An Alternative Composite Endpoint for Vital Bleaching in L*a*b* Color Space

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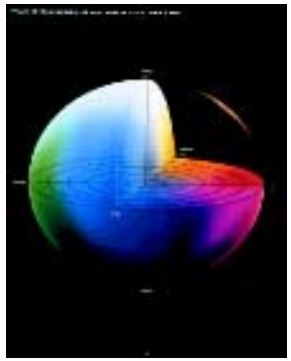
ABSTRACT

Objective: The directionless composite color endpoint ΔE* has been widely used to assess overall color change, especially in pre-clinical and clinical studies involving vital bleaching. This research introduces an alternative overall parameter to ΔE*, without some of common limitations found with that composite variable. **Methods:** A new composite parameter ΔW*, which measured the overall color change relative to pure white (L* = 100, a* = 0, b* = 0), was derived from W* = $(a^{*2} + b^{*2} + (L^*-100)^2)^{1/2}$. Change in the closeness to pure white (ΔW*) with treatment was calculated as the difference between W* at end-of-treatment and baseline. For any post-baseline L*a*b*, a negative ΔW* indicates color coordinates move closer to pure white, and hence, in a more favorable direction. ΔW* was compared to ΔE* via simulation and clinical data from a placebo group. **Results:** In the simulation, by keeping the mean of L*a*b* the same but doubling the variance, mean ΔE* increased approximately 40% while the mean ΔW* remained approximately the same. This demonstrated that the mean of ΔE* was influenced by measurement variability, while ΔW* was robust to this flaw. In addition, the clinical data demonstrated that ΔE* could give a misleading positive result when there was no whitening benefit. The placebo group (N=29) exhibited a mean ΔE* of 0.77 units, differing significantly ($p < 0.0001$) from baseline, while the individual L*a*b* color parameters indicated no significant ($p > 0.3$) whitening benefit, with mean ΔL*, Δa* and Δb* of –0.11, 0.05, and –0.05, respectively. Applying ΔW* to these data, the mean ΔW* was 0.07 ($p > 0.4$). **Conclusion:** ΔW*, a composite color endpoint in L*a*b* color space, may offer meaningful advantages over the directionless composite efficacy parameter ΔE* in vital bleaching color research.

INTRODUCTION

CIE Lab (L*a*b*) color space is a standard method to measure color. ΔE*, calculated as the distance between two color points in L*a*b* space, has been commonly used to assess overall color change and bleaching effectiveness. Regulatory agencies including ADA accept ΔE* as a valid measure for whitening. Recent studies suggest that ΔE* fails to address the direction of change. Consequently, the mean ΔE* increases as the measurement variability increases.



OBJECTIVE

The objective of this research is to introduce an alternative composite endpoint for vital bleaching measured in CIELab space L*a*b* without some of the shortcomings that are associated with ΔE*.

METHODS

Definition of ΔE*:

$$\Delta E^* = (\Delta L^{*2} + \Delta b^{*2} + \Delta a^{*2})^{1/2}$$

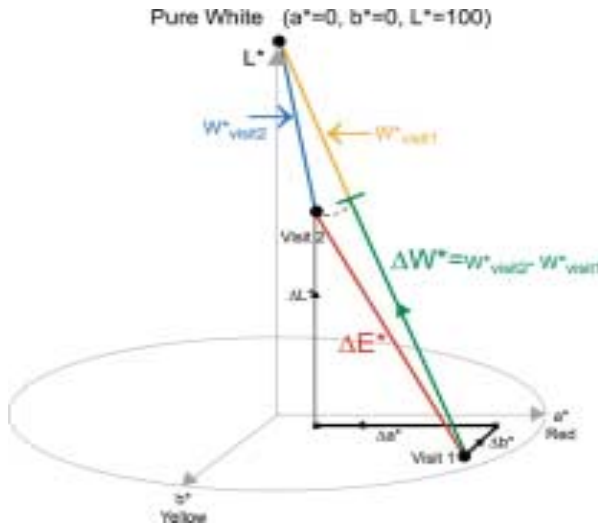
Any color change results in positive ΔE*. Greater ΔE* implies greater distance between two points in color space, not necessarily greater color improvement.

Definition of ΔW*:

$$\Delta W^* = W^*_{\text{post-baseline}} - W^*_{\text{baseline}}$$

and $W^* = (a^{*2} + b^{*2} + (L^*-100)^2)^{1/2}$

ΔW* measures the change in the distance relative to pure white color (L* = 100, a* = 0, b* = 0). A negative ΔW* value corresponds to color change toward pure white color while positive ΔW* indicates color change away from pure white.



RESULTS

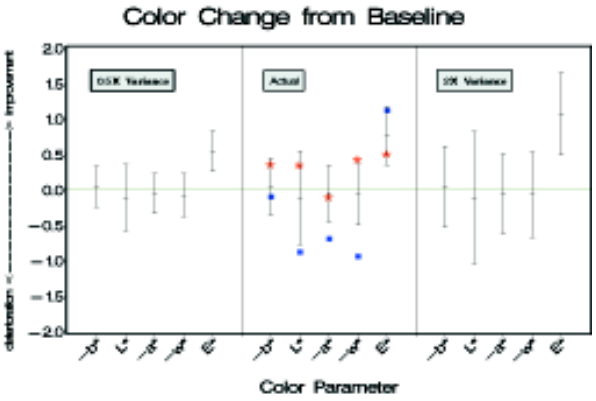
Mean color change from baseline of placebo group in a clinical trial:

Mean Color Change From Baseline for Placebo Group						
	N	ΔL*	Δa*	Δb*	ΔW*	ΔE*
Mean (SD)	29	-0.11 (0.66)	0.05 (0.40)	-0.05 (0.40)	0.07 (0.43)	0.77 (0.41)
p-values		0.39	0.51	0.40	0.40	0.0001

- ΔE* suggests that color change was statistically significantly ($p = 0.0001$) different from 0 while L*a*b* indicates no significant ($p \geq 0.39$) color changes.
- The conclusion from ΔW* is consistent with L*a*b* results.

Simulation results:

Mean ΔE* increases as variance of L*a*b* values increases, while mean ΔW* is invariant to changes in variability. With use of ΔW* instead of ΔE*, larger variation in measurement is less likely to be interpreted as meaningful color change.



CONCLUSION

ΔW*, a composite measure of closeness to pure white in L*a*b* color space, may offer meaningful advantages over the directionless composite parameter ΔE* in vital bleaching color research.

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