

To Whom It May Concern:

Please find this letter to be a formal request for research grant monies to Toyos Clinic. We are proposing a study comparing retrospective data for length of cataract procedures with an older Zeiss microscope compared to length of cataract procedure with prospective data utilizing the Zeiss Lumera microscope with Callisto software.

We are requesting a research grant of 50,000 to initiate and complete research on the time savings and improvement in operating room efficiencies during cataract surgery with the use of the new Lumera operating microscope versus an older Zeiss model operating scope. This study will utilize retrospective operating room data for the older model arm and prospective data on the Lumera arm. Two surgeons with two operating techniques (above the bag chop and stop and in the bag quadrant removal) will provide 25 cases for each arm (100 cases total) to show improved operating room efficiencies due to enhanced visualization and improved ease of surgery. Complication rates will also be compared with the expectation that fewer complications and better outcomes will be seen in the Lumera groups due to the improved retroillumination. A subgroup of toric lenses will be evaluated for improvement in visual outcomes due to markerless toric alignment provided by the Cataract Suite.

The Lumera microscope will be used for all prospective data collection and the Cataract Suite will be utilized for prospective toric analyses.

The research funds will be used to obtain and maintain IRB approval and oversight, data collection, study coordinator fees, statistical analyses and abstract and/or paper creation, submission and publication at the end of the project. Placement of abstract and/or paper will be discussed with appropriate Zeiss representatives for optimal delivery to target audiences.

Best regards,
Melissa Toyos

Zeiss Lumera Study Proposal

This study proposal will highlight the advanced technology features of the Zeiss Lumera surgical operating microscope which include but are not limited to:

- Stereo Coaxial Illumination for improved visualization
- High resolution video screen/co-observation tool to help OR staff anticipate next steps
- Integrated toric alignment tool
- Surgical microscope touch screen
- Cordless foot control for faster turnover between cases

All of these advanced features should translate into operating room efficiencies and fewer complications even in experienced surgical hands. At the time of this writing, there is no currently registered study with Clinicaltrials.gov studying improvement in surgical outcomes or operating room efficiencies when compared to older microscope technology. Both patients and surgeons will benefit from information outlining improvement to safety, efficiency and outcomes related to technologic advancements in operating microscopes.

Study size will be 100 patients total. Two surgeons with different cataract removal techniques will compare procedure times, total operating room time, visual outcomes and a separate analysis of toric outcomes. Each surgeon will provide retrospective data for 25 cases with an older Zeiss operating microscope and 25 cases prospectively with the new Lumera microscope. Patients will be followed for a normal 6 week postoperative period.

Milestones will include

- Study startup
- First patient first visit
- Data on 50 retrospective cases
- Last patient last visit
- Abstract creation
- Possible paper publication

Study design will be a mix of retrospective (older Zeiss microscope previously in use at our surgery center) and prospective data collection with the Lumera and Callisto software.

The Lumera and Callisto software system will be used for all cataract surgeries including toric analyses and lens placement.

Needs Assessment

Research on this topic is needed as over 3 million cataract surgeries are performed in the United States each year. The number of surgeries performed is growing as baby boomers age. Reimbursements continue to decline, necessitating ever improving operating and surgical efficiencies in the operating room setting for physicians and small business owners to remain financially viable. New governmental regulations dictate that physician payments will be related to patient satisfaction and outcomes which may be better provided by newer and better surgical technologies.

The Lumera operating microscope and Callisto software system provide several features that may enhance operating room flow including HD video screen and co-observant microscopes that can be independently adjusted to help operating room staff anticipate the needs of the surgeon. Enhanced retroillumination would be expected to translate into fewer complications and more confidence during surgery which could lead to less operating time, phaco energy used and improved visual outcomes. The toric alignment assistance device may lead to more accurate toric placement and improved visual outcomes after surgery.

Target audience would include all cataract surgeons both high and lower volume.

There is currently a dearth of published literature on this technology and its benefits in routine cataract surgery.¹² There are no registered similar trials on Clinicaltrials.gov³⁴

¹ Pahuja, N, Shetty R, Jayadev C, Nuijits r, Hedge B, Arora V, "Intraoperative Optical Coherence Tomography Using the RESCAN 700: Preliminary Results in Collagen Crosslinking," Biomed Res Int 2015: 2015.572698 epub 2015 Apr 6

² Salvadoe-Culia B, Behlau I , Sayegh RR, Stacy RC, Dohlman CH, Delori F, "Very low risk of light-induced retinal damage during Boston keratoprosthesis surgery: a rabbit study, Cornea, 2014 Feb 33(2) : 184-190

³ Corneal Transplantation Guided by OCT RESCAN – sponsored by Federal University of Sao Paulo; not yet recruiting

⁴ Optical Coherence Tomography – RESCAN During Dissection of Macular Membranes – sponsored by Federal University of Sao Paulo; not yet recruiting

Principal Investigators

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Sub-investigators

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Schedule of Activities

Month 1

Obtain IRB approval

Create CRF

Create Informed Consent

Begin retrospective data collection

Month 2

Begin prospective data collection

Continue retrospective data collection

Month 3

Prospective data collection

Continue retrospective data collection

Month 4

Complete retrospective data collection

Prospective data collection

Month 5

Prospective data collection

Month 6

Prospective data collection

Month 7

Begin data analysis

Month 8

Complete data analysis

Complete abstract

Month 9

Submission of abstract

Consideration of paper

Month 10

Begin paper if appropriate

Month 11

Complete paper

Begin submission process

Month 12
Paper publication

