Investigator Initiated Trial Proposal – Acrysof™ IQ Vivity™ Toric

Date: 24/12/21

Title: Visual outcomes following implantation of the Acrysof ™ IQ Vivity™ Toric Extended Vision Intraocular Lens

Setting: LEC Eye Centre, Ipoh, Malaysia

Background: The Acrysof™ IQ Vivity™ is a new non-diffractive, UV-absorbing and blue light filtering hydrophobic aspheric intraocular lens (IOL) which has been reported to provide an extended range of vision from distance to near with a low incidence of visual disturbances. The toric version also compensates for corneal astigmatism.

Objective: The primary objective of this study is to evaluate the clinical outcomes following implantation of the Acrysof™ IQ Vivity™ Toric Extended Vision IOL. Secondary objectives will include level of spectacle independence as well as the tolerance to residual astigmatism or refractive error.

Design: This is a single-centre prospective interventional study of patients with significant cataract and subsequent bilateral implantations of the Acrysof™ IQ Vivity™ Toric Extended Vision IOL. All eyes will have a refractive target of emmetropia with the IOL power which provides the first myopic target closest to emmetropia selected for implantation. Visual outcomes will be assessed up to 3 months after surgery. Target sample size will be 60 eyes of 30 patients.

Primary outcome measures at 3 months:

1. Binocular uncorrected distance, intermediate (66cm) and near (40cm) acuities. Visual acuity scores will be converted to logMAR for analysis.
2. VF-14 Quality of Life questionnaire
3. Questionnaire for Visual Disturbance (QUVID)

Secondary outcome measures:

1. Uncorrected distance, intermediate (66cm) and near (40cm) acuities
2. Best corrected distance acuity, distance corrected intermediate acuity and distance corrected near acuity
3. Monocular and Binocular Defocus Curve
4. Refractive predictability and stability
5. Rotational stability of IOL
6. Vector analysis of astigmatic correction
7. Mesopic and photopic Contrast Sensitivity with CSV 1000

Inclusion Criteria:

- Patients with visually significant cataracts in both eyes and significant pre-existing corneal astigmatism (as determined by the Barrett Toric Calculator) planned for phacoemulsification and implantation of Acrysof™ IQ Vivity™ Toric Extended Vision IOL
- Patients aged 18 years or older

Exclusion Criteria:

- Eyes with other ocular pathology which may significantly impact visual acuity (e.g. moderate to advanced age related macular degeneration, centre-involving diabetic maculopathy, moderate to advanced glaucoma, keratoconus, corneal dystrophy, etc)
- Eyes with amblyopia or strabismus
- Eyes with pre-existing zonular weakness or capsular compromise
- Eyes with intraoperative capsular rupture

- Eyes which had previously undergone refractive surgery

Study Plan: Study procedures will be conducted prospectively and results entered into a database created for the purpose of this study.

Schedule of Visits:

Procedure	Preop	Day 0	POD 1	POD 7	POD 1m	POD 3m
Demographics	√					
Medical/Ocular History	√					
Manifest Refraction	√			√	√	√
UCVA	√		√	√	√	√
BCVA	√			√	√	√
Slit lamp examination	√		√	√	√	√
Dilated fundus examination	√				√	√
Biometry	√					
IOL position				√	√	
VF-14						√
Contrast Sensitivity						√
QUVID					√	√
Adverse Events		√	√	√	√	√

Data Analysis: Descriptive statistics will be computed using Microsoft Excel and astigmatic analysis will be done using the ASSORT calculator.

Timeline and publication plan:

Items	Estimated timelines
IRB Submission	July 2021
Contracting	October 2021
First Patient First Visit	October 2021
Last Patient Last Visit	March 2022
Data Processing and Analysis	April 2022
Final Report	May 2022
Publication plans	3rd quarter 2022
Presentation plans	APACRS 2022, ESCRS 2022, AAO 2022, ASCRS 2023, APAO 2023