cleaning devices tested (from left to right): Sonicare® FlexCare with ProResults brush head, elmex® interX short brush-head toothbrush, Curaprox® CPS 15 interdental brush with holder UHS 410.
early onset periodontitis. The use of antibiotics during the study period led to exclusion. Hand dominance was documented.

**Randomization**

Patients were randomly allocated on the basis of block randomization and stratified according to plaque extent measured by the Turesky modification of the Quigley–Hein Index (TQHI; Quigley and Hein, 1962; Turesky et al., 1970; ≤1.5 or >1.5). The computerized generating of a random allocation sequence was carried out by a statistician. The allocation to treatment was concealed in an opaque, sealed, and serially numbered envelope opened by a dental hygienist after the baseline examination. The outcome examiner (DJW) was
blinded to patient allocation with respect to the used dental cleaning devices.

**Protocol**

The clinical trial consisted of three stages: screening examination (visit 1), baseline examination (visit 2), and evaluation period: the latter consisted of three further visits (3, 4, and 5) over a 12-week evaluation period. The observer was ‘blinded’ to group allocation when assessing the oral hygiene parameters.

During the first visit, patients were screened for suitability and consent was obtained. At the second visit, full mouth clinical, microbial, and molecular biological baseline investigations were recorded. Subsequently, professional prophylaxis consisting of scaling and polishing was undertaken. Sealants were applied to the patients in group 1, 2, and 3. During the 3-month observer-blinded evaluation period, all the subjects were given recall appointments at time intervals of 28 days after the baseline visit. Details can be found in Table 1.

**Interventions**

**Toothbrushes and interdental brush.** Patients of group 1 used the sonic toothbrush [Philips Sonicare® FlexCare (HX6942/04)] with brush head ProResults HX 6021/02 (Philips Oral Healthcare, Snoqualmie, Washington, USA) and patients of group 2 used a manual toothbrush (elmex® toothbrush, were instructed as follows: Sonic toothbrush. **Tooth brushing technique**

Instructions were given subsequently.

**Sonic toothbrush.** The participants of group 1, using the sonic electric toothbrush, were instructed as follows: 1. Facial surfaces: the bristles of the brush head were to be placed at a 45-degree angle between the brackets and the gingiva so the bristles pointed towards the occlusal surface (S) index; TQHI, Turesky modification of the Quigley--Hein Index; MAPI, Modified Approximal Plaque Index; PIB, Plaque Index Backet; PBI, Papillary Bleeding Index; PD, Probing Depth; BOP, Bleeding On Probing; CRT®, Caries Risk Test; MS, mutans streptococci; LB, lactobacilli; aMMP8, active Matrix Metalloproteinase-8.

**Table 1** Assessment time points of clinical, microbial, and molecular biological outcome parameters during the study. DMFT/S, decayed (D), missing (M), and filled (F) teeth (T), surface (S) index; TQHI, Turesky modification of the Quigley–Hein Index; MAPI, Modified Approximal Plaque Index; PIB, Plaque Index Backet; PBI, Papillary Bleeding Index; PD, Probing Depth; BOP, Bleeding On Probing; CRT®, Caries Risk Test; MS, mutans streptococci; LB, lactobacilli; aMMP8, active Matrix Metalloproteinase-8.

<table>
<thead>
<tr>
<th>Outcome parameter</th>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
<th>Visit 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td></td>
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<tr>
<td>DMFT/DMFS</td>
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<tr>
<td>TQHI</td>
<td>•</td>
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<tr>
<td>MAPI</td>
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<td>BOP</td>
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<tr>
<td>Microbial</td>
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<td>CRT®LB</td>
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<tr>
<td>aMMP8</td>
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</tbody>
</table>

**Measured parameters**

The clinical plaque, gingival, and caries index scores as well as periodontal, microbial, and molecular biological parameters recorded during the study are shown in Table 1. The results of the periodontal, microbial, and biological parameters will be presented separately. The TBD, based on a group-specific brushing protocol, was measured by the patients and their parents at home as described below.

**Tooth brushing technique**

After randomization, each participant received instructions from a dental hygienist of how to use the assigned brushing device during the study. Participants were given verbal instructions on ‘brushing sequence’ as well as device-specific brushing techniques. The verbal instructions were supported by practical demonstration on a plastic model with fixed appliances. All patients received written instructions comprising text and images. No further oral hygiene instructions were given subsequently.

**Sonic toothbrush.** The participants of group 1, using the sonic electric toothbrush, were instructed as follows: 1. Facial surfaces: the bristles of the brush head were to be placed at a 45-degree angle between the brackets and the gingiva so the bristles pointed towards the occlusal
surfaces. For the second run, the brush head was to be positioned at a 45-degree angle towards the incisal side of the archwire so that the bristles pointed gingival. 2. Lingual tooth surfaces: the bristles had to be positioned towards the base of the tooth to the gingival margin at a 45-degree angle to the long axis of the tooth. Patients were instructed to use light pressure, moving the bristles gently in a slight back and forward motion, so the longer bristles reached the interproximal spaces. 3. Occlusal surfaces: patients were asked to move the brush in a gentle back and forward motion parallel to the occlusal surfaces. The patients were instructed to clean the teeth in the following order: maxilla first, then mandible, in each arch beginning at the end on one side then to the other side. The starting point for right- or left-handed patients was their respective dominant side.

Manual toothbrush. The participants of group 2, 3, and 4 who used the manual toothbrush received the same instructions as the patients in the electric toothbrush group. However, patients were advised to use moderate pressure, according to the recommendations of Bass (1954), including small horizontal shifts back and forth.

Interdental toothbrush. After using the manual brush, participants of group 2 were instructed to brush each of the four surfaces around the brackets of each tooth with the interdental brush in the following way: 1. distal, 2. mesial, 3. gingival, and 4. incisal surfaces of the bracket; first in the maxilla, then in the mandible, from one side, across the top, to the other side. Each surface was to be brushed with 2–3 strokes, while the brush was pressed lightly against the bracket.

Tooth brushing frequency and assessment of TBD

All patients were instructed to brush twice daily: after breakfast and before bedtime. Patients and their parents were asked to measure tooth brushing time using the supplied stopwatch and document the required time in seconds in a diary. The brushing diaries were replaced at each visit and a new one was issued.

During the examination period, all subjects received toothpaste (elmex® 1400 ppm amine fluoride, GABA International, Therwill, Switzerland) and the group-specific brushing devices. Patients and parents were advised not to use any other dental hygiene products during the study.

Clinical plaque, gingival, and caries index scores

During the course of the study, the following plaque and gingival index scores were recorded from baseline to the end of the observational period (12 weeks):

• Plaque Index Bracket (PIB; Trimpeneers et al., 1997; Cler euchugh et al., 1998): The PIB was used to evaluate the supragingival plaque distribution around the brackets on the labial tooth surfaces. Each labial tooth surface was divided into four zones according to the position of the brackets: mesial, distal, gingival, and incisal to the bracket. Each of these zones was examined and scored as follows: PIB = 0: no plaque; PIB = 1: islands of plaque; PIB = 2: continuous line of plaque ≤1 mm; PIB = 3: continuous line of plaque greater than 1 mm.

• Papillary Bleeding Index (PBI; Saxe and Mühlemann, 1975): The PBI was determined on the labial aspect of all incisors, canines, premolars, and first molars by using a 0.5 mm diameter periodontal probe (PCP UNC15, Hu-Friedy, Tuttlingen, Germany) running gently along the gingival margin of the mesial and distal part of the papilla. After approximately 30 seconds, any bleeding was recorded using the following scoring criteria: PBI = 0: no bleeding, PBI = 1: single bleeding point; PBI = 2: several bleeding points or thin bleeding line along the marginal gingiva; PBI = 3: interdental triangle filled with blood immediately after probing; PBI = 4: profuse bleeding on probing, interdental triangle is immediately filled with blood that flows over into gingival sulcus and out of it.

• TQHI (Quigley and Hein, 1962; Turesky et al., 1970): The TQHI was used to analyse supragingival plaque distribution on labial surfaces of all incisors, canines, premolars, and first molars; lingual surfaces were not evaluated. TQHI plaque scores were recorded for each tooth for the following six rating categories: TQHI = 0: no plaque, TQHI = 1: scattered islands of plaque along the gingival margin, TQHI = 2: significant plaque line (<1 mm) along the gingival margin, TQHI = 3: plaque expansion in the cervical third of the tooth surface, TQHI = 4: plaque expansion of ≤2/3 of the tooth surface, and TQHI = 5: plaque size of more than 2/3 of the tooth surface.

• Modified Approximal Plaque Index (MAPI; Zimmer et al., 2005): The MAPI was used to analyse supragingival plaque distribution on the approximal surfaces of all incisors, canines, premolars, and first molars. The index is coded in numbers from 0 to 3 as follows: MAPI = 0: no plaque, MAPI = 1: isolated islands or a thin plaque line, MAPI = 2: solid thin plaque area, and MAPI = 3: plaque of the total interproximal area.

• DMFT/DMFS: The decayed (D), missing (M), and filled (F) teeth (T) (DMFT) were recorded for each patient at the screening examination and at the end of the study using the criteria of the World Health Organization for permanent teeth (WHO, 1997). The DMFS (S = surface) was registered as well.

Except of the DMFT/S index, all scores were assessed every 4 weeks between 4 and 6 pm. At each visit, the orthodontic archwires were removed by the clinical assistants. All examinations were carried out by two experienced orthodontists who had been calibrated.

A fluorescent plaque disclosing liquid (Plaque Test®, Ivoclar Vivadent AG, Schaan, Principado de Liechtenstein) was applied to the teeth according to the manufacturer's
recommendation before TQHI, MAPI, and PIB were recorded. Cheek retractors and cotton rolls were inserted between the upper and lower teeth and the teeth were carefully air-dried. A polymerization light (bluephase®, Ivoclar Vivadent AG, Schaan, Principado de Liechtenstein) was used to visualize plaque. To protect the eyes from halogen light, protection glasses (Uvex Skyper UV, Lean & works, Duisburg, Germany) were used by each patient, investigator, and assistance.

Orthodontic treatment

All patients were treated with stainless steel brackets of the same series (Victory™ Low Profile, 0.022 inch slot, 3M ESPE AG, Seefeld, Germany) and bands on the first molars. After the labial surfaces had been treated with ProSeal®, all completely erupted permanent incisors, canines, and premolars were bonded with Transbond™ XT (3M ESPE AG, Seefeld, Germany and Assure® Reliance Orthodontic Products, Itasca, Illinois, USA). Excess adhesive resin was removed using a scaler along the bracket base at bond. Orthodontic treatment was started with an 0.012 or 0.014 inch round NiTi wire, followed by a round 0.016 inch NiTi archwire after 4 or 8 weeks. Stainless steel ligatures (0.010 inch) were generally used to ligate the archwires. If figure of eight ligatures were used, their application was documented at each visit. No elastomeric chains were used during the observational period.

Statistics

Continuous or ordinal data were analysed by median and interquartile range (IQR) and nominal data by absolute and relative frequencies. Average brushing times per patient were calculated using means of evening measurements within each of the three 4-week observation intervals. Comparison of scores between different patient groups was by Mann–Whitney U-test for two groups and with the Kruskal–Wallis test for three or four groups. For intra-group comparison, the Wilcoxon matched pairs signed-rank test was used. Comparison of nominal data between the groups was by Fisher’s exact test. Significance level was fixed to $\alpha = 0.05$. The main outcome criterion was the change of the PIB from baseline to the end of the study after 3 months. For evaluation of the brushing devices, a closed testing procedure was used with a global three group comparison in the first step, followed by pairwise comparisons if the first step proved significant. Level of significance was set at $\alpha = 0.05$ for each step. Sample size calculation assumed the final PIB score in group 2 to be 0.25 points lower than in group 3 and 0.15 lower than in group 1 with a common standard deviation of 0.3 in all groups. The aimed power was 0.8 and a drop out of two patients per group was considered. Evaluation of the sealant application was carried by comparing group 3 with the independent group 4 as control. No adjustment of $\alpha$ levels was done when considering these two main questions because of the partial independence of the samples. Furthermore, only the comparison of the main outcome criterion can be interpreted in a confirmatory sense, while all other analyses have to be considered exploratory. SAS, version 9.3 for Windows (SAS Institute Inc., Cary, North Carolina, USA) was used for all calculations.

Results

Demographics and overall study

The study was conducted from April 2008 to April 2011. The Consolidated Standards of Reporting Trials (CONSORT) flowchart of participants, through each stage in the study, is illustrated in Figure 3.

A total of 152 patients were examined at the screening stage. Of these, 19 did not meet the inclusion criteria and 7 patients opted not to participate in the study. A total of 126 patients (61 males and 65 females) who fulfilled all inclusion criteria were admitted to the study. Random assignment resulted in 31 patients to group 1 and 3; 32 patients were allocated to group 2 and 4. During the study, three patients of group 1, two patients of group 3, and one patient of group 2 and 4 were excluded due to antibiotic treatment. One patient of group 2 was excluded because of antibacterial rinses. Age, gender, and handling score distribution across the study groups are shown in Table 2. Of the 118 subjects who completed the study, 63 (53.5 per cent) were females, 96 (81.3 per cent) were right handed, and the median age was 13.0 years (IQR: 12.25–13.9). Age ($P = 0.77$), gender ($P = 0.54$), and handedness ($P = 0.36$) did not differ significantly among the four study groups. The baseline values for clinical plaque and gingival index scores can be found in Table 4.

Compliance with brushing documentation

The diary entries for morning and evening brushing sessions differed marginally between the groups; only evening diary entries were used in this investigation. Median numbers of documented days did not differ significantly between the groups at any point (week 4: $P = 0.81$; week 8: $P = 0.24$; week 12: $P = 0.27$). However, the required time intervals of 28 days between the study examinations were not met by all

<table>
<thead>
<tr>
<th>Group</th>
<th>$N$</th>
<th>Median age in years (IQR)</th>
<th>% Male</th>
<th>% Handedness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Right</td>
</tr>
<tr>
<td>1</td>
<td>28</td>
<td>13.1 (12.0–14.0)</td>
<td>39.3</td>
<td>82.1</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
<td>12.9 (12.2–13.7)</td>
<td>56.7</td>
<td>73.3</td>
</tr>
<tr>
<td>3</td>
<td>29</td>
<td>13.0 (12.3–14.4)</td>
<td>48.3</td>
<td>82.8</td>
</tr>
<tr>
<td>4</td>
<td>31</td>
<td>12.9 (12.5–13.6)</td>
<td>41.9</td>
<td>87.1</td>
</tr>
</tbody>
</table>
participants. Eighty-five to ninety per cent of the population documented between 22 and 35 days at each examination point (Supplementary Figure 1, available online). During the study period, 10 of 354 brushing diaries were not available (week 1–4: one diary of group 1; week 9–12: three diaries of group 1, one diary of group 2, two diaries of group 3, and three diaries of group 4).

Gender and daytime impact on brushing duration

The median brushing duration for morning and evening is presented in Table 3. Intra-individual comparisons showed that brushing duration was slightly longer in the evening. Subsequent figures and data refer to the TBD in the evening, but similar results emerged for morning data. There was no significant gender difference in brushing duration (data not shown).

Dental cleaning device comparison relating to brushing duration

Brushing duration of the various groups differed significantly (overall comparison: week 1–4: \( P = 0.001 \), week 5–8: \( P = 0.016 \), and week 9–12: \( P = 0.003 \)) with higher values for the group that used two devices: manual and interdental brush (Figure 4). However, variability of the mean brushing time was also highest in group 2. No difference in the mean brushing duration between the electric and manual methods could be found (week 1–4: \( P = 0.254 \), week 5–8: \( P = 0.924 \), and week 9–12: \( P = 0.394 \)).

Evaluation of tooth brushing behaviour over time: intra-individual changes

Supplementary Figure 2 (available online) illustrates changes in the mean brushing time between two subsequent

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**Table 3** Median brushing times (seconds) of the study groups in the evening and the median differences to brushing in the morning [less (−) more (+), seconds] during the study.

<table>
<thead>
<tr>
<th>Group</th>
<th>Week 1–4</th>
<th>Week 5–9</th>
<th>Week 9–12</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Evening</td>
<td>Difference to morning</td>
<td>Evening</td>
</tr>
<tr>
<td>1</td>
<td>209.3</td>
<td>−2.0*</td>
<td>210.8</td>
</tr>
<tr>
<td>2</td>
<td>278.5</td>
<td>−6.0**</td>
<td>248.0</td>
</tr>
<tr>
<td>3</td>
<td>217.8</td>
<td>−5.1</td>
<td>210.6</td>
</tr>
<tr>
<td>4</td>
<td>202.1</td>
<td>−3.5</td>
<td>198.6</td>
</tr>
</tbody>
</table>

* \( P = 0.044 \); ** \( P = 0.017 \); *** \( P = 0.014 \).

**Table 4** Baseline values of clinical plaque and gingival index scores (median and interquartile range). S-TB, sonic toothbrush; M-TB, manual toothbrush; IDB, interdental brush; SS, surface sealant; PIB, Plaque Index Backet; PBI, Papillary Bleeding Index; TQHI, Turesky modification of the Quigley–Hein Index; MAPI, Modified Approximal Plaque Index.

<table>
<thead>
<tr>
<th>Group 1 (S-TB + SS)</th>
<th>Group 2 (M-TB + IDB + SS)</th>
<th>Group 3 (M-TB + SS)</th>
<th>Group 4 (M-TB)</th>
<th>( P )</th>
</tr>
</thead>
<tbody>
<tr>
<td>( n = 28 )</td>
<td>( n = 30 )</td>
<td>( n = 29 )</td>
<td>( n = 31 )</td>
<td></td>
</tr>
<tr>
<td>PIB</td>
<td>0.92 (0.37/1.69)</td>
<td>0.76 (0.17/1.45)</td>
<td>0.41 (0.19/0.66)</td>
<td>0.83 (0.24/1.41)</td>
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<tr>
<td>PBI</td>
<td>0.50 (0.32/1.02)</td>
<td>0.55 (0.32/0.86)</td>
<td>0.44 (0.27/0.73)</td>
<td>0.50 (0.23/0.73)</td>
</tr>
<tr>
<td>TQHI</td>
<td>1.04 (0.48/2.04)</td>
<td>1.09 (0.45/1.96)</td>
<td>1.21 (0.67/1.63)</td>
<td>1.38 (0.58/2.13)</td>
</tr>
<tr>
<td>MAPI</td>
<td>0.93 (0.43/1.34)</td>
<td>1.02 (0.59/1.68)</td>
<td>1.06 (0.41/1.45)</td>
<td>1.23 (0.55/1.64)</td>
</tr>
</tbody>
</table>

**Figure 4** Box plot of the mean brushing times (medians and interquartile ranges and 3rd and 97th percentiles; circles: mean values, asterisks: extreme values; seconds).
observation periods. From the first to the second period (week 1–4 to week 5–8), the change of the mean brushing duration decreased by 5.6 seconds in group 2 (P = 0.078) and 3.2 seconds in group 3 (P = 0.082). No change could be observed for group 1 (P = 0.54) and 4 (P = 0.45). From the second to the third period (week 5–8 to week 9–12), the brushing time remained fairly similar and no significant change in any of the four groups could be demonstrated (group 1: P = 0.34, group 2: P = 0.65, group 3: P = 0.16, and group 4: P = 0.34).

Baseline values of clinical scores

Of the 118 patients who successfully completed the study, 114 (97 per cent) had a DMFT/S of 0. Only the F component of four patients (one patient of groups 2 and 3; two patients in group 1) contributed to the DMFT/S.

Baseline values of clinical plaque and gingival index scores are shown in Table 4. Apart from PIB, all clinical scores showed equal distribution among the groups. Patients in group 3 revealed slightly lower median PIB compared with the other groups; this was not significant. The median PBI values ranged from 0.44 to 0.55 indicating a comparatively low level of gingival inflammation at baseline. Only 15.5 per cent of the study population revealed an index score of 3 and 4, which was found to be small compared with average national data: maximum PBI values of 12-year-olds with score 3 and 4 is 25.3 per cent (Schiffner et al., 2009).

Use of figure-eight ligatures

During the 12-week study period, the use of figure-eight ligatures was necessary only in two patients (one patient of group 2 at baseline and one patient of group 4 at the end of the study).

Comparison between sealed and unsealed surfaces using a manual brush

Clinical scores and their changes during the study period of 12 weeks in group 3 and 4 are shown in Table 5. The change of PIB from baseline to week 12 as main outcome criterion did not differ significantly between both groups. The difference in the distribution of the PIB scores at baseline was maintained until the end of the observation period. Like the PIB scores, PBI scores remained unchanged during the study period in all groups. Median TQHI values slightly decreased from baseline to the end of the study with no significant differences between the treatment groups. MAPI scores remained almost unchanged over time.

Comparison of different cleaning devices on sealed surfaces

Results of the clinical evaluation of the three groups using different cleaning devices are presented in Table 6. The initial hygiene scores remained fairly stable over time. No significant differences in overall change between the groups in the outcome parameters could be demonstrated. Two-by-two comparisons revealed no significant differences between PIB or other scores (data not shown). Table 6 demonstrates that the difference in PIB distribution between the groups did not change significantly over time.

In order to ascertain whether the use of an interdental brush improved oral hygiene, the PIB score was evaluated, which specifically referred to the mesial, distal, and
gingival surfaces of the teeth. However, no significant differences between the three groups could be found: mesial/distal surfaces (median/IQR): group 1: −0.15 (−1.00/0.51); group 2: 0.04 (−0.78/0.34); group 3: −0.14 (−0.35/0.25); \(P = 0.92\); and gingival surfaces: group 1: −0.01 (−0.63/0.13); group 2: 0.01 (−0.40/0.20); group 3: 0.00 (−0.20/0.19); \(P = 0.58\).

The FT/FS scores of the DMFT/S remained unchanged during the 12-week observation period.

### Comparison of different dental cleaning devices by subgroups

To test the performance of the three cleaning devices, changes in PIB scores were evaluated for three cohorts of patients with 1. initially either lower or higher TQHI values (cut-off 1.5), 2. males or females, and 3. anterior or posterior teeth. Results can be found in Table 7. PIB scores of patients with initial TQHI values ≤ 1.5 remained almost unchanged during the 12-week observation period.

### Table 6

Clinical plaque and gingival index scores of the three groups with different dental cleaning devices (median and interquartile range) on sealed teeth. S-TB, sonic toothbrush; M-TB, manual toothbrush; IDB, interdental brush; SS, surface sealant; PIB, Plaque Index Backet; PBI, Papillary Bleeding Index; TQHI, Turesky modification of the Quigley–Hein Index; MAPI, Modified Approximal Plaque Index.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group 1 (S-TB + SS)</th>
<th>Group 2 (M-TB + IDB + SS)</th>
<th>Group 3 (M-TB + SS)</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIB Base (at week 4)</td>
<td>0.92 (0.37/1.69)</td>
<td>0.76 (0.17/1.45)</td>
<td>0.41 (0.19/0.66)</td>
<td>0.83</td>
</tr>
<tr>
<td>PIB Week 8</td>
<td>0.44 (0.21/0.84)</td>
<td>0.55 (0.22/1.01)</td>
<td>0.37 (0.18/0.59)</td>
<td></td>
</tr>
<tr>
<td>PIB End</td>
<td>0.70 (0.34/1.01)</td>
<td>0.60 (0.14/1.08)</td>
<td>0.40 (0.12/0.68)</td>
<td></td>
</tr>
<tr>
<td>Change (base to end)</td>
<td>−0.11 (−1.03/0.29)</td>
<td>−0.03 (−0.56/0.16)</td>
<td>−0.08 (−0.21/0.06)</td>
<td>0.58</td>
</tr>
<tr>
<td>PBI Base</td>
<td>0.50 (0.32/0.72)</td>
<td>0.55 (0.32/0.86)</td>
<td>0.44 (0.27/0.73)</td>
<td></td>
</tr>
<tr>
<td>PBI Week 4</td>
<td>0.62 (0.41/0.90)</td>
<td>0.50 (0.32/0.77)</td>
<td>0.44 (0.27/0.68)</td>
<td></td>
</tr>
<tr>
<td>PBI Week 8</td>
<td>0.73 (0.33/0.91)</td>
<td>0.57 (0.32/0.91)</td>
<td>0.45 (0.14/0.59)</td>
<td></td>
</tr>
<tr>
<td>PBI End</td>
<td>0.68 (0.52/0.95)</td>
<td>0.50 (0.33/0.77)</td>
<td>0.59 (0.32/0.91)</td>
<td></td>
</tr>
<tr>
<td>Change (base to end)</td>
<td>0.09 (−0.23/0.33)</td>
<td>0.02 (−0.18/0.27)</td>
<td>0.14 (−0.23/0.33)</td>
<td>0.85</td>
</tr>
<tr>
<td>TQHI Base</td>
<td>1.04 (0.48/2.04)</td>
<td>1.09 (0.45/1.96)</td>
<td>1.21 (0.67/1.63)</td>
<td></td>
</tr>
<tr>
<td>TQHI Week 4</td>
<td>1.30 (0.73/2.44)</td>
<td>1.11 (0.46/2.38)</td>
<td>0.83 (0.30/1.74)</td>
<td></td>
</tr>
<tr>
<td>TQHI Week 8</td>
<td>0.83 (0.48/1.28)</td>
<td>0.96 (0.54/2.00)</td>
<td>0.75 (0.48/1.42)</td>
<td></td>
</tr>
<tr>
<td>TQHI End</td>
<td>0.90 (0.60/1.52)</td>
<td>0.96 (0.55/1.75)</td>
<td>0.92 (0.38/1.21)</td>
<td></td>
</tr>
<tr>
<td>Change (base to end)</td>
<td>−0.10 (−1.10/0.28)</td>
<td>−0.12 (−0.83/0.60)</td>
<td>−0.30 (−0.68/0.17)</td>
<td>0.75</td>
</tr>
<tr>
<td>MAPI Base</td>
<td>0.93 (0.43/1.34)</td>
<td>1.02 (0.59/1.68)</td>
<td>1.06 (0.41/1.45)</td>
<td></td>
</tr>
<tr>
<td>MAPI Week 4</td>
<td>1.57 (0.72/2.43)</td>
<td>1.18 (0.45/1.90)</td>
<td>0.95 (0.50/1.59)</td>
<td></td>
</tr>
<tr>
<td>MAPI Week 8</td>
<td>0.86 (0.33/1.57)</td>
<td>1.13 (0.44/1.64)</td>
<td>1.09 (0.50/1.36)</td>
<td></td>
</tr>
<tr>
<td>MAPI End</td>
<td>1.11 (0.64/1.48)</td>
<td>1.11 (0.40/1.59)</td>
<td>0.95 (0.32/1.41)</td>
<td></td>
</tr>
<tr>
<td>Change (base to end)</td>
<td>0.02 (−0.27/0.44)</td>
<td>−0.25 (−0.83/0.50)</td>
<td>−0.09 (−0.68/0.23)</td>
<td>0.44</td>
</tr>
</tbody>
</table>

### Table 7

PIB of the cohorts defined by initial TQHI values, gender, or location of teeth (median and interquartile range). S-TB, sonic toothbrush; M-TB, manual toothbrush; IDB, interdental brush; SS, surface sealant; PIB, Plaque Index Backet; TQHI, Turesky modification of the Quigley–Hein Index.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Group 1 (S-TB + SS)</th>
<th>Group 2 (M-TB + IDB + SS)</th>
<th>Group 3 (M-TB + SS)</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PIB ≤ 1.5: (n = 18)</td>
<td>0.54 (0.23/1.58)</td>
<td>0.63 (0.17/1.35)</td>
<td>0.38 (0.16/0.66)</td>
<td>0.04</td>
</tr>
<tr>
<td>PIB &gt; 1.5: (n = 10)</td>
<td>0.56 (0.20/0.01)</td>
<td>0.53 (0.14/1.22)</td>
<td>0.38 (0.10/0.54)</td>
<td></td>
</tr>
<tr>
<td>TQHI ≤ 1.5</td>
<td>0.09 (−0.99/0.33)</td>
<td>−0.03 (−0.30/0.19)</td>
<td>−0.09 (−0.21/0.06)</td>
<td>0.86</td>
</tr>
<tr>
<td>TQHI &gt; 1.5</td>
<td>1.42 (0.92/1.77)</td>
<td>0.76 (0.24/1.82)</td>
<td>0.50 (0.31/1.09)</td>
<td>0.15</td>
</tr>
<tr>
<td>MAPI Base</td>
<td>0.74 (0.68/1.04)</td>
<td>0.60 (0.19/0.98)</td>
<td>0.45 (0.28/1.27)</td>
<td></td>
</tr>
<tr>
<td>MAPI Change</td>
<td>−0.96 (−1.04/0.15)</td>
<td>0.01 (−1.04/0.14)</td>
<td>−0.04 (−0.23/0.17)</td>
<td>0.26</td>
</tr>
<tr>
<td>Males: (n = 11)</td>
<td>−0.15 (−1.04/0.46)</td>
<td>0.04 (−1.01/0.19)</td>
<td>−0.01 (−0.29/0.17)</td>
<td>1.00</td>
</tr>
<tr>
<td>Males Change</td>
<td>−0.07 (−1.03/0.13)</td>
<td>−0.11 (−0.30/0.14)</td>
<td>−0.09 (−0.20/0.06)</td>
<td>0.82</td>
</tr>
<tr>
<td>Females: (n = 13)</td>
<td>−0.27 (−1.13/0.45)</td>
<td>−0.15 (−1.04/0.46)</td>
<td>−0.15 (−1.04/0.46)</td>
<td>0.68</td>
</tr>
<tr>
<td>Females Change</td>
<td>−0.06 (−0.90/0.19)</td>
<td>−0.07 (−1.03/0.13)</td>
<td>−0.07 (−1.03/0.13)</td>
<td>0.57</td>
</tr>
</tbody>
</table>
during the 12-week observation period, whereas for patients with higher initial TQHI values (>1.5), the corresponding PIB scores decreased over time, particularly for participants of group 1. Although, due to the unequal distribution at baseline, the decreasing index scores in patients with higher initial TQHI values are difficult to interpret; the difference in change between the groups was not significant. The PIB scores for males/females or anterior (incisors, canines)/posterior (bicuspids, first molars) teeth were also not significantly different for the three groups. Similar results were obtained for TQHI, MAPI, and PBI scores (data not shown).

Discussion

To the best of our knowledge, this is the first prospective randomized clinical trial that provided data measuring TBD in patients with fixed orthodontic appliances using a stop-watch; to our knowledge, all previous studies assessed TBD retrospectively (Heintze et al., 1996; Kossack and Jost-Brinkmann, 2005). Various investigations on brushing time among the general population found that most patients overestimate the perceived time spent on brushing compared with actual time used. According to Saxer et al. (1998), the estimated times were approximately 50 per cent higher than actual brushing times (Saxer et al., 1998).

According to our results for home-based self-directed time measurements of electric brush users observed, overall median brushing time was 209 seconds. Using participants’ subjective evaluation, Kossack and Jost-Brinkmann (2005) reported an estimated average brushing time of 270 seconds in 13-year-old orthodontic patients when using a Waterpik® ‘sonic speed’ electric toothbrush. Heintze et al. (1996) reported that nearly 50 per cent of patients reported using an electric toothbrush for at least 180 seconds during fixed appliance treatment.

For manual toothbrush users, we found an overall median TBD of 207 seconds (group 3) and 197 seconds (group 4). Rugg-Gunn et al. (1979) reported TBD of non-orthodontic 13-year-old patients, which was only one-third of what we found. Comparing electric and manual brush users of the present study, no significant difference in mean TBD was observed. These results do not concur with those of Rosema et al. (2008), who found a significantly longer brushing time for non-orthodontic patients at 6 months recall for the electric brush users.

Patients using a combination of both a manual and interdental brush (group 2) had an average TBD of 255 seconds. Approximately 50 seconds could hence be attributed to the use of the interdental brush.

Patients using dental floss report brushing times of an average of 8.8 minutes (Kossack and Jost-Brinkmann, 2005). In case of use of the Waterpik® Flosser FL-110, an electric interdental cleaning device, patients self-reported, on average, 5.2 minutes of TBD (Kossack and Jost-Brinkmann, 2005). The increase of approximately 50 seconds reported in our investigation (group 2) was hence less than expected.

Mean brushing times of patients in group 2 were very variable; this suggests that both the complex brushing technique and sequence may not have been fully implemented, despite the instructions. Other studies have shown that repeated oral hygiene instructions improve the implementation and adoption of both brushing technique and sequence, thus leading to longer brushing times (Schlueter et al., 2010). Future research may prove whether these findings also apply to orthodontic patients, particularly users of interdental brushes.

TBD decreased during the observation period for both the manual brush and combination groups. Matič et al. (2011) using three different brushes also reported that TBD shortened over time once orthodontic patients master the technique. Schlueter et al. (2010) pointed out that complex motion sequences and techniques are difficult to adopt and require a training period. However, whether the intra-individual changes detected in the present study were related to a learning effect or simply a sign of fatigue could not be determined.

Various preventive strategies, such as fluoride toothpaste/ rinse, varnish/gel, enamel surface sealants with and without fluoride, or electrically powered toothbrushes have been recommended to reduce the risk of developing decalcification during orthodontic treatment (Derks et al., 2004). To date, there are few studies involving orthodontic patients investigating their combined effect (Øgaard et al., 2006). In our investigation, we compared for the first time the effectiveness of an electric sonic toothbrush, a manual toothbrush plus interdental brush and a manual toothbrush on a number of oral health parameters in orthodontic patients with fixed appliances and the effect of sealing enamel surfaces. Little information is currently available on the effects of sealant on tooth surfaces in the oral environment and we decided to investigate the impact of surface coating on a number of hygiene parameters.

Methodological considerations

This randomized clinical study followed the CONSORT statement (Moher et al., 2001). The age group between 11 and 15 years was selected because this group 1. is most frequently subjected to orthodontic treatment and 2. demonstrates the highest risk of developing decalcifications.

We chose a parallel-group design, which is beneficial for trials of longer duration (Heasman and McCracken, 1999). The reduction in plaque scores do not directly reflect benefits in gingival health; we hence used a 12-week observation period, which was longer than the studies included in the meta-analysis by Kaklamanos and Kalfas (2008) on the effectiveness of electric toothbrushes for orthodontic patients.

Plaque and/or gingival index scores can be influenced by the initial oral hygiene standard of the participants (Kossack and Jost-Brinkmann, 2005). Subjects were stratified according to baseline levels of plaque to ensure equal distribution
between groups, as recommended by Chilton and Fleiss (1986).

The quantification of dental plaque and/or gingival inflammation by oral hygiene indices remains the principal outcome measure in clinical trials of tooth brushes (Heasman and McCracken, 1999; Robinson et al., 2006). We used three different plaque indices: 1. the PIB, which can be considered as one of the most valid and discriminating categorical index to evaluate the amount of plaque around brackets (Al-Anazi and Harradine, 2012), 2. the MAPI to analyse the proximal surfaces, and 3. the TQHI, one of the most frequently used indices to emphasize differences in the cervical third of the tooth surface. The combination of these three indices allowed a differentiated evaluation of the typical risk areas for plaque accumulation (Klukowska et al., 2011) and white spot lesion development in the presence of fixed appliances. Since plaque accumulation and possibly gingivitis may vary with the time of the day (Chilton and Fleiss, 1986), all scores were evaluated in a defined time window on each occasion. To ensure intra-examiner agreement, examiners were calibrated prior to the study. In order to facilitate evaluation, archwires were removed to ensure best visual access, particularly at the interproximal sites and a fluorescein-containing plaque disclosing system was used; fluorescein has been shown to be more effective in disclosing proximal plaque than other disclosing agents (Lim et al., 1986).

We did not standardize TBD, however, to reduce the potential bias that this procedure would introduce in the trial, home-based self-directed time measurements were collected.

Comparison of different cleaning devices on sealed surfaces

Based on the reported brushing times, no significant differences were found between the three tested dental cleaning devices regarding plaque, gingival, and caries index scores that were assessed on buccal tooth surfaces.

Sonic versus manual brush

The present findings failed to show any significant effect of the use of a sonic toothbrush (Philips Sonicare® FlexCare) compared with a manual brush (elmex® interX short brush-head toothbrush). These results concurred with those of Kossack and Jost-Brinkmann (2005) who observed that for patients with fixed appliances, the WaterPik® sonic speed toothbrush did not clean teeth more effectively than the new generation elmex® interX short brush-head. But our findings were at odds with those of White (1996) and Ho and Niederman (1997) who found the Sonicare® brush to be more effective in removing supragingival plaque and in improving gingival health compared with conventional flat profile manual brushes. It should be noted that conventional manual toothbrushes with a flat profile are disadvantageous for the cleaning of teeth with brackets compared with more advanced bristle arrangements, such as the manual brush used in this study (Sander et al., 2005; Schätzle et al., 2009).

Our study population had generally better initial oral hygiene compared with patients of Ho and Niederman (1997) and this may explain the differences in outcome. Oral hygiene scores remained fairly stable over time, even after insertion of fixed appliances. Ninety-seven per cent of our study population revealed no clinical evidence of caries at start of the study and this confirmed good oral hygiene. It is therefore conceivable that it became more difficult to detect group differences. Future studies should try to evaluate how patients with poorer initial oral hygiene levels or higher caries rates could benefit from various oral hygiene strategies and protocols. Like the majority of studies investigating oral hygiene, we also focused on the evaluation of the plaque status of buccal surfaces. Clerehugh et al. (1998), however, demonstrated that evaluating only buccal surfaces might increase the risk of type II errors, making group differences of this particular amount more difficult to detect.

Manual and interdental versus manual toothbrush

The present study failed to show any significant clinical effect of the use of an interdental brush (Curaprox® CP515) in addition to the manual toothbrush for cleaning around the brackets. These results differ from previous studies, which revealed improved oral hygiene due to the additional effect of the use of either manual (Arici et al., 2007; Bock et al., 2010) or battery-operated interdental cleaning devices (Borutta et al., 2002; Kossack and Jost-Brinkmann, 2005). Arici et al. (2007) demonstrated that the combination of an orthodontic with an interdental brush (Oral-B®) produced a significant decrease in the mean plaque score of the anterior teeth compared with an orthodontic (Oral-B®) or a specific designed manual brush with curved bristles alone. Arici et al. (2007) included in their crossover study poor brushers, who brushed under supervision just before the outcome evaluation.

In addition to the impact of the overall oral hygiene level of the current study population, Macgregor and Rugg-Gunn (1986) pointed out that the awareness of being observed may change brushing behaviour (Hawthorne effect). The authors also investigated the proportion of time spent brushing each of 16 areas of the mouth and reported that patients were more conscientious in the way they used the allocated time and that increased attention was given to the more inaccessible areas in the mouth.

Using a split-mouth design, Bock et al. (2010) examined the additional use of either a manual interdental brush (elmex® interdental brush no. 6) or monotonufed brush (TePe® Compact Tuft) in addition to the elmex® interX manual brush. The plaque index decreased significantly with no noteworthy group differences. However, details on
brushing instructions, sequence, or times with respect to the use of the interdental brush were not reported.

In the present study, data on brushing times were available. The complex brushing technique and sequence taught in our study may not have been completely implemented or adopted, despite the initial tooth brushing instructions. To strengthen the external validity of the current results, patients received oral hygiene instructions only once. In a recent study by Berlin-Broner et al. (2012), the vast majority of patients (94 per cent) confirmed that their orthodontist informed them at least once about the importance of tooth brushing, but only 19–38 per cent of the patients reported having received reinforcement on several appointments. However, Wang et al. (2002) found that repeated motivation and oral hygiene instruction at 3-week intervals helped patients with fixed orthodontic appliances to reduce plaque accumulation when using four different dental cleaning aids. This suggests that repeated oral hygiene instructions may be helpful for patients using manual interdental brushes to achieve both good brushing technique and sequence. Future studies may be able to shed light on whether improved instructional strategies support the learning process of using interdental brushes to clean around fixed appliances and lead to reduced levels of plaque and gingivitis.

Comparison between sealed and unsealed surfaces using manual brushing

During the 12-week observation period, the overall change of plaque and gingival index scores did not differ significantly between patients with sealed or unsealed tooth enamel surfaces using manual toothbrushes (elmex® interX short brush-head toothbrush). Hence, the application of sealant does not seem to influence short-term plaque accumulation or gingival inflammation on buccal surfaces as assessed by a number of oral hygiene indices. These findings are in accordance with those of Fornell et al. (2002) who found that a hydrophobic enamel-coating polymer had no beneficial effects on plaque scores and gingival health when applied immediately after bonding and at 3-month intervals. The amount of plaque adjacent to the brackets was scored in a split-mouth study by Fornell et al. (2002) using an indexed system. In contrast, Shelburne et al. (1998) used digital image technology to monitor plaque growth ex vivo with a high degree of precision and demonstrated reductions in plaque accumulation on enamel chips coated with a filled polymer. However, Fornell et al. (2002) postulated that the effect of surfaces coating on plaque and gingival index scores might be too subtle to be reliably detected by traditional oral hygiene indices. In other words: current indices may not be sensitive enough to detect differences in oral hygiene.

Limitations of this investigation

The data of TBD reported here were based on patients’ self-reported activity. Clinical observation or video recording methods were not used but the ‘Hawthorne effect’ can be considerable when the above methods are used. Toothbrushes can be equipped with electronic systems that are capable of recording actual activity (McCraken et al., 2005; Claessen et al., 2008; Graetz et al., 2013). However, at the time of the present study, it was too difficult to incorporate these recording devices into the brushes used. Also obtaining consent without having a potential effect on the outcome is also difficult for investigations like this; our study aimed at investigating everyday TBD in a domestic environment and self-reporting appeared a reasonable method for this purpose.

A retrospective power analysis on the basis of the observed data reveals a power of 0.24 with respect to the main outcome criterion (change in the PIB) for the three group comparison of cleaning devices. This is extremely low due to the small differences and the large variances observed. To detect such differences within a study with a power of 80 per cent, for example the study would have to be run with a much larger sample size (128 per group). However, besides the problem of the relatively large variances, the observed differences are lower than expected and questionable clinically relevant.

Plaque quantification assessments used in this study were based on indices that were not designed for patients with fixed appliances. Plaque indices are not always reliable detecting small, but potentially clinically relevant changes in plaque surface areas (Pretty et al., 2005). Direct digital measurement of percentage plaque coverage is considered to be more appropriate and reproducible and with higher discriminatory power than categorical indices (Pretty et al., 2005). More recently, the digital plaque image analysis (DPIA) system has been successfully applied in a study among orthodontic patients (Al-Anezi and Harradine, 2012). The DPIA is, however, limited to the facial surfaces of the anterior teeth only and may hence not represent the oral hygiene status of the whole mouth.

Conclusions

TBD in relation to brushing instructions

1. The brushing duration of patients using electric and manual toothbrushes did not differ significantly and ranged from 197 to 209 seconds.
2. Patients brushed significantly longer if they used a combination of manual and interdental toothbrush compared with solely using a manual or electric toothbrush.
3. The brushing duration was slightly longer in the evenings compared with the mornings.
4. There was no significant gender difference in brushing duration.
5. The brushing duration showed a tendency to decrease in patients using the combination of manual/interdental toothbrush.
Tooth brushing technique and oral hygiene parameters

1. No significant differences were found between the three tested tooth brushing strategies (electric versus manual versus manual and interdental brush) regarding plaque and gingival index scores for buccal tooth surfaces. Patients using the combination of a manual and an interdental brush, although spending more time brushing, did not achieve better oral hygiene scores.

2. The findings of our studies did not show a significant effect for the use of an electric toothbrush (Philips Sonicare® FlexCare) compared with a manual brush (elmex® interX short brush-head).

3. There was no difference between subgroups; males versus females, anterior versus posterior teeth or for patients with different initial TQHI values.

Sealant application and oral hygiene parameters

1. During the 12-week observation period, the overall change of plaque and gingival index scores did not differ significantly between patients with sealed or unsealed tooth surfaces using manual toothbrushes.

2. Application of sealant does not seem to influence short-term plaque accumulation or gingival inflammation on buccal surfaces assessed by the above oral hygiene indices.

Study population

1. The initial level of oral hygiene among the present study population was found to be good and almost all patients (96 per cent) had no clinical evidence of caries and/or filled teeth (DMFT/S = 0).

2. Future investigators may choose to evaluate whether patients with poorer oral hygiene levels or higher initial caries rates might benefit from any of the tested preventive measures.

Supplementary material

Supplementary material is available at European Journal of Orthodontics online.

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