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Structured Abstract (250 words) DRAFT: 12/5/00 551 words in this draft

Purpose: Regression of refractive error after LASIK surgery is a known complication for a certain number of patients. Generally a second surgery is necessary for which FDA states it has no data to support the efficacy or safety of such surgery. There is an indication from the literature and FDA that certain pre-existing conditions such as dry eye require caution or are contraindications for LASIK surgery. Do pre-existing conditions of tear chemistry in asymptomatic patients correlate with the success or failure of LASIK surgery? Specifically, this study was undertaken to evaluate whether pre-existing (pre-surgical) lactoferrin tear protein concentration levels are correlated with 90-day post-surgical LASIK refractive outcomes.

Setting: This study took place at LASIK eye centers associated with Duke University and John's Hopkins University. (NEED specific names here).

Methods: Thirty-two asymptomatic patients with no prior LASIK surgery were evaluated and accepted for LASIK surgery based on the routine examination and acceptance/rejection policy of the facility. Excluded were patients with punctal occlusion before surgery, patients with punctal occlusion within 30 days of surgery, patients with any prior LASIK surgery, and patients with greater than –6.75D pre-operatively. Pre-operative sphero-cylinder refraction was recorded. All were asymptomatic. A pre-surgical tear sample of 0.5 μL was collected and tested for tear lactoferrin concentration levels using the Touch Tear MicroAssay System: an FDA approved rapid (5 minute), in office ophthalmic diagnostic, computer controlled system which controls for sample validity. The practitioner and the technician at the facility were blinded to the result. The result was not factored into the LASIK procedure protocol. The surgery was performed and the sphero-cylinder refraction at 90 days was performed and recorded. Data were analyzed using SAS 8.0 and S-Plus 2000 Professional Edition for Windows, Release 2. Linear fixed effect and random effect models were fit using SAS PROCs, GLM and MIXED, respectively, and generalized additive models were fit using S-Plus.

Results: Linear models including pre-LASIK refraction and lactoferrin as covariates showed the pre-LASIK refraction was not a significant predictor ($p=0.437$ and $p=0.167$ for random and fixed effect models respectively. Location of procedure was not a significant predictor ($p=0.777$ and $p=0.870$) for random and fixed effect models. A model using only lactoferrin as a predictor showed lactoferrin was found to be significant ($p=0.015$ and $p<0.001$) for random and fixed effect models respectively. Test for a loess smoother and other fitted curves showed the non-parametric effects were not statistically significant ($p=0.262$) implying that a linear fit is adequate for these data.

Conclusion: Pre-LASIK lactoferrin is a statistically significant predictor of post-LASIK refraction. A low lactoferrin level is associated with myopic outcomes and high lactoferrin levels are associated with hyperopic outcomes. The relationship is linear with normal LASIK outcomes being associated with the previously determined normal range of lactoferrin concentration levels. The implications for use of quantified tear lactoferrin levels as part of the pre-LASIK evaluation procedure are significant to the conscientious LASIK surgeon. It is not clear whether lactoferrin plays a causative role or is a marker for other factors at work in the tear film of patients presenting for LASIK surgery. Further study of this question is warranted.