INVESTIGATOR-INITIATED STUDY PROPOSAL

A Prospective Evaluation of Tissue Sealant to Prevent Epithelial Ingrowth in Repeat LASIK Surgery

The following is an investigator initiated study proposal to evaluate the relative effectiveness of the ReSure® Sealant at preventing epithelial ingrowth after LASIK flap re-lift.

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Introduction

It is well-known that a small percentage of patients will have epithelial ingrowth after primary LASIK and that preoperative refractive error is a correlated factor.[1] The effects of that ingrowth can be glare and halos; ingrowth is a significant cause of dissatisfaction after LASIK.[2] The incidence of epithelial ingrowth is significantly higher after flap re-lift for treatment of residual refractive error.[3] It has been hypothesized that cell migration into the flap/cornea interface postoperatively is a primary reason for such ingrowth.[4] A sealed interface may therefore have some utility in preventing epithelial ingrowth after flap re-lift.

The following investigator-initiated study proposal is designed to determine if a lower-than-typical rate of epithelial ingrowth occurs when a LASIK flap re-lift is performed and the replaced flap is sealed with ReSure sealant.

Study specific aims: Tissue sealant has been effectively used to prevent recurrence of epithelial ingrowth under the LASIK flap. The aim of the study is to see if tissue sealant can be used to prevent epithelial ingrowth from occurring in the first place. This would allow for patients to undergo LASIK flap lift surgery with greater safety.

Unpublished data: There is no unpublished data on the prophylactic use of tissue sealant to prevent the occurrence of epithelial ingrowth under the flap. It has been used successfully to prevent recurrence of epithelial ingrowth under the flap.

Study design and data analysis

The study will be designed as a single-arm prospective trial involving 25 eyes (of up to 25 subjects) who are presenting for LASIK retreatment. Sample size was calculated based on a nominal historical population rate of 25% ingrowth after re-lift, and an expected rate with ReSure of 5%, using an alpha of 0.05 and a power of 0.8; with these parameters a sample of 25 eyes should be sufficient to show the expected difference.

The study will involve 5 visits per eye, including a preoperative visit. Other visits will be the operative day, and 1 day, 1 week, 1 month and 3 month postoperative visits. The primary endpoint will be presence of epithelial ingrowth at 1 and 3 months after the retreatment.

Secondary endpoints will include change in refraction, best-corrected visual acuity and uncorrected visual acuity.

Inclusion criteria will be those patients who are presenting for LASIK flap re-lift and re-ablation after initial LASIK surgery. If a surgery occurs where there are intra-operative or immediate post-operative complications unrelated to the sealant the subject may be excluded from the analysis and replaced with an alternate. The data for that patient will be retained and the affected patient will be followed to monitor for adverse events, but their outcomes data would not be included in any aggregate analysis. At each visit subjects will be monitored for adverse events, whether related to the protocol regimen or not.

Significance: Late flap lift enhancements are associated with a higher rate of epithelial ingrowth under the flap margin. Many surgeons have stopped performing late flap lift LASIK enhancements and switched to PRK to avoid this complication. PRK over previous LASIK is associated with a prolonged visual recovery and short term ocular discomfort. If the tissue sealant is effective at preventing or lowering the rate of epithelial ingrowth under the flap, then late LASIK flap lift treatments could be offered with greater safety. This would benefit patients.

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