Identifiers: NCT04076072 Unique Protocol ID: 190728

Brief Title: High-speed Beveled Tip Versus Standard Tip Vitrectomy Probe: a Prospective Randomized Clinical Trial

Document Date: April 8, 2022
Statistical Analysis Plan

Objectives/Endpoints

IIT# 46218371 [Patel] High-speed beveled tip versus standard tip vitrectomy probe: a prospective randomized

Primary Objective:

- Intraoperative efficiency of vitrectomy surgery regarding time to completion of core vitrectomy and shave of vitreous base

Tissue-staining dyes will be used to visualize vitreous intraoperatively. These dyes aid in confirming completion of core vitrectomy and completion of vitreous shave. These factors will rely upon the judgement of the surgeon.

Exploratory Objective:

- Intraoperative complications (e.g. iatrogenic retinal breaks, intraocular bleeding, retinal detachment)

Postoperative complications

The study will not be sufficiently powered to assess safety. Surgeons will want to make sure there is no significant increase in complications with a different probe. However, any post operative complications would merely be an association, without any causality attributed.

Primary Endpoint:

A clinically significant difference between the two groups with 80% power at a 95% confidence interval.

A p-value of less than 0.05 will be deemed as statistically significant.

Patient Selection Criteria

IIT# 46218371 [Patel] High-speed beveled tip versus standard tip vitrectomy probe: a prospective randomized

Inclusion Criteria	Exclusion Criteria
1. Adult (>18 years) 2. Presence of pathology requiring vitreoretinal surgery • Vitreous opacities • Vitreous hemorrhage • Vitreomacular traction • Macular hole • Epiretinal membrane 3. Subjects without previous history of retinal surgery 4. Ability to consent to procedure	1. Subjects with previous incisional intraocular surgery other than uncomplicated cataract surgery with IOL placement 2. Inability to consent for procedure

Sample Size

IIT# 46218371 [Patel] High-speed beveled tip versus standard tip vitrectomy probe: a prospective randomized

Sample Size:

Target: 40 participants (20 in each cohort)

Assuming an average core vitrectomy time of 12 +/- 3 minutes, a sample size of at least 32 is needed to adequately assess for a clinically significant difference between the two groups with 80% power at a 95% confidence interval. A p-value of less than 0.05 will be deemed as statistically significant.