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Development of a stain shade guide to aid the measurement of extrinsic dental stain

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Abstract: *Background:* Accurate and reproducible assessment of extrinsic staining is pivotal to determining efficacy of some tooth whitening oral hygiene products. The aim of this study was: (1) to produce a stain shade guide to aid the *in vitro* and *in vivo* stain assessment (2) to assess intra- and inter-examiner reproducibility of stain assessment using the stain shade guide. *Method:* Using chlorhexidine and tea, perspex and acrylic teeth specimens were stained. The amount of staining on the perspex was measured with a spectrophotometer and the values obtained were assigned to the stained acrylic teeth, which were made into a stain guide. Using clinical photographs and a group of 10 volunteers, stain area and intensity were assessed using the stain guide and the recognized Lobene stain index by two examiners. The degree of intra- and inter-examiner reproducibility for these measurements were assessed using Cohen's kappa statistics. *Results:* For both the clinical examination and use of photographs, intra-examiner reproducibility for stain intensity was improved when using the stain guide compared with the Lobene Index. Similarly, when assessing inter-examiner reproducibility, stain intensity kappa values were greater using the stain guide ($\kappa = 0.82$) compared with the Lobene Index ($\kappa = 0.57$). *Conclusion:* The findings of this study would suggest that the use of the stain guide could be of importance in the assessment of extrinsic dental stain.

Key words: extrinsic dental stain; Lobene Index; spectrophotometer

Introduction

The appearance of the dentition is of concern to a large number of people seeking dental treatment and the colour of

the teeth is of particular interest. For the most part, both intrinsic and extrinsic staining contribute to the overall perception of tooth colour. The problem of tooth discolouration by extrinsic staining has been addressed by the introduction of various whitening products primarily in toothpaste. Clinical evidence of efficacy is very much dependent on well-run clinical trials which can use various methods for stain evaluation including subjective clinician assessment and objective instrumental methods (1–4). One of the most widely used subjective assessments is the Lobene Index (1968). This employs a staining evaluation using the following criteria: (0 = no stain, 1 = light stain, 2 = moderate stain, 3 = heavy stain) in which both stain area and intensity are subjectively measured at two areas of the tooth, i.e. gingival margin and body. Slight variations on the Lobene Index have been suggested which may either improve the data capture or reduce variation in the interpretation of stain (5, 6). However, it is well recognized that accurate assessment of stain is difficult and factors such as lighting conditions and inter- and intra-examiner variability may influence the outcome of clinical trials. To help overcome these problems, training of assessors before commencement of the study is very often recommended and to assess the reproducibility both within the examiner and between examiners, various statistical methods can be employed. One method is to use a Cohen's kappa statistical analysis which has been widely employed in clinical medicine to evaluate consistency in measuring clinical parameters.

The evaluation of the colour of teeth using shade guides is the major methodology employed in matching natural and artificial teeth in the construction of fixed and removable prostheses. The use of shade guides and colour comparison with the $L^*a^*b^*$ system have also been suggested to be of importance in evaluating colour (whitening) change in intrinsic staining primarily associated with looking at bleaching effects (2, 7). In terms of evaluating extrinsic staining, the use of laboratory shade guides may be of limited importance. Thus extremes of colour seen with chlorhexidine stain such as dark brown and black are outside the range of commercially available shade guides. Alternatively in the laboratory, spectrophotometry and image analysis of stained acrylic blocks or teeth may be useful; however, these methodologies are not easy to implement and the usefulness of such methods in stain assessment have not been fully evaluated (8, 9).

The aim of the present study was to produce a stain shade guide to aid *in vitro* and *in vivo* stain assessment. Stain was produced using a chlorhexidine/tea forced stain model, which has been used both *in vitro* and *in vivo* to determine the efficacy of oral hygiene products to remove or inhibit dental stain. To determine the usefulness of the guide, the recognized Lobene Index was used to determine the presence of stain both in the clinic and from clinical photographs. Both intra- and inter-examiner reproducibility of stain assessment for two examiners using the index was determined by calculating kappa statistics. Using the same methodology, the presence of stain was again calculated using the stain guides and again kappa statistics determined. The information obtained could help to establish methodology which is more reproducible and less influenced by examiner variability.

Material and methods

Development of stain guide

The method employed modifications of the chlorhexidine/tea staining on optically clear specimens *in vitro* (10). This model had been employed to assess chemical stain removal properties of 'whitening' toothpaste products (11). Briefly, the *in vitro* model cycles perspex blocks and acrylic teeth (Cosmo HXL Shade A1; DENTSPLY Brazil, Petropolis, RJ, Brazil) specimens through saliva, 0.2% chlorhexidine and finally a standard tea solution, on the hour, eight times per day (approximately 09:00–16:00 hours) (Fig. 1). Optical density readings were taken of the perspex blocks at the end of each cycle at the lambda maximum for tea (295 nm). An acrylic tooth which had been exposed to the same cycle as the perspex specimens was subsequently given a corresponding optical density. So as to provide a simple numerical value for the acrylic teeth, mean optical density (OD) values closest to 0, 0.5, 1.5 and 2.5 were allocated increasing shade guide values of 0, 1, 2 and 3 respectively. To produce a permanent and more durable shade guide, the acrylic teeth were lacquered using clear nail varnish and glued to tooth brush handles.

Stain assessment with and without using stain guide

Prestudy training session

Prestudy training for stain assessment using Lobene Index was obtained from an assessor who had extensive experience in stain assessment in numerous clinical studies. Clinical photographs were used to practice stain assessment before both the *in vitro* and *in vivo* studies.

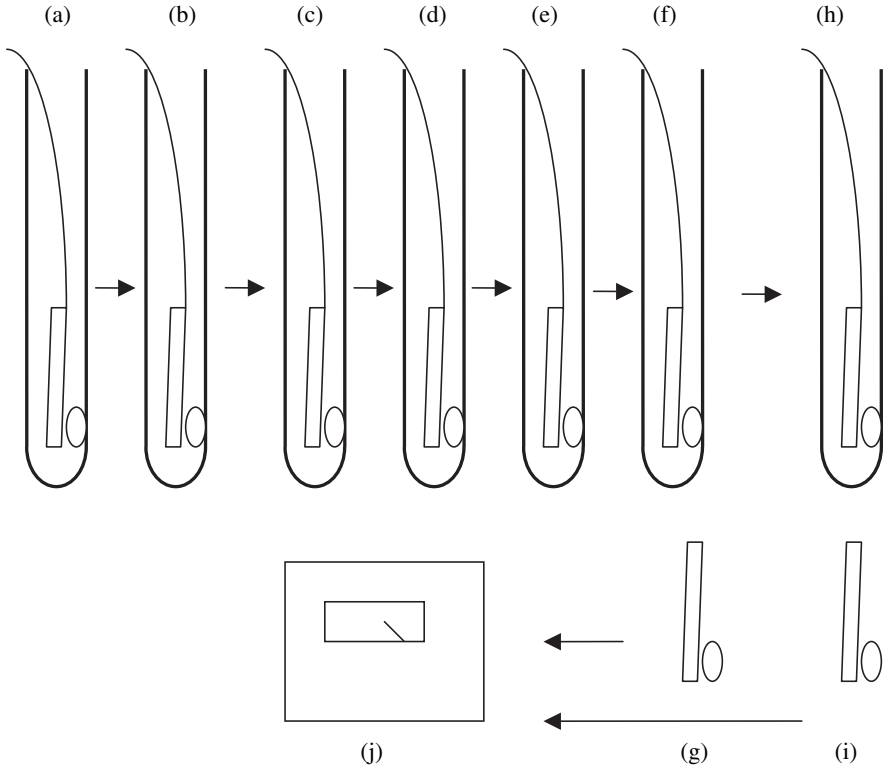

Fig. 1. Diagram showing the experimental procedure for each cycle: (a) set 1–8 containing perspex blocks and acrylic teeth placed in unstimulated saliva for 2 min; (b) removed and placed in distilled water for 30 s; (c) placed in 0.2% chlorhexidine solution for 2 min; (d) removed and placed in distilled water for 30 s; (e) placed in standard tea solution for 60 min; (f) removed and placed in distilled water for 30 s; (g) set 1 is removed and air dried; (h) set 2–8 are passed through the same cycle (a–f); (i) at the end of every cycle, one set is removed; (j) perspex blocks are used to obtain spectrophotometer values and an average value obtained for each of the set. These values correspond to staining on the acrylic teeth.

Study 1: use of clinical photographs

Ten clinical pictures of teeth with various degrees of extrinsic staining (promoted by the use of chlorhexidine) were randomly chosen and viewed on a computer (Advent 3207) using MGI Photo Suite (Version 8.1) at ×150 magnification. The labial surfaces of the upper and lower anterior 3↔3 were selected as the surfaces to be evaluated using the Lobene (1968) stain index on two separate occasions and using two different examiners. Any teeth with crowns, bridgework, large restorations or obvious intrinsic staining such as fluorosis or tetracycline staining were excluded from analysis.

The labial surface of each tooth was divided into two regions: the gingival region and the body region. The gingival region was a crescent-shaped band of the labial surface about 3 mm wide, adjacent to the free margin of the gingival and extending to the crest of the inter-dental papilla of the adjacent teeth. The remainder of the labial surface was designated the body region. The gingival and body regions were scored separately for yellow stains by use of the following criteria for intensity or severity: 0 = no stain, 1 = light stain, 2 = moderate stain, 3 = heavy stain. The extent to which these stains covered the gingival and body regions was scored according to the following criteria: 0 = no stain detected, only tooth colour, 1 = stain over one-third of the region, 2 = stain more than one-third but less than two-thirds of the region, and 3 = stain over more than two-thirds of the region.

The above procedure was repeated using the stain guide to obtain scores for stain intensity and stain area.

Study 2: clinical assessment

Volunteers were screened for the presence of extrinsic staining from the Emergency Clinic of University of Malaya, and 10 subjects (patients and nursing staff, aged 18–65 years, F:M = 4:6) randomly selected. The inclusion of these volunteers represented a wide range of the population with no intention to include or exclude individuals by way of age, sex or oral hygiene status. Informed consent from each volunteer was obtained for examination by the two examiners. Inclusion criteria included the presence of an intact dentition compromising upper and lower canine to canine and a willingness to attend two visits. Exclusion criteria included the following: (1) presence of intrinsic stain which could interfere with the interpretation of extrinsic stain, e.g. tetracycline stain, fluorosis; (2) the presence of orthodontic appliances, restorations or bridge work that would interfere with the evaluation; (3) grossly carious teeth, acute gingivitis or established periodontal disease; and (4) anyone possessing any anterior tooth coloured cast restorations or composites. Two examiners (RS and KG) were employed in separate rooms. Both these examiners assessed each volunteer twice for stain area and

intensity using the Lobene Index and the stain shade guide. The interval between each examination for any individual volunteer was a minimum of 30 min during which time another volunteer was examined. Using this methodology, any 'memory' effect would be minimized. To further assess consistency in scoring, a further assessment of inter-examiner variability was also determined the following day in which both examiners reassessed each volunteer as previously described.

Statistical analysis

A measure of agreement used in this study was the un-weighted Kappa Statistic (κ). It has a maximum of 1.00 when agreement is perfect and a value of zero indicating no agreement better than chance. Guidelines to strength of agreement are shown in Table 1.

The above statistical method was used to calculate kappa values for intra- and inter-examination by both examiners for the Lobene Index and Stain Guide assessment of clinical photographs and volunteers. Additionally, validation of the shade guide method was determined by calculating the Pearson Correlation coefficient for both methods of assessment for both examiners.

Results

Development of stain guide

The OD values and their mean values are shown in Table 2. Maximum OD values of approximately 2.5 were obtained by the sixth cycle, which corresponded to severe staining and which was assigned to the acrylic shade value of three. An OD value of 0 was assigned to a control specimen which had simply been immersed in water over the eight cycles.

Assessment of clinical photographs using shade guides and Lobene Index

Intra- and inter-examiner assessments of the clinical photographs using the Lobene Index showed kappa values ranging from 0.38 to 0.79 indicating agreement from fair to good (Table 3). A higher level of agreement was noted for stain guide measurements which ranged from 0.57 to 0.93 indicating agreement of moderate to very good. This trend was noted for all assessments of stain intensity, but not for stain area. Thus for examiner 2, assessment of stain area using the Lobene Index for intra-examiner reproducibility showed a kappa value of 0.63 and a kappa value of 0.60 with the stain guide. The Pearson correlation coefficient comparing the Lobene Index with the stain guide method found values for stain intensity of 0.85 for examiner 1 and 0.92 for examiner 2. For stain area the corresponding values were 0.88 and 0.97 respectively.

Table 1. **Guidelines to measure agreement**

Value of κ	Strength of agreement
<0.20	Poor
0.21–0.40	Fair
0.41–0.60	Moderate
0.61–0.80	Good
0.81–1.00	Very good

Table 2. **Average values obtained from perspex blocks were used to relate to scores on the stain guide**

	Perspex blocks				
Cycle	Value 1	Value 2	Value 3	Average	Acrylic teeth clinical stain guide
1	−0.037	−0.031	−0.016	−0.028	0
2	0.188	0.146	0.207	0.180	
3	0.507	0.543	0.377	0.476	1
4	0.821	0.745	0.928	0.831	
5	1.570	1.650	1.648	1.623	2
6	2.335	2.540	2.460	2.445	3
7	>3.0	>3.0	>3.0	3.000	
8	>3.0	>3.0	>3.0	3.000	

Assessment of volunteers using shade guides and Lobene Index

Assessment of intra-examiner reproducibility for both examiners using the Lobene Index showed kappa values for stain intensity of 0.61 (good agreement) and 0.80 (good agreement) (Table 4). For stain area kappa values of 0.79 (good agreement) and 0.29 (fair agreement) were shown. Inter-examiner reproducibility on day 1 and day 2 demonstrated kappa values of 0.55 and 0.57, respectively, for stain intensity. For stain

Table 3. **κ values for Lobene Index and stain guide obtained from clinical photographs**

	Lobene Index	Stain guide
Examiner 1 Intra		
Stain intensity	0.54 (70)	0.93 (97)
Stain area	0.73 (82)	0.91 (94)
Examiner 2 Intra		
Stain intensity	0.63 (75)	0.86 (93)
Stain area	0.63 (74)	0.60 (73)
Inter-relation day 1		
Stain intensity	0.79 (86)	0.93 (97)
Stain area	0.51 (66)	0.87 (92)
Inter-relation day 2		
Stain intensity	0.47 (64)	0.75 (88)
Stain area	0.38 (58)	0.57 (71)

Values in parentheses are percentage perfect agreement.

Table 4. **κ values for Lobene Index and Stain guide obtained from clinical assessment**

	Lobene Index	Stain guide
Examiner 1 Intra		
Stain intensity	0.61 (74)	0.89 (94)
Stain area	0.79 (86)	0.72 (80)
Examiner 2 Intra		
Stain intensity	0.80 (87)	0.87 (93)
Stain area	0.29 (51)	0.75 (83)
Inter-relation day 1		
Stain intensity	0.55 (71)	0.73 (85)
Stain area	0.20 (48)	0.52 (67)
Inter-relation day 2		
Stain intensity	0.57 (73)	0.82 (90)
Stain area	0.26 (50)	0.43 (60)

Values in parentheses are percentage perfect agreement.

area, these values were reduced to 0.20 and 0.26 indicating only fair agreement between the two examiners. Examinations of the volunteers using the stain guide showed consistently higher kappa values than the Lobene Index for both intra- and inter-examiner reproducibility for stain intensity but not for stain area. Thus kappa values as high as 0.89 (very good agreement) were noted for examiner 1 intra-examiner assessment compared with 0.61 (good) with the Lobene Index. Similarly, for example, inter-examiner assessments on day 2 showed higher kappa values for the stain guide of 0.82 (very good) compared with the Lobene Index value of 0.57 (moderate). The Pearson correlation coefficient comparing the Lobene Index with the stain guide method found values for stain intensity of 0.95 for examiner 1 and 0.92 for examiner 2. For stain area the corresponding values were 0.89 and 0.98 respectively.

Discussion

Extrinsic dental staining is considered a major cosmetic problem for many people who would prefer whiter teeth. This problem is reflected in the numerous whitening oral hygiene products now available for use by the public at large. Efficacy for these products may be evaluated both *in vitro* and *in vivo* using a chlorhexidine/tea stain model (4, 12, 13). Whereas the former can be measured numerically by using a spectrophotometer, the latter requires subjective evaluation by a dental examiner usually employing a recognized index such as the Lobene Stain Index (1968). Interpretation of staining can be notoriously difficult and is largely affected by considerable variation both within and between examiners. The use of dental shade guides may be of importance in measuring the effects of bleaching agents on improving the average shading of teeth (8). Their use in assessing extrinsic stain would not appear to be ideal as the range of shades does not reflect natural staining where extremes of colour homogeneity can be evident. This is particularly relevant in measuring chlorhexidine stain which can range from yellow to brown to black. For clinical evaluation of extrinsic stain, the Lobene stain index is usually used to measure both stain area and intensity but is very subjective in nature. It is also recommended that a calibration exercise is carried out and that reproducibility both within and between examiners is carried out, before any study is started.

The Cohen's kappa statistic has been used for many years in clinical medicine to determine the reproducibility, consistency or agreement in measuring clinical data. This usefulness has been illustrated in assessment of whitening oral hygiene products, where a variation of the Lobene Index has been used (5).

The findings of the study overall showed that both examiners displayed an acceptable level of intra-examiner reproducibility for both Lobene Index and the use of stain guides. This was evident particularly for stain intensity evaluation whether looking at clinical photographs or clinical examinations. This is not surprising as the stain guides were primarily developed to help in the interpretation of stain intensity rather than quantifying the extent of stain present.

Inter-examiner variability kappa values for the Lobene Index were disappointing in as much that values below 0.6 for both stain area and intensity were mostly seen for both clinical assessments and the examination of clinical photographs. In contrast, the use of the stain guides improved levels of reproducibility compared with the Lobene Index particularly for stain intensity evaluation. Thus kappa values as high as 0.93 for the clinical photographs were obtained and for the clinical exercise a value of 0.82 was seen on day 2. The consistently better kappa values for the stain guides appeared to be sustained on day 2, with the kappa values for the Lobene continuing to show less reproducibility.

Alternative methods of analysis including Fleiss' coefficient of reliability and Pearson's correlation coefficient for intra- and inter-operator reliability have more recently been used to evaluate disclosed plaque, but not stain from digital images (14). Similarly, the exercise using Pearson's correlation coefficient was used to give a measure of validation between the Lobene Index and the use of the stain guide. This assumed, of course, that the Lobene Index is a reliable and acceptable method for stain evaluation. The excellent degree of correlation between the stain guide and Lobene Index when scoring both the clinical photographs and volunteers would suggest that the stain guide method is a valid method of stain assessment. It could be

recommended, therefore, as an alternative and equally useful method of assessing stain in clinical trials.

In summary, these findings would appear to demonstrate the usefulness of the stain guides in measuring extrinsic stain intensity on a more consistent level. Subsequently, the stain guides may be recommended to be employed especially in clinical trials on whitening oral hygiene products, both in the pretrial training exercises and in the evaluation of the products themselves.

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