

Clinical application of TICL implantation for ametropia following deep anterior lamellar keratoplasty for keratoconus

A CONSORT-compliant article

Qin Qin, MD^{a,b}, Liping Yang, MD^a, Zifang He, MD^b, Zhenping Huang, MD^{a,*}

Abstract

Background: This study aimed to investigate the clinical application of phakic toric intraocular collamer lens (TICL) implantation in treating ametropia following deep anterior lamellar keratoplasty (DALK) for patients with keratoconus, especially the effectiveness and safety of high astigmatism and indications of TICL implantation after corneal transplantation.

Methods: Using the self-controlled case series observation approach, 9 patients with ametropia (9 eyes) who underwent DALK surgery for keratoconus 1.5 years ago with stitches removed 3 months ago were kept under observation from May 2013 to April 2014 in Ophthalmic Center of Nanjing Drum Tower Hospital affiliated to Nanjing Medical University. TICL implantation was performed in all patients. The uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) were examined before surgery and 1 week, 6 months, 1 year, and 2 years after surgery. Corneal astigmatism, corneal thickness, anterior chamber depth, corneal endothelial cell density (ECD), and preoperative and postoperative intraocular pressures at different time points were measured. Intraoperative or postoperative complications of TICL implantation were observed, and the safety of the operation was evaluated.

Results: The UCVA and BCVA in all operated eyes were better 6 months after surgery than before surgery. The spherical diopter and cylindrical diopter decreased to different degrees after surgery. Six months after surgery, the deviation of TICL axis in all operated eyes was less than 10 degrees, tending to be stable. No severe intraoperative or postoperative complication occurred.

Conclusion: TICL implantation was an optional choice for ametropia correction after DALK surgery, especially in patients with high astigmatism.

Abbreviations: sBCVA = best-corrected visual acuity, DALK = deep anterior lamellar keratoplasty, ECD= endothelial cell density, TICL = toric intraocular collamer lens, UCVA = uncorrected visual acuity.

Keywords: deep anterior lamellar keratoplasty, keratoconus, phakic intraocular lens implantation, toric intraocular lens

1. Introduction

Corneal transplantation is still the main treatment method for the patients with acute edema or formation of keratoconus. Deep anterior lamellar keratoplasty (DALK) implantation is an effective method for treating keratoconus, but postoperative ametropia, especially high astigmatism, often leads to poor postoperative UCVA.^[1] Although postoperative ametropia can

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be corrected by glasses or the rigid gas-permeable contact lens, the visual quality of patients is poor. At present, a variety of surgical methods have been developed to further improve the visual quality of these patients response to the proper time and conditions such as laser *in situ* keratomileusis (LASIK), surface ablation. However, in patients with high degree of ametropia and thinner corneal thickness, the probability of the occurrence of postoperative complications such as refractive regression and keratomalacia, and so on, increased. Hence, surgery was difficult to implement.^[2] The aim of this study was to explore the clinical application of phakic posterior chamber toric intraocular collamer lens (TICL, Visian ICL; STAAR Surgical) implantation for ametropia following DALK for keratoconus, especially the effectiveness and safety of high astigmatism and indications of TICL implantation after corneal transplantation.

2. Materials and methods

2.1. General information

Using the self-controlled case series observation approach, 9 postoperative patients (3 males, 7 females, 9 eyes) aged 20 to 24 years (average age 22.00 ± 0.67 years) who underwent keratoconus DALK surgery were kept under observation from May 2013 to April 2014 in Ophthalmic Center of Nanjing Gulou Hospital affiliated to Nanjing Medical University. All patients

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^a Department of Ophthalmology, Jinling Clinical Medical College of Nanjing Medical University, ^b Department of Ophthalmology, Nanjing Drum Tower Hospital Clinical College of Nanjing Medical University, Jiangsu Province, People's Republic of China.

^{*} Correspondence: Zhenping Huang, Department of Ophthalmology, Jinling Clinical Medical College of Nanjing Medical University, Nanjing, Jiangsu Province, People's Republic of China (e-mail: hzp19633@126.com).

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were treated with monocular surgery. Descemet's membrane micro perforation in peripheral zone occurred in 2 of the 9 eyes during DALK. After proper treatment, the 2 eyes did not appear obviously complications such as corneal interlaminar effusion, does not affect the prognosis. In the 9 patients, 3 patients another eye use glasses correction, 5 patients use RGP correction, 1 patient with another eye already appeared corneal opacity, plan selective penetrating keratoplasty. The inclusion criteria of this study were as follows: no active inflammation in the ophthalmic anterior segment and corneal graft transparency. The spherical diopter and cylindrical diopter of the operated eyes were 0 to -7.5 D and -1.5 to -6.0 D, respectively. The LogMAR bestcorrected visual acuity (BCVA) was 0.1-0.3. The anterior chamber depth was no less than 3mm. The central corneal endothelial cell count was no less than 2200/mm². DALK surgery was performed 1.5 years ago, and the stitches were removed 3 months ago. The status of the crystalline lens is normal. The refractive status was stable for more than 0.5 years. The exclusion criteria were as follows: cataract, glaucoma, retinal detachment, and a history of neurological eye disease. This study was approved by the ethics committee of Nanjing Gulou Hospital affiliated to Nanjing Medical University. All patients signed informed consent before treatment.

3. Methods

3.1. Preoperative examination of the operated eyes

All operated eyes underwent routine examination before refractive surgery, including the ophthalmic anterior segment examination under a slit lamp microscope, and fundus examination use a Digital Wide Field. The phoropter (Topcon, Japan) was used for subjective optometry, retinoscopy after mydriasis. A-mode ultrasound (AL-4000, Tomey, Japan) was used for measuring eye axial length. Corneal astigmatism, corneal thickness, and anterior chamber depth were measured using Oculyzer II (WaveLight, Alcon). A vernier caliper was used to measure the corneal white-to-white distance and a panoramic UBM was used to measure the Sulcus to Sulcus (STS) distance. Preoperative intraocular pressures of operated eyes were measured using a Goldman applanation tonometer (Keeler, UK). The corneal endothelial cell density (ECD) was measured using a ST3000P corneal endothelial cell counter (Topcon, Japan).

3.2. Approach of TICL implantation surgery

TICL is implantable collagen ICL produced by the STAAR company in the USA. The matched TICL was calculated using the online computing software provided by the STARR company. With the patient sitting, the horizontal axis of the eye position and the rotation circular degree of TICL were marked using markers under a slit lamp microscope. The compound tropicamide eye drops were dripped into the eyes 4 times before the surgery. The pupil diameter was expanded to more than 8mm. Peribulbar anesthesia of the operated eyes was performed. Meanwhile, oxybuprocaine hydrochloride eye drops were dripped into the operated eyes twice for surface anesthesia, with the injector installed correctly and placed in a balanced salt solution (BSS) for use. The TICL position, which needed to rotate during the operation, was determined using a circumferential marking ring. The patients underwent a right-hand side incision. Moderate amounts of sodium hyaluronate (Shandong Bausch & Lomb Freda Company) were injected into the anterior chamber through the incision. Then, the transparent cornea or corneal margin underwent a 3.2-mm incision. After 4 loops of TICL were implanted into the iris through the main and side incisions, the optical surface of TICL was adjusted to the center position. TICL was adjusted to the preoperative marker position and carefully operated to avoid corneal deformation. Then, 0.01% carbachol was injected into the eyes for myosis. The corneal margin underwent an approximately 1.5-mm incision at the 11:00 position. Peripheral iris (about $1 \times 1 \text{ mm}^2$) excision was performed through the incision. The residual viscoelastic agent was flushed out of the eyes, and BSS was injected into the anterior chamber through a watertight incision. The operated eyes were treated with tobramycin–dexamethasone ophthalmic ointment and covered using eyeshades. All operations were performed by the same experienced physician.

3.3. Postoperative management

Postoperative reaction, intraocular pressure, and visual quality were reviewed 1 day after operation. Twenty-five milligrams of oral vinegar amine was administered at the end of operation and at night on the day of surgery. Tobramycin–dexamethasone eye drops (Tobradex, Alcon) were dripped into the eyes 4 times a day for 2 weeks, and then 1% prednisone acetate eye drops (Bailite, Allergan) 3 times a day for 2 weeks. After that, pranoprofen eye drops (Pranpulin, Santen, Japan) were administered 3 times a day for 3 months. Uncorrected visual acuity (UCVA), diopter, BCVA, ECD, intraocular pressure, anterior chamber depth, TICL arch height, and axis position were examined before surgery and 1 week, 6 months, 1 year, and 2 years after surgery.

3.4. Statistical methods

Statistical analyses were performed using SPSS 16.0 (SPSS, IL). The data in this study showed normal distribution using the Shapiro–Wilk test. All data were presented as $\overline{x} \pm s$ and showed homogeneity of variance using the Levene test. Using self-controlled case series study design, the ECD and intraocular pressure in operated eyes after TICL implantation were compared with those before implantation using repeated-measures 2-way analysis of variance. The anterior chamber depth, UCVA, DCVA, and cylindrical diopter in operated eyes 2 years after TICL implantation were compared with that before surgery using the paired *t* test. Statistical significance was set a priori at 0.05.

4. Results

4.1. General conditions of operated eyes after TICL implantation

The mild Tyndall phenomenon was observed in all patients 1 day after surgery. One week after surgery, anterior chamber inflammation disappeared. The UCVA and BCVA in all operated eyes were better more than 0.5 year after surgery than before surgery. The spherical diopter and cylindrical diopter decreased to different degrees after surgery (Table 1). There was statistically significant difference between comparison of UCVA, BCVA, cylindrical diopter before and 2 years after TICL implantation, except ACD (Table 2).

4.2. Changes in ECD and intraocular pressure before and after TICL implantation

The ECD in operated eyes 6 months, 1 year, and 2 years after surgery was slightly lower than that before surgery. However, the

Table 1

Comparison of UCVA, BCVA, and refractive power before and after TICL implantation in patients with keratoconus who underwent DALK, surgery.

		Preoperation		1 week postoperation		6 months postoperation			1 year postoperation		2 years postoperation				
No.	UCVA	BCVA	Refractive power (D)	UCVA	BCVA	Refractive power (D)	UCVA	BCVA	Refractive power (D)	UCVA	BCVA	Refractive power (D)	UCVA	BCVA	Refractive power (D)
1	1.0	0.4	-6×110°	0.2	0.1	-0.25×100°	0.1	0.02	-0.5×100°	0.1	0.02	-0.5×100°	0.1	0.02	-0.5×100°
2	0.5	0.2	-4/-2.75×60°	0.1	0.1	$-0.75 \times 55^{\circ}$	0.04	0.04	$-0.25 \times 50^{\circ}$	0.04	0.04	$-0.25 \times 50^{\circ}$	0.04	0.04	$-0.25 \times 50^{\circ}$
3	0.5	0.1	-4/-1.50×65°	0.1	0.1	-0.25×65°	0.04	0.0	-0.25×65°	0.04	0.0	-0.25×65°	0.04	0.0	$-0.25 \times 65^{\circ}$
4	1.1	0.4	-7.50/-4×110°	0.1	0.0	-0.25/-0.5×105°	0.2	0.0	-0.5/-0.5×105°	0.2	0.0	-0.5/-0.5×105°	0.2	0.0	-0.5/-0.5×105°
5	0.7	0.2	-2/-3.5×75°	0.2	0.2	-0.75×75°	0.2	0.1	$-0.5 \times 70^{\circ}$	0.2	0.1	$-0.5 \times 70^{\circ}$	0.2	0.1	$-0.5 \times 70^{\circ}$
6	0.9	0.3	-3.5/-3.25×80°	0.3	0.3	-0.75×75°	0.2	0.1	$-0.5 \times 75^{\circ}$	0.2	0.1	$-0.5 \times 70^{\circ}$	0.2	0.1	$-0.5 \times 70^{\circ}$
7	0.6	0.3	-2/-4.5×135°	0.2	0.2	-0.5/-0.5×130°	0.2	0.1	-0.5/-0.5×130°	0.2	0.1	-0.5/-0.5×130°	0.2	0.1	-0.5/-0.5×130°
8	0.7	0.1	-4.25/-2.0×95°	0.2	0.0	-0.25/-0.25×100°	0.2	0.0	-0.25×100°	0.1	0.0	-0.25×100°	0.1	0.0	-0.25×100°
9	0.7	0.2	$-2.5/-3.0 \times 15^{\circ}$	0.2	0.1	$-0.25/-0.5 \times 10^{\circ}$	0.2	0.1	$-0.25/-0.5 \times 10^{\circ}$	0,2	0.1	$-0.25/-0.5 \times 10^{\circ}$	0.2	0.1	-0.25/-0.5×10°

BCVA = best-corrected visual acuity (LogMAR), DALK = deep anterior lamellar keratoplasty, TICL = phakic toric intraocular collamer lens, UCVA = uncorrected visual acuity (LogMAR).

difference had no statistical significance (F = 0.375, P = 0.825). The intraocular pressure in operated eyes slightly increased after TICL implantation compared with that before implantation. Six months after surgery, the intraocular pressure gradually stabilized, and the intraocular pressure was within the normal range. The difference had no statistical significance (F=9.871, P=0.394) in general comparison. Ocular pain and corneal edema were observed in 1 patient with high intraocular pressure. However, the symptoms disappeared 24 hours after intravenous infusion of mannitol. The intraocular pressure in another patient was 28 to 31 mm Hg (1 mm Hg=0.133 kPa) 2 weeks after surgery. Carteolol hydrochloride eye drops were dripped into eyes twice per day, and the intraocular pressure was recovered 5 days later (17 mm Hg). One month after operation, the intraocular pressure was stable (Table 3).

4.3. Changes in the anterior chamber depth before and after TICL implantation and status of postoperative TICL central sagitta

Oculyzer II and panoramic UBM measured the preoperative and 2-year postoperative anterior chamber depth was (3.15 ± 0.03) and (3.12 ± 0.03) mm, respectively. The difference had no statistical significance (t=1.56, P=0.16) (Table 2). Panoramic UBM was used to measured postoperative TICL central sagitta (the distance between the central of TICL and clear lens itself). These values are within the normal range at each time point. TICL central sagitta at 2 years postoperatively is from 0.08 to 1.12 mm, with an average of (0.48±0.24) mm.

4.4. Stability of TICL axis

TICL axis measurement methods: after mydriasis, the slit lamp light band was located at horizontal positioning level of artificial

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Comparison of UCVA, BCVA, cylindrical diopter, and ACD befor
and 2 years after TICL implantation ($\overline{x} \pm s$).

Time	No.	UCVA	BCVA	cylindrical (D)	ACD (mm)
Preoperation	9	0.74 <u>+</u> 0.21	0.24 <u>±</u> 0.11	-3.39±1.35	3.15 ± 0.03
Two years postoperation	9	0.14±0.07	0.05 ± 0.05	-0.39 ± 0.13	3.12±0.03
F		9.503	4.867	-7.200	1.560
Р		0.000	0.001	0.000	0.160 [*]

ACD=anterior chamber depth, TICL=phakic toric intraocular collamer lens (paired T test).

 $^{*}=P>0.05$, there was no, statistically significant difference.

lens, and then rotating the slit lamp light band to TICL axis marks. At this point, the location of the light band is the TICL axis. Each eye measured by 3 doctors, average as the end TICL axis. TICL axis measured respectively at the first day after surgery and 1 week, 6 months, 1 year, 2 years after surgery. The absolute value of the difference between the postoperative day 1 and 1 week, 6 months, 1 year, 2 years is the TICL axis deviation value.

One week after surgery, the deviation of TICL axis in all operated eyes was less than 5 degrees. Six months after surgery, the deviation was less than 10 degrees. The deviation tended to be stable 1 year and 2 years after surgery.

4.5. Intraoperative and postoperative complications of TICL implantation

No severe intraoperative complication occurred in all operated eyes. Two patients had postoperative glare 6 months after surgery. The intraocular pressure in only 1 patient was transient rised and recovered soon. Two years after surgery, the lens opacity in center or under the loop of TICL did not appear in all 9 patients (Fig. 1). Nine patients administered postoperative hormone and nonsteroid anti-inflammatory drops during the follow-up period had no obvious rejection.

5. Discussion

The aims of this study were to evaluate the effectiveness and safety of TICL implantation in the treatment of ametropia after DALK in patients with keratoconus, and explore whether TICL was quite an ideal method for ametropia correction after DALK surgery, and discuss indications of TICL implantation after corneal transplantation. The changes in diopter, visual acuity,

Table 3

Changes in ECD and intraocular pressure before and after TICL implant-tation ($\overline{x}\pm s).$

Time	No.	ECD (No./mm ²)	Intraocular pressure (mm Hg)
Preoperation	9	2521.2±307.2	14.56 ± 3.75
1 week postoperation	9	2494.2±306.3	16.62 ± 4.21
6 months postoperation	9	2468.6±304.5	16.57 ± 3.56
1 year postoperation	9	2430.0±305.2	15.64 ± 3.37
2 years postoperation	9	2378.4 ± 309.3	15.15±3.48
F		0.375	9.871
Р		0.825	0.394

ECD = endothelial cell count, TICL = phakic toric intraocular collamer lens (1-way analysis of variance).

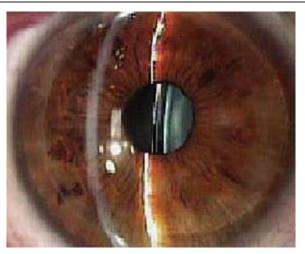


Figure 1. Observation under the slit lamp microscope 2 years after surgery. The figure showed the good position of TICL. TICL = toric intraocular collamer lens.

and ECD were observed in operated eyes of 9 patients with keratoconus who underwent TICL treatment for ametropia correction after DALK surgery.

At present, ICL has been proved to be a safe, effective, and predictable method for treating myopia and astigmatism. The ICL or TICL has been reported to correct residual ametropia after penetrating keratoplasty (PKP) and DALK surgery, especially in patients with high astigmatism. The results of more than 2 years' clinical follow-up were satisfactory.^[3,4] The research results in recent years showed that the degree of myopia that can be corrected by ICL implantation was -3 to -20 D [averaged (-10.06 ± 3.74) D]. Among these patients, 94% had 20/40 or better uncorrected visual acuity, 67.5% had residual ametropia within ± 0.50 D, and 88.2% had residual ametropia within ± 1.0 D. The postoperative BCVA in most of the patients increased; only 0.8% decreased with 2 lines or above.^[5] Studies showed that astigmatism average diopter (-9.36 ± 2.66) D (range -2.38 to -19.5 D) could be corrected to average diopter (-1.93 ± 0.84) D (range -1 to -4 D). Among these patients, 76.9% had residual ametropia within ±0.50 D and 97.3% had residual ametropia within ± 1.0 D. The postoperative BCVA in most of the patients increased in 76.4% of the patients with 1 line or above and only 1.6% with 2 lines or above.^[6] Thus, ICL and TICL are capable of correcting high myopia and astigmatism effectively.

Postoperative ametropia in both PKP and DALK is the main reason of poor visual quality and anisometropia, especially high astigmatism. Some studies reported that the dioptric situation was stable 1.5 years after cornea transplantation in the operated eyes. It was reported that 19% of the operated eyes had 5 D or above astigmatism after corneal transplantation.^[5] Previous studies have found that although postoperative ametropia can be partially corrected using glasses, soft/rigid corneal contact lens, laser in situ keratomileusis, or lens exchange, it often cannot be implemented because of various reasons: corneal contact lens cannot be used in the patients with dry eye or too steep cornea or even some patients unable to accept; glasses cannot be worn in patients with anisometropia; corneal ablation is not suitable for patients with high myopia and astigmatism, or the cutting might exacerbate some ocular surface diseases.^[7-12] Bilgihan et al^[13] reported that the correction of ametropia after PKP by photorefractive keratectomy had several unfavorable factors, such as corneal haze and refractive regression, with low patient satisfaction. The study on correction of ametropia after corneal transplantation using LASIK confirmed similar results. Although it has high predictability and about 50% of patients had error within ± 0.50 D, the application of LASIK is limited because of high myopia and astigmatism, which lead to unpredictable postoperative effect, and the risk of complications such as refractive regression and keratomalacia increases.^[14–17] Transparent lens replacement is not suitable for young patients because they need more conversion between distance and near vision. This study suggested that young patients with implanted TICL could obtain better far and near vision.

TICL implantation should also focus on the loss rate of corneal endothelial cells. In previous studies, some scholars thought that DALK surgery should be performed in the formative stage of keratoconus, as the penetration of the corneal elastic layer in the acute edema stage would result in a decrease in the number of endothelial cells and would not be suitable for the choice of the procedure.^[18] The patients in this study were in the formative stage of keratoconus. The postoperative examination after DALK surgery showed that ECD might be lower than the normal requirements of ICL surgery after examination by cytometry within a certain period of time after DALK surgery. However, it was thought that TICL was still safe because the endothelial rejection would not appear commonly in DALK. ECD and the quality of the corneal endothelial cells were enough to accept TICL implantation. Moshirfar et al^[19] studied 2 cases of patients with correction of PKP residual ametropia by anterior chamber intraocular lens implantation. No significant changes in the postoperative ECD were observed in these 2 patients. Alfonso et al^[20] performed ICL implantation on patients with PKP, with 2-year follow-up. They found that the loss rate of corneal endothelial cells was about 40% per year. Fernandes et al^[21] stated that the mean endothelial cell loss varied from 9.9% at 2 years to 3.7% 4 years postoperatively, and that this loss was more pronounced within the first 1 to 2 years, with stability or lower progression after that time. Jiménez-Alfaro et al^[22] reported that the percentage of endothelial cell loss was 6.57% 2 years after surgery. The US FDA trial demonstrated that the loss rate of corneal endothelial cells was about 3.2% per year and 8.4% to 9.7% 3 years after ICL implantation, which was similar to that post cataract.^[5] In the present study, the mean percentage of endothelial cell loss was 2.3% 3 years postoperatively, which was considerably lower than the findings in previous studies.^[22-28] Our study showed that the loss rate of corneal endothelial cells was about 3.6% in the first year and only 2.1% in the second year. Bourne et al^[29] believed that the loss rate of endothelial cells was large within 2 years after PKP surgery, about 7.8% per year 3 to 5 years after the surgery, and about 4.2% 5 to 10 years after the surgery. The ECD was usually less than 2000/ mm² after PKP^[30]. In this study, the corneal endothelial cells were retained in all patients who underwent DALK surgery. The ECD in most of the patients was higher than 2000/mm², with the endothelial cell loss rate lower than that in patients who underwent PKP surgery. It was reported that ICL implantation could be performed even though ECD was below standard. It was thought that the conclusion should take into account the longterm rejection, especially for the young patients. Implantation of ICL would have an effect on the loss of donor corneal endothelial cells, such as chronic corneal endothelial dysfunction. However, DALK has many advantages. At present, reports on special indications and contraindications of ICL surgery after corneal transplantation are rare. It is believed that the indications of

young patients with TICL implantation after PKP surgery should be strictly controlled; rejection history should be regarded as a contraindication. LASIK might be more suitable. However, ICL and TICL were more suitable for patients who underwent DALK surgery and had no rejection history. The lens opacity was studied after ICL surgery; 2.7% of the patients were found to have anterior subcapsular opacity, and 0.9% of the patients had nuclear opacity 2 to 3 years after the surgery. In the present study, lens opacity was not found in all of 9 patients with TICL implantation within 2 years after the surgery.

No intraoperative or postoperative complication occurred in all operated eyes and the postoperative visual acuity improved, indicating that TICL implantation was an optional choice for ametropia correction after DALK surgery, especially in patients with high astigmatism. We proposed that the indications of TICL implantation after DALK are as follows: no rejection history is reported, and all stitches have been removed with the refractive status stable for more than 0.5 years. Astigmatism \leq 6 D (STARR company can provide TICL correction of astigmatism degree < 6 D), ECD \ge 2000/mm², and ACD \ge 3.0 mm. Although the results of this study were ideal, it is believed that long-term follow-up is needed to further verify the reliability of the surgery and whether or not to extend the time for antirejection drug treatment. In addition, with the application of TICL V4c in China, the operation can be further simplified and ocular trauma can be reduced. Therefore, long-term, large-sample studies should be performed to further observe the long-term clinical effect of TICL.

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