EVALUATION THE RESULTS OF PHAKIC ICL SURGERY AFTER ONE MONTH IN 23 PATIENTS AT SAIGON - CAN THO EYE HOSPITAL FROM JULY 2020 TO DECEMBER 2021

Tran Van Ket*, Mai Quoc Tung*, Le Viet Phap*

ABSTRACT

Objectives: To evaluate the results of Phakic ICL surgery after one month at Saigon Can Tho Eye Hospital. **Subjects and methods:** A retrospective descriptive study evaluated one-month results in 45 eyes of 23 patients undergoing Phakic ICL surgery with Visian Staar Lens of Staar Surgical Company, from July 2020 to December 2021. Ocular biometry was evaluated using the Anterior Chamber Depth index (ACD), the White-to-White measurement (WTW), and the Vault index. Patient satisfaction was evaluated using a visual analogue scale ranging from 0 (very dissatisfied) to 10 (very satisfied). **Results:** The pre- and postoperative equivalent sphericalness were: -9.26 ± 2.91 (-16 to -3.75) and -1.15 ± 1.06, respectively, which was statistically significant (P<0.0001). The number of incremental postoperative glassless visual rows after 1-week and 1-month surgery were 7.16 and 7.25 rows, respectively. Patient satisfaction was 96%. No postoperative complication was reported. **Conclusions:** Phakic ICL surgery is highly effectively, safely, and accurately in treatment of refractive errors, including nearsightedness and astigmatism, which results in very good vision after surgery. Patient satisfaction was very high (96%). Phakic ICL could minimize postoperative dry eyes. The techinique is simple and quick technique with simple postoperative care but requires high precision.

***Keywords**: Phakic ICL, refractive errors, cataracts.*

** Saigon - Can Tho Eye Hospital*
Responsible person: Tran Van Ket
Email: gd.ct@matsaigon.com
Date of receipt: 20/2/2023
Date of scientific judgment: 15/3/2023
Reviewed date: 22/3/2023

I. INTRODUCTION

Refractive error is a common cause of vision impairment. The global number of people with refractive error has been estimated at between one and two billion [3]. Rates vary from region to region of the world, with Europeans around 25% and Asians up to 80% [5]. Myopia is one of the most common disorders of the eye [6,7]. In 2015, an estimated 23% of the world's population was nearsighted. By 2050, this number is predicted to increase to 50% [3]. Current treatments for myopia include wearing glasses, contact lenses, temporary corneal correction with Ortho K, refractive surgery (PRK, LASIK, SMILE, etc.), Phakic surgery, crystalline lens replacement surgery.

Phakic ICL (Implantable Artificial Collamer Lens; ICL) surgery is a procedure where an artificial collamer lens is placed in the cavity of the back of the iris and front of the len to correct refractive errors, improve vision without significantly changing the structure of the eye. Phakic surgery has been approved in Europe since 1997 and got approval from the U.S. Department of Health (FDA) Food and Drug Administration in 2005 [10,13]. This method has been applied in Vietnam for about 10 years [1,2]. Although Phakic ICL could cause few complications such as anterior cataracts, ICL deviation, and a risk of myopic retinopathy [1], the procedure was painless, caused little

changes in corneal structural composition, and maintained stable intraocular pressure**.** Therefore, it was common indication for patients with moderate and high myopia [1,10,13,14].

II. STUDY SUBJECTS AND METHODS

1. Study subjects

All patients underwent treatment of refractive error using Phakic ICL at Saigon-Can Tho Eye Hospital from July 2020 and December 2021.

Inclusion criteria for Phakic ICL surgery: According to the guidelines of Staar Instrument Company, where produced the Visian ICL Staar Implantable Artificial Collamer Lens – approved by the US FDA on December 22, 2005 and supplemented on March 25, 2022 [10,13], inclusion criteria were as below:

- Age between 21 to 45 years old
- No abnormal manifestations in corneal map
- Anterior Chamber Depth (ACD) ≥ 3.0mm, Anterior Chamber Angle > grade III
- No corneal pathology
- Normal partial posterior OCT
- Sufficient corneal endothelial cells according to guidelines of Europe and the American Academy of Ophthalmology [1]
- Intraocular pressure within normal limits, i.e. ≤ 21 mmHg.

Indications for Phakic ICL surgery using the Visian ICL Staar Implantable Artificial Collamer Lens included myopia correction in patients with equivalent sphericalness from -3.0 D to -20.0 D; astigmatism correction in patients with equivalent sphericality from -3.0 D to -20.0 D and cylindrical degrees from -1.0D to - 4.0 D; with ACD of at least 3.00 mm when measured from the corneal endothelial layer to the anterior surface of the lens; history of stable refraction (-0.5 D within 1 year prior to surgery) [10,13].

Exclusion criteria:

- Younger than 21 or older than 45 years old
- ACD less than 3.0mm, Anterior Chamber Angle < grade III
- Women who were pregnant or nursing babies under 6 months old
- People with too low or abnormal endothelial cell count, or endothelial dystrophy
- People with pyramidal corneas or other corneal pathology
- People with amblyopia or blindness in one eye
- People with glaucoma
- People who have cataracts and need cataract surgery.

2. Methods

A retrospective descriptive study evaluated the results of 23 patients undergoing Phakic ICL refractive surgery at Saigon - Can Tho Eye Hospital from July 2020 to December 2021.

Biometric indicators evaluating patients' eyes before and one-month after Phakic ICL surgery, measured by tomography machines from Carl Zeiss and Heisenberg - Germany, including:

- Preoperative WTW index - diameter across the cornea from temple to nose.
- Preoperative ACD index- anterior chamber depth from the back of the cornea to the front of the lens.

- The average corneal diameter index is measured by Compa (WTW ^{C}) and the Anterion machine (WTW^{A}).

- Postoperative Vault index - distance from the back of the ICL to the front of the lens.

Pre- and postoperative vision changes using preoperative glassless and glassed vision versus postoperative glassless vision were compared at two time points: 1 week and 1 month.

Patient satisfaction was evaluated using self-assessment visual analog scale, ranging from as low as 0 point (completely dissatisfied) to 10 points (extremely satisfied), then classified into 3 groups: Very satisfied (9-10 points); Satisfied (7-8 points), and Dissatisfied (<7 points).

Data analysis was performed using SPSS 16.0 software.

III. RESULTS

From July 2020 to December 2021, Phakic ICL surgeries were performed on 45 eyes of 23 patients who were eligible for inclusion, using Staar Surgical company's Visian ICL Staar Implantable Artificial Collamer Lens [13].

Of the 23 surgical patients, male patients accounted for 65% (15/23) while female accounted for 35% (6/23). Median age of patients was 29.1 ± 5.2 years old (ranging between 21-44).

Tables 1 and 2 show the results of pre- and post-operative biometric indicators. The improvements in biometric indicators were statistically significant (P<0.001).

Table 1. Pre- and postoperative eye biometrics

Eye Biometric Index	Mean ± SD	Max	Min
WTW (preoperative)	12.01 ± 0.42	12.99	11.09
ACD (preoperative)	3.25 ± 0.21	3.62	2.91
ICL size (postoperative)	13.22 ± 0.35	13.7	12.1
Vault (postoperative)	666 ± 320	1360	127
IOL size (-) WTW	1.13 ± 0.23	1.42	0.71

The average corneal diameter measured by compa was 11.94, which allowed the surgeon to select the ICL size more accurately for the patient.

Table 2. Corneal diameter measured by compa and Anterion machine

Measurement indicators	Average	Average difference (WTW^{c} - WTW^{A})	P
Average corneal diameter measured by compa (WTW^{c})	11.9	-0.067	p<0.001
Average corneal diameter measured by Anterion Machine (WTW^{A})	12.0		

Table 3 shows the improvement of eye biometrics of 45 eyes in 23 patients through pre- and postoperative comparisons at 1-week and 1-month time points.

Pre- and postoperative equivalent sphericalness were: -9.26 ± 2.91 (-16 to -3.75) and -1.15 ± 1.06, respectively, which was statistically significant (P<0.0001), thereby reflecting very good refractive improvement. The improved cylindrical refractive index was also significant, where pre- and postoperative cylindrical refraction were -1.61 ± 1.04 (-5 to -0.5) and -0.51 ± 0.49, respectively.

Table 3. Improvement between pre- and postoperative eye biometric indicators

Eye Biometric Index	Number of eyes (n)	Mean ± SD	Max	Min
Subjective spherical degree	45	-9.26 ± -2.91	-16	-3,75
Subjective cylindrical degree	42	-1.61 ± -1.04	-5	-0,50
Axle	42	116 ± 70.25	180	5
Subjective TDC	45	-10 ± -3.5	-18,5	-4,0

Table 4 compares vision changes through direct patient evaluation.

Average preoperative glassless vision according to LogMAR improved significantly, from 1.41± 0.02 (preoperative) to 0.12 ± 0.17 (glassless 1-week after surgery) and 0.11± 0.15 (glassless 1-week after surgery). The number of incremental visual rows after 1-week and 1-month surgery were 7.16 and 7.25, respectively, but they were not statistically significant.

Table 4. Pre- and postoperative vision

	Number of eyes (n)	Mean ± SD	Max	Min
Objective vision without glasses before surgery	45	1.41 ± 0.02	0.08	0.01
Objective vision with glasses before surgery	45	0.21 ± 0.14	0.8	0.1
Objective vision without glasses 1 week after surgery	45	0.12 ± 0.17	1	0.1
Objective vision without glasses 1 month after surgery	32	0.11 ± 0.15	0.9	0.3
incremental visual rows 1 week after surgery	45	7.2 ± 1.6	9.6	0.9
incremental visual rows 1 month after surgery	32	7.3 ± 1.4	8.9	2.9

Comparision between preoperative glassless vision and postoperative glassed vision showed significant improvement, from 0.19 ± 0.30 to 0.12 ± 0.17 at 1-week and 0.11±0.15 at 1-month after surgery.

Patient satisfaction was very satisfied in 8.2% (19/23), satisfied in 14% (3/23), and dissatisfied in 4% (1/23).

IV. DISCUSSION

Saigon-Can Tho Eye Hospital is the first place to implement Phakic ICL surgery in the Mekong Delta. Although the number of patients (i.e., 23 patients) who received Phakic ICL surgery in the hospital was small, the number of Phakic ICL surgeries performed in other countries in Asia was also not high. For example, the study by Shin J.Y et al. in Korea performed Phakic surgery in 40 eyes of 24 patients with Artisan pIOL intraocular lenses, and 36 eyes of 20 patients with Artiflex lenses [9]. The number was even lower in Japan, as Kamiya et al.

reported that Phakic ICL surgeries were performed on 10 eyes of 8 patients in Japan [8]. The main reason was that, although this technique has been approved in Europe and the US for approximately 20 years, its application in clinical practice in Asia has been just emerged during the last 10 years and still limited due to lack of high-level technical human resources [4,15,8,9].

The group of 23 patients who received Phakic ICL surgery at Saigon - Can Tho Eye Hospital had similar ages to other published studies. For instance, Zhao W's study in China on 65 patients reported mean age of 26.6 ± 3.7 years, which was different but not statistically significant compared to the mean age of 23 patients in this study (29.1 ± 5.2 years) [15].

In this study, two methods of measuring average corneal diameter were combined, including (1) Compa (WTW^{C})- which is the gold standard- and (2) Anterion machine measurement (WTW^{A}). Based on the measurement results, the most suitable ICL diameter was selected for each operated patient, thereby increasing the accuracy of the Phakic ICL procedure.

The lens used for patients was the Visian Staar Implantable Artificial Collamer Lens - ICL supplied by Staar Instrument Company (USA). This type of intraocular implantable lens was manufactured from Collamer, a product based on Hydroxyethyl Methacrylate (HEMA) of pig collagen biocompatible polymeric material. The lens could be foldable and very convenient for angle adjustment, which was approved by the FDA on December 22, 2005 with the generic name: Phakic Intraocular Lens (PIOL) [10], and additional approval on March 25, 2022 [13] with commercial name: EVO/EVO+ VISIAN Implantable Lens Collamer® and (EVO ICL™) EVO/EVO+ VISIAN TORIC [13].

The additional FDA-approved expanded the indication for Visian Implantable Collamer Lens for the treatment of myopia with and without astigmatism, without preoperative peripheral iris surgery. In addition, because the Lens endophthalmic implant was manufactured from pig collagen biocompatible polymeric material, it contained an ultraviolet absorber and had a special plate-haptic plate design with a central convex/concave optical zone and incorporated a front dome to minimize lens contact with the central anterior capsule [13]. Using the Visian Implantable Collamer Lens EVO/EVO+ has took advantage of a new step in the treatment of refractive errors with STAAR's CentraFLOWTM technology, which was designed to allow fluid flow through the lens, eliminating the need for peripheral iris surgery prior to intraocular implantation.

As an angle-assisted lens, the Visian Implantable Collamer Lens was relatively easy to install and had a shorter learning curve than previous versions such as ICL and Verisyse. In addition, due to the distance from the crystalline lens, the risk of developing cataracts was minimized [13].

The power of the EVO/EVO+ spherical and toroidal lens elements was the same as the original Lens (-3.0D to -16.0D for spherical lenses and -3.0D to -16.0D spherical equivalents for cylinders, power from -1.0D to -4.0D for toric lenses). The lenses had an optical diameter that varies with the dioptric power, with the smallest optical diameter was 4.9 mm and the largest was 6.1 mm. The implantable lens was foldable and inserted it into the posterior chamber through an incision of 3.5 mm or

less [13]. The EVO/EVO+ Lenses had an orientation marking on the haptic base plate to ensure that the implanted lens is oriented properly. The lenses also were designed to be placed entirely in the posterior chamber just behind the iris and in front of the anterior capsule of the lens. When positioned correctly, the lenses functioned as a refracting element to reduce moderate to high myopia and nearsighted astigmatism [13].

The above advantages of the Visian Implantable Collamer Lens have made a significant difference compared to Phakic surgery in previous years with non-CentraFLOWTM technology and non-Bio Collamer ICLs [13].

Thanks to the use of this high-quality lens, the surgical procedure becomes much more convenient than previous non-foldable lenses and helps to accurately place the lens in the intended position, minimizing complications.

Phakic ICL surgery results on 45 eyes of 23 patients with 1-month postoperative glass-free vision index were 0.11 ± 0.15, achieving similar improvement compared to Chen X's study (2017) on 40 patients and 38 eyes (0.11 ± 0.17). Biometric indicators of spherical equivalence and cylindrical refraction were also in the range of good performance shown in Tables 5 and 6, similar to the FDA's international review (2005) [13], which indicated better improvement than Artuno's study (2014) [2] and Nguyen Thanh Thuy's study (2015) [12].

Table 5. Spherical equivalence in some studies

Study author (year)	Number of patients	Preoperative spherical equivalents	Postoperative spherical equivalents
FDA (2005)[13]	105	- 9.36 ± 2.66	0.05 ± 0.46
NT Thuy (2015)[12]	54	-14.54 ± 5.61	-1.31 ± 1.17
This study	23	-9.26 ± 2.91	-1.15 ± 1.06

Table 6. Cylindrical refraction in some studies

Study author (year)	Number of patients	Preoperative cylindrical refraction	Postoperative cylindrical refraction
Arturo (2014) [2]	175	-2.63 ± 1.44	-0.97 ± 0.89
NT Thuy (2015)[12]	54	-2.37 ± 1.43	-0.85 ± 1.17
This study	23	-1.61 ± 1.04	- 0.51 ± 0.49

The patient satisfaction index showed that only 1 in 23 patients (4%) expressed dissatisfaction. The reason for dissatisfaction was in terms of delaying ICL orders by 6 months due to the COVID-19 epidemic situation, which increased the waiting time of patient. This survey results have guided us to conduct patient satisfaction assessment research in the coming time, which should be designed to address influencing factors of patient satisfaction, including service quality, administrative procedures, or financial factors. It should also be noted that Phakic surgery is not currently included in health

insurance reimbursement list, which as can significantly affect patient satisfaction, as the cost of Phakic surgery is still a major financial challenge for the majority of people, given the per capita income per year is only about 146 million VND [11].

V. CONCLUSION

Phakic ICL surgery is highly effectively, safely, accurately in treatment of refractive errors, including nearsightedness and astigmatism, which results in very good vision after surgery because it could immediately adapt to the eye accommodation.

- Patient satisfaction was very high (96%).
- Postoperative vision is higher than wearing glasses nearly 2 rows on the vision board, increasing from 0.21 to 0.11.
- ICL is the most important solution for patients with thin corneas, high degree of nearsightedness and astigmatism, which can perform on patients with - 1 D to - 20 D of nearsightedness and up to -5 D of astigmatism.
- Minimize postoperative dry eyes.
- Simple and quick technique, simple postoperative care but requires high precision.

VI. RECOMMENDATIONS

Our study results show that Phakic ICL surgery is highly effective, safe, with very few side effects. Due to the limitation of a retrospective study and the impact of COVID-19, follow-up time was only 1 month. Therefore, it is recommended to continue monitor and evaluate Phakic ICL surgery in longer periods (6 months, 12 months, and 3 years) in order to fully assess both medium and long-term impacts on the refractive improvement of patients as well as to detect late complications if any.

At the same time, our study shows that Phakic surgery technique has been completely mastered by Vietnamese ophthalmologists. It is necessary to expand training and implement this surgery on a larger scale, in order to improve quality of life and reduce costs for patients. Besides, if possible, the health insurance reimbursement for Phakic surgery would help to control and lower the rate of refractive error in the general population.

REFERENCES

1. **American of Academy of Opthalmology (EyeWiki).** Phakic Intracular Lenses: Indications and Contradications. https://eyewiki.aao.org/Phakic_Intraocular_Lenses#Indications_and_Contraindications; Accessed 15 /03/2023
2. **Arturo GB, Martha J, Enrique OG Hernandez, Tito RL, Arturo RM, Alerjandro N (2014).** Long - term refractive outcomes of posterior chamber phakic (spheric and toric implantable collamer lens) intra ocular lens implantation. *Int Ophthalmol* 34, pp. 583-590.
3. **Brien A Holden (2016),** Global prevalence of myopia and high myopia and temporal trends from 2000 through 2050. *American Academy of Ophthalmology* 2016;123:1036-1042; http://creativecommons.org/licenses/by-nc-nd/4.0/.
4. **Chen, X., Wang, X., Xu, Y., Cheng, M., Han, T., Wang, X., & Zhou, X. (2022).** Long-term comparison of vault and complications of implantable collamer lens with and without a central hole for high myopia correction: 5 years. *Current Eye Research*, *47*(4), pp. 540-546.
5. **Denniston Alastair; Murray; Philip (2018),** Oxford Handbook of Ophthalmology (4 ed.), OUP *Oxford*, pp.926.

6. **Foster; Jiang PJ; Y (2014),** Epidemiology of myopia, Eye (*London, England).* 28(2), pp.202–208.
7. **Hassan Hashemi, Akbar Fotouhi, Abbasali Yekta, Reza Pakzad, Hadi Ostadimoghaddam , and Mehdi Khabazkhoob (2018).** Global and regional estimates of prevalence of refractive errors: Systematic review and meta-analysis. *J Curr Ophthalmol.* 2018 Mar; 30(1): 3–22. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5859285/
8. **K Kamiya, K Shimizu, A Igarashi, D Aizawa and T Ikeda (2010).** Clinical outcomes and patient satisfaction after Visian Implantable Collamer Lens removal and phacoemulsification with intraocular lens implantation in eyes with induced cataract. *Eye (2010) 24,304–309;* DOI:10.1038/eye.2009.87; published online 24 April 2009
9. **Shin, J. Y., Lee, J. B., Seo, K. Y., Kim, E. K., & Kim, I. (2013).** Comparison of Preoperative and Postoperative Ocular Biometry in Eyes with Phakic Intraocular Lens Implantations. *Yonsei Medical Journal*, *54*(5), 1259-1265. https://doi.org/10.3349/ymj.2013.54.5.1259
10. **Staar Surgical (2005)**. STAAR Surgical's VISIAN ICL(TM) Receives FDA Approval.https://www.staar.com/news/2005/staar-surgicals-visian-icltm-receives-fda-approval.
11. **General Statistics Office, Ministry of Planning & Investment (2022).** Mekong Delta: Stand firm in the face of new opportunities and new opportunities. 8/9/2022. Macroeconomic page; https://consosukien.vn/do-ng-ba-ng-song-cu-u-long-vu-ng-buoc-truoc-tho-i-co-moi-va-va-n-ho-i-moi-thang-8-2022.htm
12. **Thuy, Nguyen Thanh (2015),** Study on the long-term effects of artificial lens placement on the eyes and lens bodies for the treatment of severe myopia, Doctoral Thesis in Medicine, Hanoi Medical University.
13. **United States Food and Drug Administration (2005).** Summary of Safety and Effectiveness Data. STAAR Vision ICL (Implantable Collamer Lens). PMA: P030016.
14. **Wang, X., & Zhou, X. (2016).** Update on treating high myopia with implantable collamer lenses. *The Asia-Pacific Journal of Ophthalmology*, *5*(6), pp. 445-449.
15. **Zhao, W., Zhao, J., Han, T., Wang, J., Zhang, Z., & Zhou, X. (2022).** A comprehensive investigation of contrast sensitivity and disk halo in high myopia treated With SMILE and EVO implantable collamer lens implantation. *Translational Vision Science & Technology*, *11*(4), pp. 23-23.