• Clinical Research •

Visual outcomes of implantable Collamer lens and laser-assisted *in situ* keratomileusis for all levels of myopia

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Abstract

● **AIM:** To compare the clinical outcomes of the current V4c model of the myopic implantable Collamer lens (ICL) with those of laser *in situ* keratomileusis (LASIK) for the correction of myopia ranging from −2.0 to −18.0 diopters (D).

● **METHODS:** This prospective, non-randomized study enrolled participants who underwent either LASIK or implantation of the ICL V4c at Bolor Melmii Eye Hospital. In the LASIK group, participants received Intralase LASIK (I-LASIK) using the Intralase FS-200 femtosecond laser and the MEL-80 excimer laser. Each group comprised the same number of participants and eyes (38 participants, 73 eyes).

● **RESULTS:** A total of 146 eyes from 76 participants were analyzed. Among the LASIK group, 76.3% were female, with a mean age at surgery of 29.76±5.95y (range, 20–43y). In the ICL group, 92.1% were female, with a mean age of 31.59±8.32y (range, 20–49y). Preoperative best-corrected visual acuity (BCVA) did not differ significantly between the LASIK and ICL groups (*P*=0.68). Postoperatively, the ICL group consistently demonstrated better BCVA (20/20 or better) at all follow-up points, with statistically significant differences observed at 1d (56.2% *vs* 30.1%, *P*=0.003) and 3mo (54.8% *vs* 32.9%, *P*=0.012). The mean BCVA improvement also favored the ICL group for up to 6mo postoperatively. A higher proportion of eyes in the ICL group achieved uncorrected distance visual acuity (UDVA) of 20/20 or better at 1mo (50.7% *vs* 41.1%, *P*=0.319) and 6mo (57.5% *vs* 43.8%, *P*=0.136), although these differences were not statistically significant. Predictability was comparable between the groups, except at 6mo, where fewer ICL-treated eyes were within ±0.5 D of the intended correction (49.3% *vs* 64.4%, *P*=0.094). Nevertheless, both groups achieved identical outcomes within ±1.0 D (90.4%, *P*=1.000). Between 1 and 6mo, 78.1% of eyes in the ICL group showed a change in spherical equivalent refraction of no more than 0.5 D, compared to 65.8% in the LASIK group. Refraction stability, defined as a change of less than 1.0 D, remained good in both groups throughout all follow-up periods.

● **CONCLUSION:** Both LASIK and ICL implantation leads to significant improvements in visual outcomes, with early postoperative gains observed in both groups. However, the ICL group demonstrates greater long-term improvement in BCVA compared to the LASIK group, particularly among participants with higher degrees of myopia. Visual outcomes in both groups stabilized by 6mo postoperatively.

● **KEYWORDS:** laser *in situ* keratomileusis; implantable Collamer lens; best corrected visual acuity; manifest refractive spherical equivalent

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INTRODUCTION

Myopia, widely recognized as the most common refractive error, poses a substantial challenge to quality of life by affecting individuals' daily activities and overall well-being[1]. Refractive surgery is a well-established and widely utilized method for the correction of myopia, hyperopia, and astigmatism[2]. Among these procedures, laser-assisted *in situ* keratomileusis (LASIK) remains the standard approach, with approximately 95% of participants reportedly satisfied with their visual outcomes, particularly in cases of low to moderate ametropia[3]. The procedure involves creating

a flap in the cornea, followed by a computer-controlled laser application to reshape the cornea and rectify ocular refraction issues. LASIK is renowned for its swift visual recovery and minimal patient discomfort[4-5]. LASIK improves vision by correcting refractive errors, including myopia, hyperopia, and astigmatism[6]. However, its effectiveness in correcting high refractive cylinders is limited. Factors such as residual ocular astigmatism, misalignment between refractive and topographic astigmatic axes, and internal optical astigmatism may influence postoperative outcomes, especially in participants with myopic astigmatism[7]. Various other procedures have been employed in refractive surgery, including photorefractive keratectomy (PRK), radial keratotomy (RK), laser thermal keratoplasty (LTK), and small incision lenticule extraction (SMILE), among others[8]. The introduction of laser flap makers in refractive surgery received approval from the United States Food and Drug Administration (FDA) in 1999, while the femtosecond laser, specifically for flap creation, was approved in 2001. Femtosecond laser-assisted LASIK (femto-LASIK) represents a significant innovation in the field, offering improved outcomes, greater long-term stability, and fewer complications compared to earlier techniques[9-10]. LASIK has gained popularity among participants with low to moderate myopia. Nonetheless, the application of LASIK, including femtosecond LASIK (FS-LASIK), is limited in cases of high myopia or in participants with thin corneas due to the associated risk of postoperative complications, such as corneal ectasia[11].

The implantable Collamer lens (ICL), a posterior chamber phakic intraocular lens, is widely used for the correction of moderate to high ametropia[12]. ICL surgery is designed to address refractive errors by implanting a Collamer lens into the eye. The ICL is permanently inserted throughout the surgery between the eye's natural lens and the iris, collaborating with the natural lens to refract light onto the retina, enhancing visual clarity[13-14]. In December 2005, the U.S. FDA approved the ICL for the correction of myopia ranging from −3.0 diopters (D) to −20.0 D[15]. This procedure offers several advantages: it is not limited to corneal thickness, and the ICL implant can be removed if necessary[16-17]. ICL's cost may vary, requiring individuals to verify coverage with their insurance provider[18]. The Visian ICL V4c model incorporates Central FLOW technology, which features a 360-μm central hole that facilitates natural aqueous humor circulation. This design eliminates the need for preoperative laser iridotomy and reduces the risk of cataract formation and corneal endothelial cell loss[19-20].

In Mongolia, Bolor Melmii Eye Hospital first introduced LASIK surgery in 2005, and to date, over 7000 participants have undergone PRK, LASIK, and femto-LASIK procedures at this center. ICL implantation has also been performed at the same institution since 2016, in collaboration with the Chukyo Group clinic in Japan.

The purpose of this study is to provide a detailed comparison of clinical outcomes between the current V4c version of the myopic ICL and LASIK for the correction of myopia ranging from −2.0 D to −18.0 D. Conducted in Mongolia, this research aims to evaluate the efficacy, safety, and long-term stability of both procedures in treating moderate to high myopia.

PARTICIPANTS AND METHODS

Ethical Approval The study adhered to the ethical guidelines of the Declaration of Helsinki. Written informed consent for data analysis was obtained from all participants. This study was conducted with the approval of the Research Ethics Committee of the Mongolian National University of Medical Sciences (approval number: 2021/3-6, dated May 21, 2021).

Participants This prospective, non-randomized study enrolled participants who underwent either LASIK (Carl Zeiss Meditec AG, Jena, Germany) or implantation of the ICL V4c (ICL™, STAAR Surgical, Nidau, Switzerland) at Bolor Melmii Eye Hospital. A total of 146 eyes from 76 subjects were included.

In the LASIK group, 73 eyes from 38 participants were treated. Among these 38 participants, 3 underwent surgery in only one eye. All LASIK procedures were performed using Intralase LASIK (I-LASIK) with the Intralase FS-200 femtosecond laser and the MEL-80 excimer laser. Similarly, the ICL group consisted of 73 eyes from 38 participants, of whom 3 underwent surgery in only one eye.

As noted above, each group comprised the same number of participants and eyes (38 participants, 73 eyes). Participants eligible for LASIK or ICL V4c implantation met the following criteria: age between 20 and 45y; stable refractive error, defined as a change of less than 0.5 D over the preceding 2y; spherical equivalent (SE) ranging from −2.0 to −18.0 D; astigmatism up to −4.0 D; and no contact lens use for at least two weeks prior to evaluation. For ICL implantation specifically, additional requirements included an anterior chamber depth (ACD) greater than 2.8 mm and a corneal endothelial cell density (ECD) exceeding 2000 cells/mm^2. Eyes with relatively thinner corneas were preferentially selected for ICL V4c implantation. Participants were excluded if they had a history of severe dry eye syndrome, corneal pathology, cataract, suspected keratoconus, glaucoma, neuro-ophthalmic disorders, ocular inflammation, prior ocular surgery, or chronic systemic diseases that could affect ocular health or surgical outcomes.

Surgical Procedures

Intralase LASIK The procedure begins with the creation of a corneal flap using a femtosecond laser (Intralase FS-200). The laser generates a photo-disruptive effect by inducing the formation of microbubbles composed of carbon dioxide

and water vapor within the corneal stroma. This process is precisely directed at a predetermined corneal thickness of approximately 100 μm, with laser pulses delivered in a spiral and raster scanning pattern to achieve a planar, uniform flap. The microbubble layer initially measures about 1 mm in thickness and expands to 2–3 mm as the corneal lamellae separates. During flap creation, a suction ring is applied to stabilize the globe and is released immediately after the flap is fully formed.

Following flap creation, excimer laser ablation is performed on the exposed anterior stromal surface using the MEL-80 excimer laser. The excimer laser ablates corneal tissue *via* photoablative decomposition, whereby ultraviolet (UV) radiation (wavelength approximately 193 nm) breaks molecular bonds in the corneal collagen without significant thermal damage to adjacent tissues. This precise removal of stromal tissue reshapes the corneal curvature to correct the refractive error, thereby enabling light to focus accurately on the retina and reducing dependence on corrective lenses.

Implantable Collamer lens V4c Power calculations for the ICL V4c were conducted following the manufacturer's guidelines, employing a modified vertex formula based on the patient's preoperative refractive data. The appropriate lens size was selected according to measurements of the horizontal white-to-white (WTW) corneal diameter and the ACD, ensuring optimal vaulting and positioning within the posterior chamber.

Preoperative and postoperative examinations Standard assessments performed before and after surgery included SE, uncorrected distance visual acuity (UDVA), and best-corrected visual acuity (BCVA). Slit-lamp biomicroscopy and fundus examination were conducted to evaluate the anterior and posterior segments of the eye. Intraocular pressure (IOP) was measured using a non-contact tonometer (Canon, Japan). ACD and axial length were measured with the IOL Master device (Carl Zeiss, Germany). Central corneal thickness and WTW were also determined using the IOL Master. For participants undergoing ICL implantation, additional evaluation of corneal ECD was performed to monitor endothelial health.

Surgical Technique and Follow-Ups

I-LASIK All LASIK surgeries were performed by a single experienced surgeon using the Intralase FS-200 femtosecond laser and MEL-80 excimer laser system (Carl Zeiss Meditec AG, Jena, Germany). The femtosecond laser operated at a repetition rate of 200 kHz with a wavelength of 1030 nm and a spot size of 5 μm. Flap creation parameters were standardized for all participants, including a superior hinge, a fixed flap diameter of 9.0 mm, a side cut angle of 70°, and a planned flap thickness of 110 μm. Following flap creation, myopic laser ablation was performed using the MEL-80 excimer laser, with the goal of achieving full refractive correction and postoperative emmetropia.

ICL V4c implantation ICL V4c implantations were carried out by two experienced surgeons. Preoperatively, pupils were pharmacologically dilated, and a horizontal axis mark was placed on the limbus to facilitate accurate alignment of the Toric ICL (TICL) when indicated. The anterior chamber was then filled with a viscoelastic agent (sodium hyaluronate) to maintain chamber depth and protect intraocular structures. The ICL was implanted *via* a 3.0-mm temporal corneal incision using an injector cartridge and carefully positioned in the posterior chamber, behind the iris, and in front of the natural crystalline lens. Following implantation, all residual viscoelastic material was thoroughly removed by irrigation and aspiration with balanced salt solution to minimize postoperative IOP spikes.

Postoperative care and follow-up Participants in both the LASIK and ICL groups received standardized postoperative care protocols. Follow-up examinations were scheduled for 1d, 1, 3, 6mo, and 1y after surgery to monitor visual outcomes, IOP, corneal health, and any potential complications.

Statistical Analysis Clinical outcomes for both the ICL and LASIK groups were extracted from patient records and compiled into Microsoft Excel (Microsoft Corp., Redmond, WA) for data management. Statistical analyses were performed to compare the two groups. For dichotomous variables—such as categories of BCVA and UDVA at levels of 20/15, 20/20, and refractive stability within ±0.5 D or ±1.0 D—appropriate categorical tests were applied. For ordinal categorical and interval-level data, including distributions of visual acuity, changes in UDVA or BCVA, predictability, and refractive stability, the nonparametric Mann-Whitney *U* test was used.

All data tabulation and statistical analyses were conducted using STATA version 22 (StataCorp LLC, College Station, TX, USA) and SPSS version 21.0 (IBM Corp., Armonk, NY, USA). Statistical significance was set at $P<0.05$.

RESULTS

Participants' basic characteristics and demographic information are summarized in Table 1. Among the 38 subjects treated with LASIK, 76.3% were female, with a mean age at surgery of 29.76±5.95y (range, 20–43y). In the ICL group, 92.1% of the 38 subjects were female, with a mean age of 31.59±8.32y (range, 20–49y).

Comparative Visual Acuity Outcomes: LASIK *vs* ICL for High Myopia Based on the collected data, our initial comparison focused on visual acuity outcomes. Although a greater proportion of eyes in the ICL group achieved a BCVA of 20/20 or better preoperatively (35.6% *vs* 15.1%; $P=0.003$; Table 2), the overall distribution of preoperative BCVA did not differ significantly between the LASIK and

Table 1 Preoperative participant characteristics and demographic information mean±SD

Parameters	ICL	LASIK	*P*
Spherical equivalent, D	−7.15±3.61	−6.21±2.54	0.0001
Astigmatism, D	−1.84±1.69	−1.58±1.31	0.908
Male/female	3/35	9/29	
Age, y	31.59±8.32	29.76±5.95	0.429
Education, *n* (%)			
None	0	2 (5.3)	
Basic/senior high	21 (55.3)	25 (65.8)	
Higher	17 (44.7)	11 (28.9)	
Occupation, *n* (%)			
Self-employed	11 (28.9)	15 (39.5)	
Employed in public sector	7 (18.4)	10 (26.3)	
Employed in private sector	20 (52.6)	13 (34.2)	

ICL: Implantable Collamer lens; LASIK: Laser-assisted *in situ* keratomileusis; SD: Standard deviation.

Table 2 Comparison of ICL *vs* LASIK clinical outcomes

Parameters	ICL	LASIK	*P*
BCVA (% 20/20 or better)			
Preoperative	26/73 (35.6%)	11/73 (15.1%)	0.003
1d	41/73 (56.2%)	22/73 (30.1%)	0.003
1mo	37/73 (50.7%)	30/73 (41.1%)	0.319
3mo	40/73 (54.8%)	24/73 (32.9%)	0.012
6mo	42/73 (57.5%)	32/73 (43.8%)	0.136
Loss of BCVA ≥2 lines			
1d	2/73 (2.7%)	3/73 (4.0%)	1.000
1mo	1/73 (1.4%)	6/73 (8.2%)	0.116
3mo	0/73 (0)	4/73 (5.5%)	0.120
6mo	1/73 (1.4%)	0/73 (0)	1.000
Loss of BCVA ≥1 line			
1d	6/73 (8.2%)	13/73 (17.8%)	0.139
1mo	2/73 (2.7%)	7/73 (9.6%)	0.116
3mo	3/73 (4.0%)	7/73 (9.6%)	0.326
6mo	4/73 (5.5%)	5/73 (6.8%)	1.000
Improvement of BCVA ≥2 lines			
1d	9/73 (12.3%)	2/73 (2.7%)	0.056
1mo	9/73 (12.3%)	8/73 (10.9%)	1.000
3mo	11/73 (15.1%)	7/73 (9.6%)	0.451
6mo	11/73 (15.1%)	9/73 (12.3%)	0.810
Improvement of BCVA ≥1 line			
1d	23/73 (31.5%)	13/73 (17.8%)	0.083
1mo	23/73 (31.5%)	19/73 (26.0%)	0.584
3mo	23/73 (31.5%)	18/73 (24.6%)	0.462
6mo	23/73 (31.5%)	20/73 (27.4%)	0.717
Change in BCVA (mean line change)			
1d	0.63±1.48	0.05±1.27	0.083
1mo	0.67±1.43	0.39±1.47	0.858
3mo	0.69±1.48	0.33±1.4	0.619
6mo	0.63±1.74	0.65±1.17	0.839

BCVA: Best corrected visual acuity; LASIK: Laser *in situ* keratomileusis; ICL: Implantable Collamer lens.

ICL groups (*P*=0.68). Postoperatively, at all follow-up visits from 1d to 6mo, the ICL group consistently demonstrated a higher percentage of eyes attaining BCVA of 20/20 or better compared to the LASIK group, with statistically significant differences observed at 1d (56.2% *vs* 30.1%; *P*=0.003) and 3mo (54.8% *vs* 32.9%; *P*=0.012).

When considering the full distribution of BCVA values rather than focusing solely on the 20/20 threshold, the ICL group consistently demonstrated superior BCVA at all postoperative visits from 1 to 6mo. At baseline, 35.6% of eyes in the ICL group had a BCVA of 20/20, which remained stable at 50.7% at 1mo, improved to 54.8% at 3mo, and further increased to 57.5% at 6mo (Table 2). In contrast, the LASIK group started with 15.1% of eyes achieving 20/20 or better BCVA at baseline, improved to 41.1% at 1mo, decreased to 32.9% at 3mo, and rose again to 43.8% at 6mo postoperatively. Preservation of BCVA was superior in the ICL group both during the immediate postoperative healing period and throughout the 6-month follow-up. The incidence of losing two or more lines of BCVA was higher in the LASIK group during the early postoperative period, although this difference did not reach statistical significance (1mo: 8.2% *vs* 1.4%; *P*=0.116; Table 2). Improvement of more than two lines in BCVA was more pronounced in the ICL group compared to the LASIK group at 1mo (12.3% *vs* 10.9%; *P*=1.000), 3mo (15.1% *vs* 9.6%; *P*=0.451), and 6mo (15.1% *vs* 12.3%; *P*=0.810). Similar trends were observed when analyzing gains and losses of at least one line of BCVA (Table 2). Losses of one or more lines were more frequent in the LASIK group at 1mo (9.6% *vs* 2.7%; *P*=0.116). Conversely, gains of at least one line were consistently greater in the ICL group at all time points. At the 6-month follow-up, 31.5% of participants in the ICL group experienced an improvement of one or more lines of BCVA, compared to 27.4% in the LASIK group. The mean change in BCVA favored the ICL group significantly up to 6mo postoperatively (Table 2). Both groups exhibited improvements as early as 1-day post-surgery, with results stabilizing by 6mo. Overall, the ICL group demonstrated superior mean improvement in BCVA, particularly during the first 6mo following surgery.

Improvement in UDVA Following LASIK and ICL for High Myopia Next, we performed an analysis to determine the differences in UDVA between the methods. UDVA improved markedly in both groups (Table 3). The proportion of eyes achieving 20/20 or better UDVA was significantly different between the groups at 1mo (ICL group: 50.7% *vs* LASIK group: 41.1%; *P*=0.319) and 6mo postoperatively (ICL group: 57.5% *vs* LASIK group: 43.8%; *P*=0.136). Although the proportion of eyes with 20/40 or better UDVA was identical on the first postoperative day (95.6% in both groups; *P*=1.000),

the ICL group demonstrated a higher proportion of eyes with 20/40 or better uncorrected acuity at 1mo through 6mo. However, these differences were not statistically significant. The results showing that, both LASIK and ICL groups experienced significant improvements in UDVA after surgery, with the ICL group maintaining slightly better visual outcomes over time, though the differences were not substantial.

Comparison of Predictability and Refractive Cylinder Between LASIK and ICL Predictability, defined as the proportion of eyes achieving refractive correction within ±0.5 and ±1.0 D of the intended target, was comparable between the LASIK and ICL groups at all postoperative visits (Table 4). Specifically, the LASIK group demonstrated predictability rates of 64.4% within ±0.5 D and 90.4% within ±1.0 D, consistent with previously reported outcomes for LASIK. Prior studies have documented predictability within ±0.5 D ranging from 66% to 81%, and within ±1.0 D ranging from 84% to 95%. Although the preoperative SE and refractive cylinder were higher in the ICL group compared to the LASIK group (1.84±1.69 *vs* 1.58±1.31 D; *P*=0.908), postoperative values were significantly lower in the LASIK group at all follow-up visits (Table 4).

Predictability was comparable between the two groups at all postoperative visits, except at the 6-month follow-up. At this time point, the proportion of eyes within ±0.5 D of the intended refractive correction were lower in the ICL group compared to the LASIK group (49.3% *vs* 64.4%; *P*=0.094). However, the percentage of eyes within ±1.0 D was identical between the groups, with both achieving 90.4% (*P*=1.000) at 6mo postoperatively (Table 4).

Refraction Stability Comparison Between LASIK and ICL Refraction stability, defined as the proportion of eyes with a change of less than 0.5 D, was significantly better in the ICL group compared to the LASIK group over the 6-month follow-up period (Table 5). Specifically, between 1 and 6mo postoperatively, 78.1% of eyes in the ICL group exhibited a change in SE of no more than 0.5 D, compared to 65.8% in the LASIK group. When assessed using a broader threshold of less than 1.0 D change, refraction stability was generally favorable in both groups at all time points, with no statistically significant differences observed. Importantly, this analysis considered the full distribution of refractive changes rather than relying solely on ±0.5 or ±1.0 D cutoffs.

Table 3 Improvement in UCVA following LASIK and ICL for high myopia

Parameters	ICL	LASIK	*P*
UDVA (20/20 or better)			
1d	41/73 (56.2%)	22/73 (30.1%)	0.003
1mo	37/73 (50.7%)	30/73 (41.1%)	0.319
3mo	40/73 (54.8%)	24/73 (32.9%)	0.012
6mo	42/73 (57.5%)	32/73 (43.8%)	0.136
UDVA (20/15 or better)			
1d	3/73 (4.1%)	0/73 (0)	0.245
1mo	0/73 (0)	0/73 (0)	1.000
3mo	0/73 (0)	0/73 (0)	1.000
6mo	0/73 (0)	2/73 (2.7%)	0.497
UDVA (20/40 or better)			
1d	70/73 (95.6%)	70/73 (95.6%)	1.000
1mo	71/73 (97.3%)	67/73 (91.8%)	0.275
3mo	70/73 (95.6%)	69/73 (94.5%)	1.000
6mo	71/73 (97.3%)	73/73 (100%)	0.497

UDVA: Uncorrected distance visual acuity; LASIK: Laser *in situ* keratomileusis; ICL: Implantable Collamer lens.

Table 4 Comparison of predictability and refractive cylinder between LASIK and ICL

Parameters	ICL	LASIK	*P*
Predictability (±0.5 D)			
1d	37/73 (50.7%)	32/73 (43.8%)	0.507
1mo	37/73 (50.7%)	32/73 (43.8%)	0.507
3mo	36/73 (49.3%)	39/73 (53.4%)	0.741
6mo	36/73 (49.3%)	47/73 (64.4%)	0.094
Predictability (±1.0 D)			
1d	63/73 (86.3%)	58/73 (79.5%)	0.380
1mo	63/73 (86.3%)	58/73 (79.5%)	0.380
3mo	67/73 (91.8%)	60/73 (82.2%)	0.139
6mo	66/73 (90.4%)	66/73 (90.4%)	1.000
Mean sphere			
Preoperative	−7.15±3.61	−6.21±2.54	0.000
1d	0.06±0.46	0.36±0.69	0.068
1mo	0.06±0.46	0.36±0.69	0.064
3mo	0.01±0.46	0.26±0.57	0.100
6mo	−0.05±0.52	0.11±0.61	0.082
Mean cylinder			
Preoperative	1.84±1.69	1.58±1.31	0.908
1d	0.96±0.66	0.64±0.56	0.001
1mo	0.96±0.66	0.64±0.56	0.001
3mo	0.91±0.63	0.61±0.52	0.004
6mo	0.89±0.62	0.56±0.32	0.004

LASIK: Laser *in situ* keratomileusis; ICL: Implantable Collamer lens.

DISCUSSION

This study demonstrates significant advantages in visual acuity, safety, and efficacy for both LASIK and ICL V4c implantation in the correction of high myopia over a 6-month follow-up period in Mongolia. Both procedures yielded comparable visual outcomes and safety profiles, with no loss of BCVA observed in either group at 6mo postoperatively. From a safety perspective, our findings reveal a 0 incidence of BCVA loss greater than two lines in the LASIK group at 6mo, consistent with or better than the 0–0.9% range reported in FDA-approved LASIK clinical trials (Table 6). This underscores

Table 5 Refraction stability comparison between LASIK and ICL

Parameters	ICL	LASIK	*P*
Stability of SE (±0.5 D)			
1d to 1mo	73/73 (100%)	73/73 (100%)	1.000
1 to 6mo	57/73 (78.1%)	48/73 (65.8%)	0.140
Stability of SE (±1.0 D)			
1d to 1mo	73/73 (100%)	73/73 (100%)	1.000
1 to 6mo	61/73 (83.6%)	67/73 (91.8%)	0.207

LASIK: Laser *in situ* keratomileusis; ICL: Implantable Collamer lens; SE: Spherical equivalent.

the high safety profile of LASIK, aligning with previously established standards. Regarding efficacy, UDVA outcomes in our LASIK cohort were broadly comparable to those reported in FDA excimer LASIK trials. Specifically, 43% of eyes in our study achieved 20/20 or better UDVA, compared to 59% in FDA trials, while 100% attained 20/40 or better vision, slightly surpassing the 97% reported by the FDA. These results indicate that both LASIK and ICL V4c provide effective correction for high myopia, although our LASIK group demonstrated a somewhat lower proportion of eyes achieving 20/20 UDVA (Table 6).

Various studies have undertaken comparative analysis of the visual outcomes and complications associated with ICL, SMILE, and LASIK surgeries, yielding insightful findings. One study comparing these procedures revealed no significant differences in postoperative visual outcomes, safety, and efficacy indices among SMILE, FS-LASIK, and ICL, highlighting their comparable performance[21]. Conversely, a Meta-analysis examining visual outcomes, optical quality, and aberrations of SMILE and ICL indicated that ICL exhibited superior safety, efficacy, predictability, and stability compared to LASIK[22]. Moreover, a retrospective study underscored ICL's safety and efficacy in high myopia cases, demonstrating comparable long-term visual stability and patient satisfaction for low myopia correction[23]. Additionally, a comparative analysis between ICL and LASIK accentuated ICL's efficacy for individuals with higher myopic degrees, contrasting LASIK's affordability and shorter recovery period[24]. A comparative study scrutinized the indications and outcomes of surgery for high myopia, explicitly focusing on the ICL and LASIK. This research aimed to assess the safety and effectiveness of ICL versus LASIK for participants with high myopia, providing crucial insights into the suitability of each procedure for this demographic[25-26].

Visual acuity improved to 20/20 or better in 39.6% of the eyes treated, with both surgical techniques showing significant postoperative gains. These findings corroborate earlier studies by Varshney *et al*[12] and Ye *et al*[27], who reported favorable refractive outcomes following refractive surgery. Notably, our results align with those of Sanders *et al*[15], who documented 100% of ICL eyes and 86% of FS-LASIK eyes achieving 20/20 vision at 1y, although their study focused on lower myopia (up to −6 D). Our inclusion of a broader myopia range (−2 to −20 D) adds clinical relevance, particularly given that FS-LASIK has been associated with increased regression and suboptimal outcomes for myopia exceeding −5 D. Further supporting our findings, a study from Fudan University Hospital in China reported that 94% of participants undergoing ICL implantation achieved postoperative 20/20 vision, with 42% gaining two or more lines[20]. In our cohort, 49.3% of eyes had a SE within ±0.50 D, and 90.4% within ±1.0 D, comparable to Miao *et al*'s[20] results (60% and 83%, respectively) and to Shimizu *et al*'s[28] 2016 findings (88% within ±0.50 D and 96% within ±1.0 D), and Jiang *et al*[29], 2021 findings SE ±0.5 D was achieved in 97.92% in ICL group and 68.97% in FS-LASIK group.

In this study, participants had a significant improvement in visual acuity in the third and sixth months postoperatively, there was a significant increase in visual acuity in ICL group than in the FS-LASIK group. Similarly, Sallam *et al*[30], indicated there was a significant increase in visual acuity in ICL group than in the FS-LASIK group. Collectively, these data affirm the safety and effectiveness of both procedures for high myopia correction.

In conclusion, both LASIK and ICL V4c implantation demonstrate comparable safety and efficacy for the treatment of high myopia in Mongolia. Outcomes with the ICL align closely with FDA benchmarks and, in many instances, match or exceed those achieved by LASIK. Future studies employing matched preoperative refractive profiles and larger sample sizes will further elucidate the relative advantages of these surgical options and optimize patient selection.

This study has several limitations that should be acknowledged. Study design: A retrospective design was adopted due to the high cost of prospective data collection. While this approach allowed us to analyze existing data, it inherently carries a risk of selection bias and incomplete data capture. A prospective study would enable more rigorous control of baseline characteristics, standardized follow-up, and systematic data collection, thereby improving the internal validity of future findings. Baseline refractive characteristics: The groups were not matched for preoperative SE, with the ICL cohort demonstrating, on average, 0.94 D greater myopia. This discrepancy may have introduced bias in favor of LASIK, as higher baseline myopia is typically associated with less predictable refractive outcomes. If baseline refractive errors were evenly matched, a more precise comparison of the two surgical techniques could be achieved. Astigmatic differences: Preoperative cylindrical error was lower in the LASIK group;

Table 6 Comparison to FDA refractive target values at 6mo after surgery

Variable	ICL	LASIK	FDA refractive target value
BCVA loss>2 lines	1.4%	0–1%	<5% refractive lasers
BCVA loss≥2-lines	1.4%	0	<5% refractive implants
BCVA>20/40 or better	100%	95%–100%	85%≤7 D preoperative MRSE
Predictability ±1.0 D	90%	90%	75%≤7 D preoperative MRSE
Predictability ±0.5 D	49%	64.0%–75.3%	50%≤7 D preoperative MRSE
Stability endpoint criteria	100%	95%–100%	95%≤1 D change between 2 consecutive visits

FDA: The United States Food and Drug Administration; LASIK: Laser *in situ* keratomileusis; ICL: Implantable Collamer lens; BCVA: Best corrected visual acuity; MRSE: Manifest refractive spherical equivalent; D: Diopter.

however, postoperative cylinder was significantly reduced in this group, reflecting effective astigmatic correction. Matching participants for baseline cylinder would allow a more balanced evaluation of astigmatic correction efficacy between the two procedures. Sample size and representativeness: The relatively small sample size and gender imbalance—largely due to the limited annual number of ICL procedures performed in Mongolia (4–6 cases per year)—may restrict the generalizability of the results. Larger, more balanced cohorts would enhance the statistical power of subgroup analyses and strengthen the external validity of the findings. Distribution of myopia severity: Participants with all degrees of myopia were included in varying numbers, which limited the ability to compare outcomes across different severities. Stratified recruitment in future studies would enable a clearer understanding of whether one procedure is superior in specific ranges of myopia. Follow-up duration: The relatively short follow-up period limited assessment of long-term efficacy and safety outcomes. Extending follow-up intervals would provide valuable insights into the stability of refractive correction and the incidence of late complications. Despite these limitations, our study provides an initial comparative assessment of LASIK and ICL in the Mongolian context. As the number of ICL procedures continues to increase in the country, addressing these limitations in future prospective, large-scale, and long-term studies will yield more definitive evidence regarding the relative efficacy, safety, and suitability of these surgical options across different degrees of myopia.

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