

Intraoperative Nerve Identification with Fluorescein Sodium

Statistical Analysis Plan

NCT06054178

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Statistical Analysis

Images containing the facial nerve and nerves of interest will be captured using a custom imaging system approved by the Stanford IRB and Zeiss Yellow 560 (YE560) filter. An additional white light color image will be obtained by a separate camera in the same position as the Zeiss microscope or custom imaging system.

Images were post-processed utilizing Python 3 and Fiji distribution of ImageJ. For all images, 5 or 10 dark frames were acquired for each exposure time and averaged. These averaged dark frames were then used to subtract the dark current from each experimental image. Images were then further corrected for exposure time to yield units in counts/s. The displayed linear contrast on each image was optimized and adjusted in Fiji.

Weber values for the fluorescence nerve images were calculated to define contrast with the following:

$$\frac{I_s - I_b}{I_b}$$

where I_s represents the specified region of interest while I_b represents the region of background.

Average dose of IV sodium fluorescein administered by weight (mg/kg) and average time to imaging after dose administration will also be monitored. Facial nerves when in the surgical field and visualized by imaging will be simultaneously validated with electrostimulation/EMG (Medtronic). The surgeons will respond from a scale from the choices of (1) no correlation, (2) some correlation, (3) good correlation, (4) excellent correlation.