Daly, S., Seong, J., Parkinson, C. R., Newcombe, R. G., Claydon, N. C. A., & West, N. X. (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. *Journal of Dentistry*, 105, [103579]. <https://doi.org/10.1016/j.jdent.2020.103579>

Peer reviewed version

Link to published version (if available):
[10.1016/j.jdent.2020.103579](https://doi.org/10.1016/j.jdent.2020.103579)

[Link to publication record in Explore Bristol Research](#)
PDF-document

This is the author accepted manuscript (AAM). The final published version (version of record) is available online via Elsevier at <https://doi.org/10.1016/j.jdent.2020.103579> . Please refer to any applicable terms of use of the publisher.

University of Bristol - Explore Bristol Research

General rights

This document is made available in accordance with publisher policies. Please cite only the published version using the reference above. Full terms of use are available:
<http://www.bristol.ac.uk/red/research-policy/pure/user-guides/ebr-terms/>

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

Sinéad Daly^a, Joon Seong^a, Charles Parkinson^b, Robert Newcombe^c, Nicholas Claydon^a, Nicola West^{a*}.

^aClinical Trials Group, School of Oral and Dental Sciences, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY, UK

^bGlaxoSmithKline Consumer Healthcare, Weybridge, Surrey, KT13 0DE

^cCardiff University, Cardiff, CF10 3AT

Author job titles and email addresses:

S Daly, Research Associate, S.Daly@bristol.ac.uk; J Seong, Clinical Research Fellow, J.Seong@bristol.ac.uk; C Parkinson, CR Parkinson, Medical Affairs Director GSK, charles.x.parkinson@gsk.com; RG Newcombe, statistician, newcombe@cardiff.ac.uk; N Claydon, Clinical Research Fellow, N.Claydon@bristol.ac.uk; NX West, Professor in Restorative Dentistry, N.X.West@bristol.ac.uk.

Short title: Intraoral scanning for non-invasive gingivitis assessment

***Corresponding Author**

Professor Nicola West,
Periodontology Clinical Trials Unit,
Bristol Dental School,
Lower Maudlin Street,
Bristol, BS1 2LY, UK.

Tel.: +44 (0)117 342 9638;

fax: +44 (0)117 342 4000.

E-mail address: n.x.west@bristol.ac.uk (N.X. West).

Key Words: gingivitis, intra-oral scanner, MGI, inflammation

Conflict of Interest and Funding Statement

This study was carried out by the Clinical Trials Unit at Bristol Dental Hospital. This study was funded by GSK Consumer Healthcare, UK. CP is an employee of GSK and GSK contributed to the design of the study and the manuscript. NW and JS contributed to the design of the study. The study was carried out, analysed and prepared for publication by SD, JS, NC, RN and NW.

Acknowledgements

Nikki Hellin, Emma Macdonald and Maria Davies from the Clinical Trials Unit at Bristol Dental Hospital who contributed to the work presented in this manuscript. We would also like to acknowledge and express our thanks to Helen Roberts, 3Shape for supporting this study with the loan of the TRIOS scanner.

Abstract

Objectives: To compare gingival inflammation scores obtained chairside using the non-invasive modified gingival index (MGI) with MGI scores from an intraoral scan (IOS) captured at the clinical visit but viewed 10 days later.

Methods: Single visit, anterior teeth, observational, proof of concept study in healthy adult participants with a spectrum of gingival inflammation. One investigator performed both clinical and intraoral scan MGI assessments, a second repeated the MGI evaluation from the IOS.

Results: 23 participants aged 18-72 yielded data for 552 gingival sites. There was agreement at 90% of sites comparing clinical with IOS MGI scores. The commonest disagreements were MGI grade 0 read as 1 and 2 read as 3, the highest single probability of error occurring where a clinical score of 0 was scored 1 from the IOS: 0.118 and 0.129 for examiners 1 and 2 respectively. The second most common probability of error occurred where an IOS score of 3 was scored clinically as 2: 0.089 and 0.097 for examiners 1 and 2 respectively. MGI scores from the scans were similar for both examiners (91% agreement), with no discrepancies of greater than 1 scale point. There was very close agreement between clinical MGI and IOS colour/texture scores.

Conclusion: This study conclusively demonstrated that the MGI score from the scanned image was very similar to the MGI scored clinically. This study confirms that a digital IOS accurately captures gingival contour images allowing a clinician to determine health or degree of gingival inflammation from it using MGI scores.

Clinical Significance Statement

This study confirms that IOS images of teeth and soft tissues are sufficiently accurate to allow the clinical evaluation of health or inflammatory gingival status using non-invasive indices. IOS has great potential for efficient and accurate data capture, for general practice and research facilitating remote evaluation and data verification.

ISRCTN: [80682472](https://www.isrctn.com/80682472)

Introduction

Clinical gingival health is associated with an inflammatory infiltrate and a host response consistent with homeostasis [1]. Gingivitis is a reversible condition confined to the gingiva, which if untreated, can progress to periodontitis. Periodontitis is an irreversible condition, characterised when severe by bone loss [2], tooth loss and adverse effects on quality of life [3]. The prevention of periodontitis is conditional on the control of gingivitis [4], the most common cause of which, is the accumulation of dental plaque [5,6]. Implementation of successful plaque control by daily, self-directed good oral hygiene [7] allows a return to gingival health [8]. However, it has been shown that the majority of patients do not brush their teeth effectively [9]. In addition, they are often unaware that they are suffering from gingival inflammation, with gingivitis being diagnosed and demonstrated to them only when they attend for a dental appointment [10]. For the majority of patients, the combination of an excellent oral hygiene homecare regimen and regular supportive periodontal care is necessary to maintain oral health [11].

The diagnosis of gingivitis by the clinician relies on the identification of signs and symptoms of inflammation resulting from the disease process in the gingival tissues. This assessment is either non-invasive using a visual technique, or invasive using instrumentation [12]. Indices to assess the severity of changes to the gingivae have been developed with the aim of providing a clinical assessment that is as objective as possible. The Modified Gingival Index (MGI) is an example of a wholly non-invasive index that is visual and whereby the characteristic inflammatory changes at the gingival margin are evaluated by the assessment of changes in colour, texture and oedema [13]. Invasive indices such as the gingival index (GI) [14] use a periodontal probe which is used to gently probe around the gingival sulcus of each tooth in the mouth to enable bleeding and qualitative changes in the marginal and interproximal tissues to be recorded. All current gingival indices measure similar parameters related to gingival inflammation, are all subjective in nature and all require expert examiner training and knowledge to examine a patient at multiple sites to arrive at an appropriate diagnosis and management strategy [12].

The introduction of Computer Aided Design – Computer Aided Manufacture (CAD-CAM) technology in the early 1980's has enabled the direct and non-invasive acquisition of data from the oral cavity [15]. In principle, three dimensional (3D) intra oral scanners (IOS) project a light source on to the object to be scanned and the images captured by imaging sensors are processed by scanning software to produce triangulated point clouds that enable a virtual 3D surface model to be created [16-18]. Initially, the technology was used for the accurate manufacture of restorative prostheses (such as inlays, onlays, short span fixed bridgework) and digital impressions as well as surgical guides for

implants and implant crowns [16]. In the field of implantology IOS is increasingly used in place of conventional impressions and a 2020 systematic review indicated that scanners utilising active wavefront sampling are more accurate than other techniques employed [19]. More recently application has been extended to being used as a tool for the diagnosis and treatment planning for orthodontic patients [17]. The accuracy of IOS has been demonstrated to be sufficient for the acquisition of diagnostic or orthodontic models and comparable to conventional impression techniques [20,21].

Rosin et al [22] demonstrated that changes in gingival margin volume could be detected by 3D scans of impressions when converted into replicas, suggesting that imaging could be used to assess gingival oedema. In a subsequent IOS study, Newby et al [23] demonstrated *in vivo* that reductions in clinical contour volume correlated with improvements in standard clinical gingivitis indices for oral areas that had received dental prophylaxis. Similar studies [24,25] using digital cameras with colour calibration/software have shown that changes in gingival health assessed by standard non-invasive gingival indices may also be detected as a change in gingival redness on a digital image, indicating that digital imaging may be used to record gingival inflammation by changes in redness. While digital images captured by camera do result in a permanent record of the status of gingival health at a particular timepoint the IOS provides additional advantages. To accurately follow changes of an oral area over time the lighting of the images must be consistent. While digital cameras do not adjust for different lighting conditions, the IOS has its own source of light which is calibrated each clinical session such that no additional light is needed and it is not affected by surrounding lighting conditions. The position of the IOS from the tooth is also fixed whereas it is not possible to standardise the focal distance using a camera and an IOS can also image lingual and palatal surfaces inaccessible to a camera. In addition, while a camera can only capture a 2D image the IOS captures the oral cavity in 3D making it possible to manipulate the image so that you can see around the tooth in the same way as you would review the entire gingival margin in the clinic, rather than observing a tooth from a specific angle or direction.

The acquisition of digital data with IOS represents a novel methodology to unequivocally capture and store source data from the gingival tissues more rapidly than standard non-invasive clinical records with enough detail to enable clinicians to also assess a multitude of other oral health parameters used to evaluate oral health. This addresses the shortcomings of most oral health studies using conventional assessment indices, in that they lack objectivity, comparability and validity [26]. IOS furthermore, may record data at an instant as per observational studies or in sequence, as per intervention studies. Such images may focus on the gingival tissues to aid clinicians to diagnose the

severity and extent of gingival inflammation, or on disclosed plaque to evaluate plaque scores by conventional plaque indices. Whichever parameter is investigated, IOS methodology ensures rapid and objective data capture that can be evaluated remotely outside clinical time at a different time point and validated by third party assessment.

The Trios3 scanner is the 3rd generation scanner developed and manufactured by 3Shape®. It is a scanner which uses confocal microscopy to capture images of the dento-gingival tissues with integrated features of colour, high definition and digital shade determination to differentiate between teeth and gingival tissues [18]. To determine the accuracy of MGI scored from the Trios3 IOS, this proof of concept study scored clinical gingival health and inflammation with non-invasive MGI and compared these scores with MGI scored from the IOS taken at the clinical visit but viewed 10 days later.

Materials and Methods

Study Design and Conduct

This study was a blind (blind to the clinicians assessing the 3D image scans) single visit part mouth observational study in healthy adult participants who had a range of gingival inflammation. It was designed to compare colour/texture and gingival inflammation scored contemporaneously in a clinical environment, with that scored remotely following a 3D intraoral scan of the same. No clinical interventions were undertaken. This study was approved by the North East-York Research Ethics Committee (REF 19/NE/0351) and completed following Good Clinical Practice Guidelines.

Potential participants were recruited from a clinical trials unit database of people who had expressed an interest in taking part in clinical trials. Participants who gave informed consent were assessed for eligibility. Eligible participants were adults with at least 20 natural teeth who were not currently undergoing orthodontic treatment and had no signs of untreated caries, no significant periodontitis or any periodontal pockets ≥ 4 mm in anterior dental sextants.

Following enrolment in the study, a maximum of 12 scorable teeth (teeth with natural tooth surface at the gingival margin) from canine to canine (FDI teeth 13-23, 33-43) in the upper and lower anterior sextants, for each participant, were assessed clinically for gingival inflammation. We chose anterior teeth for this proof of principal study as they are accessible and tend to have fewer restorations adjacent to the gingival margin. One score for the buccal gingival unit and one score for the lingual marginal unit of each tooth was recorded according to MGI [13]. Colour and texture at 2 buccal gingival sites in the same sextants per participant were pre-identified by the examiner and also scored. The examination was conducted using a standard mirror for clinical examination and loupes. Immediately

following the clinical assessments, a 3D scan of the evaluated areas for each participant was also taken using a 3Shape camera (3Shape A/S, Copenhagen, Denmark) ensuring that the same scored teeth and gingival units in the anterior sextants were imaged. Prior to the use of the scanner at each session it was white/colour balanced and calibrated to ensure consistent reproduction of colour as per the manufacturer's instructions. Scans were taken in the dental surgery using standard lighting conditions and teeth were dried. Ten days after the clinical assessment, the original and a second examiner evaluated the anonymised 3D Intra-oral scans and attributed an MGI score for all scorable teeth in the study sextants. Additionally, they recorded colour and texture scores at the 2 pre-identified buccal sites.

Study Assessments

The gingival condition was assessed using the ordinal MGI 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] [13]. For the additional data, a binary index was adopted with colour being recorded as red or pink and texture recorded as smooth or stippled. For the purposes of this proof of principle study, the clinical assessment of the MGI was assumed to be correct so that the generated data points could be used as a reference to gauge the direction (over or under score), extent (degree of disagreement) and frequency (the number of times the assessments vary for each clinical examination) of variation. The two clinicians experienced in using the MGI index were trained in the use of the scanner and calibrated prior to the commencement of the study, Kappa value >0.8.

Statistical Methods

Sufficient adult participants in good general health were accepted onto the study in order to obtain at least 210 scorable buccal or lingual anterior tooth sites and a minimum number of scorable sites with each MGI score as follows: 0 - 80 sites; 1, 2, and 3 – 40 sites each; 4 – 10 sites. It was deemed that a minimum of 20 participants (480 potential scorable sites) who fulfilled the eligibility criteria would need to be enrolled to achieve the minimum of 10 sites with a score of 4.

Cross tabulations were constructed to compare clinical and scan derived MGI scores recorded by each examiner and to compare examiner scan derived MGI scores. Disagreements between MGI scores were highlighted and disagreement probabilities calculated for disagreements between consecutive scores, with confidence intervals calculated using Wilson's method [27]. The degree of examiner over-rating of IOS scores was calculated with confidence intervals according to the method of Tango [28].

Cross tabulations were also constructed to compare clinical and scan derived colour and texture scores recorded by each examiner and to compare between examiner differences in the scan derived scores.

The agreement between the clinical MGI scores and the clinical colour and texture scores were summarised using the generalised Mann-Whitney statistic U/mn analysis [29].

The clinical assessment of MGI was considered for the purposes of the study to be the correct and reference evaluation.

Results

Between 4 and 18 December 2019, 23 participants aged 18 to 72 years old were recruited to the study. There were 15 female and 8 male participants, 22 of whom were White and 1 of Asian ethnicity. No adverse events were reported. The number of scorable sites greatly exceeded the 210 minimum required for the study. Clinically, of the 552 possible gingival scores, there were 85 MGI scores of 0, 117 scores of 1, 162 scores of 2, 146 scores of 3, 30 scores of 4 and 12 were unscorable.

Representative images of each MGI score as captured by the scan are shown in Figure 1. The frequencies of agreements and disagreements between the scan and clinical MGI score for each examiner are shown in Table 1. The patterns for the two examiners were similar: the most common disagreements were to score a scan as 1 when the clinical score was 0 and to score a scan as 3 when the clinical score was 2. There were no statistically significant differences when examining differences by surface or arch.

Table1. Cross-tabulation of clinical score vs examiner score from the scan.

		Scan read by Examiner 1					
	Score	0	1	2	3	4	Total
Clinical	0	75	10	0	0	0	85
	1	6	103	8	0	0	117
	2	0	7	141	14	0	162
	3	0	0	3	141	2	146
	4	0	0	0	2	28	30
	Total	81	120	152	157	30	540
		Scan read by Examiner 2					
	Score	0	1	2	3	4	Total
Clinical	0	74	11	0	0	0	85
	1	3	106	8	0	0	117
	2	0	6	141	15	0	162
	3	0	0	6	139	1	146
	4	0	0	0	1	29	30
	Total	77	123	155	155	30	540

The frequencies of all disagreements comparing the clinical MGI scores to the scan derived MGI scores for examiners 1 and 2 are shown in Table 2, the most frequent disagreements are indicated in bold, these were common to both examiners.

Table 2. Frequencies of all disagreements comparing the clinical MGI scores to the scan derived MGI scores for examiners 1 and 2

	Examiner 1		Examiner 2	
	Proportion	95% CI*	Proportion	95% CI*
Probability that scan read as:				
0 is a clinical score of 1	0.074	0.034 - 0.152	0.039	0.013 - 0.108
1 is a clinical score of 2	0.058	0.029 - 0.116	0.049	0.023 - 0.102
2 is a clinical score of 3	0.020	0.007 - 0.056	0.039	0.018 - 0.082
3 is a clinical score of 4	0.013	0.003 - 0.045	0.006	0.001 - 0.036
1 is a clinical score of 0	0.083	0.046 - 0.147	0.089	0.051 - 0.153
2 is a clinical score of 1	0.053	0.027 - 0.100	0.051	0.026 - 0.099
3 is a clinical score of 2	0.089	0.054 - 0.144	0.097	0.060 - 0.154
4 is a clinical score of 3	0.067	0.018 - 0.213	0.033	0.006 - 0.167
Probability that a clinical score of:				
0 will be read as 1 from scan	0.118	0.065 - 0.203	0.129	0.074 - 0.217
1 will be read as 2 from scan	0.068	0.035 - 0.129	0.068	0.035 - 0.129
2 will be read as 3 from scan	0.086	0.052 - 0.140	0.093	0.057 - 0.147
3 will be read as 4 from scan	0.014	0.004 - 0.049	0.006	0.001 - 0.038
1 will be read as 0 from scan	0.051	0.024 - 0.107	0.026	0.009 - 0.073
2 will be read as 1 from scan	0.043	0.021 - 0.086	0.037	0.017 - 0.078
3 will be read as 2 from scan	0.021	0.007 - 0.059	0.041	0.019 - 0.087
4 will be read as 3 from scan	0.067	0.018 - 0.213	0.033	0.006 - 0.167

*Wilson et al [27]

Accepting the clinical examination as the baseline referral point there was a good deal of accord between both clinical and scan scores, however there was a tendency for both examiners to over, rather than under-rate the severity of gingival disease as scored by MGI from the scans. The extent of over scoring is summarised in Table 3. Examiner 1 tended to over-read scans by an average of 0.030 per grade, relative to their clinical scores, demonstrating that clinically meaningful disagreements were present and significant ($p=0.027$) but few in number. Scans read by examiner 2 were similar but not identical. However, it is more pertinent to look at these figures in relative terms: the former is 14 out of 162, the latter is 10 out of 85.

Table 3. The degree of over-rating of scan scored MGI by each examiner

Examiner	Proportion Overrated	95% CI*	p-value
1	(34-18)/540 = 0.030	0.004 – 0.057	0.027
2	(35-16)/540 = 0.035	0.010 – 0.063	0.008

*Tango et al [28]

Results for colour and texture demonstrated that for every one of the 46 sites scored, the 6 binary scores produced by clinical scoring of colour and texture and subsequent scoring of colour and texture by examiners 1 and 2 were always identical. Furthermore, all MGI scores of zero had a normal colour (pink), and all scores of 2, 3 or 4 had an abnormal colour (red); those with score 1 were approximately equally divided between the two colourings. The generalised Mann-Whitney statistic U/mn analyses [29] in Table 4 express this, near perfect agreement between the clinical MGI scores and the clinical colour and texture scores. The texture was interpreted as a binary score of stippled or oedematous and mirrored the colour scores.

Table 4. Comparison scan derived MGI score compared with scan derived colour score for both examiners

Examiner	U/mn	95% CI
1	0.992	0.865 – 0.9995
2	0.984	0.851 – 0.998

Discussion

This study aimed to determine whether scans captured by the Trios 3Shape scanner can be used to identify areas of gingival health or gingival inflammation when compared to conventional clinical records obtained using a standard assessment and gingival index. The MGI [13] represents the gold standard for non-invasive scoring for gingival health and inflammation [30]. The ability to use a scanned image to score gingivitis with MGI, differentiating between the degrees of gingival inflammation, was conclusively demonstrated in this study. Not only was an excellent level of intra-examiner agreement confirmed, but also there was no clinically relevant difference between the inter-examiner scanned images scores when considering direction, extent and frequency of variation. Indeed, there were no discrepancies of more than one point on the MGI scale anywhere, between the two examiners reading the image or between either examiner reading the image and the clinical grade.

More in depth analysis revealed the observers reading the scans both tended to overrate the score by a similar degree rather than underrating the severity of gingivitis, although these discrepancies were few in number. Interestingly, proportions representing how often substantial disagreements occurred for both examiners showed that the most frequent disagreement was to score a scan as 1 when the clinical score was 0 and to score a scan as 3 when the clinical score was 2. The appearance and clinical diagnosis of gingivitis is a continuum, so these results are not surprising and indeed there is frequent subjectivity when scoring visually [24]. Reassuringly there was no suggestion that one observer read consistently higher than the other. The examiners undertaking the MGIs were extremely experienced

clinicians, trained and calibrated for this study. Some degree of variation between examiners scoring a site would seem both acceptable and realistic with a continuous scale.

Confronted with a crosstabulation of two ordinal variables as in this study, it is instinctive to undertake a rank correlation or some similar measure such as weighted kappa, with a suitable confidence interval to test agreement. Analysed this way our data would indicate an extremely strong, significant association between the two scores but would not identify where scores diverged. Quantifying the degree of disagreement between the two sets of ratings identifies how often there are discrepancies and where these occur most frequently so whether they might be clinically relevant and meaningful can be judged.

One of the objectives of the study was to recruit volunteers with a substantial numbers of sites with a spectrum of possible scores ranging from 0 to 4, anticipating that fewer participants would score 4 than any other score. In the event, 30 surfaces scoring 4 were obtained, along with much higher numbers of other scores. This reflected that sufficient numbers of volunteers were recruited and ample number of sites could be considered and scored for comparison of visual and scanned images, ensuring the power of the study was met.

A healthy gingival margin should be pink visually as there is no inflammation and in contrast gingivitis is the result of inflammation of the gingival margin and reddening and swelling. Considering the high definition of the scan and excellent examiner agreement for MGI gingival scoring, it was not surprising that there was perfect agreement between the binary colour and texture indices in the 46 additional sites selected, indicating the strong relationship between the clinical MGI scores and the clinical colour and texture scores. The sites were scored as pink for health or red for inflammation which appeared to have great clarity when visualising the scans and were straightforward to differentiate. Similarly, with the binary texture scores that mirrored the colour assessments showing health and disease, these could be easily and accurately identified with reproducible accuracy. This again validated the high level of discrimination which can be achieved with this scanning technology and is very encouraging for the dental profession with regard to the benefits of scanning patients in the future to record the gingival tissues to aid diagnosis and identify treatment needs. The colour and texture scores may be able to be used in conjunction with the MGI scores to help discrimination with discrepancy resolution.

Clinical gingival health on an intact periodontium has now been defined in the 2017 World Workshop in Periodontal Diseases and Conditions, by the absence of bleeding on probing, erythema and oedema, patient symptoms, and attachment and bone loss [1]. Previous epidemiological data on the prevalence of gingivitis suffered from the lack of a universally adopted case definition, figures varying as widely as 6% to 94%, due to the use of indices that measure gingival inflammation at individual sites rather

than considering the patient's mouth as a whole [31]. Localized clinical inflammation is reported to affect almost 95% of the population. With the increased use of digital scanning technology in the dental arena, there is now scope for dental health professionals to be able to rapidly record and store accurate 3D images of the whole mouth using non-invasive methodologies. This aids the dentist to rapidly assess the complete dentition and periodontium and monitor oral health if the scans are repeated at subsequent appointments. There is no robust evidence to clearly differentiate mild, moderate, and severe gingivitis, with definitions defined by percentage of bleeding on probing in the 2017 World Workshop as mild = < 10%, moderate = 10%-30%, severe = > 30% sites affected [1]. Since IOS can allow correlation to clinical scores, this technique could be evaluated further to enable oral healthcare professionals to scan the mouth with a non-invasive methodology, preferred by patients, and use algorithms to determine gingival health and disease according to the New 2017 Classification [8]. Furthermore, they provide a pictorial take home report for the patient as a behaviour modification tool to improve oral health and oral health related quality of life.

Conventional indices have been long established to evaluate the oral health status of individuals and to generate epidemiological data recording periodontal, gingival and plaque status in research studies. The variety and number of indices for each oral health parameter reflects the complexity of capturing, analysing and presenting data that is standardised, comparable and reproducible for validation purposes. Oral health indices rely on experienced, trained clinical assessors spending considerable costly clinical time evaluating oral conditions, such as gingival inflammation, which need to be recorded chairside for the data to be contemporaneous. This is a tried and tested technique but suffers the shortcomings that multiple clinical decisions are required for each subject, which can result in fatigue and data drift. Furthermore, the source information cannot be examined for validity on a subsequent occasion. The implication of this, is that observational and intervention studies, being subjective in nature, suffer from a lack of objectivity and as a result clinical investigators have adopted several measures to improve the credibility of the data. These measures range from adoption of industry standards such as Good Clinical Practice (GCP), to pre study training and the adoption of repeat scoring throughout, either by the same or an alternative investigator. Statistical analysis of the data set is able to confirm or otherwise, the consistency and accuracy of scoring, but it is not able to determine that the data evaluated is an accurate representation of the clinical picture. The advantage of IOS is that the original record can be assessed and scored by any number of individuals at a later time point, with much reduced clinical time and for both the clinician and the patient. One could also envisage a step further when software technology is utilised to assess the scans and categorise the findings.

Intra-oral scanning (IOS) represents the adaptation of existing technology to rapidly capture in a standard and secure form, the data which can be used for analysis off-clinic and at a later time. The nature of IOS implies that the images may be used for recording data for non-invasive indices only, however, the images themselves may be standardised and third party validated as well as stored to comply with data protection. This ensures that the clinical time associated with any clinical research and examination is minimised as it is limited to data capture. It also ensures that the assessment and subsequent analysis may be conducted and validated off-site and by more than one examiner for accuracy and reproducibility. In particular, this should facilitate the move for evaluation methodology away from ordinal to ratio indices, thereby increasing the clinical relevance of the findings and also be of benefit for medico-legal purposes.

Conclusions

This study confirms that the same clinical conclusion may be reached whether observational data is collected conventionally or using IOS. The results of both data sets are comparable and show clinically meaningful high level of agreement, demonstrating conclusively that these images can be later analysed using the same non-invasive index used chairside, to produce the same clinical results. In addition, IOS ushers in an era of clinical research where source data capture is separated from data analysis, is objective, standardised, rapid and may be performed by clinical staff who need not be trained to investigator standard. The impact of this study represents a paradigm shift for data collection for non-invasive indices as it is faster, requires fewer members of the research team, an increased capacity for study volunteers and an opportunity to evaluate and process the data statistically off-site. This evaluation may be validated for governance purposes when required and as such represents a new gold standard for randomised controlled oral health studies. Furthermore, the authors envisage the adoption of IOS methodology to become the industry standard for gingival measurement studies as it enable a shift to ratio indices with more meaningful clinical conclusions and a transparent evaluation of inter and intra examiner variability. This level of agreement for examiner calibration for a clinical gingivitis study conducted to good clinical standards supports a recommendation for routine use of digital intra-oral scanning to record gingival inflammation for observational or intervention research studies and in general dental practice.

References

- [1] I.L.C. Chapple, B.L. Mealey, T.E. Van Dyke, P.M. Bartold, H. Dommisch, P. Eickholz, M.L. Geisinger, R.J. Genco, M. Glogauer, M. Goldstein, T.J. Griffin, P. Holmstrup, G.K. Johnson, Y. Kapila, N.P. Lang, J. Meyle, S. Murakami, J. Plemons, G.A. Romito, L. Shapira, D.N. Tatakis, W. Teughels, L. Trombelli, C. Walter, G. Wimmer, P. Xenoudi, H. Yoshie, Periodontal health and gingival diseases and

- conditions on an intact and a reduced periodontium: Consensus report of workgroup 1 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions, *J. Clin. Periodontol.* 45 (2018) S68-S77. <https://doi.org/10.1111/jcpe.12940>.
- [2] C.A. Ramseier, A. Anerud, M. Dulac, M. Lulic, M.P. Cullinan, G.J. Seymour, M.J. Faddy, W. Bürgin, M. Schätzle, N.P. Lang, Natural history of periodontitis: Disease progression and tooth loss over 40 years, *J. Clin. Periodontol.* 44 (2017) 1182-1191. <https://doi.org/10.1111/jcpe.12782>.
 - [3] J. Fuller, N. Donos, J. Suvan, G. Tsakos, L. Nibali, Association of oral health-related quality of life measures with aggressive and chronic periodontitis, *J. Periodontal Res.* 55 (2020) 574-580. doi: 10.1111/jre.12745.
 - [4] I.L. Chapple, F. Van der Weijden, C. Doerfer, D. Herrera, L. Shapira, D. Polak, P. Madianos, A. Louropoulou, E. Machtei, 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-S76. <https://doi.org/10.1111/jcpe.12366>. PMID: 25639826.
 - [5] H. Löe, E. Theilade, S.B. Jensen, Experimental gingivitis in man, *J. Periodontol.* 36 (1965) 177-187. <https://doi.org/10.1902/jop.1965.36.3.177>.
 - [6] E. Theilade, W.H. Wright, S.B. Jensen, H. Löe, Experimental gingivitis in man. II. A longitudinal clinical and bacteriological investigation, *J. Periodontal Res.* 1 (1966) 1-13. <https://doi.org/10.1111/j.1600-0765.1966.tb01842.x>.
 - [7] E. Figuero, D.F. Nóbrega, M. García-Gargallo, L.M. Tenuta, D. Herrera, J.C. Carvalho, Mechanical and chemical plaque control in the simultaneous management of gingivitis and caries: a systematic review, *J. Clin. Periodontol.* 44 (2017) S116-S134. <https://doi.org/10.1111/jcpe.12674>.
 - [8] J.G. Caton, G. Armitage, T. Berglundh, I.L.C. Chapple, S. Jepsen, K.S. Kornman, B.L. Mealey, P.N. Papapanou, M. Sanz, M.S. Tonetti, A new classification scheme for periodontal and peri-implant diseases and conditions - Introduction and key changes from the 1999 classification, *J. Clin. Periodontol.* 45 (2018) S1-S8. <https://doi.org/10.1111/jcpe.12935>.
 - [9] 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>.
 - [10] B. Blicher, K. Joshipura, P. Eke, Validation of self-reported periodontal disease: a systematic review, *J. Dent. Res.* 84 (2005) 881-890. <https://doi.org/10.1177/154405910508401003>.
 - [11] N.P. Lang, P.M. Bartold, Periodontal health, *J. Clin. Periodontol.* 45 (2018) S9-S16. <https://doi.org/10.1111/jcpe.12936>. PMID: 29926485.
 - [12] L. Trombelli, R. Farina, C.O. Silva, D.N. Tatakis, Plaque-induced gingivitis: Case definition and diagnostic considerations, *J. Clin. Periodontol.* 45 (2018) S44-S67. <https://doi.org/10.1111/jcpe.12939>.
 - [13] R.R. Lobene, T. Weatherford, N.M. Ross, R.A. Lamm, L.A. Menaker, A modified gingival index for use in clinical trials, *Clin. Prev. Dent.* 8 (1986) 3-6.
 - [14] H. Löe, J. Silness, Periodontal disease in pregnancy. I. Prevalence and severity, *Acta. Odontol. Scand.* 21 (1963) 533-551. <https://doi.org/10.3109/00016356309011240>.
 - [15] T.R. Schoenbaum, Decoding CAD/CAM and digital impression units, *Dent Today.* 29 (2010) 140, 142, 144-5.

- [16] F. Beuer, J. Schweiger, D. Edelhoff, Digital dentistry: an overview of recent developments for CAD/CAM generated restorations, *Br. Dent. J.* 204 (2008) 505-511. <https://doi.org/10.1038/sj.bdj.2008.350>.
- [17] C.B. Martin, E.V. Chalmers, G.T. McIntyre, H. Cochrane, P.A. Mossey, Orthodontic scanners: what's available? *J. Orthod.* 42 (2015) 136-143. <https://doi.org/10.1179/1465313315Y.0000000001>.
- [18] M. Imburgia, S. Logozzo, U. Hauschild, G. Veronesi, C. Mangano, F.G. Mangano, Accuracy of four intraoral scanners in oral implantology: a comparative in vitro study, *BMC Oral Health.* 17 (2017) 92. <https://doi.org/10.1186/s12903-017-0383-4>.
- [19] S. Kachhara, D. Nallaswamy, D.m. Ganapathy, V. Sivaswamy, V. Rajaraman V, Assessment of intraoral scanning technology for multiple implant impressions - A systematic review and meta-analysis. *J. Indian Prosthodont. Soc.* 20 (2020) 141-152. https://doi.org/10.4103/jips.jips_379_19.
- [20] G. Rossini, S. Parrini, T. Castorflorio, A. Deregisbus, C.L. Debernardi, Diagnostic accuracy and measurement sensitivity of digital models for orthodontic purposes: A systematic review, *Am. J. Orthod. Dentofacial. Orthop.* 149 (2016) 161-170. <https://doi.org/10.1016/j.jado.2015.06.029>.
- [21] J. Abduo, M. Elseyoufi, Accuracy of Intraoral Scanners: A Systematic Review of Influencing Factors, *Eur. J. Prosthodont. Restor. Dent.* 26 (2018) 101-121. https://doi.org/10.1922/EJPRD_01752Abduo21.
- [22] M. Rosin, Ch. Splieth, M. Hessler, Ch. Gärtner, B. Kordass, T. Kocher, Quantification of gingival edema using a new 3-D laser scanning method, *J. Clin. Periodontol.* 29 (2002) 240-246. <https://doi.org/10.1034/j.1600-051x.2002.290310.x>.
- [23] E.E. Newby, A. Bordas, C. Kleber, J. Milleman, K. Milleman, R. Keogh, S. Murphy, A. Butler, M.L. Bosma, Quantification of gingival contour and volume from digital impressions as a novel method for assessing gingival health, *Int. Dent. J.* 61 (2011) 4-12. <https://doi.org/10.1111/j.1875-595X.2011.00043.x>.
- [24] H. Seshan, M. Shwetha, Gingival inflammation assessment: Image analysis, *J. Indian Soc. Periodontol.* 16 (2012) 231-234. <https://doi.org/10.4103/0972-124X.99267>.
- [25] Y. Mayer, O. Ginesin, E.E. Machtei, Photometric CIELAB Analysis of the Gingiva: A Novel Approach to Assess Response to Periodontal Therapy, *J Periodontol.* 88 (2017) 854-859. <https://doi.org/10.1902/jop.2017.170004>.
- [26] N.C. Claydon, C. Hall, A.J. Hughes, D. Shaw, J. Seong, M. Davies, N.X. West, Randomized controlled trial to study plaque inhibition in calcium sodium phosphosilicate dentifrices, *J. Dent.* 46 (2016) 61-67. <https://doi.org/10.1016/j.jdent.2016.01.003>.
- [27] E.B. Wilson, Probable inference the law of succession, and statistical inference, *J. Am. Stat. Assoc.* 22 (1927) 209-121.
- [28] T. Tango, Equivalence test and confidence interval for the difference in proportions for the paired-sample design, *Stat. Med.* 17 (1998) 891-908. [https://doi.org/10.1002/\(sici\)1097-0258\(19980430\)17:8<891::aid-sim780>3.0.co;2-b](https://doi.org/10.1002/(sici)1097-0258(19980430)17:8<891::aid-sim780>3.0.co;2-b).
- [29] R.G. Newcombe, Confidence intervals for an effect size measure based on the Mann-Whitney statistic. Part 2: asymptotic methods and evaluation, *Stat. Med.* 25 (2006) 559-573. <https://doi.org/10.1002/sim.2324>.
- [30] British Society of Periodontology, The good practitioner's guide to periodontology, 3rd version (2016) https://www.bsperio.org.uk/assets/downloads/good_practitioners_guide_2016.pdf

- [31] I.L. Chapple, P. Bouchard, M.G. Cagetti, G. Campus, M.C. Carra, F. Cocco, L. Nibali, P. Hujoel, M.L. Laine, P. Lingstrom, D.J. Manton, E. Montero, N. Pitts, H. Rangé, N. Schlueter, W. Teughels, S. Twetman, C. Van Loveren C, F. Van der Weijden, A.R. Vieira, A.G. Schulte, Interaction of lifestyle, behaviour or systemic diseases with dental caries and periodontal diseases: consensus report of group 2 of the joint EFP/ORCA workshop on the boundaries between caries and periodontal diseases, *J. Clin. Periodontol.* 44 (2017) S39-S51. <https://doi.org/10.1111/jcpe.12685>.

Figure Legends

Figure 1. Representative intra-oral images of MGI scores 0-4