

# **Comparing Visual Outcomes after FemtoLASIK and Implantable Collamer Lens in Treatment of Myopia**

Thesis

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By

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## INTRODUCTION

Myopia known as “short sightedness” causes blurring of vision for distant objects but clearer for near objects. In myopic eyes, the light comes to a focus point before it reaches the retina. When moving closer to an object, this changes the focusing of the light and the object is then in focus on the retina and so looks clearer. Myopia depends on the length of the globe, the corneal steepness, and the lens power.

Classification of myopia:

- Mild myopia: power up to - 4.00 diopters (D)
- Moderate myopia: -4.00D to -8.00D
- High myopia: > -8.00D

ICL implantation can correct myopia, hyperopia, or astigmatism, with clinical and visual results as good as or better than laser procedures. Patients who are not suitable candidates for corneal reshaping procedures, and in whom optical correction with spectacles or contact lenses is either challenging or have poor results, can benefit from ICL surgery.

One of the problems for LASIK application for myopic patients is the risk of post-LASIK ectasia which is believed to be reduced using femto LASIK and the ability of creation of smaller flap thickness. Less high order aberrations are induced with femto LASIK compared to the conventional approach. Results in terms of contrast sensitivity, especially in high spatial frequencies, are better with femto LASIK compared to the conventional method.

This study evaluates the effect of each modality treatment on the visual outcomes in treatment moderate myopic patients. <sup>(1)</sup>

Phakic intraocular lenses (PIOLs) are generally accepted as an alternative treatment for ametropic correction among different types of refractive correction. Rapid visual recovery, high efficacy, predictability and stability of visual quality, preservation of accommodation, and reversibility are several privileges that have been attributed to PIOL implantation. <sup>(2, 3)</sup>

The Visian Implantable Collamer Lens (ICL; STAAR Surgical Co, Monrovia, California) is approved by the United States Food and Drug Administration (FDA) for the treatment of moderate to severe myopia. The lens material, trade-named Collamer, is a hydrophilic collagen-polymer combination with a water content of 34% and a refractive index of 1.45.<sup>(2)</sup>

Recently, a new ICL (V4c) , with a 360  $\mu\text{m}$  central hole that allows for the natural flow of aqueous humor without the need for a peripheral iridotomy, which may reduce the risk of anterior capsular opacification and cataract formation comparing to the old forms of ICL.<sup>(4,5)</sup> Previous studies have shown that the pupil constriction in response to light can affect the vault, eventually causing the ICL to move posteriorly towards the crystalline lens, leading to a significant decrease in central vault under photopic conditions.<sup>(4,6)</sup>

Femtosecond (FS) laser is an infrared laser with a wavelength of 1053 nm. It works by producing photo-disruption or photoionization of the optically transparent tissue such as the cornea.<sup>(1)</sup> Application of FS results in the generation of a rapidly expanding cloud of free electrons and ionized molecules. The acoustic shock wave generated results in disruption of the treated tissue.<sup>(7)</sup>

FS laser has pulse duration ranging 10 to 15 seconds. Reducing the pulse duration reduces the amount of collateral tissue damage which makes FS laser safe to be used in corneal surgeries.<sup>(8, 9)</sup>

The Wave Scan Wave Print System (Visx, Inc.) is a diagnostic instrument designed to measure and display refractive errors and wave front aberrations of the eye using a Hartmann-Shack wave front sensor. A small spot of laser light is projected onto the retina and reflects back through the pupil. The light exiting from the eye is imaged by a lens let array, and the array of spot images is captured by a video sensor. The location of each spot gathered from the video sensor is then compared to the theoretical ideal locations, and the eye's wave front aberrations are computed. The measurements with this device are centered on the center of the entrance pupil and taken without pupil dilation.<sup>(10)</sup>

Contrast sensitivity is defined as the inverse of the contrast value at threshold. Contrast sensitivity is plotted on a chart in which the x axis is the spatial frequency, and the y axis is contrast sensitivity in log scale. Spatial frequency is specified in cycles per degree (cpd), which corresponds to the spatial frequency of the sine wave grating in terms of size, using cycles per degree of visual angle as the unit. Maximal contrast sensitivity function is at 3 to 6 cpd. The curve of contrast sensitivity is bell shaped. At the high frequency end, where contrast sensitivity is lowest, 100% contrast is needed, it corresponds to visual acuity. <sup>(11)</sup>

## **AIM OF THE WORK**

This study aims to compare visual outcomes after Femto LASIK and implantable collamer lens in treatment of moderate myopia.

## SUBJECTS & METHODS

- **Type of Study:** Prospective observational study
- **Study Setting:** Magrabi Eye Hospital, Cairo, Egypt
- **Study Period:** 24 months. The patient will be assessed on interval: preoperatively, 1 month, 3 months and 6 months postoperatively.
- **Study Population:**
  - Inclusion Criteria:
    - Moderate myopia (-4D to -8D)
    - Age >18 years
    - Clear optical media
    - No ocular pathology
  - Exclusion Criteria:
    - Mild (<-4D) or high (>-8D) myopia, hyperopia
    - Patients with media opacity
    - Patients with associated ocular pathology
    - Patients with corneal topography not fitting to either treatment modalities
- **Sampling Method:** Convenience non-random sampling technique will be followed

- **Sample Size:** 120 eyes will be included in the study, and they will be divided into four groups:
  - Group 1: includes 60 eyes undergoing ICL surgery
    - Divided into two subgroups:
      - Group 1A: includes patients with simple myopia
      - Group 1B: includes patients with compound myopic astigmatism
  - Group 2: includes 60 eyes undergoing femtoLASIK surgery
    - Divided into two subgroups:
      - Group 2A: includes patients with simple myopia
      - Group 2B: includes patients with compound myopic astigmatism
- **Ethical Considerations:** This study will be conducted after the approval of the institutional ethical committee and after obtaining an informed written consent from every patient
- **Study Tools:**
  - Slit Lamp Biomicroscopy
  - Pentacam for full corneal topography profile (Oculus)
  - Wave scan J&J vision Visx for assessment of aberrations
  - PeliRobson Chart for testing of contrast sensitivity
- **Study Procedure:** Patients will be diagnosed according to:
  - Full detailed history
  - Complete clinical ophthalmological examination including visual acuity assessment with best correction, anterior segment examination, IOP measurement, fundus examination, cycloplegic refraction and contrast sensitivity testing
  - Investigations: corneal topography, aberrations screening
  - Post-operative follow up including visual acuity assessment with best correction, aberrations screening and contrast sensitivity testing on interval 1 month, 3 months and 6 months postoperatively

**Statistical Analysis & Package:** The collected data will be revised, coded, tabulated, and introduced to a PC using statistical package for social sciences (IBM SPSS 20.0). Data will be presented and suitable analysis will be done according to the type of data obtained for each parameter.

- Descriptive Statistics:

- Mean, Standard deviation ( $\pm$ SD) and range for parametric numerical data, while Median and Interquartile range (IQR) for non-parametric data
- Frequency and percentage of non-numerical data

- Analytical Statistics:

- Pearson Correlation Coefficient (r): Correlation was used as a measure of the strength of a linear association between two quantitative variables. The Pearson correlation coefficient, r, can take a range of values from +1 to -1. A value of 0 indicates that there is no association between the two variables. A value greater than 0 indicates a positive association; that is, as the value of one variable increases, so does the value of the other variable. A value less than 0 indicates a negative association; that is, as the value of one variable increases, the value of the other variable decreases
- P-value: Level of significance:
  - $P > 0.05$ : Non significant (NS)
  - $P < 0.05$ : Significant (S)
  - $P < 0.01$ : Highly significant (HS)



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