· Original article ·

Clinical efficacy of Toric ICL implantation and its effect on corneal astigmatism and aberration

Gai-Ping Du[1], *Hui-Ling Guo*[2], *Jing-Jing Jiang*[2], *Li-Qiang Wang*[2]

引用:杜改萍,郭惠玲,蒋晶晶,等. Toric ICL 植入术的临床疗效以及对角膜散光和像差的影响. 国际眼科杂志 2021;21(10):1675-1679

Foundation item: The Medical Big Data Research and Development Program of the General Hospital of Chinese PLA (No.2018MBD-016)

[1]Department of Ophthalmology, No. 971 Hospital of the Chinese PLA Navy, Qingdao 266071, Shandong Province, China

[2]Department of Ophthalmology, No.1 Medical Central of the Chinese PLA General Hospital, Beijing 100853, China

Correspondence to: Li - Qiang Wang. Department of Ophthalmology, No. 1 Medical Central of the Chinese PLA General Hospital, Beijing 100853, China. liqiangw301@126.com

Received: 2021-03-29 Accepted: 2021-07-30

Toric ICL 植入术的临床疗效以及对角膜散光和像差的影响

杜改萍[1],郭惠玲[2],蒋晶晶[2],王丽强[2]

基金项目:解放军总医院医疗大数据研发项目(No.2018MBD-016)

作者单位:[1](266071)中国山东省青岛市,中国人民解放军海军第971医院眼科;[2](100853)中国北京市,中国人民解放军总医院第一医学中心眼科

作者简介:杜改萍,毕业于解放军医学院,博士后,副主任医师,研究方向:眼屈光、眼视光、角膜病、斜弱视。

通讯作者:王丽强,毕业于解放军医学院,博士后,主任医师,副主任,研究方向:角膜病、眼屈光、眼化学性伤. liqiangw301@126.com

摘要

目的:研究 Toric 植入术(ICL)的临床疗效以及对角膜散光和高阶像差(HOA)的影响。

方法:前瞻性非随机临床实验研究。共纳入57例患者102眼行 Toric ICL 植入术以矫治近视散光。分别于术前和术后6mo测量裸眼视力、最适屈光度、最佳矫治视力、最适散光度、角膜散光、高阶像差并记录。检查仪器为角膜地形图、眼前节分析系统和波前像差分析仪。

结果:术后93.80%患眼等效球镜≤-1.00D,85.30%患眼等效球镜≤-0.5D。术后66.30%患眼裸眼视力≥20/25,65.50%患眼裸眼视力≥20/20;角膜散光和高阶像差手术前后比较没有统计学意义。全眼三叶草和彗差手术前后比较差异无统计学意义。

结论:所有眼球的近视和散光得到有效矫治。角膜切口对高阶像差和散光没有影响。

关键词:Toric ICL;近视;像差;散光;角膜

Abstract

• AIM: To investigate the refractive outcomes and changes of corneal astigmatism and higher - order aberrations (HOAs) after Toric implantable Collamer lens implantation (Toric ICL).

• METHODS: Prospective nonrandomized clinical trial studies. This study included 102 eyes of 57 patients underwent Toric ICL for myopic astigmatism correction. Uncorrected visual acuity (UCVA), manifest refraction, best spectacle-corrected visual acuity (BSCVA), manifest refractive cylinder, the corneal astigmatism and HOAs were measured preoperatively and up to 6mo after surgery. The vectors were measured using corneal topography, the Pentacam HR system and Wavefront analyzer.

• RESULTS: Postoperative, the percentage of eyes had a spherical equivalent refraction within -1.00 D were 93.80%. The percentage of eyes within -0.50 D of emmetropia were 85.30%. The percentage of eyes which postoperative UCVA ≥ 20/25 was 66.30% and the percentage of eyes which postoperative UCVA ≥ 20/20 was 65.50%. The corneal astigmatism and aberrations preoperatively showed no statistical significance compared with postoperative. The total eyes aberrations and coma resulted in slight changes and had no statistically significant.

• CONCLUSION: The corneal incision of Toric ICL implantation caused no changes in astigmatism and higher-order wavefront aberrations of cornea.

• KEYWORDS: Toric implantable Collamer lens; myopia; higher-order aberration; astigmatism; cornea

DOI:10.3980/j.issn.1672-5123.2021.10.02

Citation: Du GP, Guo HL, Jiang JJ, *et al*. Clinical efficacy of Toric ICL implantation and its effect on corneal astigmatism and aberration. *Guoji Yanke Zazhi* (*Int Eye Sci*) 2021; 21(10): 1675-1679

INTRODUCTION

The Toric implantable Collamer lens (Toric ICL) is an alternative for astigmatic correction and it features a plate-haptic design with central convex/concave optical zone, and cylinder in a specified axis location as required, to

address each patient's astigmatic condition[1]. It has the same designs with ICL in shape, thickness, materials and configuration. Recently, a large number of studies have shown that ICL implantation can achieve good results in correcting myopic astigmatism[2-3]. Compared with refractive corneal surgery, Toric ICL implatation, which does not change the shape of the cornea, has been showed to successfully corrected myopia and astigmatism and relatively small risk of introducing corneal higher-order aberration (HOA)[4]. But previous studies[5] reported decreased optical quality in pseudophakic eyes, which increased HOAs (coma, trefoil, tetrafoil) generated on the cornea. The main reason for these results is the corneal incisions and optical characteristics of IOL. Long *et al*[6] reported that the placement of the incision on the steepest meridian of the cornea can be beneficial if preoperative astigmatism was ≥0.75 diopter (D). With our present data, there have been few reports of changes to HOAs after Toric ICL implantation[7], and the changes in HOAs of Toric ICL and the reasons for HOAs changes are also not explained in detail. The main purpose of this study is to evaluate the vision outcomes and the changes in corneal astigmatism and inducing HOAs after Toric ICL insertion, and to evaluate its relationship to the operation factors and optical characteristics of IOL.

SUBJECTS AND METHODS

Nonrandomized clinical trial studies included 102 eyes from 57 patients (36 females, 21 males) after Toric ICL (ICM version 4) implantation surgery performed by the same surgeon from Jun. 2015 to Jun. 2017. The average age was 28.9(range: 18-49) years. Preoperative characteristics and parameters of Toric ICL were showed in Table 1. The study was conducted in accordance with the tenets of the Declaration of Helsinki. All the participants gave their written informed consent.

Surgical Procedure To avoid postoperative pupil block, all the patients were performed 2 peripheral iridotomies at 1:00 and 11:00 in every eye two week before surgery with a neodymium: YAG laser (Lumenis, US). To prevent eye rotation in the recumbent position, the patients were marked corneal horizontal axis in sitting position by using slit-lamp before surgery.

0.5% tropicamide was used for dilating the pupil patient, made a 3.0 mm, self-sealing, temporal clear corneal incision. After injecting viscoelastic agents into the anterior chamber of eye, implanted a model V4 Toric ICL behind the iris and in the ciliary sulcus with an injector cartridge. If necessary to adjust the axis of astigmatism, the Toric ICL was softly manipulated according to the axis of astigmatism. The Toric ICL axis was adjusted to the horizontal meridian at most 15 degrees. Any remaining viscoelastic agents were meticulously aspirated. After the surgery, intraocular pressure was measured per 1h and topical anti-glaucoma eye drops were used if necessary. After the surgical, levofl oxacin eye drops (Cravit; Santen, Tokyo, Japan), fluorometholone eye drops (Flarex; Alcon Laboratories Inc, Ft Worth, Tex) were routine used four times a day for 2wk.

Table 1 Basic data of the 57 patients (102 eyes) $\bar{x}\pm s$

Parameters	Value (range)
Age (y)	28.9±8.7 (18-49)
M/F (%)	63.16%
Preoperative data	
Manifest sphere (D)	-12.31±3.97 (-4.75- -22)
Manifest cylinder (D)	-2.70±0.77 (-1.50- -4.50)
Corneal astigmatism (D)	-1.90±1.33
Toric ICL length (mm)	11.98±0.38 (-11.5-12.5)
Toric ICL power (D)	-19.06±3.28 (-13- -23)
ACD (mm)	3.21 ±0.25
Corneal diameter(mm)	11.69±0.32 (-11.1-12.5)
ECD (cells/mm^2)	2876±570
Postoperative data	
Manifest sphere (D)	-0.12±0.61
Manifest cylinder (D)	-0.24±0.58
Corneal astigmatism (D)	-2.04±1.05
Induced corneal astigmatism (D)	-0.04±0.35
ECD (cells/mm^2)	2793±456

ICL: Implantable Collamer lens; ACD: Anterior chamber depth; ECD: Endothelial cell density.

All patients underwent pre- and postoperative examinations that included the uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), corneal astigmatism and ocular wavelight aberration. The corneal astigmatis was measured by corneal topography (Wavelight, Erlangen, Germany), the corneal aberration was measured by using the Pentacam HR system (Oculus, Wetzlar, Germany) and the ocular HOAs were measured by Wavelight analyses (Wavelight, Erlangen, Germany) respectively preoperation and at 12mo after surgery. All examinations were averaged three times and performed by the same examiner.

Statistic Analysis Software SPSS 22.0 (IBM, USA) for Windows was used for statistical analysis. The results were presented in terms of means and SD and the statistical results were considered significant if $P < 0.05$. The comparison between the two groups was performed using the paired t-test.

RESULTS

Postoperative UCVA of 20/20 were 56 eyes (54.50%) and preoperative BSCVA of 20/20 were 34 eyes (33.30%). Postoperative UCVA of 68 eyes (66.30%) were ≥20/25 and UCVA of 90 eyes (87.90%) were ≥20/32 (Figure 1). Postoperative UCVA of 100% eyes was the same or greater than preoperative BSCVA.

Manifest refractive cylinder at 12mo postoperative (Figure 2). Postoperatively, no eyes had ≥-2.50 D of refractive cylinder. Postoperatively, 93.80% of eyes had ≤-1.00 D refractive cylinder and 85.30% of eyes had ≤-0.50 D refractive cylinder.

Postoperatively, the Toric ICL showed clockwise misalignment in 33 (32.40%) of 102 eyes, counterclockwise misalignment

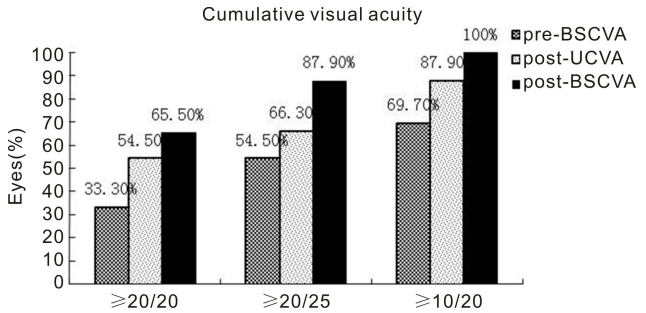

Figure 1 A bar graph of preoperative BSCVA, postoperative UCVA and postoperative BSCVA.

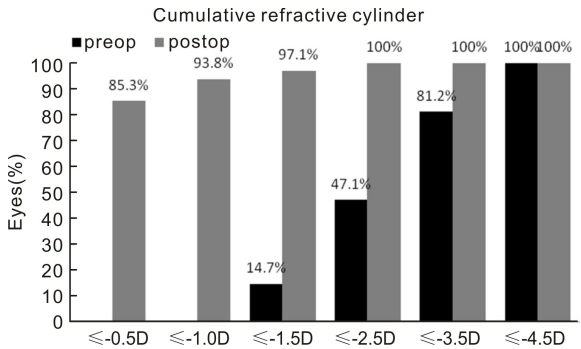

Figure 2 Preoperative (n = 102 eyes) versus 12mo postoperative (n=98 eyes) manifest refractive cylinder for the Toric ICL.

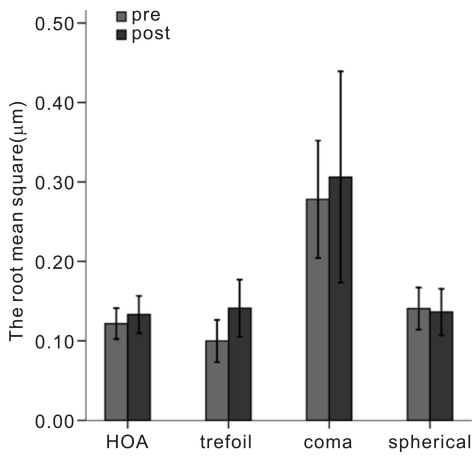

Figure 3 Bar graphs preoperative and postoperative total eye HOA, trefoil, coma, and spherical aberration.

in 24 (23.50%) eyes, and no misalignment was observed in 45 (44.10%) eyes. There was no eye need a second procedure to rotate the Toric ICL back position. Figure 3 shows the deviation of the achieved correction of cylinder from the intended cylinder of correction. The tendencies of under correction showed increasing, but most patients had the targeted correction cylinder within ±0.5 D.

The comparison of corneal curvature and astigmatism preoperatively were compared 12mo postoperatively. The corneal curvature showed slightly changed (43.12±2.08 D *vs* 44.42±2.08 D). No statistically significant differences were found pre- and postoperatively (P=0.329). But the corneal astigmatism showed some changes, and did not show levels of statistical significance (−1.90±1.33 D *vs* −2.04±1.05 D, P=0.408). The mean astigmatism change of corneal was −0.14±0.35 D pre- and postoperatively.

Table 2 Comparison of preoperative and postoperative corneal HOA in patients underwent Toric ICL insertion in the treatment of myopia $\bar{x}\pm s$

Zernike coefficient (μm)	Preoperative	Postoperative	P
Z_3^{-3}	0.017±0.201	−0.058±0.382	0.180
Z_3^{3}	−0.012±0.078	0.0194±0.117	0.247
Z_3^{-1}	0.017±0.201	−0.058±0.382	0.203
Z_3^{1}	−0.128±0.266	−0.165±0.267	0.294
Z_4^{0}	0.141±0.071	0.136±0.078	0.709
Trefoil	0.100±0.073	0.141±0.100	0.070
Coma	0.278±0.205	0.306±0.369	0.631
HOAs	0.122±0.005	0.133±0.063	0.243

Z_3^{-3}: Vertical trefoil; Z_3^{-1}: Vertical coma; Z_3^{1}: Horizontal coma; Z_3^{3}: Oblique trefoil; Z_4^{0}: Primary spherical aberration; HOA: Higher-order aberration; Trefoil: $\sqrt{(Z_3^3)^2+(Z_3^{-3})^2}$.

Table 3 Comparison of preoperative and postoperative total ocular HOA in patients underwent Toric ICL insertion in the treatment of myopia $\bar{x}\pm s$

Zernike coefficient (μm)	Preoperative	Postoperative	P
RMS	0.677±0.716	0.592±0.290	0.587
Spherical	0.034±0.151	−0.096±0.141	0.002
Coma	0.328±0.268	0.256±0.164	0.285

HOA: Higher-order aberration; RMS: Root mean square value.

Corneal Higher-order Aberrations Postoperatively, coma aberration increased slightly from 0.28±0.21 μm to 0.31±0.37 μm in eyes underwent Toric ICL implantation (P=0.170) (Figure 3). The trefoil aberrations also increased slightly from 0.10 before surgery to 0.14 after surgery, but no statistically significant differences were found (P=0.631). Spherical-like aberrations (Z_4^0) did not show levels of statistical significance (0.141±0.071 μm *vs* 0.136±0.078 μm, P=0.709). HOAs of total corneal increased slightly, and did not show levels of statistical significance (0.122±0.005 μm *vs* 0.133±0.063 μm, P=0.243) (Table 2).

The HOAs of the total eye slightly decreased on average after surgery (preoperative: 0.677±0.716 μm; 12mo postoperative: 0.592±0.290 μm). However, the difference was not statistically significant (P=0.587). The changes in coma resulted in only slight changes had no statistically significant. The spherical aberration had a negative shift compared with preoperatively (preoperative: 0.034±0.151 μm; 12mo postoperative: −0.096±0.141 μm), there was a statistically significant difference (P=0.002) (Table 3).

Complications Postoperatively, there were no lens opacities, chronic inflammation of the anterior chamber, or retinal detachment have been noted until the following examination, but this study is only of 12mo duration. Five patients complained of nighttime haloes around lights, none preventing driving.

DISCUSSION

About high myopic astigmatism patients who were not suitable for excimer laser corneal surgery according to the current

recommended standards criteria, the Toric ICL is an alternative refractive treatment. In our study, Toric ICL implantation safely and significantly decreased refractive astigmatism by 85.30% and improved both UCVA and BSCVA. Our results showed that 93.80% eyes had MRSE within 1.00 D of emmetropia, which is consistent with other scholars reporting[8]. These results indicate the Toric ICL can reduce astigmatism from 1.00-4.50 D.

The main objective of this study was to investigate whether the Toric ICL insertion could affect the corneal optical characteristic, and the ocular HOA changes after the Toric ICL insertion. Cataract surgery combined with intraocular lens implantation has been reported to induce and increase HOAs, the optical properties of intraocular lenses and corneal incisions are the main causes of these changes[9]. Corneal incisions can alter the corneas optical power, generating Surface Asymmetry Index (SAI) and postoperative changes in aberration[10]. There were no previous reports of such changes after Toric ICL implantation. Similar reports from HAO follow cataract surgery through a clear corneal incision and other types of intraocular lens implantation (Artisan, Artilex Ophtec BV, Groningen, Netherlands, and ICL)[11]. Elies *et al*[1] proved that Toric ICL can effectively correct myopic astigmatism with excellent stability and minimal changes in corneal astigmatism (1.82 @ 178.6) compared with preoperative values (1.99@178.2). Marcos *et al*[12] studied the changes of corneal aberrations after cataract surgery with 3.2 mm clear corneal incision (CCI). They reported increases in HOA RMS in third, fourth and fifth order RMS, in Z_3^{-3} and Z_4^{-4}. Shimizu *et al*[13] compared the corneal aberration changes between the <3.2 mm-incision group and the 3.2-4.5 mm-incision after ICL implantation and found the RMS value of whole eye HOA changed little after <3.2 mm-incision surgery inducing from the changes in spherical aberration and trefoil, whereas the RMS value of whole eye HOA changed greater after 3.2-4.5 mm incision surgery ducing from a significant changes in trefoil. Tazib and associates noted a increase in Z_3^{-3} after Artisan and Artilex implantation due to larger corneal incision, and Artisan implantation makes even bigger changes in Z_3^{-3}[14]. Hashemian *et al*[15] studied and found that surgically induced astigmatism was less than 0.25 D, and trilobular and coma aberrations did not change after ICL and Toric ICL insertment. Our results were consistent with the above results. And in addition, we also observed the changes of the corneal aberration in our research, and found that there was no influence on the corneal astigmatism and corneal aberration after the Toric ICL implanted in patients with high myopic astigmatism. In our results we found no significant changes in refractive or corneal astigmatism after surgery. The reason may be that the corneal temporally incision is no longer than 3.0 mm and we placed a 1.5 mm perfusion incision on corneal superior meridian, and the two incisions is symmetrically with each other, which will not change corneal optical power and reducing corneal HOAs by surgery. So the corneal incision is not caused a surgically induced corneal astigmatism. The same report can see in the biaxial microincision cataract surgery (B-MICS), their conclusion coincides with ours. Recent studies by Can *et al*[16] showed no change in corneal aberrations after B-mics surgery. No change in corneal astigmatism or corneal HOAs such as spherical or coma was found in their study. Our results further confirm these findings and found that the changes induced 3 mm corneal incision resulting in corneal aberration was not significant and the overall total RMS of total HOAs did not change significantly (Table 2).

We must recognize the fact that after Toric ICL implantation the eye is effectively a three lens system: the cornea, the Toric ICL, and the crystalline lens. The "anatomical" deviation in such cases would not correspond exactly tothe "optical" deviation[17]. Gualdi *et al*[18] found that a titled or torqued IOL will produce significant coma postoperatively. Incorrect alignment of the Toric IOL will result in postoperative astigmatism on the internal wavefront map. Alfonso *et al*[19] found that RMS and coma were consistent after ICL implantation, and the spherical aberration was lower than that before implantation. Seo *et al*[20] reported that HOAs increased significantly after ICL insertion. The coma and spherical did not show significant changes. Marcos *et al*[12] reported that the results of inducing trefoil and reducing spherical were consistent findings after ICL implantation. They found negative shift of spherical aberration and no significant change in overall RMS of total HOA in the small-incision group had. This agreed with our results. In our results, the RMS of total HOAs decreased from preoperative 0.68 μm to postoperative 0.59 μm. We also found that a negative shift of spherical aberration caused by Toric ICL. The minimal changes in spherical and coma further support the Toric ICL aspherical design to compensate for the corneal spherical aberration. Meantime, postoperatively coma decreased but had no significant differences compared with the preoperative lever, the Toric ICL decentration and tilted may have a relation with the coma. The possible explanation maybe that although the Toric ICL rotated but its haptic design did not make it deviate from the optic too much. There was only one patient in our case whose Toric ICL maximum misalignment was 20° from the intended axis, but the UCVA was 20/20. There were some limitations in this study: the little sample observed, the short period of followup time, and all the patients came from monocentric.

In conclusion, the corneal incision of Toric ICL implantation caused no changes in astigmatism and HOAs of cornea. Our results showed that the Toric ICL implantation had decreased the total ocular aberration and induced negative spherical aberration, this investigation found no statistically significant change in any of the HOAs postoperatively. However, there were no correlative reports about the changes of HOAs in

previous reports. Our results indicate that Toric ICL implatation may reduce in postoperative HOAs. This was likely due to the size and location of the incision. Another reason might be the small number of patients, thus sampling error cannot be fully excluded. Further study need to be performed.

REFERENCES

1 Elies D, Alonso T, Puig J, Gris O, Güell JL, Coret A. Visian toric implantable collamer lens for correction of compound myopic astigmatism. *J Refract Surg Thorofare N J* 2010;26(4):251-258

2 Kamiya K, Shimizu K, Kobashi H, Igarashi A, Komatsu M. Three-year follow-up of posterior chamber toric phakic intraocular lens implantation for moderate to high myopic astigmatism. *PLoS One* 2013;8(2):e56453

3 Coskunseven E, Kavadarli I, Sahin O, Kayhan B, Pallikaris I. Refractive outcomes of 20 eyes undergoing ICL implantation for correction of hyperopic astigmatism. *J Refract Surg* 2017;33(9):604-609

4 Mertens EL. Toric phakic implantable collamer lens for correction of astigmatism: 1-year outcomes. *Clin Ophthalmol* 2011;5:369-375

5 Denoyer A, Denoyer L, Marotte D, Georget M, Pisella PJ. Intraindividual comparative study of corneal and ocular wavefront aberrations after biaxial microincision versus coaxial small-incision cataract surgery. *Br J Ophthalmol* 2008;92(12):1679-1684

6 Long DA, Monica ML. A prospective evaluation of corneal curvature changes with 3.0- to 3.5-mm corneal tunnel phacoemulsification. *Ophthalmology* 1996;103(2):226-232

7 Igarashi A, Kamiya K, Shimizu K, Komatsu M. Visual performance after implantable collamer lens implantation and wavefront-guided laser *in situ* keratomileusis for high myopia. *Am J Ophthalmol* 2009;148(1):164-170.e1

8 Sanders DR, Schneider D, Martin R, Brown D, Dulaney D, Vukich J, Slade S, Schallhorn S. Toric implantable collamer lens for moderate to high myopic astigmatism. *Ophthalmology* 2007;114(1):54-61

9 Assaf A, Kotb A. Ocular aberrations and visual performance with an aspheric single-piece intraocular lens: Contralateral comparative study. *J Cataract Refract Surg* 2010;36(9):1536-1542

10 Yao K, Tang XJ, Ye PP. Corneal astigmatism, high order aberrations, and optical quality after cataract surgery: microincision versus small incision. *J Refract Surg Thorofare N J* 2006;22(9 Suppl):S1079-S1082

11 Tong N, He JC, Lu F, Wang Q, Qu J, Zhao YE. Changes in corneal wavefront aberrations in microincision and small-incision cataract surgery. *J Cataract Refract Surg* 2008;34(12):2085-2090

12 Marcos S, Rosales P, Llorente L, Jiménez-Alfaro I. Change in corneal aberrations after cataract surgery with 2 types of aspherical intraocular lenses. *J Cataract Refract Surg* 2007;33(2):217-226

13 Shimizu K, Kamiya K, Igarashi A, Shiratani T. Intraindividual comparison of visual performance after posterior chamber phakic intraocular lens with and without a central hole implantation for moderate to high myopia. *Am J Ophthalmol* 2012;154(3):486-494.e1

14 Parsipour F, Razmju H, Khatavi F, Panahi M, Nouralishahi A, Peyman A. Wavefront aberration and contrast sensitivity after implantation of foldable and rigid iris claw phakic intraocular lenses: Artiflex versus artisan. *Indian J Ophthalmol* 2016;64(5):382-386

15 Hashemian SJ, Farrokhi H, Foroutan A, Jafari ME, Hashemian SM, Alemzadeh SA, Hashemian MS. Ocular higher-order aberrations changes after implantable collamer lens implantation for high myopic astigmatism. *J Curr Ophthalmol* 2018;30(2):136-141

16 Can İ, Bayhan HA, Çelik H, Ceran BB. Comparison of corneal aberrations after biaxial microincision and microcoaxial cataract surgeries: a prospective study. *Curr Eye Res* 2012;37(1):18-24

17 Sheng XL, Rong WN, Jia Q, Liu YN, Zhuang WJ, Gu Q, Sun Y, Pan B, Zhu DJ. Outcomes and possible risk factors associated with axis alignment and rotational stability after implantation of the Toric implantable collamer lens for high myopic astigmatism. *Int J Ophthalmol* 2012;5(4):459-465

18 Gualdi L, Cappello V, Giordano C. The use of NIDEK OPD Scan II wavefront aberrometry in toric intraocular lens implantation. *J Refract Surg* 2009;25(1 suppl):S110-S115

19 Alfonso JF, Lisa C, Fernández-Vega Cueto L, Fernandes P, González-Méijome JM, Montés Micó R. Comparison of visual and refractive results of Toric Implantable Collamer Lens with bioptics for myopic astigmatism. *Graefes Arch Clin Exp Ophthalmol* 2013;251(3):967-975

20 Seo JH, Kim MK, Wee WR, Lee JH. Effects of white-to-white diameter and anterior chamber depth on implantable collamer lens vault and visual outcome. *J Refract Surg* 2009;25(8):730-738