Distance And Intermediate Visual Acuity After Phacoemulsification Using A New Generation Monofocal Intraocular Lens Compared To Standard Monofocal Intraocular Lens

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Cairo University

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Faculty of Medicine, Cairo University Postgraduate Research Protocol Template

1. Study

a- Proposed Study Title: Distance And Intermediate Visual Acuity After Phacoemulsification Using A New Generation Monofocal Intraocular Lens Compared To Standard Monofocal Intraocular Lens .
b- Degree : Masters of ophthalmology.
c- Date of Registration of MSc or MD: October 2019.

3. Scientific committee approval

(Was it scientifically approved by the department?) Yes

Date of approval:

4. Background and Rationale:

Cataract surgery is the most commonly performed surgery of the eye and monofocal intraocular lenses are the most widely used intraocular lenses. With the aspheric technology using the aspheric intraocular lenses like TECNIS 1-piece (Johnson & Johnson Vision, Santa Ana, CA, USA) can provide negative spherical aberration and results in better contrast sensitivity and visual quality [(1), (2)].

Standard monofocal lenses only allow the patient's vision to focus at one distance (i.e. distance or near), thus patients receiving monofocals often require glasses after surgery to improve their near and/or intermediate vision.

Multifocal lenses are designed to split incident light into two or more points of focus, but these lenses are limited by the demands of minimizing optical aberration and balancing the focused and out -of -focus images [(3)]

Multifocal IOLs are diffractive IOLS and are known for dysphotopsia (including glare and halos) that can negatively impact the quality of vision [(4)].

In contrast to monofocal and multifocal IOLs, EDOF lenses e.g Symphony IOL (Johnson & Johnson Vision, Santa Ana, CA, USA) are IOLs that provide an extended range of focus above a defined functional visual acuity threshold to provide useful distance and intermediate vision.
Therefore, EDOF lenses should provide functional vision over a range of distances while ideally reducing the incidence of "bothersome" halos or glare which offer advantages to accommodate the patient's lifestyle [5].

The new Tecnis® Eyhance IOL (model ICB00, Johnson & Johnson Vision, Santa Ana, CA, USA), It is claimed to be an effective option for patients regarding better intermediate visual acuities relative to the standard monofocal intraocular lenses. It is a refractive modified monofocal lens with 0.50 D of additional power in its central 2-mm zone featuring a continuous change in power from the periphery to the center of the lens, creating a unique anterior surface that improves intermediate vision, maintains distance image quality comparable to aspheric monofocal IOLs, with similar profile of photic phenomenon and keeps on reducing spherical aberration close to zero [6].

Considering the marginal price difference between the new Eyhance lens and the Tecnis monofocal aspheric lens, and the potential additional benefits of improving the intermediate distance vision while preserving the optical quality and minimal photic phenomena [7], we believe that proper study of the outcomes of using this lens could influence our choice of monofocal intraocular lenses in cataract patients. Hence, the objective of the study is to evaluate the distance, intermediate visual acuities, assess contrast sensitivity and photic phenomena, in patients undergoing cataract extraction with implantation of Tecnis® Eyhance (model ICB00, Johnson & Johnson Vision, Santa Ana, CA, USA) or Tecnis® 1-piece (model ZCB00, Johnson & Johnson Vision, Santa Ana, CA, USA) [8], [9].

5. Objectives:

1- Comparison of uncorrected and best corrected distance and intermediate vision in patients whom implanted with monofocal TECNIS Eyhance ((model ICB00) or TECNIS 1-piece (model ZCB00) IOLs after phacoemulsification.

2- Evaluation of contrast sensitivity between the two patient groups.
3- Evaluation of photic phenomena.

6. Study Design:

- Descriptive: - Survey (cross sectional) ☐
  - Qualitative ☐
- Analytic: - Observational: - Case-control study ☐
  - Cross sectional analytic study ☐
  - Cohort (Longitudinal) study ☐
  - Experimental: - Randomized Clinical Trial ☐ Phase:
  - Non-randomized clinical trial ■
  - Animal study ☐
  - Cellular study ☐
- Others: Please describe: **Prospective case series**

7. Study Methods

- **Population of study:**

Patients undergoing cataract surgery and implantation of monofocal intraocular lens Tecnis® Eyhance 1-piece
Or Tecnis® 1-piece

- **Study location:**

Kasr Alainy & Eyecare center, Maadi, Cairo.(ETDRS chart, Pelli Robson illuminated chart, OPD scan being not available at Kasr Alainy hospitals).

- **Inclusion criteria:**

– Patients aged more than 50-75 years old undergoing cataract surgery.
– Preoperative corneal astigmatism equal to or less than 0.75 D.

- **Exclusion criteria:**

– Other ocular comorbidities such as glaucoma, corneal opacities, chronic or recurrent anterior uveitis, diabetic retinopathy, age -related macular degeneration.
– Previous ocular surgeries.
– Undergoing combined surgeries.

Methodology in details:

40 eyes of 20 patients will be included in this prospective study. The Tecnis® Eyhance IOL will be implanted in 20 eyes of 10 patients (group 1), and 20 eyes of 10 patients will be implanted with Tecnis® 1-piece (group 2).

Preoperative assessment:

All selected patients will receive thorough explanation of the study design and aims, and an informed consent will be obtained from all patients.

Eyes before intervention will be subjected to:

- Measurement of uncorrected and best-corrected distance visual acuity using ETDRS chart.
- Slit lamp examination.
- Measurement of intraocular pressure using applantation tonometer.
- Dilated fundus examination using binocular indirect slit lamp biomicroscopy.
- Specular microscopy .

- Optical biometry using (IOLMaster 500; Carl Zeiss Meditec AG, Jena, Germany) and using online Barrett's universal formula. With target refraction of 0 or +0.25 D in the Eyehance group While in the Tecnis group the dominant eye will be aimed at 0 D and the non-dominat eye for -0.5 D.

Surgical intervention:

Surgery will be performed under topical anaesthesia using topical Benoxinate or local anaesthesia using peribulbar Lidocaine injection.

- Speculum used to maintain lids open.
- Clear corneal incision placed superotemporally using 2.2 mm keratome and paracenteses are placed using 15 superblade at 90 degrees to the main wound.
- Followed by formation of anterior chamber using Ophthalmic Viscoelastic Device (hydroxypropyl methylcellulose).
- Continuous curvilinear capsulorrhexis is created using straight sharp tipped Uttrata's capsulorrhexis forceps aiming at 5 mm size.
- Phacoemulsification of nucleus
- Bimanual irrigation and aspiration of cortical material.
- Injection of Ophthalmic Viscoelastic Device to form anterior chamber and inflate the capsular bag.
- Implantation of Eyhance or Tecnis® 1-piece intraocular lens in capsular bag.
- Irrigation and aspiration of Ophthalmic Viscoelastic Device.
- Injection of intracameral moxifloxacin in the capsular bag and hydration of self-sealing clear corneal incisions.

Post-operative:

All patients will receive a topical antibiotic (moxifloxacin) and steroids (Prednisolone acetate) eyedrops in a slow tapering course over 4 weeks.

Follow up:

All patients will be examined at day 1, 1 week and 1 month and 3 months postoperative.

At three months follow up all patients will be evaluated regarding:

- Corrected and uncorrected distance (at 6 meters) and intermediate (at 66cm) vision both uniocular and binocular.
- Photopic contrast sensitivity using Pelli Robson chart illuminated chart with controlled ambient illumination
- Mean binocular defocus results will be measured and defocus curves of the two lenses will be created.
- A questionnaire to evaluate the photic phenomena and spectacle independence will be explained and filled by the patients.

Distance visual acuities will be examined by ETDRS chart and intermediate and near visual acuity by Jaeger chart at 66 cm and 33 cm respectively
Measured values of the visual acuity will be expressed in decimal values and will be converted to logMAR values.

- **Intervention:**

■ Diagnostic intervention (please describe):

■ Therapeutic intervention (please describe): phacoemulsification, Eyhance IOL or TECNIS 1-piece IOL implantation.

☐ No intervention

Both diagnostic and therapeutic.

- **Does the research involve?**

■ Human participants

☐

Biological samples/Tissues

☐ Identifiable private data/Information

- **Type of consent of study participants:**

■ Written consent

☐ Oral consent

☐ No consent needed (Please justify)

- **Potential risks:**
(Please mention all risks involved even mild ones as pain, discomfort, chance of infection or psychological effects)

1- Risks related to surgical intervention including corneal oedema, infection, retinal detachment, hemorrhage, IOL displacement, elevated intraocular pressure, optic atrophy,
2- Risks related to intraocular lens including photic phenomena as halos and glare.

- **Confidentiality of data:** will be maintained in a secure file with the investigators.

9- Study outcomes:

- **Primary outcomes** (Most important measurable outcomes)

Uncorrected and best-corrected distance, and intermediate visual acuity.

- **Secondary outcome parameters** (other outcomes to be assessed)

1) contrast sensitivity.
2) Photic phenomena.
3) Spectacle independence.

10- Sample size (number of study subjects included and justification including the clinical and statistical assumptions supporting sample size calculation)

With a sample size of 18 (9/group), we will have a power of 95% to assess whether the mean logMAR For UIVA is significantly lower in the new monofocal IOL (~0.16 +/-0.06) compared to the standard monofocal IOL with a mean logMAR for UIVA Of ~0.27 (0.06), using a 2 samples means test and a significance level of 0.05

11- Statistical analysis (Please describe your data analysis plan)

Statistical plan

Summary statistics will be done, categorical variables would be presented as frequency and percentages and numerical ones as mean (SD) or median (IQR) as appropriate.

Comparison between the two groups will be done using the Students t test or the Wilcoxon rank sign test according to data normality. The Chi squared test will be used to compare categorical variables. $P<0.05$ will be considered significant. STATA 15.1 will be used for the analysis.

12- Source of funding: (Please include source of funding even if self funding)

- Faculty of Medicine, Cairo University ☐

- Other sources:

  Please specify: self funding

13- Time plan:

- When to start?
  Just after thesis registration

- When expected to finish?
  within 6 months or as soon as number of participants has been reached.

- When to publish? As soon as results are available.

14- References:

1. Jafarinasab, M. R., Feizi, S., Baghi, A. R., Ziaie, H., & Yaseri, M. (2010). Aspheric versus spherical posterior chamber intraocular lenses. *Journal of ophthalmic & vision research*, *5*(4), 217.

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4. Sheppard, A. L., Shah, S., Bhatt, U., Bhogal, G., & Wolffsohn, J. S. (2013). Visual outcomes and subjective experience after bilateral implantation of a new diffractive trifocal intraocular lens. *Journal of Cataract & Refractive Surgery*, *39*(3), 343-349.

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6. Tognetto, D., Cecchini, P., Giglio, R., & Turco, G. (2020). Surface profiles of new-generation IOLs with improved intermediate vision. *Journal of Cataract & Refractive Surgery*, *46*(6), 902-906.

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9. Mencucci, R., Cennamo, M., Venturi, D., Vignapiano, R., & Favuzza, E. (2020). Visual outcome, optical quality, and patient satisfaction with a new monofocal IOL, enhanced for intermediate vision: preliminary results. *Journal of Cataract & Refractive Surgery*, *46*(3), 378-387.

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