

## **Therapeutic effectiveness of toric implantable collamer lens in treating ultra-high myopic astigmatism.**

**Dekun Li<sup>#</sup>, Mei Li<sup>#</sup>, Zhenkai Liu, Jiaojiao Ling, Feng Ke, Fang Li, Hongmei Gu, Jie Shao, Jinqiang Yu\***

Department of Ophthalmology, Renmin Hospital, Hubei University of Medicine, Shiyan, Hubei Province, PR China

<sup>#</sup>These authors contributed equally to this work

### **Abstract**

**With a rapid increase in the prevalence of Ultra-High Myopic Astigmatism (UHMA), especially in the youth, there have been many studies on visual correction. In our study, we investigated the clinical value of the Toric Implantable Collamer Lens (TICL) in UHMA. We conducted a retrospective study between 2011 and 2013. TICL implantation was performed on fifteen UHMA patients (30 eyes), and all these patients were regularly followed up for 12 months. The preoperative and postoperative data, including Uncorrected Visual Acuity (UCVA), Best Corrected Visual Acuity (BCVA), Intraocular Pressure (IOP), and corneal endothelial counts, were all analysed using the paired-sample t-test. The 12-month spherical mirror (SPH) of the surgical eye was -0.25~+0.25 D, and the Cylinder mirror (CYL) was 0~-0.50 D. Twenty patients exhibited an increase in UCVA by one level in comparison to the preoperative BCVA, amounting to a 66.7% increase; 20.0% of patients exhibited an increase in UCVA by two levels. A comparison between the preoperative and postoperative IOP showed no statistically significant difference. No difference was also found in mean corneal endothelial counts before and after the operation. A decrease in visual acuity was observed in one eye at the 3<sup>rd</sup>-month of review; this was corrected by TICL position adjustment. Precisely measuring the preoperative parameters, selecting the appropriate TICL, more thoroughly aspirating sodium hyaluronate intraoperatively, and maintaining a stable IOP were important for maintaining the effectiveness, safety and stability of TICL in treating UHMA.**

**Keywords:** Ultra-high myopia, Astigmatism, I/A, Posterior chamber TICL.

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### **Introduction**

Worldwide, Refractive Error (RE), particularly myopia, is the primary cause of visual impairment [1]. Presently, the incidence of myopia, particularly high myopia, has been increasing quickly [2,3] with a corresponding increase in clinical costs [4]. As this decrease in vision influences the studies, work, and life of myopic patients [5] correcting high myopia is always an important research topic in the field of ophthalmology [6]. With improvements in excimer laser equipment and the microkeratome, the treatment of nearsightedness, farsightedness, and astigmatism using the excimer laser has achieved a good clinical efficacy, where the effects of treatment on low to moderate myopia are overwhelmingly positive. Excimer laser treatment is also favored by doctors and patients for its significant clinical effects, safety, and reliability. With treatment expansion, its disadvantages have also become more prominent [7]. First, corneal refractive surgery with excimer laser is highly dependent on the pupil size, corneal thickness, corneal curvature, and non-matching cutting areas [8], so it is delimited to correct myopia only within -10.0 D or less, and is not

recommended for certain patients, such as those with corneal pannus, dry eye, and thin corneas, among others. Second, in most patients with high myopia, more corneal tissues need to be cut, and this would involve the removal of normal corneal tissues. Clinical efficacies of this, however, are poor, and might lead to serious complications after the surgery, such as postoperative aberrations, refraction rollback, and corneal ectasia, among others [9]. Corneal refractive surgery is thus not suitable for these patients.

With the improvements in intraocular lens material technologies and surgical techniques, the developments in lens refractive surgery expand the indications of refractive surgery. Consequently, lens refractive surgery has received more attention from clinicians and is used for more clinical applications. Lens refractive surgery includes crystalline lens removal in addition to intraocular lens implantation and phakic intraocular lens implantation. Crystalline lens removal with intraocular lens implantation is suitable for myopic patients over 50 y old. After the surgery, the patient would also have the intraocular lens. Shortcomings include the loss of normal regulatory functions, cystoid macular edema, and after-

cataract, among others. Phakic intraocular lens implantation includes the anterior chamber angle-support type, iris-fixation type, posterior chamber ciliary groove-fixation type, and ciliary groove-suspension type. The anterior chamber angle-support type and iris-fixation type were prone to cause the continuous loss of corneal endothelium and iris injury; hence, their clinical applications have reduced. Because the posterior chamber ciliary groove-fixation type and ciliary groove-suspension type use longer distances to the corneal endothelium, the risks are relatively smaller. Although lens opacification is a concern, an opaque lens can be replaced surgically. The intraocular lens material of the two former types is Polymethacrylates (PMA); hence, the incision is larger, and surgically-induced astigmatism occurs easily. Toric Implantable Collamer Lens (ICL) is formulated with a new intraocular lens material, collamer, which is a copolymer of dihydroxyethyl methacrylate and collagen and has good optical properties and biocompatibilities. It is also flexible and could be injected through a 3.2 mm incision. Hence, this material would overcome the shortcomings of the two former types of lens refractive surgeries. Furthermore, because of rotation stability, the astigmatic correction through the ciliary groove-suspension type is limited. A better alternative for patients with middle-high complex myopic astigmatism is the use of the ciliary groove-suspension type toric implantable collamer lens (TICL) which offers rotational stability [10,11]. With continuous developments in TICL implantation, an increasing number of patients with middle-high myopic astigmatism could select TICL as a treatment modality. Numerous studies have shown that astigmatism correction using TICL were significant. The patients could not only obtain substantially increased Uncorrected Visual Acuity (UCVA), but also gain high-definition visual quality. In addition, the operation safety was high, and the operations were reversible [12]. TICL implantation could correct high myopic astigmatism in patients not suitable for treatment with excimer laser, and it is currently one of the ideal refractive surgery methods. Not only does it have good predictability, safety, and stability, it also has a wide adaptive range of refraction, causes minimal damage to endothelial cells, and preserves the natural regulatory functions of human eyes [13]. At present, it has been widely used in clinical practice. For patients with high myopic astigmatism due to a limited corneal thickness or a possible abnormal corneal shape, TICL implantation should be selected first as it could not only avoid cornea-related complications but also result in better visual qualities [14]. Owing to the accompanying astigmatism, TICL implantation needs to strictly position the astigmatic axis; the axis must be stably fixed inside the posterior chamber ciliary groove to ensure optimal postoperative treatment effects.

Since 2011, our department has performed TICL implantation on 15 ultra-high myopic astigmatism (UHMA) patients (30 eyes) and achieved good results.

## Methods

### *General information*

TICL implantation was performed in our department from March 2011 to March 2013, on fifteen UHMA patients (30 eyes), including seven males (14 eyes) and eight females (16 eyes), between 20 and 35 y of age (mean age:  $26.42 \pm 5.15$  y). Inspections were performed after 6 weeks for patients with rigid corneal contact lenses, and after 4 w for those wearing soft corneal contact lenses, and the results were as follows: SPH -8.0~-21.0 D (mean  $-12.42 \pm 3.86$  D), CYL -1.50~-6.50 D (mean  $-2.56 \pm 1.32$  D), and equivalent SPH -14.56 D. The preoperative Best Corrected Visual Acuity was (BCVA) 0.25~1.0, and among those six eyes were  $\leq 0.4$  (15%), 25 were from 0.5 to 0.8 (62.5%), and nine eyes were  $\geq 1.0$  (22.5%).

### *Patient screening*

All the patients with UHMA fully understood and signed the informed consent form before the TICL implantation, and could be regularly followed up after the surgery. All the patients were strictly screened, and excluded if accompanied with other eye diseases such as eye infection, severe dry eye, irregular astigmatism, keratoconus, glaucoma, pigment dispersion syndrome, and uveitis, and retinopathy, which might affect the central vision. Those with macular degeneration, intraocular surgery, cataracts, glaucoma, Fuchs' corneal endothelial dystrophy or other corneal diseases, diabetes, other systemic collagen allergic diseases, patients with only one eye, pregnant patients and breast-feeding patients were also excluded. Ophthalmic inspection showed that the corneal endothelial cell count was greater than  $2500/\text{mm}^2$ , and the depth from the corneal endothelium to the anterior chamber was greater than 3.2 mm.

### *Preoperative inspections*

Preoperative inspections included UCVA, BCVA, subjective optometry, mydriatic optometry, slit lamp inspection, Intraocular Pressure (IOP) by non-contact tonometer (NT-510, DINEK), UBM inspection, ultra-ocular axial measurement, three-mirror fundus inspection, corneal endothelial cell count, corneal thickness inspection, corneal topography, and corneal white-white distance (WTW). All the data were registered and filed in detail.

### *Preoperative preparations*

The surgical eye preparation was performed with an Yttrium Aluminium Garnet (YAG) laser drilling 2 w before the surgery, which ideally penetrated the iris root at the 10:00 and 2:00 position around the iris to form the undercut hole (diameter at least 0.6 mm). Before the surgery, 5 g/L cravit eye drops were administered 4 times a day consecutively for 3-5 d. The tear duct of the surgical eye was rinsed with 0.9% sodium chloride injection once daily for 3 d. Mydriasis was performed 60 min before the surgery with mydrin eye drops. One drop was administered to each patient on the surgical eye every 10 min;

this was repeated three times. Oxybuprocaine hydrochloride eye drops were applied 30 min before the surgery with one drop every 5 min for three or four times. The 0° and 180° of the eye were positioned around the corneal limbus 5 min before the surgery with a marker pen under a slit lamp microscope. Lastly, the TICL axis was adjusted during surgery when necessary.

**Determination of IOL degrees**

TICL (collagen-copolymer material, STAAR collamer) used in the surgery can be folded into dual-concave one-piece shapes; four models (M115, 120, 125, and 130) were manufactured by STAAR (Swiss). The calculation software provided by STAAR was used to adjust the diameter, refraction degree, and astigmatic degree of TICL after referring to the anterior chamber depth, WTW, and other parameters measured before the surgery. Furthermore, angle rotations along the horizontal axis and its schematic diagrams were also calculated to select the appropriate TICL.

**Surgical procedures**

All the surgeries were performed by the same skilled surgeon: the surgical eye was focally disinfected, regularly paved the towels, and TICL installation parameters re-checked. A 3.2 mm incision and an auxiliary incision at the 12:00 position was made along the temporal transparent corneal edge. Sodium hyaluronate was injected into the anterior chamber, and one disposable pusher was used to inject TICL into the anterior chamber through the main incision. After the TICL was naturally spread out, the microscopic re-positioning hook was used to place the four loops of TICL between the iris and lens, and fixed afterward inside the ciliary groove. The TICL was finely adjusted, kept in the center of the lens, and then rotated to the corneal edge marker with reference to its unique diamond logo. The sodium hyaluronate of the anterior chamber was flushed with Advanced Medical Optics (AMO) phacoemulsification instrument I/A. The anteroposterior balance of TICL was adjusted afterward, and the incision completely closed. Tobradex eye drops and ointment were applied to the surgical eye for 1 w.

**Postoperative follow-up**

All the patients were followed up regularly for 12 months. The patients were followed up in the following order: postoperative day 1 (D1), day 2 (D2), day 3 (D3), week 1 (W1), month 1 (M1), month 3 (M3), month 6 (M6), and month 12 (M12).

Long-distance UCVA, slit-lamp microscopy, IOP by non-contact tonometer (NT-510, DINEK), corneal endothelial cell inspection, chamber angle inspection by UBM, refraction status, mydriatic TICL vault, axial position, and lens were all tabulated.

**Statistical analysis**

The comparisons between the preoperative and postoperative inspection results were performed using SPSS17.0 statistical software; all data before and after the surgery were analysed using the paired t-test, with P<0.05 considered as a statistically significant difference.

**Results**

**Surgical results**

The patients' UCVA before and after the surgery within different equivalent SPH ranges were shown in Table 1. Equivalent SPH (-8.0~21.0 D) were divided into -17.0~-16.75 D, -12.0~-16.75 D and -8.0~-11.75 D, respectively. In -17.0 D~-16.75 D, the preoperative BCVA was 0.25~0.5; in -12.0 D~-16.75 D, the preoperative BCVA was 0.5~0.8; in -8.0 D~-11.75 D, the preoperative BCVA was more than 1.0. We observed changes in vision, during D1, W1, M1, M3 and M12 after the surgery. Twenty eyes had preoperative UCVA<0.1 (20/30); 10 eyes were within the range of 0.1 to 0.3 (10/30). On postoperative D1, 5 eyes had UCVA ≤ 0.5 (5/30), while 25 eyes had UCVA ≥ 0.5 (25/30). One week after the surgery, 2 eyes had UCVA ≤ 0.5 (2/30), while 28 eyes had UCVA ≥ 0.5 (28/30). One month after the surgery, 28 eyes had UCVA ≥ 0.5 (28/30), and this was kept stable from M3~M12. Twelve months after the surgery, 20 eyes had UCVA ≥ 0.5, accounting for 83.3% (20/30), and six eyes had UCVA ≥ 1.0, accounting for 20% (6/30). The preoperative and postoperative (M12) IOP, corneal endothelial count, SPH, and CYL are shown in Table 2. In M12, SPH was within -0.25~+0.25 (mean ± standard deviation: 0.21 ± 0.11D); CYL was within 0 to 0.50 (mean ± standard deviation: 0.19 ± 0.08 D). Twenty eyes exhibited an increase in UCVA by one level compared with the preoperative BCVA, accounting for 66.7%. 20.0% increase in UCVA by two levels. A comparison between preoperative and postoperative SPH showed a statistically significant difference (t=105.36, P<0.01); in addition, the comparison of preoperative and postoperative CYL also showed a statistically significant difference (t=3.89, P<0.01).

**Table 1.** Comparison of preoperative and postoperative UCVA within different equivalent SPH ranges.

Equivalent (D)	SPH	Preoperative BCVA	Postoperative D1	Postoperative W1	Postoperative M1	Postoperative M3	Postoperative M12
-17.0~21.0		0.25~0.5	10	9	2	3	2
-12.0~16.75		0.5~0.8	15	15	22	21	22

-8.0~11.75	≥ 1.0	5	6	6	6	6
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**Table 2.** Comparison of the mean values before and after the surgery ( $\bar{x} \pm s$ ).

	Before surgery	Postoperative M12	t	p
IOP (mmHg)	15.49 ± 1.07	15.40 ± 1.04	0.33	0.74
Corneal endothelium count (cells/mm <sup>2</sup> )	2840.75 ± 83.04	2837.75 ± 82.95	0.15	0.88
SPH (D)	-12.42 ± 3.86	0.23 ± 0.21	105.36	P<0.01
CYL (D)	-2.56 ± 1.32	0.15 ± 0.16	3.89	P<0.01

### IOP

The average IOP was 15.49 ± 1.07 mmHg preoperatively, while it was 15.7 ± 1.32 mmHg on D1. The difference between these values was not statistically significant ( $t=0.42$ ,  $P=0.67$ , D1). The average IOP at M12 was 15.40 ± 1.04 mmHg, showing no statistically significant difference ( $t=0.33$ ,  $P=0.74$ ). No patient exhibited an increase in IOP postoperatively.

### Cornea

Four eyes had mild corneal endothelial edema around the incision 4 h after the surgery, which faded after local application of Tobradex eye drops and ointment for 2-3 d. The average preoperative corneal endothelial count was 2865 ± 252.5/mm<sup>2</sup>, while it was 2828 ± 269.3/mm<sup>2</sup> at M12 ( $t=0.15$ ,  $P=0.88$ ); the difference was not statistically significant.

### TICL and lens

The patients were regularly followed up until M12. Mydriatic inspection revealed that all the patients' own lenses were intact and transparent, and had no appearance of spotty or patchy turbidity. The TICL optical zone surface of several patients exhibited spot-like pigment adhesions, and the TICL central optical zone was kept about 0.5~1 CT gap away from the patients' own lens. The TICL vaults were uniform and stably balanced, and the two eyes were symmetric. During M3 of regular follow-up, one patient complained that the visual acuity of his right eye declined. A mydriatic inspection revealed that the right TICL vault was imbalanced, with the refraction noted as +1.25/-3.50 × 145°. This indicated that the right TICL rotated 45°. The patient was re-anesthetized in order to adjust the right TICL through slight rotation, thus returning the TICL to the exact position. Postoperative visual acuity was restored to 0.8, with the right eye refraction being +0.25/-0.25 × 10°. The rest of patients did not complain of rotational TICL displacement.

### Discussion

Ophthalmic refraction correction surgery can be divided into corneal refraction correction surgery and lens refraction correction surgery, based on the surgical site involved [15]. Due to the continuing improvements in excimer laser equipment and surgical instruments, with the emergence of all-

femtosecond laser in particular, excimer laser corneal refraction correction surgery has become the mainstay in current ophthalmic refraction correction surgery for the treatment of low to moderate myopia [16]. However, this surgical technique has limited application in high myopia, especially ultra-high myopia, and it cannot be performed in patients with thin corneas, corneal pannus spots, and large astigmatism. Laser surgery for high myopia requires cutting away the excess corneal tissue, resulting in large changes in the tissue morphologies of the anterior corneal surface and potentially causing serious complications such as aberration rollback, corneal ectasia, keratoconus, and significantly decreased visual quality [17]. Furthermore, patients with a high long-term risk of developing a corneal flap, such as athletes and stuntmen, should not be considered for laser surgery. The complementary elements in excimer laser corneal refraction correction surgery, Implantable Contact Lenses (ICL), have been clinically implemented for more than ten years, and have obtained increasing favor with clinicians. TICL was developed from ICL, and it could simultaneously correct myopia, astigmatism, and farsightedness. TICL is made with a new artificial lens material and shows better optical performance and a softer texture, which allows it to be fixed in the ciliary groove, stably rotated, and exhibit good long-term effects in treating astigmatism. It uses micro-incisions and is reversible, with a large refraction adaptation range, while only causing minor injury to the endothelial cells, thereby reducing its effects on the autoregulatory functions of human eyes [18]. Currently, it is being used widely in clinical scenarios and has become the mainstream in correcting high and ultra-high myopia.

One of the major postoperative complications of TICL use was high IOP [19], and the main reasons for high IOP in these patients were as follows: (1) sodium hyaluronate was intraoperatively left in the posterior chamber and pupil area, thus blocking the chamber angle; and (2) the use of steroids induced ocular hypertension. During the surgery, we used the I/A system (AMO phacoemulsification instrument). The aspiration handle was extended into the anterior chamber through the 3.2 mm incision, with a negative vacuum of 300 mmHg and 30% flow, so the perfusion and aspiration would be much more thorough with little residual sodium hyaluronate. No patient exhibited high IOP in the early stages after the surgery. YAG laser drilling two weeks before the surgery was

performed on the surgical eye, which penetrated the iris root at the 10:00 and 2:00 positions around the iris to form the undercut hole (with a diameter at least 0.6 mm). Even if the TICL optical zone caused a pupillary block, the outflow of aqueous humor would not be affected, thus ultimately avoiding the pupillary block that causes an increase in IOP. The period of routine postoperative local application of TobraDex eye drops and ointment did not exceed one week in order to avoid the high IOP caused by long-term local hormone usage. The patients had no postoperative ocular hypertension during the follow up.

Generally, patients with high myopia may also show astigmatism. As a result, these patients may not benefit from the correction effects of frame glasses. Because the frame glasses are some distance away from the cornea, the objects refracted by the lens would be shrunk by various degrees when projected onto the retina. As narrowing of the magnification is positively correlated with the lens degrees, the zoom-out times of objects in ultra-high myopia would be large. This in turn made it difficult for the glasses-corrected visual acuity to reach BCVA. When TICL is implanted into the eye, it would be close to the node of the refractive system, so that the changes in the object magnification ratio would be extremely small, which would reduce the aberrations, and magnify the objects, subsequently improving the patients' visual quality [20]. Compared with frame glasses, the postoperative UCVA after the TICL implantation could be increased by one or two levels compared to the preoperative BCVA. The follow-up assessments in this study showed that 20 patients exhibited UCVA increase by one level compared to the preoperative BCVA, accounting for 66.7%, with 20.0% showing an increase of two levels over the baseline. This indicates that the TICL implantation had good effects.

Cataracts have been reported to be complications of TICL implantation in studies in China and abroad [21-23]. With the constant improvements in TICL materials, however, the procedure has become safer and with fewer side effects. TICL is made of Collamer material, which adds collagen into silica gel. As a result, the material is more hydrophilic and lighter, with more elasticity, and is closer to the physiological state. After folding, it could be injected through the 3.2 mm corneal limbal incision, and then fixed behind the iris's ciliary groove. This would form an ideal optical zone equivalent to the corneal plane with long-term rotational stability. TICL could also be used to correct astigmatism and limit the off-axis incident light. The incidence of glare and halos would be less, thereby allowing normal functions of the iris to be maintained. Its optical unit exhibits a convex shape, and the unit is far away from both the corneal endothelium and lens. The unit only contacts the peripheral zones of the iris and the front surface of the lens. The TICL optical part, thus, is in a state of suspension, which reduces damage to the corneal endothelial cells, and reduces mechanical injury from the TICL on the anterior capsule of the lens. All the operations were performed by an experienced surgeon. The operations were gentle enough to avoid surgically induced lens damage as well as the occurrence of cataracts. Though the average number of corneal

endothelial cells decreased slightly in comparison with the preoperative endothelial cell count, the difference was not statistically significant ( $P=0.88>0.05$ ).

During the follow-up assessments, one patient complained of a decline in the visual acuity in his right eye in the third month of regular review. Mydriatic inspection revealed that the right TICL vault and position were imbalanced, with the refraction being  $+1.25/-3.50 \times 145^\circ$ . This indicated that the right TICL rotated  $45^\circ$ . After rotation and readjustment of the right TICL, the postoperative visual acuity was restored to 0.8. The rest of the patients did not complain of rotational displacement of TICL. UBM was performed to check the TICL and chamber angle, which revealed that the TICL vault and position were imbalanced, with uneven gaps between its four loops and the chamber angle. This was considered to be caused by an inclination during TICL implantation that led to TICL rotation, which was followed by significant astigmatism and decreased vision. After re-adjusting the TICL position, this patient's astigmatism and visual acuity were corrected. The rest of the patients showed uniform TICL vaults and stable balance in the routine postoperative reviews. The optical part was parallel and equivalent to the corneal plane. UBM inspection revealed that the TICL's loops uniformly contacted with the chamber angle, with no compression or bending, and that the gaps were uniform, indicating that the TICLs implanted were suitable for the patient's ciliary groove's diameter. Consequently, we believe that accurately measuring the anterior chamber depth and WTW is critical in ensuring postoperative stability of TICL implantation. When measuring WTW preoperatively, UBM inspection should be performed simultaneously, and it should always be performed by the same surgeon to guarantee the identity, continuity, and precise measurement for the objective selection of IOL with the right diameter. Accurate determination of the IOL diameter was important for achieving postoperative stability of TICL implantation. When necessary, however, a panoramic UBM could be performed to directly measure the distance between the two ciliary grooves, which would make the implantation even more accurate and reliable.

In light of these findings, we suggest that precise measurement and objective selection of IOLs with a suitable diameter should be performed to ensure the safety and effectiveness of TICL implantation in treating UHMA and restoring the patient's visual acuity. We summarized "seven preconditions," or "seven goals" for treatment success: select the appropriate patient (good condition); reserve the right lens (good measurement); prepare fully (good peri-iris incision); install the lens smoothly (good preview); perform skilled specification (good practice); handle the emergency properly (good IOP); and perform close postoperative observation (good postoperative observation). All of these steps must be followed to ensure surgical quality. We believe that ICL and TICL implantation had significant effects on ultra-high myopia, and the indications might be appropriately extended to moderate and high myopia. TICL could be used not only for artificial lens implantation for hyperopia and cataracts, but also for the treatment of post-excimer laser residual refraction [24] and stable keratoconus [25]. The present study, however, only sampled UHMA

patients. Moreover, the patient amount was relatively small, and the postoperative follow-up only lasted 12 months. This condition required further observation for assessment of its long-term effects.

## Conclusion

In conclusion, lens refraction correction surgery is the preferred option for high myopia, especially ultra-high myopia. Our study confirmed that TICL implantation would lead to significant vision improvement. With negative vacuum aspiration of sodium hyaluronate during the operation and two holes at the iris root to avoid aqueous humor block, no postoperative ocular hypertension was recorded in any patient within twelve months of follow-up.

## Conflict of Interest

All authors have no conflict of interest regarding this paper.

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**\*Correspondence to**

Jinqiang Yu

Department of Ophthalmology

Renmin Hospital, Hubei University of Medicine

PR China