A randomised controlled trial evaluating the impact of oral health advice on gingival health using intra oral images combined with a gingivitis specific toothpaste.

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Short title: Oral hygiene behaviour change to improve gingival health

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Abstract

Objectives: Does a complex intervention of oral hygiene advice (OHA) delivered with intra-oral scanner images, anti-gingivitis toothpaste and motivational reminders, improve oral health more than a standard of care control arm of fluoride toothpaste, with OHA without scanner images?

Methods: Adult participants with pre-existing gingivitis were randomised to intervention or control. Following enrolment, baseline and each subsequent visit (V) (3-weeks, V2; 3-months, V3; 6-months, V4) followed the same schedule. Bleeding on Probing (BOP) was assessed and Intra Oral Scan IOS(1) recorded. Plaque was disclosed, scored and re-scanned (IOS(2)). The intervention group received OHA with IOS images, control group receiving OHA without IOS images. Participants brushed with their allocated toothpaste (fluoride, control; anti-gingivitis, intervention), IOS(3) was recorded. Between visits participants brushed with their allocated toothpaste, intervention group received motivational reminders.

Results: BOP scores from baseline were significantly improved in the intervention group compared to control at all visits for all surfaces ($p<0.001$); differences at V4 were 0.292 (all), 0.211 (buccal/labial) and 0.375 (lingual/palatal). Plaque scores from baseline pre-brushing to each visit pre- and post-brushing also favoured the intervention group, the difference always significant on lingual/palatal surfaces ($p<0.05$), significant for all but pre-brushing-V4 ($p<0.05$) on all surfaces, but only significant for pre-brushing-V3 ($p<0.05$) buccally/labially. Differences from baseline to post-brushing at V4 were: 0.200 (all), 0.098 (buccal/labial) and 0.291 (lingual/palatal).

Conclusion: A complex intervention comprising OHA delivered with IOS-images, anti-gingivitis toothpaste and motivational reminders improved gingival health more than existing standard of care-OHA together with a standard fluoride toothpaste over a 6-month period.

Clinical Significance Statement

Intra-oral scans (IOS) are now frequently used in general dental practice for a variety of purposes. IOS use, in combination with motivational texts and an anti-gingivitis toothpaste, could be further deployed to promote oral hygiene behaviour change in patients and improve gingival health, in a cost-effective manner**.**

Introduction

Gingivitis is a prevalent condition that primarily arises in response to the persistence of dental plaque at the gingival margin [1]. Whilst gingivitis is reversible, untreated gingivitis can lead to periodontitis which is irreversible, negatively affecting quality of life (QoL) and having systemic consequences[2-4]. The global burden of severe periodontal disease increased by 67% between 1990 and 2013, routinely self-performed oral hygiene being the most important behaviour modification for the prevention of gingivitis and subsequent periodontitis [5]. Further, economic analysis shows that eliminating gingivitis using home care prevention techniques had a positive return on investment in all the European countries in the study of The Economist Intelligence Unit [6].

It is the responsibility of dental care professionals to provide oral hygiene advice (OHA) so that patients understand the significance and requirement to maintain and improve their oral health [7-9]. Prevailing rates of gingivitis remain high [3] notwithstanding studies indicating that OHA is routinely provided, with 80% of dental attenders in a 2018 PHE study confirming they had received OHA [10] and 96% of dentists confirming they provided OHA routinely[11]. Furthermore, 53% of participants in the 2018 PHE study had gingival inflammation as indicated by bleeding on probing (BOP) [10], suggesting a lack of efficacy from the OHA received. It has been suggested that this may be because patients have been provided with advice that conflicts with that delivered by other healthcare professionals [12]. Alternatively, it may reflect anecdotal evidence that OHA may often be too minimal to be effective, such as a reminder to perform toothbrushing [13]. While studies that have examined what comprises standard OHA are lacking, the wide variation in the approaches considered suggest a lack of focus with respect to OHA goals [14].

A systematic review of OHA efficacy found evidence to support the effectiveness of written and verbal information for educating patients [14]. Verbal advice was shown to be effective in improving oral health determined clinically through improvements in patient-reported behaviour [14]. Effectiveness of behaviour change techniques for plaque control based on goal setting, planning and self-monitoring in periodontal patients was also confirmed by systematic review [15]. However, in a recent RCT, the provision of personalised OHA based on behaviour change theory comprising advice/instruction in self-diagnosis and brushing techniques/use of interdental aids, together with an agreed action plan, was no more successful at improving oral hygiene than standard OHA [13]. Thus the need for developing additional effective tools to improve OHA is still unanswered.

Intra oral scanners (IOS) originally designed for computer aided design/computer aided manufacture (CAD/CAM) for the fabrication of prosthetic restorations are now used in orthodontics and an

increasing number of other applications [16,17]. Improvements in accuracy and the capture of colour and texture ensure that IOS are able to image soft as well as hard dental tissues. Indeed, we have recently shown that IOS images (TRIOS®3 3shape) are accurate enough for remote and non-contemporaneous independent scoring of gingival inflammation using the modified gingival index [18]. Pictorial information could potentially provide a useful tool to help delivery of OHA; a recent pilot study showed that images from an intra-oral camera used during the provision of OHA improved oral health outcomes more than the standard of OHA used in general dental services [19].

While OHA is fundamental for improving oral hygiene, toothpastes to combat mild to moderate gingivitis are also improving; systematic reviews have demonstrated that stannous fluoride (SnF) toothpastes achieve better gingival outcomes than conventional fluoride controls [20,21]. Toothpastes containing triclosan have also been shown to be effective anti-gingivitis toothpastes. One review showed that those containing triclosan-copolymer or chlorhexidine are more effective anti-plaque agents than SnF [22], while another showed favourable results for SnF for bleeding on probing (BOP) outcomes [23]. More recently, toothpastes containing 67% sodium bicarbonate have been shown to reduce plaque and improve gingivitis [24]. While evidence suggests that individuals do not brush their teeth well enough to remove dental plaque sufficiently [25,26], using a toothpaste with proven anti-gingivitis benefit will optimise any oral hygiene regime.

Most intervention studies endeavour to investigate a single parameter in a controlled environment to limit the variables under consideration. However, the provision of OHA is a complex intervention, where the oral healthcare professional uses the best set of tools to explain to the patient what they should be doing to improve their oral hygiene technique, using behaviour change techniques, and recommending appropriate toothbrush, toothpaste and interdental aids. This study will test a complex intervention comprising OHA delivered with the aid of IOS images, an anti-gingivitis toothpaste containing 67% sodium bicarbonate, and frequent motivational reminders as compared to the standard of OHA attained in the general dental services for the improvement of gingival health. The hypothesis being there will be no significant difference between the two interventions with regard to gingival health improvement.

Materials and Methods

Study Design and Conduct

This study was a blind (blind to the clinician assessing gingivitis and plaque) parallel, randomised controlled trial (RCT) in adults with early gingivitis. It was designed to compare the gingival health of

participants after the provision of either the standard of oral hygiene advice (OHA) currently provided in the general dental services, or a complex intervention comprising standard OHA supplemented with the use of intra-oral scans, motivational text reminders and an anti-gingivitis toothpaste after 3 weeks, 3 and 6 months. The study was approved by East of Scotland Research and Ethics Service (21/ES/0036), completed following Good Clinical Practice guidelines and prospectively registered on a publicly accessible clinical trials database.

The primary outcome was the evaluation of the complex intervention of oral hygiene behaviour modification using intra-oral scans in combination with an anti-gingivitis toothpaste on gingival health, as measured by bleeding on probing to indicate health or gingival inflammation [27] over 6 months; compared to the standard of care provided in general dental practice with utilisation of preferred home care products (control group).

Potential participants were recruited from the dental clinical trials unit database of individuals who had expressed an interest in taking part in clinical trials. Potential participants were provided with an information sheet and invited to a screening appointment to which they were asked to bring the toothbrush and toothpaste that they normally used. At screening those who gave informed consent were assessed for study eligibility by the main (blinded) study dentist and enrolled where they met the study criteria. Eligible participants were healthy adults with at least 10 teeth (excluding those with crowns or bridges) in the region 16 to 26 (FDI notation) across both dental arches, with at least 6 sites (buccal or palatal) in this region with a bleeding on probing (BOP) score of 1 as assessed by Ainamo and Bay [27] as per the inclusion criteria. Participants were excluded if they were currently using orthodontic appliances, had obvious signs of untreated caries, had any site with a periodontal pocket depth of $\geq$4mm, had a modified gingival index score of 4 on any site 16-26 [28], had any condition that is known to affect gingivitis, or had an allergy to any of the anti-gingivitis toothpaste ingredients as per the study exclusion criteria.

Following enrolment in the study, participants were asked to complete a questionnaire about their home oral hygiene regime. The oral hygiene questionnaire also contained one image of gum health, one of gingivitis and one of periodontitis; participants were asked to say which image represented which oral health condition and signal which they thought matched their own oral health.

Randomisation was undertaken by an unblinded study team member. Participants were randomised in order of enrolment to the study, to either test or control group, in accordance with the randomisation schedule provided by the study statistician. The allocation of participants to

intervention or control was concealed from all staff involved in recruitment and/or study assessments.

In the clinic, the blinded study dentist (assessor) recorded BOP scores using the gingival bleeding index (GBI) [27] from 16 to 26 for both upper and lower arches, buccally and palatally. Clinical assessments and intra-oral scans (IOS) using the TRIOS®3 scanner (3Shape, Niels Juels Gade 13, 1059 Copenhagen K, Denmark) followed the same pattern at baseline and each subsequent study visit (3 weeks, 3 months and 6 months). Following BOP scoring using GBI [27], participants in both groups were scanned (IOS 1), plaque was disclosed using a vegetable dye (MIRA-2-TON, Hager & Werken, GmbH & Co. KG) and scored using the Silness and Loe index [29] and then scanned again (IOS 2), all conducted by the main (blinded) study dentist. In a separate room, the second unblinded study dentist then provided each group with OHA. In the control group, OHA was delivered as per the standard of OHA given in the general dental services, and participants were not shown IOS 1 or 2, while in the test group, OHA was provided with the aid of IOS 1 and 2. Both groups were then asked to brush their teeth for 2 minutes using their own toothbrush (a standard manual brush was provided for those who had forgotten this) and the study toothpaste. The test group were asked to use an anti-gingivitis toothpaste (Corsodyl® Complete Protection Extra Fresh containing sodium bicarbonate 67%, sodium fluoride 0.31% (1400ppmF-)), and the control group were asked to use the toothpaste they had brought with them or were provided with a standard fluoride toothpaste (Colgate® Cavity Protection containing sodium monofluorophosphate 0.76% (1000ppmF^-) and sodium fluoride 0.1% (450 ppmF^-)). Following the participants return to the clinic, the main (blinded) study dentist took a third scan (IOS 3) to capture plaque deposits remaining after OHA and toothbrushing and scored plaque as before. All participants then returned to the separate room, where the unblinded study dentist showed the test, but not the control group IOS 3, and areas that still needed improvement were indicated using this IOS. Test group participants were given anti-gingivitis toothpaste to use instead of their normal toothpaste for the duration of the study, together with copies of their IOS which were annotated with the areas where they needed to focus their oral hygiene (OH). The control group were meanwhile asked to continue with their normal oral hygiene regime using their normal toothbrush and toothpaste and not alter this during the study period.

Between appointments, test group participants were sent follow up reminders about toothbrushing and OHA by an unblinded study team member. Compliance with OHA and allocated product use (test group) was verified at the start of visits 2-4 by the unblinded dentist, as were adverse events (AEs).

A secondary study objective was to compare the accuracy of intra-oral 3D scanner derived assessment of plaque score compared to standard clinically derived direct scoring of clinical plaque score at all time points for test and control groups. A minimum of 10 days after each study appointment the blinded first clinician assessed IOS 2 and 3 for plaque scores by Silness and Loe [29]. All study visits were undertaken at one site, a UK dental hospital.

Study assessments

Bleeding on probing (BOP) assessment as measured using the GBI [27] was performed through gentle probing of the orifice of the gingival crevice at 6 sites per tooth, bleeding that occurred within 10 seconds was scored as 1 and no bleeding in this period was scored as 0. The 3 buccal/labial surface scores and 3 lingual palatal scores were added together to generate a single score for each surface. The overall participant BOP score was calculated as the buccal/labial score + the palatal/lingual score divided by the total number of surfaces scored.

Plaque was scored clinically using the Silness and Loe Plaque Index [29] at 4 sites buccally (mesial buccal, buccal and distal buccal, and palatal) of each tooth following plaque disclosure. The index is a 4-point scale: Score 0, absence of microbial plaque; score 1, thin film of microbial plaque along the free gingival margin; score 2, moderate accumulation with plaque in the sulcus; score 3, large amount of plaque in sulcus or pocket along the free gingiva margin, each site being allocated a score 0-3. The overall participant plaque score was calculated as total score for the 4 sites divided by the total number of sites.

Statistical Methods

Sufficient adult participants in good general health were accepted onto the study in order to obtain BOP data from 80 after 6 months. The power calculation was based on data from Midwood *et al* [30], from this we anticipated a mean % bleeding of 28 (SD 20) at 6 months in the control group and hypothesised that the intervention would reduce this mean by 50% also with SD 20. With 40 participants per group, there was power over 80% (approx. 88%) to detect this difference using a test at the usual 5% 2-sided α level.

Clinical outcomes between intervention and control groups were analysed by ANCOVA, using the pre-brushing score at visit 1 as co-variate (BOP and plaque), to determine differences in outcomes at each subsequent time point. For all analyses, mean differences with confidence intervals are reported as well as p-values.

Crosstabulations were constructed to compare clinical and scan derived plaque scores. Disagreements between plaque scores were highlighted and analysed as the tendency to over-read rather than under-read the IOS as compared to the clinical scores were determined with confidence intervals [31].

Results

This study was carried out from 15th June 2021 to 16th March 2022, and randomised 85 participants, 42 to the control and 43 to the intervention group (Figure 1). Two participants, one in each group withdrew from the study. There were no AEs.

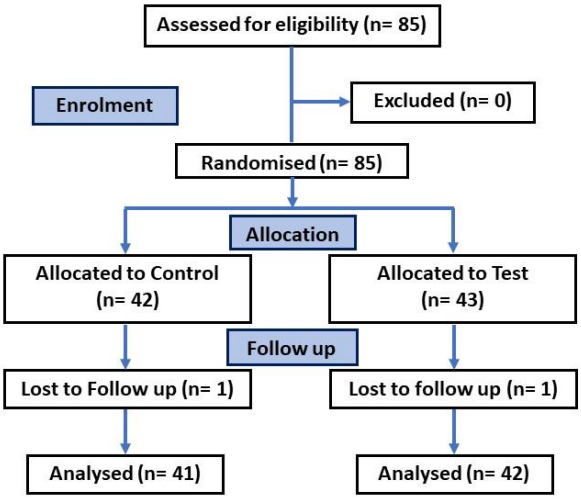

Figure 1: Patient flow through the study

The study recruited more women (64%) than men (36%) with a median age of 43, 82% of participants were white, 15% Asian and 2% black. The majority were non-smokers (60%), and 32% ex-smokers for 6 months with the remainder either smoking or vaping currently. Overall, the treatment groups were well-balanced in terms of demographics.

The average age in the control and test groups were similar, 40 and 44 years, respectively, both groups contained more females than males; control 60%, intervention, 67% and the majority of participants in both groups were white (control, 81%; intervention, 83%).

Home oral hygiene regime

Participants' oral hygiene habits at home and their perception of their oral health are shown in table 1. Overall participant habits were similar for both groups.

Participants who indicated they used interdental aids or mouthrinses were also asked about the frequency of use within the previous week. Of the participants that had used mouthrinses, 37% in the control and 32% in the intervention group had used these daily, and of those who had used interdental aids, daily use was reported by 32% in both groups. For both mouthrinses and interdental aids the other frequencies of use reported were spread relatively evenly from once to 4 times/week.

Table 1: Home oral hygiene habits and perceptions of oral health

		Control, n=42 n (%)*	Intervention, n=43 n (%)*	All, n=85 n (%)*
Brushing frequency	Brush 1x day	6 (14.3)	3 (7.0)	9 (10.6)
	Brush 2x day	33 (78.6)	39 (90.7)	72 (84.7)
	Brush 3x day	3 (7.1)	1 (2.3)	4 (4.7)
Brush type	Manual	12 (28.6)	12 (27.9)	24 (28.2)
	Electric	24 (57.1)	25 (58.1)	49 (57.6)
	Both	6 (14.3)	6 (3.1)	12 (14.1)
Type of toothpaste	Regular Fluoride	31 (73.8)	39 (90.7)	70 (82.3)
	Specialty	8 (19.0)	3 (7.0)	11 (12.9)
	Other	3 (7.1)	1 (2.3)	4 (4.7)
Type of mouthrinse (if used)**	Listerine	6	9	15
	Colgate Total	6	3	9
	Corsodyl 2%	4	3	7
	Other	3	5	8
Type of interdental aid (if used)*	Floss	10	11	21
	Flossettes	6	8	14
	Single tufted brush	3	3	6
	Interdental brush	14	18	32
	Air flosser	0	1	1
	Water flosser	1	1	2
Perception of own oral health	Excellent	1 (2.4)	3 (7.0)	4 (4.7)
	Very good	13 (31.0)	13 (30.2)	26 (30.1)
	Good	20 (47.6)	15 (34.9)	35 (41.1)
	Fair	8 (19.0)	11 (25.6)	19 (22.3)
	Poor	0 (0.0)	1 (2.3)	1 (1.2)
Known gum problem***	Gum inflammation	8	11	19
	Gums bleed	14	16	30

*% given where all participants were able to response and could only select one response
** participants could select more than one choice for these questions
***only answered by those with a known gum problem

Results from the questionnaire including images of periodontal diseases (Figure 2) showed all but 1 participant in each group identified the image of periodontitis as disease, and 2 in the control and 4 in the intervention group indicated that this best represented their current oral health status. Participants were much less certain of whether the other 2 images represented oral health or

disease with little difference between the groups. Combined participant responses for the gingivitis image indicated that 11% did not know, 73% thought this was health and 16% disease. For the health image these figures were 25% (did not know), 49% (health) and 26% (disease); 49% participants identified the gingivitis image as that which best represented their current oral health.

Figure 2: Clinical images from the oral hygiene questionnaire showing (A) gingivitis, (B) health and (C) periodontitis.

Clinical scores

Participant BOP scores are shown in table 2, and analysis of differences between control and intervention group are shown in table 3. BOP scores improved steadily across all surfaces from visit 1 to visit 4 in the intervention group, but not control. For both groups lingual/palatal scores at baseline were higher than buccal/labial scores, and these improved most in the intervention group while they worsened progressively in the lingual/palatal group.

Table 2: BOP proportion at the start of each visit for all surfaces and by surface.

	All		Buccal/Labial		Lingual/Palatal	
	Intervention mean (SD)	**Control mean (SD)**	**Intervention mean (SD)**	**Control mean (SD)**	**Intervention mean (SD)**	**Control mean (SD)**
Visit 1	0.43 (0.22)	0.44 (0.20)	0.37 (0.26)	0.38 (0.21)	0.48 (0.23)	0.49 (0.22)
Visit 2	0.27 (0.20)	0.43 (0.20)	0.20 (0.20)	0.36 (0.24)	0.33 (0.21)	0.50 (0.22)
Visit 3	0.20 (0.16)	0.45 (0.20)	0.15 (0.18)	0.37 (0.24)	0.24 (0.17)	0.52 (0.21)
Visit 4	0.17 (0.15)	0.46 (0.21)	0.14 (0.18)	0.36 (0.26)	0.19 (0.14)	0.57 (0.23)

Table 3: Between-groups comparison of BOP proportion adjusted for the corresponding visit 1 value.

Visit	Adjusted difference[1]	95% confidence limits		p value
		Lower	**Upper**	
ALL surfaces				
2	0.15	0.11	0.20	<0.001
3	0.24	0.20	0.28	<0.001
4	0.29	0.25	0.34	<0.001
Buccal only				
2	0.15	0.09	0.21	<0.001
3	0.21	0.14	0.27	<0.001
4	0.21	0.15	0.28	<0.001
Lingual/palatal only				
2	0.16	0.10	0.23	<0.001
3	0.28	0.22	0.34	<0.001
4	0.37	0.31	0.44	<0.001

[1] Adjusted difference: control – intervention score, adjusted for baseline score (visit 1) as a covariate

Participant plaque scores are shown in table 4. In both groups at each visit plaque scores improved greatly post-toothbrushing, with the highest pre- and post- toothbrushing scores at visit 1. Pre- and post-brushing scores were better (lower), albeit sometimes marginally in the intervention group compared to the control group at visits 2-4. The biggest differences between the groups were seen on lingual/palatal surfaces.

Table 4: Plaque scores pre and post toothbrushing at each visit for all surfaces and by surface

		All		buccal/labial		Lingual/Palatal	
		Intervention mean (SD)	**Control mean (SD)**	**Intervention mean (SD)**	**Control mean (SD)**	**Intervention mean (SD)**	**Control mean (SD)**
Visit 1	Pre	1.77 (0.53)	1.70 (0.53)	1.68 (0.69)	1.58 (0.67)	1.85 (0.50)	1.81 (0.56)
	Post	0.64 (0.50)	0.76 (0.49)	0.49 (0.47)	0.56 (0.48)	0.78 (0.59)	0.95 (0.59)
Visit 2	Pre	1.32 (0.48)	1.43 (0.56)	1.24 (0.61)	1.30 (0.69)	1.39 (0.50)	1.55 (0.58)
	Post	0.42 (0.35)	0.56 (0.40)	0.35 (0.40)	0.40 (0.40)	0.50 (0.39)	0.72 (0.51)
Visit 3	Pre	1.45 (0.53)	1.67 (0.54)	1.41 (0.63)	1.52 (0.74)	1.49 (0.57)	1.81 (0.52)
	Post	0.46 (0.43)	0.62 (0.43)	0.31 (0.36)	0.41 (0.41)	0.61 (0.58)	0.83 (0.56)
Visit 4	Pre	1.53 (0.48)	1.62 (0.59)	1.42 (0.62)	1.43 (0.71)	1.64 (0.54)	1.81 (0.60)
	Post	0.47 (0.37)	0.64 (0.43)	0.32 (0.33)	0.39 (0.35)	0.62 (0.52)	0.89 (0.61)

When changes in plaque scores post-toothbrushing were adjusted for their associated pre-toothbrushing score, there was no significant difference in the magnitude of improvement in pre- to post- toothbrushing at any visit between the groups. Apart from visit 3 lingual/palatal surfaces, the data favoured the intervention group.

Table 5 gives comparisons of plaque scores between intervention and control groups at each time point, adjusted for the corresponding pre-brushing level at baseline (visit 1). Pre and post-toothbrushing intervention group plaque scores were significantly better than control scores at all visits after baseline on lingual/palatal surfaces, and at almost all visits when all buccal and lingual/palatal surfaces were considered together. No significant difference between groups in plaque score at any visit pre- or post-toothbrushing was seen in buccal/labial surfaces.

Table 5: Between-groups comparison of plaque scores at each time point, adjusted for the corresponding pre-brushing score at visit 1.

ALL surfaces				
Visit	Adjusted difference	95% confidence limits		p value
		Lower	Upper	
1-post	0.18	0.04	0.31	0.012
2-pre	0.17	0.02	0.31	0.026
2-post	0.16	0.02	0.30	0.024
3-pre	0.27	0.11	0.42	0.001
3-post	0.19	0.04	0.35	0.017
4-pre	0.15	-0.02	0.31	0.080
4-post	0.20	0.06	0.34	0.007
Buccal/Labial only				
1-post	0.12	-0.03	0.28	0.106
2-pre	0.13	-0.04	0.31	0.134
2-post	0.08	-0.08	0.23	0.322
3-pre	0.19	0.00	0.38	0.046
3-post	0.13	-0.02	0.28	0.098
4-pre	0.09	-0.10	0.28	0.350
4-post	0.10	-0.03	0.22	0.128
Lingual/palatal only				
1-post	0.20	0.03	0.37	0.019
2-pre	0.20	0.03	0.36	0.018
2-post	0.24	0.07	0.40	0.005
3-pre	0.35	0.17	0.52	<0.001
3-post	0.25	0.04	0.45	0.019
4-pre	0.20	0.02	0.39	0.034
4-post	0.29	0.09	0.49	0.006

[1] Adjusted difference: control – intervention score, adjusted for pre-toothbrushing baseline score (visit 1) as a covariate.

The comparison of IOS with clinical plaque scores is shown in table 6. There were a total of 550 disagreements out of a possible 56952 (0.97%), almost all by a single grade demonstrating an excellent level of agreement. For 418 sites (0.734%) IOS over-read, and for 132 sites (0.232%) IOS under-read, relative to clinical scoring. IOS were over-scored more frequently than underscored by 0.502% (95% CI 0.423% to 0.585%), which although significant (p<0.001) due to the size of the dataset this difference is very small.

Table 6: Cross-tabulation of clinical score vs IOS plaque score

IOS	Score	0	1	2	3	Total
Clinical	0	**23659**	87	6	0	23752
	1	27	**12064**	200	2	12293
	2	6	43	**14214**	123	14386
	3	0	2	54	**6465**	6521
	Total	23692	12196	14474	6590	56952

Discussion

This study has demonstrated that the complex intervention of OHA tailored to the participant with the aid of IOS images showing their plaque levels pre- and post- toothbrushing, together with an anti-gingivitis toothpaste and weekly OHA reminders significantly improved BOP compared to standard OHA. Improvements in pre- and post- toothbrushing plaque scores (from baseline pre-toothbrushing) were also significantly better in the intervention than in the control group at almost all visits (all tooth surfaces), but differences were less marked than those seen for BOP. The hypothesis was disproved demonstrating that gingival health, ie BOP scores and plaque (the prerequisite for gingivitis) was improved with the complex intervention as compared to the standard of OH in the general dental services. IOS images of disclosed plaque were of sufficient quality to allow accurate scoring from the scans, with few disagreements between clinical and scan derived plaque scores.

Most study participants were regular dental practice attenders who usually visited at least once a year (70%), in line with the 71% reported by the Care Quality Commission [32]. While only 18% disclosed they had been diagnosed with gum disease (gingivitis) by their dentist, OHA would ideally be provided at all dental appointments [9]. Participants in the present study were not specifically asked whether they had received OHA, but most brushed at least twice daily and used a power-brush, and a third reported daily use of mouthrinses and interdental devices. This suggests that these participants were aware of the measures required to achieve good oral health, however, all had mild or moderate gingivitis as a pre-requisite for study enrolment. This observation supports previous findings that generally toothbrushing is not practiced adequately enough to remove all dental plaque [26,33] and suggests that current standards of OHA are not effective.

This complex intervention was delivered to those with gingivitis aiming to treat the condition. The use of IOS is a tailored patient-specific behaviour change intervention and the use of behaviour change techniques have been shown to be effective for improving oral health [14], particularly those with goal setting, planning and self-monitoring [34]. In the present study, using the IOS images participants in the intervention group were able to clearly see the areas where they had not removed dental plaque with toothbrushing. They were provided with guidance to clean these areas effectively as well as tools for ensuring that these areas were well addressed as part of their oral care routine. The IOS pre- and post- brushing on visits 2-4 allowed the participants to self-monitor, and while no significant differences in plaque score between the groups were seen when comparing pre-and post-toothbrushing improvements in a single visit (potentially due to a Hawthorne effect

[35]), overall plaque scores and BOP improved significantly more in the intervention group from baseline pre-toothbrushing.

The lack of difference between the groups when pre- to post- brushing improvements in plaque were compared on a single visit is likely due to the lower pre-brushing scores in the intervention group resulting in a smaller change (improvement) when compared to post-brushing. Improvements in plaque score from visit 1 were significant pre and post-brushing at all visits when lingual/palatal surfaces were analysed separately. These surfaces had the highest BOP and pre-brushing plaque scores on visit 1 reflecting similar findings from a previous study, which also reported a higher frequency of BOP on lingual/palatal surfaces [36]. By contrast, on buccal/labial surfaces only the visit 1 to visit 3 pre-brushing score was significantly better in the intervention vs control group on buccal/labial surfaces. Previous studies have shown that natural tendencies for toothbrushing are to start on buccal surfaces [37], and that individuals spend little time brushing lingual/palatal surfaces [38]. In the present study the improvements in BOP score seen in the intervention as compared to the control group were also always greatest on lingual/palatal surfaces. This suggests that changes in participant brushing habits to focus more in this area was a key factor which may have been aided by the IOS, as it is the primary method of removing plaque is by the mechanical action of tooth brushing [2].

The complex intervention in the present study also included an anti-gingivitis toothpaste containing 67% w/w sodium bicarbonate. Recent pooled analysis confirmed that twice-daily use of 67% w/w sodium bicarbonate toothpastes was more effective than use of fluoride control toothpastes for plaque reduction and improvement of gingival health in participants with gingivitis [24]. However, the studies pooled included a pre-treatment full-mouth prophylaxis so the action of the toothpaste was against immature plaque. The present study carried out no prophylaxis therefore the toothpaste acted both on surfaces that had been cleaned effectively by tooth-brushing and those with residual plaque. Pre-prophylaxis was not included as it does not reflect the population's habits on a day-to-day basis, and the authors felt it important to generate clinical data reflecting the real world. Interestingly, the previously published pooled analysis showed greater 'between treatment' improvements on buccal/labial surfaces than on lingual surfaces for both plaque and gingival scores [24]. This contrasts with the bigger differences seen lingual/palatally in the present study. Taken together this suggests that the toothpaste is contributing to the improvements seen in oral health in the intervention group, but that lingual/palatal improvements may be more influenced by the OHA delivered using IOS.

In the present study differences between the intervention and control group were much more apparent for BOP than for plaque score. This may reflect the Hawthorne effect, at least in part, where participants in both groups were conscious of being in the study from the point that they received their reminder about the study visit until the visit was complete, so brushed their teeth better ahead of and during the visit than they had done between visits. Thus, for buccal/labial surfaces which scored lower for plaque than lingual/palatal surfaces from visit 1, plaque scores between the groups were more similar than would be expected given the much greater between group difference observed for BOP presumably arising from the better day to day reduction in plaque in the intervention group. The improvements in BOP can be attributed to the mechanism of action of the bicarbonate toothpaste, which both physically displaces plaque from the tooth surface, and interferes with the adhesion characteristics of the biofilm leading to a reduction of biofilm structural integrity [39,40]. Even small reductions in plaque can provide significant improvements in gingival health [24].

A secondary aim of this study was to determine whether the images captured were accurate enough to allow remote plaque scoring. In a previous study we demonstrated that it was possible to score gingival inflammation accurately from TRIOS®3 IOS images using the modified gingival index and colour/texture scores [18]. Here, we demonstrate that the TRIOS®3 is also capable of capturing images of disclosed plaque that can be scored accurately. This helps to standardise outcomes and overcome clinician variation in the recording of clinical scores, as a clinician can review and score plaque from a series of IOS that may have been captured by different treating clinicians over time. In addition, being able to review a series of IOS together removes variation that can be introduced by factors such as time of day/daylight. The visibility of plaque on a scan is excellent in that it can be accessed from any angle and will therefore give a fuller picture than standard clinical scores.

Conclusions

Clinical guideline evidence of the highest level, S3 [9], demonstrate the benefit of behaviour modification with respect to oral hygiene in the management of periodontal diseases with the recommendation that this should be included in the first step of patient management of this condition. IOS are becoming increasingly common fixtures in dental practices, and would appear good tools to deliver OH behaviour management change in an individually tailored pictorial form. IOS together with use of reminder texts and an effective anti-gingivitis toothpaste appear a winning combination intervention to successfully improve oral health scores in individuals with mild to moderate gingivitis. Furthermore, the images obtained from the IOS used in this study were accurate

enough to allow off site and non-contemporaneous scoring of dental plaque, which is likely to impact future study design and management.

References

[1]. S. Murakami, B.L. Mealey, A. Mariotti, I.L.C. Chapple ILC, Dental plaque-induced gingival conditions, J. Periodontol. 89 (2018) S17-S27. https://doi.org/10.1002/JPER.17-0095.

[2]. I.L. Chapple, F. Van der Weijden, C. Doerfer, D. Herrera, L. Shapira, D. Polak, P. Madianos, A. Louropoulou, E. Machte, N. Donos, H. Greenwell, A.J. Van Winkelhoff, B. Eren Kuru, N. Arweiler, W. Teughels, M. Aimetti, A. Molina, E. Montero, F. Graziani, Primary prevention of periodontitis: managing gingivitis, J. Clin. Periodontol. 42 (2015) S71-76. https://doi.org/10.1111/jcpe.12366

[3]. L. Trombelli, R. Farina, C.O. Silva, D.N. Tatakis, Plaque-induced gingivitis: Case definition and diagnostic considerations, J. Periodontol. 89 (2018) S46-S73. https://doi.org/10.1002/JPER.17-0576.

[4]. L.B. Wong, A.U. Yap, P.F. Allen, Periodontal disease and quality of life: Umbrella review of systematic reviews, J. Periodontal Res. 56 (2021) 1-17. https://doi.org/10.1111/jre.12805.

[5]. S. Jepsen, J. Blanco, W. Buchalla, J.C. Carvalho, T. Dietrich, C. Dörfer, K.A. Eaton, E. Figuero, J.E. Frencken, F. Graziani, S.M. Higham, T. Kocher, M. Maltz, A. Ortiz-Vigon, J. Schmoeckel, A. Sculean, L.M. Tenuta, M.H. van der Veen, V. Machiulskiene, Prevention and control of dental caries and periodontal diseases at individual and population level: consensus report of group 3 of joint EFP/ORCA workshop on the boundaries between caries and periodontal diseases, J. Clin. Periodontol. 44 (2017) S85-S93. https://doi.org/10.1111/jcpe.12687.

[6]. The Economist Intelligence Unit, Time to take gum disease seriously – the Societal and economic impact of periodontitis. https://impact.economist.com/perspectives/sites/default/files/eiu-efp-oralb-gum-disease.pdf, 2021 (accessed 22 December 2022).

[7]. J. Steele, J. Clarke, E. Roone, T. Wilson, NHS dental services in England. An independent review led by Professor Jimmy Steele. http://www.sigwales.org/wp-content/uploads/dh_101180.pdf, 2009 (accessed 22 December 2022)

[8]. R.E. Humphreys, W. Richards, P. Gill, Perceptions of first year foundation dentists on oral health education and its role in general dental practice, Br. Dent. J. 209 (2010) 601-606. https://doi.org/10.1038/sj.bdj.2010.1133.

[9]. N. West, I. Chapple, N. Claydon, F. D'Aiuto, N. Donos, M. Ide, I. Needleman, M. Kebschull, 2021. British Society of Periodontology and Implant Dentistry Guideline Group Participants. BSP implementation of European S3 - level evidence-based treatment guidelines for stage I-III periodontitis in UK clinical practice, J. Dent. 106, 103562. https://doi.org/10.1016/j.jdent.2020.103562.

[10]. Public Health England. 2020. National Dental Epidemiology Programme for England - Oral health survey of adults attending general dental practices. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/891208/AiP_survey_for_England_2018.pdf 2018 (accessed 22 December 2022).

[11]. H. Yusuf, G. Tsakos, A. Ntouva, M. Murphy, J. Porter, T. Newton, R.G. Watt, 2015. Differences by age and sex in general dental practitioners' knowledge, attitudes and behaviours in delivering prevention, Br. Dent. J. 219, E7. https://doi.org/10.1038/sj.bdj.2015.711.

[12]. A. Sheiham, R.G. Watt, The common risk factor approach: a rational basis for promoting oral health, Community Dent. Oral Epidemiol. 28 (2000) 399-406. https://doi.org/10.1034/j.1600-0528.2000.028006399.x.

[13]. J. Clarkson, C. Ramsay, T. Lamont, B. Goulao, H. Worthington, P. Heasman, J. Norrie, D. Boyers, A. Duncan, M. van der Pol, L. Young, L. Macpherson, G. McCracken, Examining the impact of oral hygiene advice and/or scale and polish on periodontal disease: the IQuaD cluster factorial randomised controlled trial, Br. Dent. J. 230 (2021) 229-235. https://doi.org/10.1038/s41415-021-2662-3.

[14]. E. Kay, D. Vascott, A. Hocking, H. Nield, C. Dorr, H. Barrett, A review of approaches for dental practice teams for promoting oral health, Community Dent. Oral Epidemiol. 44 (2016) 313-330. https://doi.org/10.1111/cdoe.12220.

[15]. J.T. Newton, K. Asimakopoulou, Managing oral hygiene as a risk factor for periodontal disease: a systematic review of psychological approaches to behaviour change for improved plaque control in periodontal management, J. Clin. Periodontol. 42 (2015) S36-S46. https://doi.org/10.1111/jcpe.12356.

[16]. F. Mangano, A. Gandolfi, G. Luongo, S. Logozzo, Intraoral scanners in dentistry: a review of the current literature, BMC Oral Health. 17 (2017) 149. https://doi.org/10.1186/s12903-017-0442-x.

[17]. R. Siqueira, M. Galli, Z. Chen, G. Mendonça, L. Meirelles, H.L. Wang, H.L. Chan, Intraoral scanning reduces procedure time and improves patient comfort in fixed prosthodontics and implant dentistry: a systematic review, Clin. Oral Investig. 25 (2021) 6517-6531. https://doi.org/10.1007/s00784-021-04157-3.

[18]. S. Daly, J. Seong, C. Parkinson, R. Newcombe, N. Claydon, N. West, 2021. A proof of concept study to confirm the suitability of an intra oral scanner to record oral images for the non-invasive assessment of gingival inflammation, J. Dent. 105, 103579. https://doi.org/10.1016/j.jdent.2020.103579.

[19]. J.A. Holloway, J. Seong, N.C.A Claydon, M. Davies, N. Hellin, I. Khan, N.X. West, 2022. A pilot study to evaluate the impact of digital imaging on the delivery of oral hygiene instruction, J. Dent. 118, 104053. https://doi.org/10.1016/j.jdent.2022.104053.

[20]. A. Johannsen, C.G. Emilson, G. Johannsen, K. Konradsson, P. Lingström, P. Ramberg, 2019. Effects of stabilized stannous fluoride dentifrice on dental calculus, dental plaque, gingivitis, halitosis and stain: A systematic review, Heliyon. 5, e02850. https://doi.org/10.1016/j.heliyon.2019.e02850.

[21]. D. Clark-Perry, L. Levin, Comparison of new formulas of stannous fluoride toothpastes with other commercially available fluoridated toothpastes: A systematic review and meta-analysis of randomised controlled trials, Int. Dent. J. 70 (2020) 418-426. https://doi.org/10.1111/idj.12588.

[22]. M. Escribano, E. Figuero, C. Martín, A. Tobías, J. Serrano, S, Roldán, D. Herrera, Efficacy of adjunctive anti-plaque chemical agents: a systematic review and network meta-analyses of the Turesky modification of the Quigley and Hein plaque index, J. Clin. Periodontol. 43 (2016) 1059-1073. https://doi.org/10.1111/jcpe.12616.

[23]. S. Sälzer, D.E. Slot, C.E, Dörfer, G.A. Van der Weijden, Comparison of triclosan and stannous fluoride dentifrices on parameters of gingival inflammation and plaque scores: a systematic review and meta-analysis, Int. J. Dent. Hyg. 13 (2015) 1-17. https://doi.org/10.1111/idh.12072.

[24]. C.R. Parkinson, A. Butler, M.R. Ling, 2022. Antigingivitis efficacy of a sodium bicarbonate toothpaste: Pooled analysis, Int. J. Dent. Hyg. 12626. https://doi.org/10.1111/idh.12626.

[25]. F. Van der Weijden, D.E. Slot, Oral hygiene in the prevention of periodontal diseases: the evidence, Periodontol. 2000. 55 (2011) 104-123. https://doi.org/10.1111/j.1600-0757.2009.00337.x.

[26]. N.C. Claydon, Current concepts in toothbrushing and interdental cleaning, Periodontol. 2000. 48 (2008) 10-22. https://doi.org/10.1111/j.1600-0757.2008.00273.x.

[27]. J. Ainamo, I. Bay, Problems and proposals for recording gingivitis and plaque, Int. Dent. J. 25 (1975) 229-235.

[28]. R.R. Lobene, P.M. Soparkar, M.B. Newman, The effects of a sanguinaria dentrifice on plaque and gingivitis, Compend. Contin. Educ. Dent. 7 (1986) S185-S188.

[29]. J. SilnessJ, H. Loe, Periodontal disease in pregnancy. II. Correlation between oral hygiene and periodontal condition, Acta Odontol. Scand. 22 (1964) 121-135. https://doi.org/10.3109/00016356408993968.

[30]. I. Midwood, M. Davies, R.G. Newcombe, N. West, Patients' perception of their oral and periodontal health and its impact: a cross-sectional study in the NHS, Br. Dent. J. 227 (2019) 587-593. https://doi.org/10.1038/s41415-019-0721-9.

[31]. R.G. Newcombe, Confidence intervals for the mean of a variable taking the values 0, 1 and 2, Stat. Med. 22 (2003) 2737-2750. https://doi.org/10.1002/sim.1479.

[32]. Care Quality Commission. Annual Report 2018/19. https://www.cqc.org.uk/sites/default/files/20190812_annualreport201819.pdf, 2019 (accessed 15 October 2022).

[33]. G.A. Van der Weijden, K.P Hioe, A systematic review of the effectiveness of self-performed mechanical plaque removal in adults with gingivitis using a manual toothbrush, J. Clin. Periodontol. 32 (2005) 214-228. https://doi.org/10.1111/j.1600-051X.2005.00795.x.

[34]. J.T. Newton, K. Asimakopoulou, Behavioral models for periodontal health and disease, Periodontol. 2000. 78 (2018) 201-211. https://doi.org/10.1111/prd.12236.

[35]. P. Sedgwick, N. Greenwood, 2015. Understanding the Hawthorne effect, BMJ. 351, h4672. https://doi.org/10.1136/bmj.h4672

[36]. J. Seong, D. Bartlett, R.G. Newcombe, N.C.A Claydon, N. Hellin, N.X. West, Prevalence of gingival recession and study of associated related factors in young UK adults, J. Dent. 76 (2018) 58-67. https://doi.org/10.1016/j.jdent.2018.06.005.

[37]. M. Galinsky, A. Plasschaert, K. Konig K, Ergonomics of toothbrushing, J. Dent. Res. 54 (1975) L115-L115.

[38]. I.D. Macgregor, A.J. Rugg-Gunn, A survey of toothbrushing sequence in children and young adults, J. Periodontal Res. 14 (1979) 225-230. https://doi.org/10.1111/j.1600-0765.1979.tb00227.x.

[39]. M.S. Putt, K.R. Milleman, A. Ghassemi, L.M. Vorwerk, W.J. Hooper, P.M. Soparkar, A.E. Winston, H.M. Proskin, Enhancement of plaque removal efficacy by tooth brushing with baking soda dentifrices: results of five clinical studies, J. Clin. Dent.19 (2008) 111-119.

[40]. J. Pratten, J. Wiecek, N. Mordan, A. Lomax, N. Patel, D. Spratt, A.M. Middleton, Physical disruption of oral biofilms by sodium bicarbonate: an in vitro study, Int. J. Dent. Hyg. 14 (2016) 209-214. https://doi.org/10.1111/idh.12162.