Surgical Luminaires with Adjustable Spectrum

Kevin W Houser, PhD, PE; Jeffrey J Mundinger

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What is the Innovation?

Surgeons evaluate subtle differences in the visual appearance of internal anatomy during many surgical procedures. The quality of light provided by the surgical luminaire plays a role in providing the information necessary for accurate visual evaluations. LEDs are overtaking conventional sources—such as xenon, halogen and metal halide—because of their increased efficiency, long lifetime, and reduced heat at the surgical site. Their availability in a wide range of spectral power distributions (SPDs) permits the development of spectrally tunable surgical luminaires, where an array of LEDs with distinct SPDs can be mixed to produce a variety of spectra from a single luminaire.

One method of adjusting the spectrum of a surgical luminaire is by varying correlated color temperature (CCT). At its simplest, this is achieved by the linear combination of two types of white phosphor-converted (PC) light emitting diodes (LEDs) with individual CCTs near the extremes of the desired CCT range. A prototype surgical luminaire employing this technique was created, where PC-LEDs were proportionally blended to create four spectra defined by their CCT: 3000, 4000, 4500, and 5100 K. All conditions exhibited excellent color rendering with color fidelity indices of 92 and color gamut indices of 105 ± 2.1

The prototype surgical luminaire was employed to illuminate a large midline incision in a 200 lb pig. An experiment was designed to study surgeons': 1) perceived ability to effectively evaluate the color appearance of the pig's internal anatomy under each spectrum, and 2) interest in using a variable CCT surgical luminaire if it were available. An overarching objective of this study was to understand the promise of this technology. That is, just because LEDs make it possible to create a variable CCT surgical luminaire, is it worthwhile?

What are the Key Advantages Over Existing Approaches?

The light spectrum from LEDs can be engineered to enhance the color difference between a small set of tissues with well-defined spectral reflectance functions of clinical interest.²⁻⁴ LEDs have been employed for contrast enhancement in endoscopy.⁵⁻⁷ The spectrum of a surgical luminaire affects color discrimination and contributes to the accurate diagnosis of tissue abnormalities. While it is impractical to create an adjustable spectrum surgical luminaire with conventional light sources, it is practical with LEDs. Indeed, commercially available products already exist. However, and despite commercialization efforts, we are unaware of any studies that support or refute the clinical efficacy of variable CCT surgical luminaires for open surgery. This study addresses that void.

Is There Evidence Supporting the Benefits of the Innovation?

A sedated 200 lb adult pig received a large midline incision, exposing five organs of interest: bladder vasculature, colon, omentum (adipose), liver, and xyphoid process (bone). Participants included 12 male and 4 female practicing surgeons, all practicing in the Cleveland, Ohio area and affiliated with Case Western Reserve University and the Cleveland Clinic. Surgical experience ranged from 3 to 38 years (avg. 15 years), with 11 surgical specialties represented (Bariatric, Cardiac, Cardiothoracic, Colorectal, General, Laparoscopy, Oncology, Orthopedic, Pediatric, Thoracic, Transplant). Ages ranged from 28 to 73 years (avg. 46 years) and heights ranged from 5'-1" to 6'-4" (avg. 5'-10"). Eleven surgeons wore glasses or contacts. All surgeons passed a six-plate Ishihara test for color vision abnormalities.

Surgeons were asked to evaluate the pig's internal anatomy by orally responding to questions posed by an experimenter. For each lighting condition, surgeons observed and manipulated anatomy of interest for two minutes to allow for chromatic adaptation. This was done because we were concerned with evaluations after

the visual system had adjusted to changes in illumination spectra, which are distinct from initial reactions. The pig was situated on a surgical table with a sliding top; surgeons were instructed to move the table horizontally to place organs of interest under the most concentrated light. This allowed the surgical luminaire to remain stationary and at the same vertical distance throughout the experiment, limiting variation in illuminance and shadowing. Each session closed with a demographic survey; the entire process took about 30 minutes per participant.

All four spectra were highly rated (Figure). There was no statistically significant difference between the 4000, 4500, and 5100 K spectra. The 3000 K spectrum was least effective. Participants moderately agreed that the color appearance of internal anatomy was altered by the different spectra. They were undecided whether the differences were large enough to increase risk of surgical error or influence surgical decisions. They were largely undecided as to whether they would select different spectra during a single procedure, for different procedures, or for different anatomy.

The linear mixing for variable CCT employed in this experiment did not provide obvious utility for surgeons making visual diagnoses. This is likely because all four conditions exhibited exceptional colorimetric properties; they were not specifically designed to enhance (or inhibit) the contrast of any particular internal organ. The spectrum by surgeon interaction is significant in all models where it could be estimated, suggesting that surgeons will develop individual spectral preferences.

What are the Barriers to Implementing This Innovation More Broadly?

Surgeons may be reluctant to utilize spectral tuning features until they are able to develop familiarity with the available spectra. Spectral optimization requires a thoughtfully constructed objective function, for example, enhancement of contrast between normal and cancerous colon tissue, based on spectral characterization of those tissues. Narrowly targeted spectral optimization could provide clear recommendations and encourage the adoption and use of spectrally tunable surgical luminaires.

In What Time Frame Will This Innovation Likely Be Applied Routinely?

Commercially available surgical luminaires with variable CCT already exist. Yet, they are technology-driven products created because LEDs have made it possible to vary CCT; they exist in the absence of evidence that that there is a clinical benefit to varying CCT. Indeed, the variable CCT employed in this experiment did not result in markedly different evaluations, suggesting that it is unnecessary to employ variable CCT in a surgical luminaires if the range of conditions are all designed for rendering a broad range of tissues with high color fidelity. Looking ahead, it may be more fruitful to engineer variable spectrum surgical luminaires with spectra that enhances contrast of specific tissues, which may find narrower application within specific surgical specialties. This will require further engineering development and iterations of prototype and visual evaluation by surgeons in a variety of specialties. The widespread use of such solutions is likely several years off.

ARTICLE INFORMATION

Author Affiliations: The Pennsylvania State University, Department of Architectural Engineering, University Park, Pennsylvania.

Corresponding Author: Kevin W. Houser, PhD, PE, Department of Architectural Engineering, The Pennsylvania State University, University Park, PA 16801 (<u>khouser@engr.psu.edu</u>).

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Figure. Questionnaire Excerpt and Responses from Participating Surgeons.

A. The content of the survey questions is summarized along with available responses and their scales. The first section, composed of questions 1 - 7, was repeated for each of the four spectrums. The second section, composed of questions 8 - 14, was repeated only once for each surgeon.

B. Summary of responses to questions 1 – 5. The error bars are 95% confidence intervals. Though 3000 K was rated as least effective of the four conditions, surgeons agreed that all conditions were effective.

C. Summary of responses to questions 9 – 14. The error bars are 95% confidence intervals. An average score of 3.5 indicates that the participating surgeons were undecided.

| Q# | Question | Scale | Strongly Agree | 6 | | | | |
|-----|---|---|----------------|--------|------------|--------|--------|--------|
| 1-5 | This light spectrum is very effective at allowing you to properly evaluate the color appearance of [Organ: 1. Vasculature (Aorta), 2. Colon, 3. Adipose Tissue (Omentum), 4. Liver, 5. Bone] | Strongly Disagree (1) – Strongly Agree (6) | | 5 | ł | ł | Ŧ | ł |
| 9 | There were significant differences in the color appearance of the internal anatomy under the 4 light spectrums | Strongly Disagree (1) – Strongly Agree (6) | Undecided | 4 3 | 3000 K | 4000 K | 4500 K | 5100 K |
| 10 | The color appearance differences were large enough to influence surgical decisions. For example, you can imagine a situation where internal anatomy may appear diseased under one of the 4 light spectrums, but healthy under one of the other 4 | Strongly Disagree (1) – Strongly Agree (6) | | | | Spec | trum | |

| Q# | Question | Scale | Strongly Agree, Very Likely, or | 6 | | | | | | |
|----|---|---|---|---|----|-----|-----|-----|-----|-----|
| 11 | How likely would you be to use different spec- trums for <u>different surgical procedures</u> | Very Unlikely (1) – Very Likely (6) | Unconcerned | 5 | Ţ | т | | | | |
| 12 | How likely would you be to use different spec- trums during a <u>single surgical procedure</u> | Very Unlikely (1) – Very Likely (6) | Undecided | 4 | | | | | | |
| 13 | How likely would you be to use different spec- trums for <u>different internal anatomy</u> | Very Unlikely (1) – Very Likely (6) | Strongly Disagree, Very Unlikely, or Very Concerned | | | | | 1 | | |
| | | | | 1 | Q9 | Q10 | Q11 | Q12 | Q13 | Q14 |
| 14 | With an adjustable color lighthead, are you concerned about increased risk of surgical errors since different light spectra can alter the color appearance of internal anatomy | Very Concerned (1) – Unconcerned (6) | | | | | | | | |

