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Final Report
Bleaching Effects of a Novel Test Whitening Strip and Rinse: Addendum: Vita 3-D Shade Reference Guide Measurements

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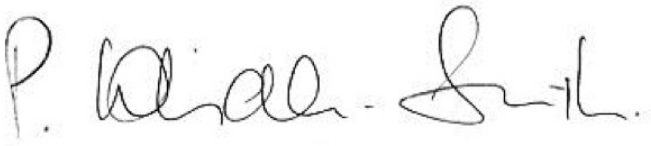

Bleaching Effects of a Novel Test Whitening Strip and Rinse

Protocol: same as for eponymous parent study as documented in our report of 11/2/2016.

Study 1: OE strips

A total of 5 extracted teeth were used. They were selected from 20 teeth which were all stained as per original protocol. For ease and translatability of comparison, 5 teeth with matching degrees of staining were selected for this study from the 20 stained samples. Tooth colors were measured by 1 experienced, blinded, pre-standardized examiner using standard colorimetry (as described in our previous study) and the Vita 3-D shade guide. Lighting was indirect and standardized and all measurements were repeated 3 times.

At baseline, samples 1-3 had a shade of 3M2; samples 4 and 5 had a baseline shade of 2M1. After 10h treatment with OE strips, samples 1-3 lightened to shade 1M1. Samples 4 and 5 also lightened to shade 1M1.

OE strips				
SAMPLE #	**Samples 1-5**	**Samples 1-5**	**Samples 1-3**	**Samples 4,5**
	Mean L #	***Mean B #***	***Vita 3-D Shade***	***Vita 3-D Shade***
Baseline	69.66	13.35	3M2	2M1
10h exposure	79.84	11.85	1M1	1M1

Study 2: OE Mouthwash

A total of 5 extracted teeth were used. They were selected from 20 teeth which were all stained as per original protocol. For ease and translatability of comparison, 5 teeth with matching degrees of staining were selected from the 20 stained samples. Tooth colors were measured by 1 experienced, blinded, pre-standardized examiner using standard colorimetry (as described in our previous study) and the Vita 3-D shade guide. Lighting was indirect and standardized and all measurements were repeated 3 times.

At baseline, samples 6 and 7 teeth had a baseline shade of 4M1; samples 8-10 had a baseline shade of 3M2. After 48h treatment with OE mouthwash, teeth 6 and 7 lightened to shade 3M1. Samples 8-10 also lightened to shade 3M1.

OE mouthwash				
SAMPLE #	**Samples 6-10**	**Samples 6-10**	**Samples 6,7**	**Samples 8-10**
	Mean L #	***Mean B #***	***Vita 3-D Shade***	***Vita 3-D Shade***
Baseline	68.99	11.17	4M1	3M2
48h exposure	71.30	10.10	3M1	3M1

CONCLUSION

The results of study 1 demonstrated that the OE whitening strip consistently lightens the shade of the teeth by up to 12 shades. Moreover, the results of study 2 confirmed that OE whitening mouthwash consistently lightens the shade of the teeth by up to 7 shades. Variables may include the color and microanatomy of the existing teeth, as well as the cause of discoloration, and the application duration of the whitening agent.

Context and Discussion

The person having ordinary skill in the dental art (e.g., a dentist or dental hygienist) is able to practice the methods of the present invention to determine improvement in tooth shade (i.e., lightening) by assessing the tooth visually using a dental shade guide. The closest shade is selected from the standard shade guide that matches the color of the tooth.

Shade can be, and in preferred embodiments of the present invention, is described according to the Munsell color space in terms of value, chroma, and hue, each defined below.

“Value” indicates the lightness of a color. Lightness is defined by the Commission Internationale de l’Eclairage (“CIE”) as the “brightness of an area judged relative to the brightness of a similarly illuminated area that appears to be white or highly transmitting.”

“Chroma” is the degree of color saturation, and is defined by the CIE as the “colourfulness of an area judged as a proportion of the brightness of a similarly illuminated area that appears white or highly transmitting.”

“Hue” is the attribute of a color that enables the clinician to distinguish between different families of color, and defined as the “attribute of a visual perception according to which an area appears to be similar to one of the colours: red, yellow, green, and blue, or to a combination of adjacent pairs of these colours considered in a closed ring”. Hue is represented by A, B, C or D on the commonly used VITA Classic shade guide.

In certain embodiments, improvement in tooth shade (i.e., lightening) is measured using the VITA TOOTHGUIDE 3-D MASTER® system –a dental shade guide comprised of 26 shade tabs based on a color classification principle where the values of lightness, chroma, and hue have been positioned an equal distance from each other. See FIG. 1.

The VITA TOOTHGUIDE 3-D MASTER® system is organized into five primary value levels, arranged from the lightest (value level 1) to the darkest (value level 5), left to right. These values, in turn, are further distributed (subdivided) based on chroma and hue. Within each of the five groups, shade tabs are arranged vertically according to chroma (pale to saturated and horizontally according to hue (yellowish to reddish).

In embodiments of the present invention in which improvement in tooth shade is assessed based on the VITA TOOTHGUIDE 3-D MASTER® system, value is determined first followed by chroma. Hue is determined last, by matching with shade tabs of the value and chroma already determined. In these embodiments, the phrase "improvement in shade" is assessed by a three-step process as described immediately below.

Using a light source with a color temperature corresponding to "daylight light" (from 4600K - 6500K, more preferably from 5500K to 6500K), lightness, chroma and hue are determined.

First, the lightness of a patient's tooth is determined by holding the shade guide (i.e., sample) directly in front of the tooth, at a distance of approximately 25 - 30 cm. The trained observer (e.g., clinician) assigns a "value" (lightness level) on a six-point scale of 0, 1, 2, 3, 4 or 5, with 0 being light and 5 being dark. When selecting the lightness level, the observer begins by looking at the dark end (5) and moves toward the light end (0).

Next, the observer matches chroma (pale or saturated). The observer starts by removing a shade guide with the middle hue (M) from the selected lightness level. The observer then chooses one of three chroma within the selected lightness level.

As a final step, the observer determines hue by comparing the selected shade guide to the shade guide directly to the left (L) and right (R), and determines whether the tooth is more yellow (L) or red (R) than the middle (M) shade guide.

The observer may, and in certain embodiments does, score chroma and hue using the 7-point plot shown in FIG. 3.

In preferred embodiments of the present invention the trained observer assigns an initial (baseline) shade based on the VITA TOOTHGUIDE 3-D MASTER® system, and then assigns a corresponding Shade Number ranging from 1 to 26. See FIG. 2. The observer then tracks improvement (lightening) of tooth shade based on reduction (lowering) of the shade number.

In particularly preferred embodiments, practicing the methods of the present invention produces an improvement in tooth shade by lowering shade number by at least three. For example, shade number is reduced from 12 to 9.

Other tooth shade guides are known to the person having ordinary skill in the dental arts and can be used to assess lightening achieved by practicing the methods of the present invention. Non-limiting examples of shade guide systems include: VITA Classical (VITA North America, Yorba Linda, CA 92887) and CHROMASCOP® (Ivoclar Vivadent, Inc., Amherst, NY).

The VITA CLASSICAL A1-D4® system is arranged by four hues – “A”, “B”, “C”, or “D”, and subdivided as follows: A1, A2, A3, A4 – reddish to brownish; B1, B2, B3, B4 – reddish to yellowish; C1, C2, C3, C4 – greyish; D2, D3, D4 – reddish to greyish.

The CHROMASCOP® system is arranged by value levels covering the area of the CIE 1976 (L*a*b*) color space of “natural teeth”. Five groups – ranging from white, yellow, light brown, grey, to dark brown – have tabs representing different chroma and hue.

In the CIE 1976 (L*a*b*) system, where "L*" value represents comparative lightness / darkness (lower L* being indicative of darker), and "a*" and "b*" values are chromaticity coordinates (red-green and blue-yellow, respectively). See, A.R. Robertson, “The CIE 1976 color-difference formulae,” Color Res. Appl. Vol. 2, pp. 7–11 (1977). Each of the

L*, a* and b* can be plotted in three-dimensional space to characterize a color in absolute terms. The magnitude of the difference between two colors, as perceived by the human eye, is proportional to the distance between two points defining the two colors on the three-dimensional plot. The difference between the two colors, the Euclidean distance (ΔE), is defined by the following equation: $\Delta E^*ab = [(\Delta L^*)^2 + (\Delta a^*)^2 + (\Delta b^*)^2]^{½}$. An increase in b* indicates tooth color is trending towards yellow; a decrease in b* means the color is trending towards blue.

In embodiments based on the CHROMASCOP®, and VITA CLASSICAL A1-D4® systems, the observer assigns one of twenty-six shade numbers in FIG. 2 at baseline and throughout treatment (i.e., practicing the methods of the present invention). FIG. 2 also provides a conversion between VITA TOOTHGUIDE 3D MASTER®, CHROMASCOP®, and VITA CLASSICAL A1-D4® systems.

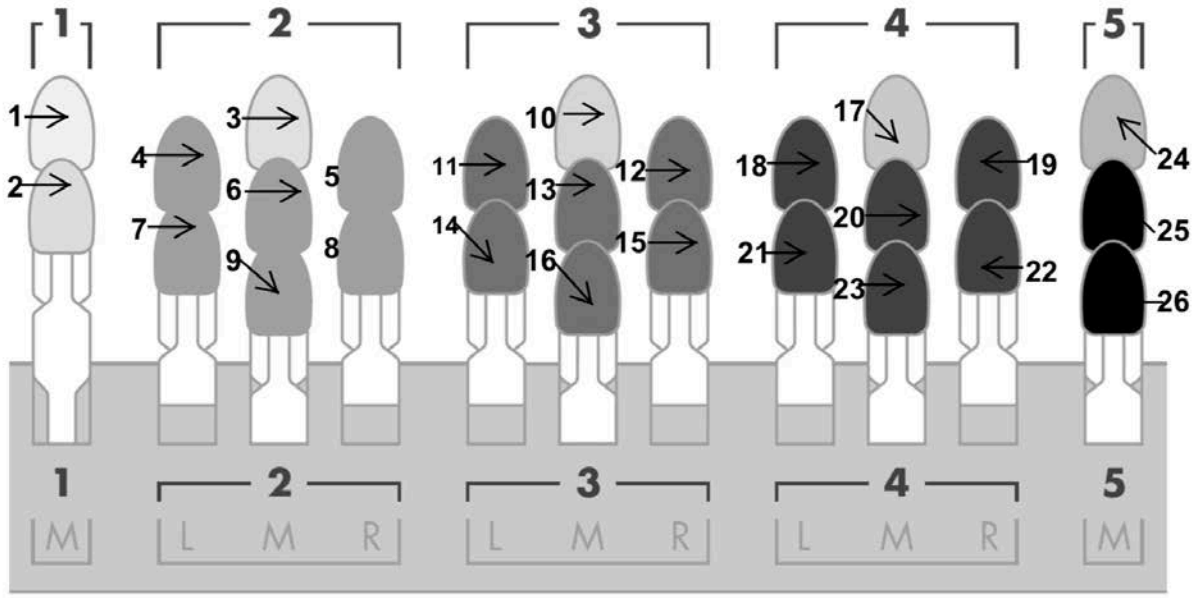

FIG.1

Shade #	VITA TOOTHGUIDE 3D MASTER®	CHROMASCOP®	VITA CLASSICAL A1-D4®
1	1M1	110	A1; B1
2	1M2	110	A1; B1
3	2M1	120	C1
4	2L1.5	130	B2
5	2 R1.5		
6	2M2	140	A2
7	2L2.5		
8	2R2.5		
9	2M3		
10	3M1		
11	3L1.5	430	C2 C3
12	3R1.5	410	D3
13	3M2	210	A3
14	3L2.5	310	B3
15	3R2.5	230	A3.5
16	3M3	320	B4
17	4M1		
18	4L1.5	430 (grey) 510 (brown)	C2 C3
19	4R1.5		
20	4M2		
21	4L2.5		
22	4R2.5	340 (grey) 530 (brown)	A4
23	4M3		C4
24	5M1		
25	5M2	520	A4
26	5M3		

FIG. 2

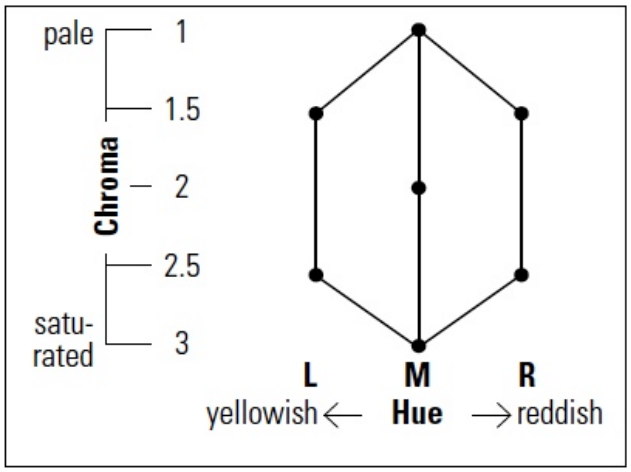

FIG. 3