Identifiers: NCT04076072 Unique Protocol ID: 190728

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

Document Date: Document Date: March 1, 2019
Study Protocol

Contact Information

*First Name	Shriji
*Last Name	Patel
Address	2311 Pierce Avenue
City	Nashville
State	Tennessee
Zip	37232
*Telephone	2019256754
*E-mail Address	Shriji.patel@vanderbilt.edu
*Country	United States

Organization/Institution Information

*Organization/Institution Name	Vanderbilt University Medical Center

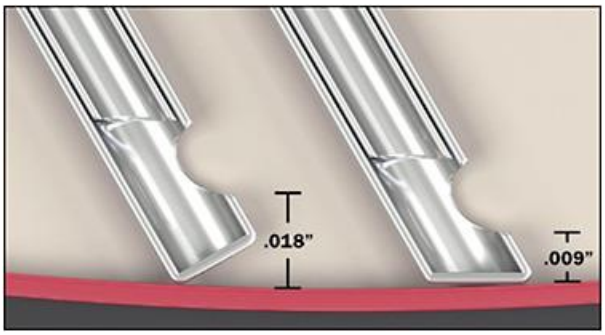
Proposal Summary

*What type of study is your request?	Clinical Study
*Therapeutic Area	Surgical
Surgical Area	Retina
*Proposal Title	Comparison of beveled-tip vs. standard-tip vitrectomy probe
*Preferred submission option	

Proposal Summary

High-speed beveled tip versus standard tip vitrectomy probe: a prospective randomized clinical trial

Background
The Advanced Ultravit High-Speed Beveled Probe (Alcon) has a beveled-tip design that allows the cutting port to come closer to the retina compared to the previous vitrector probe design. This allows the surgeon to maneuver in tight tissue planes and increases the functionality of the vitrector probe. This in combination with the increased cut rate of 10,000 independent cuts per minute reduces traction on the retina and increases efficiency of vitreous removal.



Purpose
-Compare the efficiency and safety of the new Utravit High-Speed Beveled Probe compared to the current standard vitrector probe.

Primary objectives:
-Time to completion of core vitrectomy
-Time to completion of shave of vitreous base

Secondary objectives:
-Intraoperative complications (e.g. iatrogenic retinal breaks, intraocular bleeding, retinal detachment)
-Postoperative complications

Enrollment Period:
9 months

Study Duration:
12 months

Sample Size Calculation
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.

Study Design:
This is a prospective, randomized controlled trial comparing the efficiency and safety of the Ultravit High-Speed Beveled Probe with the current Alcon vitrector probe in a cohort of patients undergoing routine vitrectomy surgery.

Inclusion criteria:
The study population will be male and female patients 18 years old or older with the presence of pathology requiring vitreoretinal surgery (vitreous opacities, vitreous hemorrhage, vitreomacular traction, macular hole, epiretinal membrane) without previous history of vitreoretinal surgery.

Written informed consent must be obtained before any enrollment in the study

Exclusion criteria:
-Previous incisional intraocular surgery other than uncomplicated cataract surgery with intraocular lens placement
-Inability to consent for procedure

Procedures and Assessments:
All patients will undergo baseline testing in the study eye including:
-BCVA
-intraocular pressure
-slit-lamp examination
-360 degree indirect ophthalmoscopy

Methods:
On the day of surgery, patients will be randomized to the Ultravit High-Speed Beveled Probe or the current non-beveled Alcon Probe. All patients will undergo routine vitrectomy surgery as scheduled; patients will be masked to the vitrector probe used. Time to completion of vitrectomy and time to completion of vitreous base shave will be recorded by a masked timer.

All examination will be repeated as regularly scheduled postoperative visits by a masked reader. Safety will be assessed at each visit by evaluation for any adverse events.