

Clinical Comparison of Length of Cataract Procedures With Zeiss Lumera Versus Older Zeiss Microscope

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Statistical Analysis Plan

Version 2

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Study Protocol

Purpose and Relevant Scientific Background

To evaluate the operating times and surgical efficiencies of two different operating microscopes Leica StativS3B, Leica Microsystems, Wetzlar, Germany and OPMI Lumera T with Callisto software (Carl Zeiss Meditec, Inc., Dublin, CA) for uncomplicated cataract surgery at a single center. Both systems contain apochromatic optics, Schott-style glass and focused beams aligned with the microscope oculars. Lumera provides a xenon illumination source while Leica utilizes halogen as its illumination source. Xenon illumination sources generally provide greater brightness of illumination.

Methods

This was a retrospective review of surgical charts by two experienced high volume surgeons looking at total surgical times recorded in the chart. Traumatic and complicated cataract cases were excluded. Two focused beam microscopes were assessed.

Design: this was a single site prospective trial

1. Data Source

Data will be collected from procedures performed by two experienced cataract surgeons in a single surgery site specifically evaluating surgical times with two different microscopes in uncomplicated phacoemulsification procedures.

2. Analysis objectives

Data will be analyzed to evaluate whether one microscope may give an surgical efficiency advantage over the other. Both microscopes utilize apochromatic optics, Schott-style glass and focused beams aligned with microscope oculars. Lumera utilizes a xenon illumination source and Leica utilizes halogen as the illumination source.

3. Populations

Sequential patients undergoing uncomplicated phacoemulsification.

4. Endpoints

The primary endpoint will be operating time in minutes.

5. Statistical analysis plan

The data will be analyzed for mean time per procedure and standard deviations.