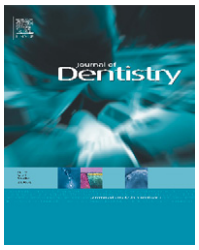
available at www.sciencedirect.com

ScienceDirect

journal homepage: www.intl.elsevierhealth.com/journals/jden



A clinical study to evaluate the efficacy of a novel tray based tooth whitening system

Naveen Mohan [a], *Stephen Westland* [b], *Paul Brunton* [c], *Roger Ellwood* [d], *Iain A. Pretty* [e,*], *Wen Luo* [f]

[a] *Turner Dental School, University of Manchester, England, UK*
[b] *Department of Colour Science, Centre for Design Technology, University of Leeds, England, UK*
[c] *Department of Restorative Dentistry, University of Leeds, England, UK*
[d] *Dental Public Health, Turner Dental School, University of Manchester, England, UK*
[e] *Department of Restorative Dentistry, Turner Dental School, University of Manchester, England, UK*
[f] *Centre for Colour Design Technology, University of Leeds, England, UK*

ARTICLE INFO

Article history:
Received 28 June 2007
Received in revised form
1 October 2007
Accepted 3 October 2007

Keywords:
Tooth whitening
Digital imaging
Whiteness indices
Tooth whiteness
Tooth bleaching
Colour measurement
Colour parameter
Whiteness measurement
Colour indices

ABSTRACT

Objectives: The study was designed to test the whitening efficacy of a new prefabricated tray based whitening system. *Methods*: A parallel, examiner blind, stratified two group clinical study was carried out in the Department of Fixed and Removable Prosthodontics, Leeds Dental Institute, United Kingdom. Forty-nine male and female subjects aged 18–70 years participated in the study and they underwent both clinical and digital evaluation at baseline, 3, 7 and 14 days, respectively. The non-intervention control group was given no treatment and the test group received a tray based whitening system (Colgate Visible White PF Mint, Colgate Palmolive Company, NY, USA) that uses a 6% hydrogen peroxide gel applied in the tray twice daily for 30 min. Digital images of teeth were captured using a Jai 3CCD digital camera under an annular LED illumination array (SCHOTT North America, Inc., USA) and the data obtained was used to calculate colour parameters (L^*, a^* and b^*) and whiteness index WIO. *Results*: Clinical data and digital data showed significant difference for the Visible White group from the control group for the mean difference in its values from the baseline to each visit ($p < 0.001$). Digital data showed significant correlation to clinical data. *Conclusion*: In the present study statistically significant tooth whitening was evident after 3 days treatment with the tray based whitening system and colour improved with continued usage over 14 days. It also supports our previous study results that the WIO index is appropriate for assessing changes in tooth whiteness.

1. Introduction

During the last decade there has been an increase in the availability of products that claim to have the ability to whiten teeth. Most of these products deliver their benefits either by increasing the efficiency of surface cleaning or by reducing the intrinsic or extrinsic stain by neutralising the colour using agents like hydrogen peroxide or carbamide peroxide. Measurement and further analysis of the effect of these whitening products using an appropriate parameter and technique would enable us to compare the efficacy of different products. There are a number of methods available for measuring the

* *Corresponding author at*: Dental Health Unit, 3A Skelton House, Lloyd Street North, Manchester Science Park, Manchester, England M15 6SH, UK. Tel.: +44 161 226 1211; fax: +44 161 232 4700.
E-mail address: iain.pretty@manchester.ac.uk (I.A. Pretty).
0300-5712/$ – see front matter
doi:10.1016/j.jdent.2007.10.002

whitening effect, both instrumental and visual. The traditional visual assessment using shade guides is still one of the most common methods employed to assess tooth-colour changes.[1] The commonly used instruments in dental research to measure tooth colour are colourimeter, spectrophotometer, spectroradiometer and digital camera.

The product related factors that influence the whitening efficacy of a bleaching system would be the type of bleaching agent (hydrogen peroxide, carbamide peroxide, etc.), concentration, frequency, duration of each application, period of treatment and accelerators.[2] Two of the key factors in determining the overall tooth whitening efficacy from peroxide containing products are concentration and duration of application. Even though higher concentrations are more effective than lower, it can approach the efficacy of higher concentrations with extended treatment times.[2] The optimum level of concentration and the overall treatment period has been researched for quite some time in dentistry. An in vitro study conducted by Sulieman et al.[3] reported a higher ΔE value for 5% hydrogen peroxide applied 12 times compared to 35%, 25% and 10% applied 1, 2 and 7 times, respectively.

The mode of application of the product on the tooth surface also effects the treatment. Several delivery systems like strips, shields, trays and applicator brushes have been tested clinically to determine the most efficient and less time consuming method. A broad range of peroxide-based treatments are currently available including those that are professionally administered and dispensed (custom-tray-based systems), and self-directed (over-the-counter).[4] Professional tray based bleaching systems are advantageous in that the bleaching is professionally carried out, this results in less gingival irritation and the patients have access to expert opinion regarding other local side effects such as sensitivity or mucosal irritation.

The present study investigates the efficacy of a tray based whitening system that uses a 6% hydrogen peroxide gel in terms of whiteness index and clinical shade guide scores. The primary objective of the study is to investigate the whitening efficacy of the bleaching system in 3 days. It was also designed to examine the whitening effect at 7 and 14 days.

2. Hypothesis

The null hypothesis of no difference between the whitening gel group and the no treatment group was tested against the hypothesis that whitening gel provided a significant improvement in tooth whiteness.

3. Materials and methods

A parallel, examiner blind, stratified two-group clinical study was carried out in the Department of Fixed and Removable Prosthodontics, Leeds Dental Institute, United Kingdom in June 2006. The study protocol and informed consent were reviewed and accepted by Leeds (East) Research Ethics Committee. The study population comprised of healthy adult volunteers who consented to have their teeth whitened. Candidates who expressed their interest in participating in the study were invited to the initial screening procedure. Candidates were screened by the dental examiner to identify the exclusion/inclusion criteria. Subjects were included if they were aged 18–70 years, were available for the 2-week duration of the study and had a minimum of 20 uncrowned teeth with at least 6 upper front teeth without crowns or large restorations. A minimum baseline shade of A3 on one or more of the upper front teeth was also required. Study participants were excluded from the study if they had orthodontics bands, partial removable dentures, advanced periodontal disease, tumours of the soft or hard tissues of the oral cavity, five or more carious lesions requiring immediate restorative treatment, allergy history, participation in another clinical study within 1 month prior to the study, recent whitening or bleaching of teeth, pregnant women and medical conditions which would compromise the subject's safety or the study results. Fifty patients were finally accepted onto the study.

The digital evaluation was carried out in a darkened surgery to avoid ambient light falling on the tooth surface. A Digital Imaging system (Fig. 1) which comprised of a Jai 3CCD camera (JAI A.S, Copenhagen, Denmark) mounted in a fixed position relative to the subject providing live videos through a frame grabber card (Flashpoint 3D 4xl card, Integral Technologies Inc, Indiana, USA) connected to the computer. The light source was provided by an annular LED illumination array (SCHOTT North America, Inc., Elmsford, NY, USA). The measurement distance of the camera was fixed at 12.5 cm from the subject. Specular reflection was minimised with the help of a polarisation filter which was placed in front of the camera. The intensity of illumination was measured and controlled using a program written in MATLAB version 7.0 (The MathWorks Inc., Massachusetts, USA). A camera characterisation model converting the linearised camera RGB → CIE XYZ, was constructed based on a linear transform, the co-efficient of which were optimised based on a set of reference tooth samples (The Vita 3D Shade Guide, Vident, California, USA).

Balancing the two groups on the basis of baseline tooth colour, subjects were randomly assigned to either a tray based bleaching system or a non-treatment control group. All subjects were provided with a soft-bristled adult toothbrush (Colgate Total Toothbrush, Colgate Palmolive Company, New York, USA) and a 50 ml tube of a non-whitening dentifrice (Colgate Cavity Protection Great Regular Flavour, Colgate

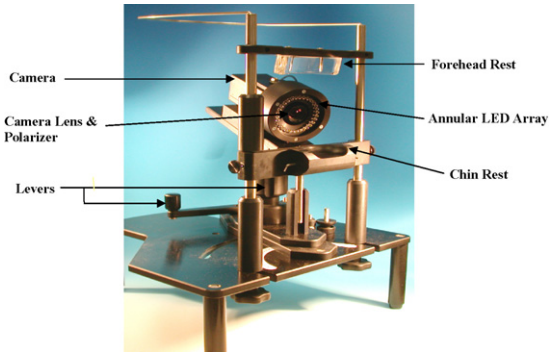


Fig. 1 – Digital imaging system.

Palmolive (UK) Ltd. Guildford, UK) for home use. They were instructed to brush their teeth for 1 min at least twice a day (morning and evening) with the toothpaste. The candidates in the test group were assigned a tray based tooth whitening system (Colgate Visible White PF mint, Colgate Palmolive Company, New York, USA) and were advised to use it in accordance with the manufacturer's instructions for 14 days. This involved a tray loaded with the whitening gel containing 6% hydrogen peroxide gel applied in the tray twice daily (morning and evening) for 30 min for the duration of the study. All the subjects were instructed to use only the products provided during the 2-week study period.

Teeth analysed were the maxillary right and left central incisors, lateral incisors and canines. Blinded visual assessments and scoring were carried out at the baseline level and after 3, 7 and 14 days for both groups. This was carried out visually using shade guides (Vitapan Classical, VITA Zahnfabrik, Germany) which consisted of a range of tooth-shaped tabs of various colours that were matched to the colour of the subject's teeth. The clinical scores were determined by assigning a numerical score ranging from 1 to 16 based on the sequence from B1 (1) to C4 (16) recommended by the manufacturer. The shade tabs were arranged from the lightest to the darkest in the order B1, A1, B2, D2, A2, C1, C2, D4, A3, D3, B3, A3.5, B4, C3, A4, C4.[5] All subjects underwent an evaluation of their oral soft tissues at each of their visits to the dental facility. This examination included an evaluation of soft and hard palate, gingival mucosa, buccal mucosa, mucogingival fold areas, tongue, sublingual and submandibular areas, salivary glands, tonsilar and pharyngeal areas. The results of this evaluation were recorded on the Oral Soft Tissue and Tooth Colour Assessment Form.

Table 1 – Comparing the mean, mean difference and standard deviation for the clinical vita shade guide score and digital data (L^*, a^*, b^* and WIO)

Data	Group	Baseline	3 days	7 days	14 days	Change 3 days	Change 7 days	Change 14 days
Clinical Score	Test (24)							
	Mean	11.48	6.41	6.00	4.32	−5.07**	−5.48**	−7.16**
	S.D.	2.26	1.93	2.86	2.51	1.56	2.40	2.20
	Control (25)							
	Mean	10.85	9.29	9.64	10.22	−1.56	−1.21	−.63
	S.D.	1.98	1.78	2.06	1.69	1.77	1.77	1.38
L^*	Test (24)							
	Mean	56.15	57.54	58.78	59.71	1.38*	2.62**	3.56**
	S.D.	3.99	3.71	3.81	3.64	1.34	1.46	1.84
	Control (25)							
	Mean	57.53	57.88	58.17	58.01	0.34	0.64	0.48
	S.D.	3.28	3.31	3.41	3.32	0.84	0.81	0.80
	Calibration (49)							
	Mean	55.77	55.70	56.26	56.17	−0.08	0.48	0.39
	S.D.	0.43	0.43	0.48	0.34	0.71	0.71	0.62
a^*	Test (24)							
	Mean	8.76	8.10	7.20	7.03	−0.65**	−1.55**	−1.72**
	S.D.	1.74	1.61	1.53	1.38	0.48	0.76	0.76
	Control (25)							
	Mean	8.33	8.24	7.79	8.09	−0.09	−0.54	−0.24
	S.D.	1.31	1.29	1.36	1.38	0.31	0.31	0.36
	Calibration (49)							
	Mean	5.43	5.51	4.99	5.26	0.07	−0.44	−0.17
	S.D.	0.18	0.13	0.35	0.27	0.26	0.45	0.37
b^*	Test (24)							
	Mean	23.76	22.43	20.65	19.88	−1.33**	−3.11**	−3.90**
	S.D.	2.65	2.99	2.98	2.97	1.49	1.92	1.96
	Control (25)							
	Mean	23.61	23.61	23.19	23.46	0.002	−0.42	−0.15
	S.D.	3.09	3.10	2.96	3.03	0.32	0.47	0.50
	Calibration (49)							
	Mean	0.14	0.24	0.21	0.30	0.10	0.07	0.16
	S.D.	0.14	0.19	0.09	0.08	0.21	0.12	0.15
WIO	Test (24)							
	Mean	−73.68	−64.87	−54.56	−49.79	8.81**	19.12**	23.88**
	S.D.	18.99	19.15	17.96	17.56	7.92	10.08	10.78
	Control (25)							
	Mean	−68.83	−67.84	−64.95	−66.79	0.98	3.87	2.04
	S.D.	15.09	15.33	15.30	15.91	2.49	3.16	2.79

* $p < 0.05$.
** $p < 0.001$.

Three images of the anterior teeth were captured at each visit starting at baseline, then after 3, 7 and 14 days of treatment. The images were taken from central, right lateral and left lateral viewpoints. A geometry stabilising system (Fig. 1) was employed for camera movement. This facility enabled the operator to move the camera horizontally at an angle of 30° from the central position to the lateral positions on either side. Tooth colour was measured from the standardised digital images captured at each position and stored for further evaluation.

The camera and light were switched on at least an hour before the start of each day's procedure to obtain stable camera and lighting conditions. A calibration card made of a grey patch from the ColorChecker DC chart (GretagMacbeth, NY, USA) was used at the start and end of the image capture for each subject. The card was used as a means to check and adjust the intensity of the illumination between the measurements to ensure that there was no variation. Images of the card were captured for each subject and were used as a comparison to adjust the height of the camera assembly at their subsequent visits.

Capturing software (QLF, Inspektor Research Systems, Amsterdam, The Netherlands) was used to capture the images. The resultant images were analysed using bespoke software written in MatLab 7.0 (The MathWorks Inc., MA, USA). The software analysed a region of interest from each image using an outline provided by the operator. In this study the whole buccal surface of each individual tooth (upper anteriors) were assessed. The output value from the software was RGB values. Mean RGB values were calculated, linearised[6] and converted to XYZ values by means of the characterisation model. The XYZ values were transformed into CIELAB space and the whiteness index WIO[7,8] was calculated. Currently different whiteness indices are being used to measure tooth whiteness. In order for a whiteness index to be valid, it must be used on the type of material for which it is intended. The coefficients of the CIE WIC formula were optimised according to visual results on tooth-colour samples and a new optimised formula was developed which is the WIO index for teeth.[7]

The data obtained was analysed statistically using SPSS version 12.0 (SPSS Inc., IL, USA). The data obtained for each tooth was aggregated, first tooth-wise (Central incisor, Lateral incisor and Canine) and then values for the same tooth for different views were amalgamated to obtain subject-wise scores. An independent sample t-test was carried out to compare the test and control groups; comparison of mean values was made between the two groups for the clinical parameters and WIO index for the changes in its values from baseline to each subsequent visit. Scatter graphs were plotted to assess the potency of the whiteness index to differentiate between treatments. Pearson correlation coefficients were obtained to compare clinical visual assessments to digital data.

4. Results

Forty-nine subjects completed the study, with 25 in the test group and 24 in the control group. One subject failed to attend the 7-day visit from the control group due to ill-health and was withdrawn from the study. Data for colour analysis and comparisons were available for all the subjects who completed the study.

Mean and standard deviations of the clinical scores, colour parameters (L^*, a^* and b^*) and whiteness index were calculated for each time period (Table 1) and an Independent Sample t-test was carried out. This was done to compare the mean values between the control and test groups for each period and also between the changes in the values from baseline to each examination period.

4.1. *Baseline data*

The mean baseline clinical score was 11.48 for the test group and 10.85 for the control group. A mean WIO of −73.68 for the test group and −68.83 for the control group was obtained from digital analysis. Neither the clinical data nor the digital data showed any statistically significant difference at the baseline between the control and the test group (Table 2).

4.2. *Three-day data*

The clinical scores showed a mean change of 5.07 for the test group and 1.56 for the control group. WIO values showed a mean difference of 8.81 and the control group showed a negligible change in 3 days of only 0.98 units. Both the clinical and digital data showed a statistically significant difference between the test and control group for its mean difference at $p < 0.001$.

4.3. *Seven and 14 days data*

For the clinical data the mean shade difference was 5.48 and 7.16 in 7 and 14 days, respectively, for the test group. Digital data showed a similar trend where the mean differences in the WIO values obtained were 19.12 and 23.88 for each visits. The test group showed a statistical difference from the control group ($p < 0.001$) in 7 and 14 days of treatment for both clinical and digital data.

Table 2 – Showing the correlation of clinical scores to digital data over the study period

Number of Subjects	Digital Data	Duration (days)	Pearson Correlation coefficient
49	ΔL^*	3	−0.310*
		7	−0.501**
		14	−0.779**
49	Δa^*	3	0.436*
		7	0.510**
		14	0.793**
49	Δb^*	3	0.408*
		7	0.509**
		14	0.800**
49	ΔWIO	3	−0.421*
		7	−0.538**
		14	−0.829**

* Correlation is significant at the 0.05 level.
** Correlation is significant at the 0.001 level.

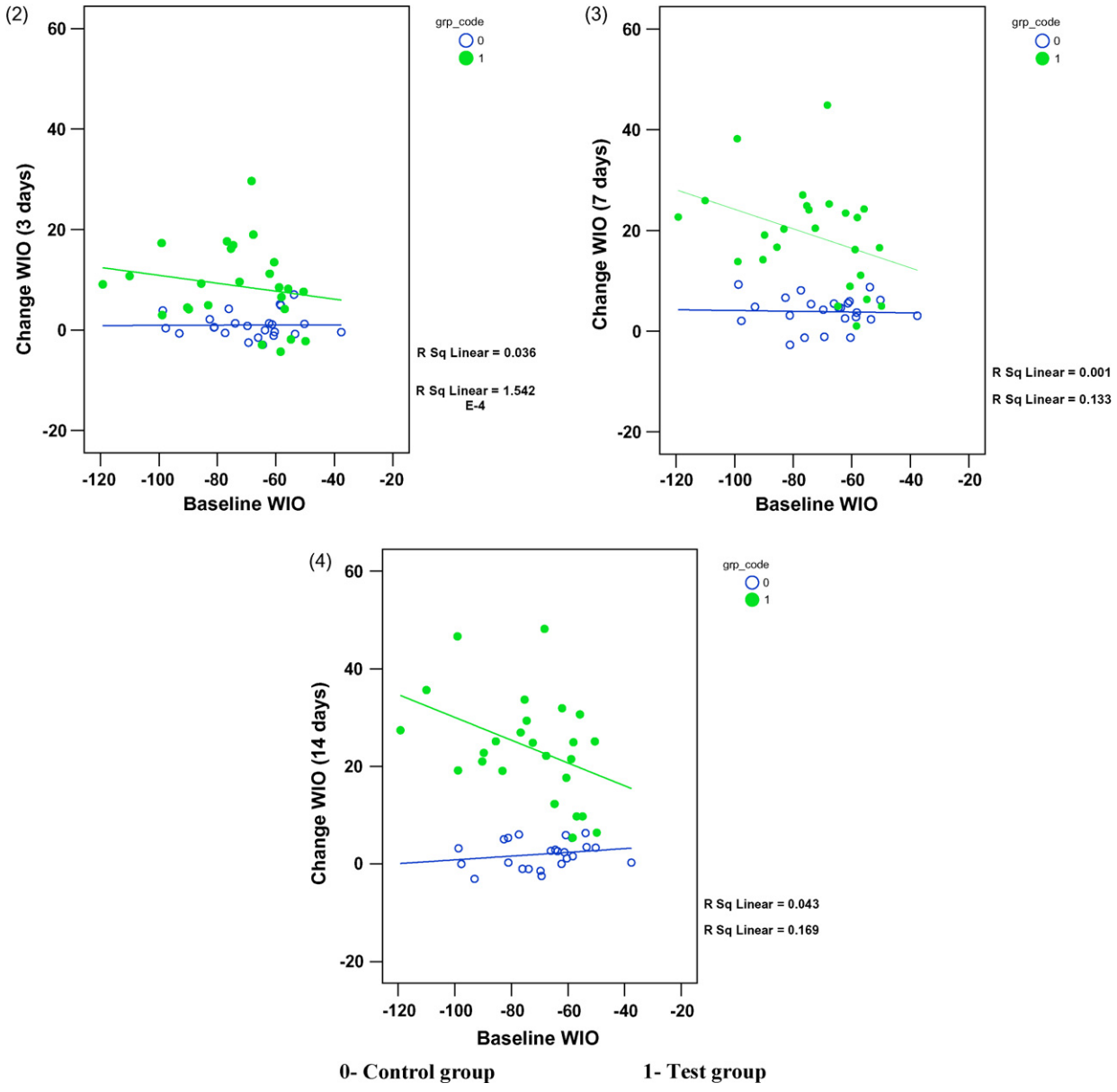
4.4. *Data overview*

The mean difference for both clinical and digital data showed a statistical difference ($p < 0.001$) between the control and test group at the 3 days visit. Figs. 2–4 indicated that the control group was fairly stable with not much change over the study period for both clinical and digital evaluation. The calibration card showed stable b^* values of 0.14, 0.19, 0.09, and 0.08 for each visit. The WIO index was plotted with its baseline value against corresponding change for each visit and the separation between the control and test was evident at 3 days and increased over the study period (Figs. 2–4). The control group had its values scattered around 0 indicating less change. It was observed that the digital data showed statistically significant correlation with the clinical data at $p < 0.05$ in 3 days and $p < 0.001$ in 7 and 14 days.

5. Discussion

There are significant numbers of tooth whitening products that are available in the market. It is not only whitening efficacy but also factors such as the duration of treatment, time period of application, mode of application, longevity of the whitening effect that influence the popularity of the product amongst consumers.[9] Bleaching teeth under dental supervision has been emphasised by different investigators due to the fact that it offers patients the option of different products and, most importantly, initial clinical examination and diagnosis.[10]

The advantages of using computer processing of digitised images to monitor the changes in the colour parameters has been recommended by Bentley et al.[11] Some researchers have investigated the use of instruments like Chromameters to measure the colour of teeth but have reported the variability of



Figs. 2–4 – Graph plotted with mean baseline WIO values against the change in its value for each visit—control and test group (subject wise).

such techniques compared to the clinical visual techniques.[12] Guan et al. reported that the digital imaging system is more reliable in tooth-colour quantification than the Spectrophotometry.[13] Small areas of measurement on the tooth surface and repositioning the device on the same measurement area is difficult using a Chromameter whereas the Imaging system facilitates easy capturing of digital images and their further analysis to quantify the colour parameters.

Literature and published reports indicate that most of the whitening studies which have been carried out have taken into account the ΔL^*, Δb^* or ΔE values. Changes in the WIO index[7] was considered in the present study as it was reported as the most suitable index to measure the tooth whiteness.[8] The WIO index (Figs. 2–4) indicated fairly good separation of the products from 3 days which increased over the study period re-affirming the suitability of the index as reported in previous study.[8]

The present trial demonstrated a significant whitening effect for the use of the whitening system which contained 6% hydrogen peroxide gel from as early as 3 days on both clinical and digital evaluation. Clinical evaluation showed a decrease in the mean shade guide score of about 5 units in 3 days which further decreased to more than 7 units in 14 days. Digital evaluation indicated a whitening index WIO change of 8.81 units which was approximately a 12% increase in whiteness compared to the baseline in 3 days. It further increased by 19.12 (25.95%) and 23.88 (32.41%) in 7 and 14 days, respectively. It should be noted that supply of tooth whitening products with greater than 0.01% peroxide is illegal in the UK under the EU Cosmetic Directive.

Collins et al. reported statistically significant improvement ($p < 0.05$) in the mean tooth shade score of 0.75 and 1.02 units after 1 and 2 weeks compared to baseline using a 6% hydrogen peroxide gel applied using a disposable cotton bud applicator.[10] Even though a statistical difference was observed in the study, a noticeable colour difference with the reported shade guide improvement would be debatable. After a 15 days treatment period, the custom-tray group using 5% carbamide peroxide showed a significant ($p < 0.002$) reduction in yellowness, Δb^* of -1.83 and lightness ΔL^* of 1.45 units.[14] The present study indicated a significant difference with a reduction in b^* value of 1.33 in 3 days time and a 2 weeks mean difference of 3.90 units. The mean difference for the L^* value was 1.38 units in 3 days which eventually increased to 3.56 in 14 days.

Statistically significant correlation between the clinical and digital data and stable b^* values for the calibration card over the study period demonstrates the reliability and robustness of the digital system.

6. Conclusion

The clinical trial showed a significant and meaningful improvement in the whiteness index (WIO) for the test product over the study period from 3 days both for the clinical and digital data. WIO is a suitable whiteness index which could be used to measure the whitening changes to discriminate between products in clinical trials. The Imaging system is stable and robust and could be employed in the measurement and comparability of the whitening effects of different treatments.

REFERENCES

1. van der Burgt TP, ten Bosch JJ, Borsboom PC, Kortsmit WJ. A comparison of new and conventional methods for quantification of tooth color. *Journal of Prosthetic Dentistry* 1990;**63**:155–62.
2. Joiner A. The bleaching of teeth: a review of the literature. *Journal of Dentistry* 2006;**34**:412–9.
3. Sulieman M, Addy M, MacDonald E, Rees JS. The effect of hydrogen peroxide concentration on the outcome of tooth whitening: an in vitro study. *Journal of Dentistry* 2004;**32**: 295–9.
4. Gerlach RW, Zhou X. Vital bleaching with whitening strips: summary of clinical research on effectiveness and tolerability. *Journal of Contemporary Dental Practice* 2001; **2**:1–16. Aug 15.
5. Swift Jr EJ, Miguez PA, Barker ML, Gerlach RW. Three-week clinical trial of a 14% hydrogen-peroxide, strip-based bleaching system. *Compendium of Continuing Education in Dentistry* 2004;**8**:27–32. Aug; 25.
6. Westland S, Ripamonti C. Computational colour science using MATLAB. London: John Wiley & Sons; 2004.
7. Luo W, Westland S, Ellwood R, Pretty IA. Evaluation of a whiteness formulae for teeth. *10th Congress of the International Colour Association*. 2005:100–4.
8. Luo W, Westland S, Brunton P, Ellwood R, Pretty IA, Mohan N. Comparison of the ability of different colour indices to assess changes in tooth whiteness. *Journal of Dentistry* 2007;**35**:109–16.
9. Pretty IA, Ellwood RP, Brunton PA, Aminian A. Vital tooth bleaching in dental practice: 1 Professional bleaching. *Dental Update* 2006;**33**:288–90. 293–296, 299–300.
10. Collins LZ, Maggio B, Liebman J, Blanck M, Lefort S, Waterfield P, *et al.* Clinical evaluation of a novel whitening gel, containing 6% hydrogen peroxide and a standard fluoride toothpaste. *Journal of Dentistry* 2004;**32**: 13–7.
11. Bentley C, Leonard RH, Nelson CF, Bentley SA. Quantitation of vital bleaching by computer analysis of photographic images. *Journal of the American Dental Association* 1999;**130**:809–16.
12. Goodson JM, Tavares M, Sweeney M, Stultz J, Newman M, Smith V, *et al.* Tooth whitening: tooth color changes following treatment by peroxide and light. *Journal of Clinical Dentistry* 2005;**16**:78–82.
13. Guan YH, Lath DL, Lilley TH, Willmot DR, Marlow I, Brook AH. The measurement of tooth whiteness by image analysis and spectrophotometry: a comparison. *Journal of Oral Rehabilitation* 2005;**32**:7–15.
14. Gerlach RW, Barker ML, Tucker HL. Clinical response of three whitening products having different peroxide delivery: comparison of tray, paint-on gel, and dentifrice. *Journal of Clinical Dentistry* 2004;**15**:112–7.