



## **Evaluating Perceptual Color Reproducibility of Whole-Slide Imaging Devices**

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Clinical Area: Digital Pathology

#### REGULATORY RELEVANCE

Demonstrating quantitative methods for comparing color performance of a 510(K) whole-slide imaging submission against its predicate device

#### **ABSTRACT**

The color reproducibility of two whole-slide imaging (WSI) devices was evaluated with real tissue slides. Three tissue slides – human colon, skin, and kidney were used to test a modern and a legacy WSI devices. The color truth of the tissue slides was obtained using a multispectral imaging system. The output WSI images were compared with the color truth to calculate the color difference for each pixel. A psychophysical experiment was also conducted to measure the perceptual color reproducibility (PCR) of the same slides with 4 subjects. The results show that the mean color differences of the modern, legacy, and monochrome devices are 10.94, 22.35, and 42.74  $\Delta E_{00}$ , while their mean 70.35%, 23.06%, and PCRs 0.91%, respectively.

#### INTRODUCTION

#### **Motivation**

Color reproducibility is an essential factor when evaluating WSI devices substantial equivalence. Color truth is required to assess color reproducibility.

#### Challenge

> Color truth of biological tissues is difficult to measure due to their microscopic structures.

#### **Existing Methods**

> Artificial color test targets were used. However, they differ from biological tissues in spectral and structural characteristics and therefore might confound evaluation results.

#### Our Approaches

- > Developed a multispectral imaging system to measure the color truth for each pixel
- Compare WSI optical devices microscope to determine color perceptual reproducibility

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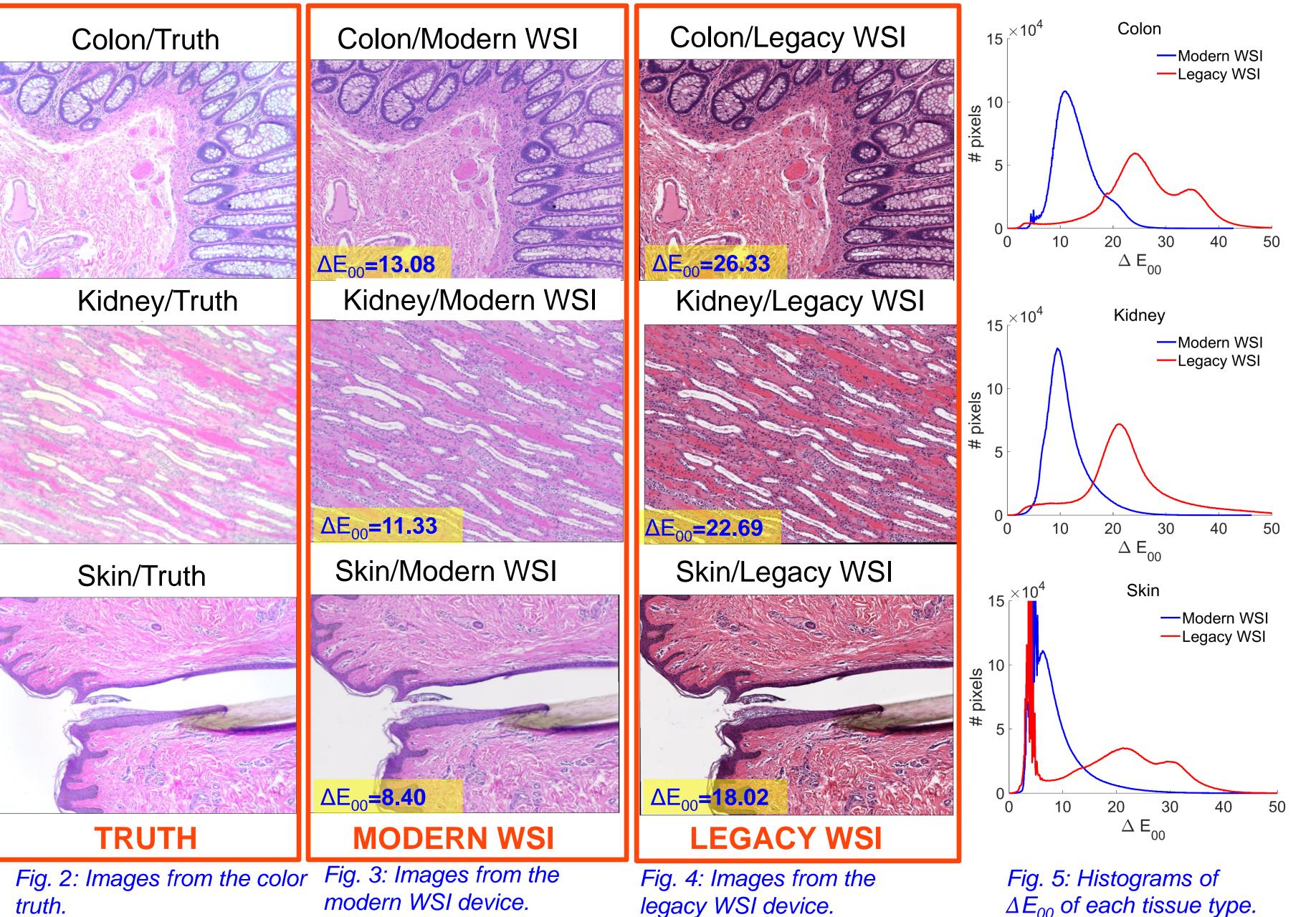
#### Table 1: Perceptual Color Reproducibility

#### Perceptual Color Reproducibility (%) Colon 69.08 0.75 Kidney 70.82 24.65 1.01 0.91 70.35 Mean

#### **METHOD** Multi-CIEDE2000 **Spectra** Color lmager Difference Tissue WSI Correlation Human **Optical** Observer Microscope | Optical

Fig. 1: Methodology workflow. The superscript numbers indicate the corresponding figures for each block.

# COLOR DIFFERENCES ( $\Delta E_{00}$ )



#### PSYCHOPHYSICAL EXPERIMENT

- Objective: Determine perceptual color reproducibility quantitatively > Study design: Scale PCR of 4 display images (truth, modern WSI,
- legacy WSI, and monochrome in Fig. 6) with respect to the microscope image (Fig. 7)
- > Psychophysical method: Cross-modality ratio scaling perceptual color reproducibility vs. perceptual length
- > Subject task: For each image, place a mark on a line to represent its perceptual color reproducibility. The left end of the line represents the least PCR, while the right end the most (Fig. 8).

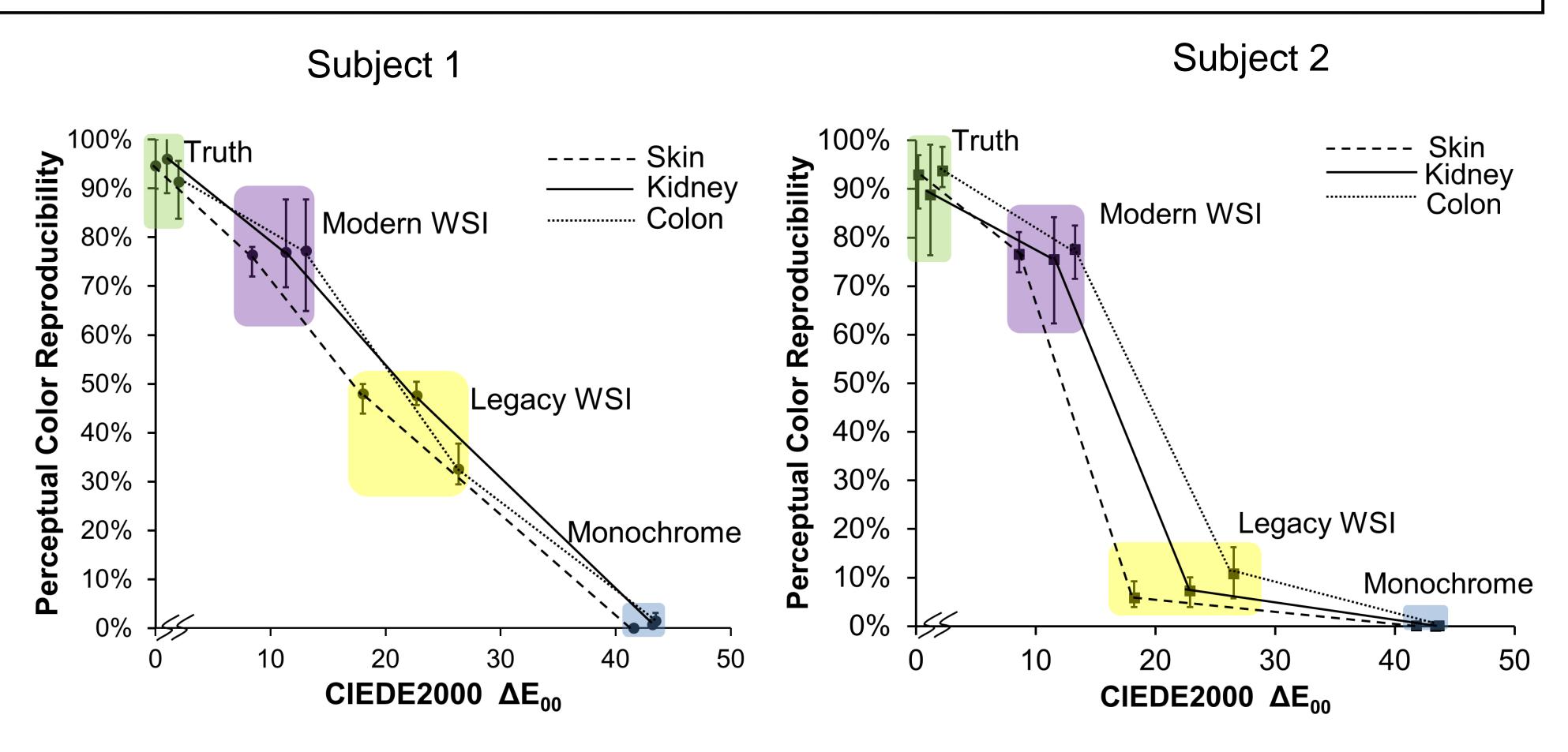
> 4 subjects, 6 trials per image

Fig. 8: Responses to the stimuli in Fig. 6 and 7 from 4 subjects.

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Fig. 6: Display images

#### PERCEPTUAL COLOR REPRODUCIBILITY VS. ΔΕ<sub>00</sub>



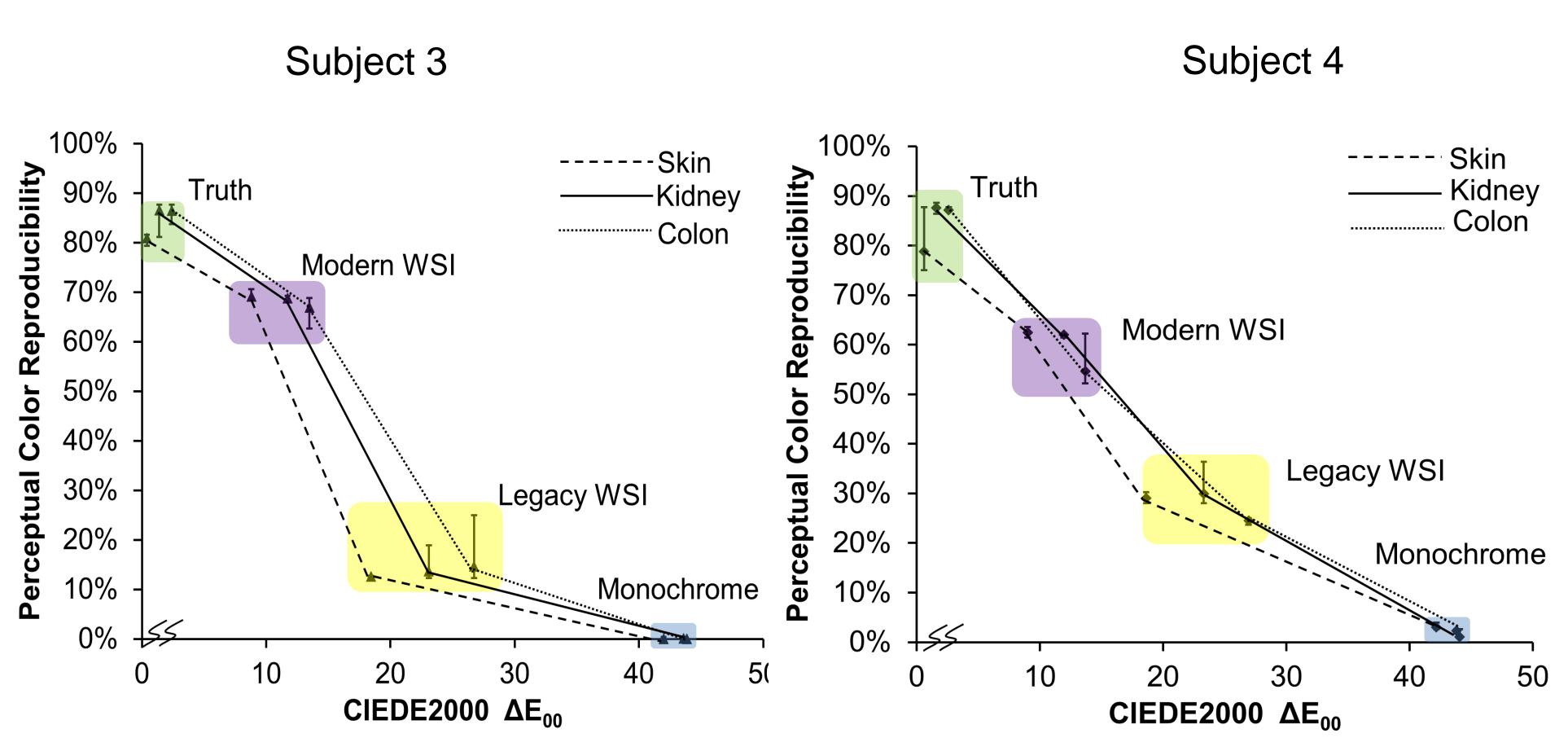


Fig. 9: PCR vs. color difference of 3 tissue types (colon, kidney, and skin) and 4 devices (truth, modern, legacy, and monochrome) from 4 subjects. Each data point represents the mean PCR of 6 trials, while the error bars represent the range. For clarity, the data points, especially the "truth" dataset, are slightly staggered in the X-axis direction.

#### **FINDINGS**

- $\triangleright$  Monochrome images ( $\Delta E_{00}$ =42.74) have near zero PCR (0.91%) in high consensus.
- $\succ$  Truth images ( $\Delta E_{00}=0$ ) were not perfectly reproduced on the display and perceived as predicted by CIEDE2000 (PCR=88.77%).
- $\triangleright$  Modern WSI has  $\Delta E_{00}=10.94$  and PCR=70.35%.
- $\triangleright$  Legacy WSI has  $\Delta E_{00}=22.35$  and PCR=23.06%.
- $\triangleright$  Both PCR and  $\Delta E_{00}$  can perfectly detect legacy vs. modern WSI devices (sensitivity=specificity=100%).
- > Inter-reader variability in PCR for legacy WSI is greater than modern WSI (lower consensus).
- > Subject 1 and 4 show near linear responses. Legacy WSI was lowly scaled by subject 2 and 3.

#### CONCLUSION

The non-inferiority of color reproducibility in the modern WSI device was deduced using two quantitative methods...

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