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Title: A pilot study to evaluate the impact of digital imaging on the delivery of oral hygiene instruction.

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Short title: Provision of pictorial report for improved gum health

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Key words: plaque reduction, gingivitis, intra-oral scanner, pictorial report, oral hygiene instruction, behaviour modification

Conflict of Interest and Funding Statement

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Acknowledgements

We would like to Stancel Coughlan at Acteon who supported this study.
Abstract

Aims:

To determine whether personalised Oral Hygiene Advice (OHA) using an intra-oral-camera (IOC) combined with standard OHA as provided in general dental practice reduces plaque levels after 4 weeks more than the provision of standard OHA.

Materials and Methods:

22 healthy adult participants diagnosed with gingivitis took part in this pilot parallel-designed, randomised, examiner-blind, 2x treatment, study regarding their home-care oral hygiene habits and attitudes to oral health. An IOC-image was taken and plaque, gingival and bleeding scores were recorded. Test group participants received standard OHA with IOC-images to indicate areas for improvement, control group participants received standard OHA. Questionnaires and plaque, gingival and bleeding scores were repeated after 4 weeks. Plaque was scored from the IOC-images and scores compared to clinical plaque scores.

Results:

Lifestyle habits, attitudes to oral health, plaque (0.63vs0.61, control vs test) and bleeding scores (1.17vs0.96, control vs test) were similar at baseline. After 4-weeks, plaque scores improved more in test as compared to control group (39.4vs20.6%, p<0.05, while gingival and bleeding scores approached significance. There was no difference in lifestyle habits between groups, but the test group reported significantly greater confidence in adhering to their bespoke oral health plan. Agreement between the clinical and IOC plaque scores was good.

Conclusions:

Use of IOC further personalises the prevailing standard of oral hygiene advice and generates great patient engagement with pictorial reports to facilitate a more in-depth patient explanation of their gingival health, resulting in significant plaque reduction and improved gingival health compared to the standard OHA alone.

Clinical Significance

Clinically significant improved plaque control can be achieved by individuals with mild-moderate gingivitis following one episode of personalised tailored IOC OHA combined with the standard of OHA provided in the general dental services compared to only the latter. IOC better engages patients and facilitates remote index scoring.
Introduction

Periodontitis is a common oral disease reported to affect 45 to 50% of adults globally [1], that has a negative effect on quality of life [2], is associated with systemic diseases [3], and is irreversible in the majority of cases resulting in bone and tooth loss if untreated [4]. Periodontitis is preceded by gingivitis, which is both preventable and reversible [5]. Therefore, the key to preventing periodontitis is preventing or treating gingivitis.

Gingivitis is highly prevalent affecting most adolescents and about 70% of adults [6] and can be prevented or controlled by self-directed oral hygiene to remove dental plaque [7]. Home oral care regimes including mechanical plaque removal by tooth brushing and interdental cleaning can reduce plaque to the levels required for oral health provided that cleaning is thorough and frequent [8]. Some adjunctive chemotherapeutic agents present in toothpastes and mouthrinses have also been shown to reduce or control mild to moderate gingivitis [9-10]. However, most individuals do not clean their teeth effectively enough to achieve oral health [11-13].

If delivered effectively a single oral hygiene instruction together with professional mechanical plaque removal (PMPR) can result in a significant reduction in gingival inflammation [12]. However, patient compliance with oral hygiene advice (OHA) has been cited as a problem [13]. A recent study demonstrated that 53% of dental practice patients had gingival bleeding on gentle probing [14], indicative of active gingivitis or periodontal disease where pocket depth is >4mm [4,15]. Such data suggests that it is likely that the OHA delivered has not been retained or has perhaps not been delivered in a way that the patient truly understands. A study of dentist and patient recollection of a consultation demonstrated that dentists recalled significantly more content than patients and reported giving more OHA than patients remembered [16]. Traditionally OHA is delivered verbally or in written form such as leaflets, with some evidence suggesting that leaflets may be seen as impersonal [17]. Recent UK guidelines on the management of periodontal diseases recommend that OHA should be personalised [4], and evidence indicates that personalised information and guidance are the first step in achieving behaviour changes that will improve long term patient oral health [18].

New tools to help the clinician deliver OHA in a way that resonates with the patient are being developed. Risk management where patients are categorised according to their oral health risk and given verbal OHA together with a traffic light risk card; red (high), amber (medium) and green (low) has been explored. However, participants reported preferring verbal OHA without the risk cards, and there were no differences in self-reported oral hygiene practices between the groups [19]. Studies of social media have demonstrated that its use improves knowledge and understanding of health topics, but have not tested whether this knowledge translates to behaviour change [20]. By contrast,
Evidence indicates that personalised messaging to improve OHA compliance is likely to yield greater improvement in plaque and gingival indices as compared to standard OHA provision [21-22]. However, the studies in these reviews [21-22] have been predominantly of adolescents in orthodontic settings, thus further studies of adults are needed to determine how universal this finding is.

An emerging tool for the provision of OHA is the use of intra-oral imaging. A new generation Intra-oral cameras (IOC) now have the ability to capture the gingival and hygiene status of the patient [19]. These electromagnetic cameras have colour calibration and software which capture changes in redness allowing the detection of gingival inflammation [23-24]. Recently, it has been demonstrated that using non-invasive gingival indices digital gingival images could be used for the clinical evaluation of gingival health or inflammation [25]. There is also evidence from studies of heart disease that images related to heart disease risk together with text are better at motivating behaviour change than the use of text alone [26-27]. This suggests that the use of IOC images in conjunction with verbal OHA might improve patient adherence to their prescribed oral hygiene regime.

This pilot study aimed to determine if personalised OHA using a patient report generated by an IOC that can accurately capture tissue inflammation combined with the standard of OHA provided in the general dental services results in greater improvements in plaque control and gingival health after 4-weeks as compared to the provision of standard OHA alone. The null hypothesis was that there would be no difference in OHA scores between the participant group receiving the personalised OHA and the group that did not after 4-weeks. In addition, the accuracy of plaque scoring determined from IOC images as compared to clinical plaque scoring following disclosure was determined.

Methods

Study design

This was a parallel, randomised (1:1 ratio), examiner-blind, 2 treatment, pilot study in participants diagnosed with gingivitis. The study, undertaken by a UK dental school team, was approved by the South East Scotland REC 01 (IRAS ID:265051) and conducted according to good clinical practice and the declaration of Helsinki.

Recruitment and eligibility

Individuals who had expressed an interest in taking part in dental clinical trials and who were registered to the UK University’s Dental Clinical Trials Unit’s database were approached to take part.

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in the study. Potential participants were supplied with a participant information sheet and invited to a screening appointment. Volunteers who attended a screening appointment at the UK dental hospital gave informed consent to take part in the study were assessed for eligibility by the primary study dentist. Eligible participants were adults who were not currently receiving orthodontic treatment, who had a minimum of 12 scorable teeth (natural teeth without coronal restorations) and at least 4 teeth in the upper and lower anterior sextant of their mouths with no calculus or staining present with a modified gingival index (MGI) score [28] of at least 1 and not greater than 3 on at least 2 of the anterior teeth. Participants on courses of anti-inflammatory, antimicrobial or anti-statin medications, or who had periodontal disease modifying factors such as being immunocompromised, or a smoker/user of nicotine e-cigarettes were excluded.

**Intervention phase**

All enrolled participants were shown standard pictures of teeth and gingivae and asked to indicate whether they thought the pictures demonstrated gingival health or disease and to identify which image they felt best represented their current oral health, questionnaire 1. An intra Oral Camera (IOC) captured images of the anterior upper and lower study teeth (3-3) including at least two teeth with an MGI score of at least 1 and not greater than 3 identified by the primary study dentist (blinded). Following the IOC the primary study dentist recorded participants oral health of the upper and lower anterior sextants using MGI [28], the gingival bleeding index [29], and plaque score after disclosing the teeth with a vegetable dye [30]. Participants were then randomised by unblinded study staff to test or control group (1:1) according to a pre-determined randomisation schedule provided by the study statistician generated using SAS software V15.2, and their randomisation number which had been assigned in ascending numerical order as they were deemed eligible for enrolment onto the study. All participants were then asked to complete a questionnaire, questionnaire 2, that explored their oral hygiene regime, aspects of their oral health, how motivated they were to achieve good oral health and any concerns they had about their oral health.

Participants in the control group then received the prevailing standard of OHA provided in the general dental services from the second study dentist (unblinded), with the same instruction delivered to all participants. This instruction followed the standards for the dental team as published by the GDC [31] and taught at dental school of twice daily oral hygiene with toothbrushing with a toothpaste and interdental cleaning in order to help achieve optimal oral health. Participants in the test group were shown the IOC of their mouth as a video and as images in the form of a pictorial report by the second study dentist (unblinded) who used these to explain their current gum condition, including where the gingivae were healthy and where they exhibited gingival
inflammation, they were also given OHA in the same way as the control group. All OHA (both groups) was provided by the same unblinded second study dentist. The test group were then given the report to take home with them together with a leaflet on oral health and a mouth mirror to use at home. Participants in both groups were then asked to complete a short questionnaire, questionnaire 3, about their attitudes to oral health asking whether they thought gum disease was a serious oral health concern, untreated bleeding gums would lead to gum disease, whether they were concerned about their gum health, and for their thoughts about the oral health plan they had been given.

Participants returned to the study site after 4 weeks. At this visit participants completed questionnaire 2 again about their oral hygiene regime, gingival health, how motivated they were to achieve good oral health and any concerns they had. They were also asked to complete the short questionnaire 3 about their attitudes to oral health a second time. All participants were then assessed for plaque accumulation and gingival health and a further scan of their mouth was taken by the primary study dentist. Following the completion of study assessments the second (unblinded) study dentist reviewed the videos from visit 1 and images from both visits with participants in the control group as well as providing them with their pictorial reports, a mouth mirror and an information leaflet to take away. Participants in the test groups were also provided with their pictorial report from visit 2. Participants in the test group were asked to rate the utility of the scans.

After all participants had completed the study, a third blinded clinician used the anonymised IOC to score plaque at both study visits for all participants, so that these scores could be compared with the clinical plaque scores.

**Dental assessments and calibration**

Gingival health was assessed using the non-invasive MGI [28] at 2 sites per tooth on a 5-point scale [0 = normal (absence of inflammation); 1 = mild inflammation (slight change in colour, little change in texture) of any portion of the gingival unit; 2 = mild inflammation of the entire gingival unit; 3 = moderate inflammation (moderate glazing, redness, oedema, and/or hypertrophy) of the gingival unit; 4 = severe inflammation (marked redness and oedema/hypertrophy, spontaneous bleeding, or ulceration) of the gingival unit]. Bleeding on probing was scored using a 2-point code at 4 sites per tooth where No (0) = no bleeding and Yes (1) as described by Ainamo & Bay [29]. Plaque was scored clinically by the primary (blinded) study dentist and from images captured from the IOC taken prior to plaque disclosure by a third blinded clinician. The intra-oral diagnostic camera (Soprocare Acteon®) was used on a mode which allows the detection of dental plaque without the need for plaque disclosure, whilst still enabling distinction between gingival health and disease to be determined by the image observer. Images taken of the participants mouths prior to and after
plaque disclosure were scored for plaque using a 2-point code at 4 sites per tooth (buccal and lingual/palatal) where 0 = no plaque and 1 = plaque following the method established by O’Leary et al [30].

Questionnaires

Questionnaire 1 contained 3 images depicting either health, gingivitis or periodontitis. An overview of questionnaires 2 and 3, based in part on those used previously by this research team [32-33], but adapted for this study, and how they were adjusted for each visit is shown in table 1.

Table 1. Questions asked in questionnaires 2 and 3. Questions that were adjusted for visit 1 or 2 are indicated.

<table>
<thead>
<tr>
<th>Question</th>
<th>Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Questionnaire 2 – Home-care oral hygiene behaviours</strong></td>
<td>1</td>
</tr>
<tr>
<td>• What is your: (date of birth, age, gender)</td>
<td>Both</td>
</tr>
<tr>
<td>• How many times per day do you regularly brush your teeth? (&lt;1/day, 1/day, 2/day &gt;2/day)</td>
<td>Both</td>
</tr>
<tr>
<td>• When do you normally brush your teeth? (morning, evening, day)</td>
<td>Both</td>
</tr>
<tr>
<td>• Do you normally brush your teeth (before breakfast, after breakfast, neither, both?)</td>
<td>Both</td>
</tr>
<tr>
<td>• Which kind of toothbrush do you use the most often? (Manual or power)</td>
<td>Both</td>
</tr>
<tr>
<td>• Are you right or left-handed?</td>
<td>Both</td>
</tr>
<tr>
<td>• Do you currently use a toothpaste? (yes, no):</td>
<td>Both</td>
</tr>
<tr>
<td>o if yes, which?</td>
<td>Both</td>
</tr>
<tr>
<td>• Do your gums bleed when you brush your teeth? (yes, no)</td>
<td>Both</td>
</tr>
<tr>
<td>• Do you think you have bad breath? (yes, no)</td>
<td>Both</td>
</tr>
<tr>
<td>• Do you use any of the following additional teeth cleaning aids? (Dental Floss, Flossettes, Single tufted brush, Interdental brusheses, Air flosser, Water flosser, none)</td>
<td>Both</td>
</tr>
<tr>
<td>o If yes, how often do you use them? (daily, weekly, occasionally)</td>
<td>Both</td>
</tr>
<tr>
<td>• Are you currently concerned about your oral health? (yes, no)</td>
<td>Both</td>
</tr>
<tr>
<td>o If yes, what are your concerns? (Condition of teeth, Function of teeth, Appearance, Breath, Sensitivity, Other/not sure)</td>
<td>Both</td>
</tr>
<tr>
<td>• Has your diet changed since you started the study with us? (yes, no, not sure)</td>
<td>Both</td>
</tr>
<tr>
<td>• How would you rate your current oral health? (excellent, very good, good, fair, poor, not sure)</td>
<td>Both</td>
</tr>
<tr>
<td>• Are you motivated in maintaining oral health? (very, fairly, neither/nor, not, not sure)</td>
<td>Both</td>
</tr>
<tr>
<td>• Has your motivation to maintain your oral health changed since you started the study with us? (yes, no)</td>
<td>Both</td>
</tr>
<tr>
<td>• Was the pictorial report of your oral health provided in this study useful for you? (very, fairly, neither/nor, not, not sure)</td>
<td>Both</td>
</tr>
<tr>
<td>• How often did you refer to your pictorial report provided in this study (Daily, Weekly, Didn’t refer to it)</td>
<td>Both</td>
</tr>
</tbody>
</table>

**Questionnaire 3: Attitudes to oral health and the oral health plan**

All answered on a scale of 1 (not at all) to 10 (extremely so):

• Do you think bleeding gums and gum disease is a serious health concern?
• If my bleeding gums are left untreated the likelihood that I will develop gum disease in the future is high

Both | 1
- Following my Oral Health plan over the next 4 weeks will improve the health of my mouth and reduce my risk of developing gum disease
- Following my Oral Health plan over the next 4 weeks has improved the health of my mouth and reduced my risk of developing gum disease
- I know I can follow my Oral Health plan over the next 4 weeks
- I know I can continue to follow my oral health plan in the future
- Following my Oral Health plan will be difficult to do
- Following my Oral Health plan will be difficult to maintain
- My gum disease concerns me

**Statistical Methods**

This was a pilot study, therefore the sample size of 20 participants was for the purposes of estimation rather than hypothesis testing and is in line with Whitehead et al [34]. The assumed SD (pooled) of plaque scores was around 2.65. The sample size was generated using NQUERY V8.7.2. A sample size of 10 per group (20 in total) ensured that the 95% CI for the mean difference in the change from baseline plaque scores lay to within about 0.16 units of any observed difference. The intent to treat (ITT) population was defined as all participants randomized to study intervention.

The difference in change from baseline (clinical and image scores) after 4 weeks between test and control groups was reported using Least Squares Means from a model-based analysis adjusting for baseline (GLM). For questionnaire variables, analysis using a generalized linear model was used, and Spearmans’ Rank correlation was used to assess the association between image and clinical plaque scores.

**Results**

Between 16th September 2020 and 4th November 2020, 22 participants were enrolled in this pilot randomized trial. Patient flow through the study is shown in Figure 1, no AEs were recorded.

All participants were white, 36% of participants were male, and the median age (range) was 45.5 (18-73) with no significant differences in demographics between the control and test groups. All participants correctly identified the image of periodontal disease as disease on the first questionnaire, and none indicated it represented their current health. Most participants, (the same number in each group (9/11)), also correctly identified the image of health, however, only 3/11 (both groups) correctly identified the image showing gingivitis as disease, 5/11 (both groups) thought this image represented health, while the remainder didn’t know/didn’t answer. Overall, 10 participants identified the image of health and 12 that of gingivitis as representative of their current disease, the control group favouring the ‘health image’ (7/11) while the test group favoured the gingivitis image (8/11).
The combined data for all participants about oral hygiene habits, health and motivation at baseline (questionnaire 2) is shown in Figure 2. The data indicated that, most participants brushed their teeth at least twice daily, used a power toothbrush and additional tooth-cleaning aids weekly, the most interdental brushes the preferred aid. Only 5 participants reported bleeding gums and 9 indicated they were concerned about their oral health. On a scale of 1-4, most rated their current oral health as a 2 or 3 (good or fair) and the majority were either fairly or very motivated to maintain good oral health. There were no significant differences between test and control group for any item.

Baseline participant attitudes to gum disease and the oral health care plan they had been given (questionnaire 3) are shown in Figure 3. Average scores indicated that participants thought gum disease was quite serious (mean 7.64 +/- 2.04) and that bleeding gums if untreated were likely to lead to gum disease with bone loss (mean 8.68 +/- 1.55). Similarly, participants were positive about their oral health plan and that it would reduce their risk of getting gum disease (mean 8.14 +/- 1.13) and their ability to carry out their plan (mean 8.76 +/- 1.30), and indicated that they did not believe it would be hard to follow (mean 2.33 +/- 1.74). There were no significant differences in any of these parameters between the control and test group at baseline.

Mean plaque scores at baseline and after 4 weeks for test and control groups as measured clinically or from the captured IOC images are shown in table 2. Participants in the test group at visit 2 (after 4 weeks) had the lowest absolute plaque scores by both measures.

Table 2: Summary Statistics of Clinical Plaque and Image Plaque Scores at baseline and week 4 (Visit 2)

<table>
<thead>
<tr>
<th></th>
<th>Control (n=11)</th>
<th>Test (n=11)</th>
<th>Difference*</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline Visit 2</td>
<td>Baseline Visit 2</td>
<td></td>
<td>p-value</td>
</tr>
<tr>
<td>Image Plaque score</td>
<td>n (% total) mean (SD)</td>
<td>n (% total) mean (SD)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>11 (100%) 0.78 (0.18)</td>
<td>11 (100%) 0.61 (0.16)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical Plaque Scores</td>
<td>11 (100%) 0.63 (0.23)</td>
<td>11 (100%) 0.50 (0.19)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The comparison of change from baseline between test and control groups as measured clinically or from the IOC images are shown in table 3. A significant difference in favour of the test group was shown clinically, but did not quite reach significance when measured from IOC images. An example of an IOC image is shown in Figure 4.

Table 3: Statistical Analysis of Change from baseline to week 4 in Plaque Clinical and Image Scores

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Control group</th>
<th>Test group</th>
<th>Difference*</th>
<th>95% CI</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LS Mean</td>
<td>LS Mean</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Plaque scores recorded from the IOC-images were consistently slightly higher than those obtained clinically, but there was a significant positive agreement between the scores ($\rho = 0.89$, $p < 0.001$).

Mean MGI and BI scores at baseline and after 4 weeks for test and control groups are shown in table 4. Participants in the test group at 4 weeks had the lowest absolute MGI and BI scores.

| Table 4: Summary Statistics of MGI and BI Scores at baseline and week 4 (Visit 2) |
|------------------|------------------|------------------|------------------|------------------|------------------|
|                   | Control (n=11)   | Test (n=11)      |                   |                   |                   |
|                   | Baseline         | Visit 2          | Baseline          | Visit 2          |                   |
| MGI Scores        |                   |                   |                   |                   |                   |
| n (% total)       | 11 (100%)        | 11 (100%)        | 11 (100%)        | 11 (100%)        |                   |
| mean (SD)         | 3.25 (0.82)      | 2.61 (1.42)      | 3.14 (0.66)      | 1.91 (0.78)      |                   |
| BI Scores         |                   |                   |                   |                   |                   |
| n (% total)       | 11 (100%)        | 11 (100%)        | 11 (100%)        | 11 (100%)        |                   |
| mean (SD)         | 1.17 (0.57)      | 0.78 (0.68)      | 0.96 (0.45)      | 0.36 (0.33)      |                   |

The comparison of change from baseline between test and control groups as measured by MGI or BI are shown in table 5. Improvements in both measures favoured the test group, but did not quite reach significance apart from MGI when only absolute change was considered.

| Table 5: Statistical Analysis of Change from baseline to week 4 in MGI and BI Scores |
|------------------|------------------|------------------|------------------|------------------|------------------|
|                   | Test             | Control          | Difference*      | 95% CI           | p-value          |
|                   | LS Mean          | LS Mean          |                  |                  |                  |
| MGI Score         |                   |                   |                  |                  |                  |
| Change            | -1.21             | -0.67            | 0.54             | 0.05, 1.03       | 0.0328*          |
| %Change           | -38.92            | -26.43           | 12.49            | -2.89, 27.88     | 0.1055           |
| BI Score          |                   |                   |                  |                  |                  |
| Change            | -0.62             | -0.37            | 0.25             | -0.04, 0.54      | 0.0921           |
| %Change           | -62.84            | -43.70           | 19.14            | -1.65, 39.92     | 0.0690           |

Oral healthcare habits improved in both groups, all but one participant reporting brushing at least twice daily (in the control group), and the frequency of daily use of interdental cleaning aids increasing from 5/22 at the start of the study to 11/22 after intervention. Participants in both groups were also more motivated to maintain their oral health at the end of the study than before, however there were no significant differences in any oral hygiene habit, participant reported oral health, or
motivation between the 2 groups. There were also no differences in participants attitudes to gum
disease seriousness and outcome if it is not treated, but the test group were significantly more
positive about whether following their oral health plan would be difficult to do \( p < 0.05 \). All of the
test group also indicated that they found the pictorial report useful \((4/11)\) indicating very useful
while \((7/11)\) indicated it was fairly useful, the majority using it weekly \((8/11)\), while \(3/11\) didn’t refer
to it between the study appointments.

**Discussion**

This pilot study set out to determine if IOC images used to personalise OHA by providing a visual
snapshot of the oral sites lacking attention by participants current oral hygiene practices would
improve gingival health more than the standard of OHA delivered in the general dental service alone
after 4-weeks. While oral health improved in both groups, it was demonstrated that the use of a
patient report featuring an IOC image during OHA resulted in significantly improved clinical plaque
scores as compared to the provision of standard OHA alone. Similarly, clinical gingival indices, and
plaque scores measured from intra-oral scans, were also improved in both groups, but greater
improvements were seen in the group who received the patient report, although the findings for
these measurements did not reach significance.

It would be expected that clinical plaque and gingival scores would improve in both groups over the
4 weeks of the study as each received OHA. Similar improvements in oral health indices in control
groups have been reported in other studies seeking to determine if IOC provided as an OHA adjunct
enhanced outcomes more than the OHA/treatment alone \([35-36]\). In both of these studies, although
there were improvements in both participant groups at least some study outcomes were
significantly greater in participants who were shown with explanation the IOC images as compared
to those in the control group. By contrast, in a study that examined the use of quantitative light-
induced fluorescent (QLF) images in which mature plaque fluoresces provided together with verbal
OHA, as compared to verbal OHA alone, study participants all at medium or high risk of poor oral
health preferred verbal OHA without the image \([19]\). However, there were technical issues
encountered with the QLF imaging resulting in some poor-quality outputs, and in the one site where
imaging was good, on short-term follow up there was a significantly greater reduction in plaque in
those who had received the QLF image.

In the present study while clinical plaque scores were significantly better following IOC with OHA,
gingival scores were not significantly different between groups even though they favoured the test
group. This could reflect the fact that while improvements in plaque score due to better tooth-brushing and interdental cleaning can be seen quickly, to move participants from disease to health further regular reiteration, reinforcement and encouragement are needed to reduce plaque accumulation to a sufficient degree [37-38]. This study as a pilot study was deliberately of short duration, the study by Willershausen et al [36] was of similar length and only examined plaque accumulation. By contrast the Study by Arajuo et al [35] was 4 months, and demonstrated significant differences in bleeding in marginal probing scores between groups at this timepoint. It is recognised with general consensus that plaque inhibitory activities should be proven in long-term, at least 6 months home-use, randomised clinical trials (RCT) [39], and studies to test interventions designed to change behaviour should take place over years not months [40], and the authors have planned a larger longer follow up study.

Self-reported oral hygiene habits also improved in both groups in the present study with no differences seen between groups. As well as the fact that all participants received OHA, at baseline the majority were power brush users, used interdental brushes at least weekly, reported that gingivitis was quite serious and that bleeding gums could lead to tooth loss. In addition, they were almost all fairly or very motivated to maintain good oral health and confident about following an oral hygiene regime. This suggests that this groups of participants were already conscious of the need for good oral health and not completely representative of the population as a whole. Motivated individuals on a study are more likely to adhere to oral hygiene/study regimes than individuals in a real-life scenario. Participation bias is a recognised problem for randomised clinical trials and different trial designs to address this are now being explored [41].

Interestingly, there was a significant difference in how easy it would be to follow the oral hygiene regime between groups at the end of the study, values for the control group increasing in difficulty to adhere, while the test group decreased in difficulty to adhere indicating that at the end of the study they were more confident in following their oral hygiene plan. This may suggest that the provision of an image for reference/recall is valuable. Similar to the findings of a previous study [35], participants in the test group also reported finding the images useful.

In this pilot study there were only 11 participants assigned to each group. In addition, assessment was limited to the anterior sextant teeth as these are readily accessible and this also was designed to limit the length of study appointments for participants. The small sample size was for the purposes of estimation rather than hypothesis testing as a larger study to confirm the findings of the present study is planned. The study findings indicate that there was sufficient power to detect a difference in clinical plaque score, but for other measures a larger sample size would be needed. The decision to
use only the anterior sextent teeth for the pilot study means that it is not possible to generalise these findings to the whole oral cavity. The study was a proof of principle study to ascertain the ability and limitations of the IOC and was undertaken to inform a larger follow-on study. Anterior teeth are generally cleaning more effectively that the posterior teeth [42], and the follow-on study will assess IOC for the whole mouth.

The present study demonstrated that there was a good agreement between plaque scored from the IOC captured images and those scores recorded following clinical disclosure, although the change in image score while favouring the IOC intervention did not reach significance, unlike the clinical evaluation. In addition, the scan scores were consistently slightly higher than those recorded on clinic. Similar findings for the IOC have been reported in a previous study in which it was shown that Turesky-modified Quigley Hein index plaque score [43] and the Silness and Loe gingival inflammation index [44-45] were both scored slightly higher when scored from the IOC image than clinically [46]. It is suggested that some plaque-free teeth were scored from the images as having plaque and as the plaque index used was binary, this resulting in the IOC plaque score not quite reaching significance in the small pilot study. However, the authors concluded that with training on plaque free teeth scoring errors would be reduced and that the IOC used in PERIO mode reliably evaluates plaque and gingival inflammation.

**Conclusion**

Within the limitations of this study, it was demonstrated that clinically significant improved plaque control could be achieved in individuals presenting with mild to moderate gingivitis when incorporating IOC. This was demonstrated with one episode of personalised tailored oral hygiene instruction in the form of a video and pictorial report compared to the prevailing information conferred in the standard of OHA only provided in the general dental services. Furthermore, clinical plaque images captured with IOC compared favourably with clinical plaque scores.

Larger and long term studies are required to validate the use of IOC in the delivery of oral hygiene advice. This proof of principle study supports the use of IOC data capture to record oral findings for clinical records.
Figure 1 (CONSORT Diagram) shows the flow of participants in the trial.

**Enrollment**

Assessed for eligibility (n=23)

Excluded (n=1)
Not meeting inclusion criteria (n=1)
Declined to participate (n=0)
Other reasons (n=0)

Total Randomized (n=22)

Allocation

Test (n=11)
Completed baseline visit (n=11)
Completed Visit 2 (n=11)

Control (n=11)
Completed baseline visit (n=11)
Completed Visit 2 (n=11)

Follow up

Analysis

Available for analysis of primary outcome (n=22)
Missing or incomplete data for primary outcome (n=0)
Figure 2: Participant oral health habits, concerns and motivation at baseline. For bleeding gums, bad breath and OH concern, those who reported having these are displayed. IDB = interdental brush, IDA = interdental aid, OH = oral health.

Figure 3: Participant oral attitudes to gum disease and their oral health care plan at baseline (Q1: Do you think bleeding gums and gum disease is a serious health concern?; Q2, If my bleeding gums are left untreated the likelihood that I will develop gum disease in the future is high; Q3, Following my Oral Health plan over the next 4 weeks will improve the health of my mouth and reduce my risk of developing gum disease; Q4, I know I can follow my Oral Health plan over the next 4 weeks; Q5, Following my Oral Health plan will be difficult to do; Q6, My gum disease concerns me.

Figure 4: A representative picture of teeth imaged using the IOC, Plaque shows as yellow.
References


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