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Research Article

Preliminary Clinical Study of a LenSx Femtosecond Laser-Assisted Limbal Relaxing Incision for the Correction of High Myopia with Low to Moderate Astigmatism in Posterior Implantable Collamer Lens Implantation

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Purpose. To evaluate the safety, efficacy, and predictability of implantable collamer lens (ICL) implantation combined with a LenSx femtosecond laser-assisted limbal relaxing incision (LRI) for the correction of corneal astigmatism. *Methods*. This prospective study enrolled 64 eyes (54 patients) with high myopia with low to moderate regular corneal astigmatism. They were divided into an ICL group with ICL implantation (18 patients, 20 eyes), a TICL group with toric ICL implantation (17 patients, 23 eyes), and a LenSx + ICL group with a LenSx femtosecond laser-assisted LRI and an ICL implantation (19 patients, 21 eyes). Visual acuity, astigmatism correction ability, and visual quality were measured before and 1, 3, and 6 months after surgery. *Results*. The postoperative visual acuity of the 3 groups was higher than the preoperative visual acuity ($P < 0.01$), and the improvements in the LenSx + ICL group and the TICL group were greater than those in the ICL group ($P < 0.01$). The LenSx + ICL and TICL groups had less residual astigmatism and a higher astigmatism correction index (CI) than the ICL group ($P < 0.01$). There was no significant difference among the three groups in total high-order aberrations (HOAs) before and after surgery ($P > 0.05$). *Conclusion*. LenSx femtosecond laser-assisted LRI can effectively correct low to moderate corneal astigmatism during ICL implantation surgery. It can achieve similar clinical effects in the short term compared with TICL implantation.

1. Introduction

In recent years, the implantable collamer lens (ICL, STAAR Surgical Co.) has become one of the mainstream of intraocular refractive surgeries due to its effectiveness, safety, and predictability [1]. There are two methods for patients who decide to receive treatment with ICL implantation with corneal astigmatism less than −1.50 D. One way is to implant toric ICL, but this procedure can have some disadvantages, such as lens rotation and long waits [2]. The other method is ICL implantation, but residual astigmatism after surgery is often accompanied by a decline in visual acuity, as well as contrast sensitivity and night vision [3]. In 2009, femtosecond laser-assisted cataract surgery (FLACS, Alcon Surgical, Inc.) began to be applied. In addition to incision making, lens capsule release, and lens nucleus fragmentation, some scholars have attempted to resolve corneal astigmatism with femtosecond laser-assisted limbal relaxing incision (LRI) and have achieved ideal results [4–6]. However, there have been no relevant reports on the application of femtosecond laser-assisted LRI in ICL implantation. In this study, we compared LenSx femtosecond laser-assisted LRI combined with ICL implantation with traditional TICL and ICL implantation to explore the safety, effectiveness, and stability of this new method.

2. Methods

2.1. Patients. From January 2019 to May 2019, 54 patients aged 18–44 years old with high myopia between -6.00 D and −14.75 D and low to moderate regular corneal astigmatism between −0.75 D and −1.50 D were recruited from the Chongqing Aier-Mega Eye Hospital (Chongqing, China). According to the principles of random selection and voluntary participation, the patients were divided into 3 groups, including 20 eyes of 18 patients in the ICL group, 23 eyes of 17 patients in the TICL group, and 21 eyes of 19 patients in the LenSx + ICL group. There were no statistically significant differences among the 3 groups before the operation (Table 1). The inclusion criteria of the three groups were consistent with the consensus of ICL clinical experts, and the corneal astigmatism of the patients was consistent with the total astigmatism.

The uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), residual astigmatism, and correction index (CI) were collected before and 1, 3, and 6 months after surgery. The iTrace analyzer (Collin, Tracy, USA) measured and recorded the total high-order aberrations (HOAs) and modulation transfer function (MTF) values to observe the astigmatism correction and visual quality of the patients after surgery. Vector analysis was performed utilizing the Alpins vector method with ASSORT software (ASSORT Pty; Cheltenham, Victoria, Australia) to show the magnitude and directionality of the residual astigmatism. The UDVA and CDVA were examined using a logarithmic visual acuity chart and converted to the logMAR scale for statistical analysis.

This study was approved by the medical ethics committee of Chongqing Aier Eye Hospital [batch number: 2019 (IRB010)], and all patients signed the informed consent documentation. This study adhered to the tenets of the Declaration of Helsinki.

2.2. Surgical Procedures. In the LenSx + ICL group, astigmatism axis location was determined using online software (Abbott Medical Optics, USA, available at http://www.lricalculator.com) before ICL implantation. Individual surgeons' surgically induced astigmatism was considered to be 0.5 D (Figure 1). The computer automatically calculated the position, depth, and arc length of the limbal relaxing incision according to the vector calculator. The depth of the limbal relaxing incision (the setting depth was 85% of the corneal thickness) was measured under the guidance of an anterior optical coherence tomography segment. Patients were moved to a conventional operating table after the LRI was finished, and the remaining steps were completed according to the conventional ICL surgery procedure. In the ICL group, after surface anesthesia, the surgeon made a 3 mm main incision at the scleral limbus, slowly implanted the lens into the anterior chamber, and adjusted the lens into the ciliary sulcus under the iris to ensure a centered position of the ICL. The postoperative eye was treated with TobraDex eye ointment and covered well. In the TICL group, the surgeon simply rotated the lens according to the astigmatism axis provided by the STAAR company after implantation.

All of the operations were performed by an experienced surgeon without any complications.

2.3. Statistical Analysis. All of the statistical analyses were performed using SPSS software (version 19, SPSS Inc). The figures were drawn using GraphPad Prism software (version 8, GraphPad Software). The data are presented as the mean ± standard deviation. Student's t-test was used for normally distributed data, and the Mann–Whitney U test was used for nonnormally distributed data. One-way ANOVA was used to analyze the differences among the 3 groups of different operative methods, and LSD was used to perform additional multiple comparison tests. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Surgical Complications. The postoperative follow-up found that, in the LenSx + ICL group, there was only a short arc-length relaxing incision left under the cornea after the surgery (Figure 2). There was no bleeding or infiltration of the incision, the tightness was good, and no complications (such as infection or poor healing of the incision) occurred.

3.2. Visual Acuity. The visual acuity before and after surgery in each group is shown in Table 2. Figure 3 shows that the UDVA in the 3 groups at 1, 3, and 6 months after surgery was better than the CDVA before the operations, and the differences were all statistically significant ($P < 0.05$).

We further compared the CDVA before and after surgery in the 3 groups (Figure 4). At 1, 3, and 6 months after the operations, the CDVA was improved compared with that before surgery, and the differences were statistically significant ($P < 0.05$).

3.3. Residual Astigmatism and CI. Residual astigmatism was shown using the astigmatism double-angle plot of the Alpins vector analysis method (Figures 5 and 6). Compared with the ICL group, the LenSx + ICL group and the TICL group had smaller residual astigmatism at 1, 3, and 6 months after the operations, and the differences were statistically significant ($P < 0.01$). Further comparison was preformed between the LenSx + ICL group and the TICL group, and the residual astigmatism of the LenSx + ICL group was slightly lower than that of the TICL group at 1 month after surgery, whereas that of the TICL group was lower than that of the LenSx + ICL group at 3 and 6 months after surgery; however, these differences were not statistically significant ($P > 0.05$). Table 3 and Figure 7 showed the CI ($\mathrm{CI} = |\mathrm{SIA}|/|\mathrm{TIA}|$) values for the 3 groups at 1, 3, and 6 months after the operations. Among these groups, the LenSx + ICL group and the TICL group had higher CI than the ICL group, and the differences were statistically significant ($P < 0.01$). However, there was no statistically significant difference between the LenSx + ICL group and the TICL group after surgery ($P > 0.05$).

3.4. Total HOAs and MTF Values. None of the total HOAs in the 3 groups before or 1, 3, or 6 months after surgery showed statistically significant differences ($P > 0.05$) (Table 4 and Figure 8).

Table 5 shows that there were no statistically significant differences in the MTF values among the 3 groups before the operations at pupil diameters of 3 mm or 5 mm ($P = 0.722$,

Table 1: Preoperative data of patients.

Parameter	LenSx + ICL group	TICL group	ICL group	P value
Age (years)	24.19 ± 5.65	26.83 ± 7.99	23.60 ± 3.77	0.18
Number of eyes	21	23	20	—
Spherical refraction (D)	−8.41 ± 1.68	−8.19 ± 2.25	−7.89 ± 1.64	0.67
Cylindrical refraction (D)	−1.18 ± 0.18	−1.25 ± 0.19	−1.12 ± 0.18	0.38

Note: there was no statistical difference among the three groups before operation.

Figure 1: Example of LRI surgical planning (https://www.lricalculator.com).

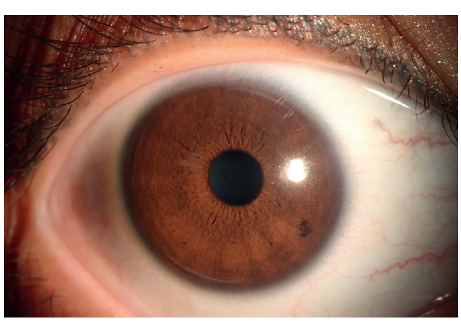

Figure 2: The location of the cornea limbal relaxing incision in the LenSx + ICL group after surgery (the red arrow in the Figure shows the location of limbal relaxing incision).

$P = 0.849$). Figure 9 shows the comparison among the 3 groups after surgery that the MTF values of the TICL group were always slightly higher than those of the LenSx + ICL group, but the differences were not statistically significant ($P > 0.05$). The MTF values in the TICL group were always higher than those in the ICL group, and the differences were statistically significant ($P < 0.01$). Except for the condition of a 3 mm diameter pupil at 6 months after surgery, the MTF values in the LenSx + ICL group were always better than those in the ICL group, whether at 1, 3, or 6 months after the operation ($P < 0.05$).

4. Discussion

Astigmatism is one of the common types of refractive error in the eye. Previous studies have reported that nearly 80% of individuals with refractive errors have astigmatism of varying degrees, and approximately 25% of individuals have astigmatism greater than −1.00 D [7]. Astigmatism greater than −0.75 D can cause diplopia, blurred vision, and photophobia [8]. The STARR company launched TICL implantation for astigmatism correction; however, the lens can rotate in the ciliary sulcus after implantation, which can lead to a decrease in astigmatism correction or create a new astigmatism. Panel C [9] showed that an axial deviation of 10 degrees in TICL could only correct 2/3 of the estimated astigmatism, and a deviation of 30 degrees had no correction effect at all. If the deviation exceeds 30 degrees, there will be symptoms such as diplopia, dazzle, and decreased visual acuity, which have a significant impact on patients [10–12]. Some scholars have attempted to perform LRIs to resolve the corneal low to moderate astigmatism in ICL implantation

Table 2: The UDVA and CDVA before and after surgery in each group.

Parameter		Pre-CDVA (LogMAR)	Post-CDVA (LogMAR)	Post-UDVA (LogMAR)
1 month	LenSx + ICL group	0.052 ± 0.051	−0.043 ± 0.050	−0.038 ± 0.059
	TICL group	0.030 ± 0.047	−0.083 ± 0.058	−0.083 ± 0.058
	ICL group	0.025 ± 0.044	−0.025 ± 0.055	−0.025 ± 0.055
	P value	$P = 0.154$	—	—
3 months	LenSx + ICL group	0.052 ± 0.051	−0.076 ± 0.044	−0.029 ± 0.046
	TICL group	0.030 ± 0.047	−0.091 ± 0.060	−0.083 ± 0.072
	ICL group	0.025 ± 0.044	−0.040 ± 0.050	−0.015 ± 0.049
	P value	$P = 0.154$	—	—
6 months	LenSx + ICL group	0.052 ± 0.051	−0.071 ± 0.046	−0.033 ± 0.048
	TICL group	0.030 ± 0.047	−0.078 ± 0.052	−0.083 ± 0.065
	ICL group	0.025 ± 0.044	−0.055 ± 0.051	−0.020 ± 0.052
	P value	$P = 0.154$	—	—

logMAR = logarithm of the minimum angle of resolution, CDVA = corrected distance visual acuity, UDVA = uncorrected distance visual acuity, Pre = preoperative, and Post = postoperative. Means ± SD, the P values in the table shows the comparison among the three groups.

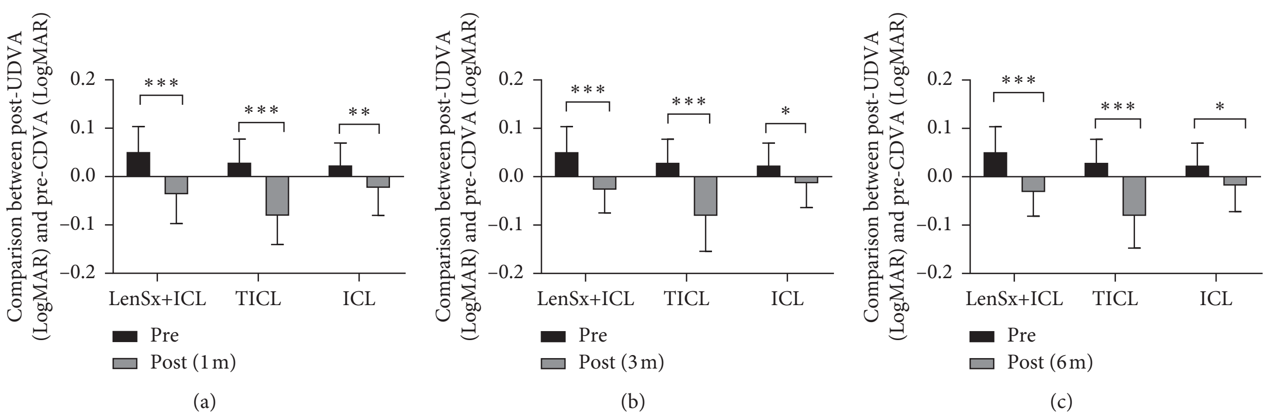

Figure 3: The postoperative LogMAR UDVA and preoperative LogMAR CDVA in three groups after surgery at 1, 3, and 6 months (the results are expressed as means ± SD, * means $P < 0.05$, and *** means $P < 0.001$). (a) Comparision between post-UDVA (LogMAR) and pre-CDVA (LogMAR). (b) Comparision between post-UDVA (LogMAR) and pre-CDVA (LogMAR). (c) Comparision between post-UDVA (LogMAR) and pre-CDVA (LogMAR).

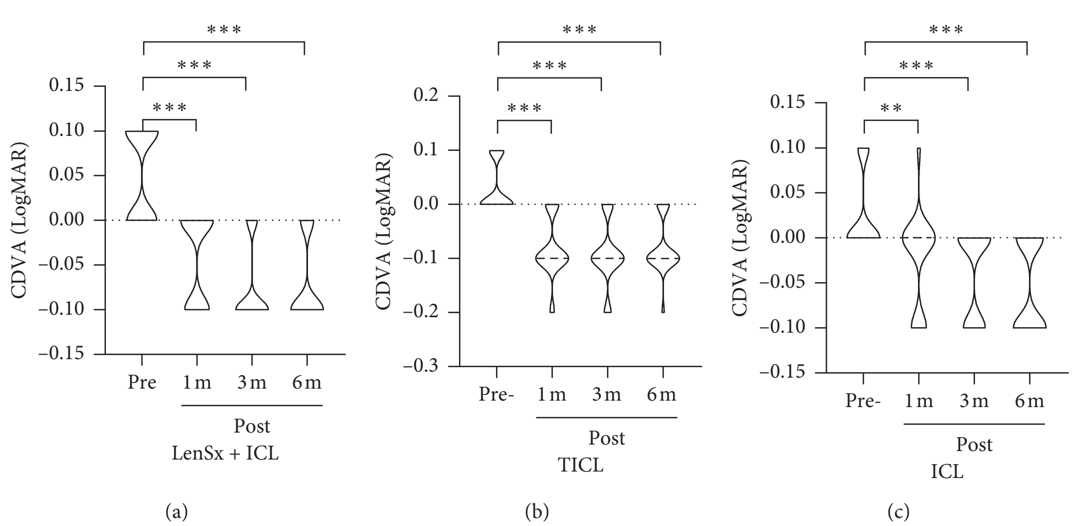

Figure 4: The LogMAR CDVA before and after surgery at 1, 3, and 6 months in three groups (the results are expressed as means ± SD, ** $P < 0.01$, and *** $P < 0.001$).

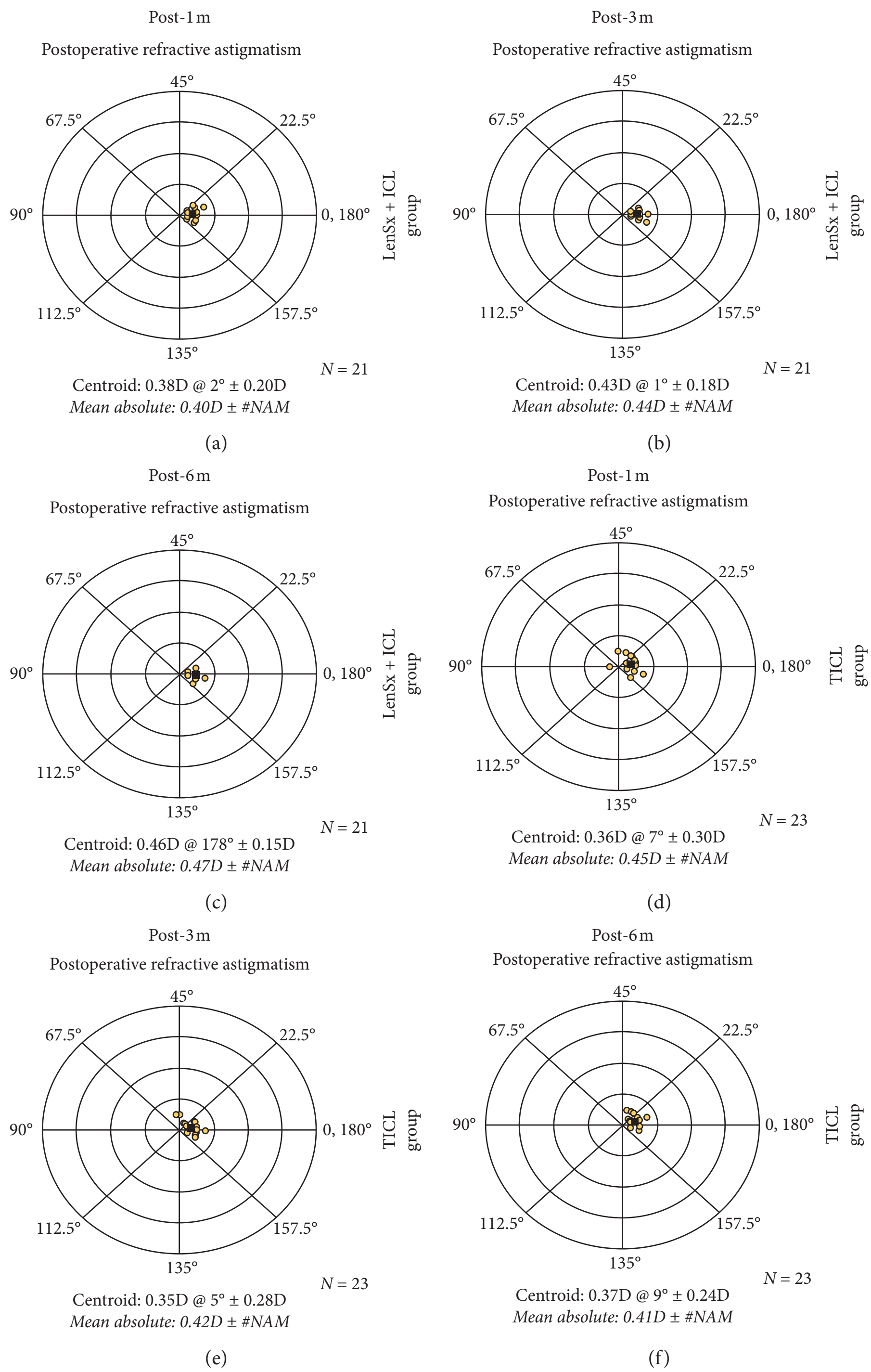

Figure 5: Continued.

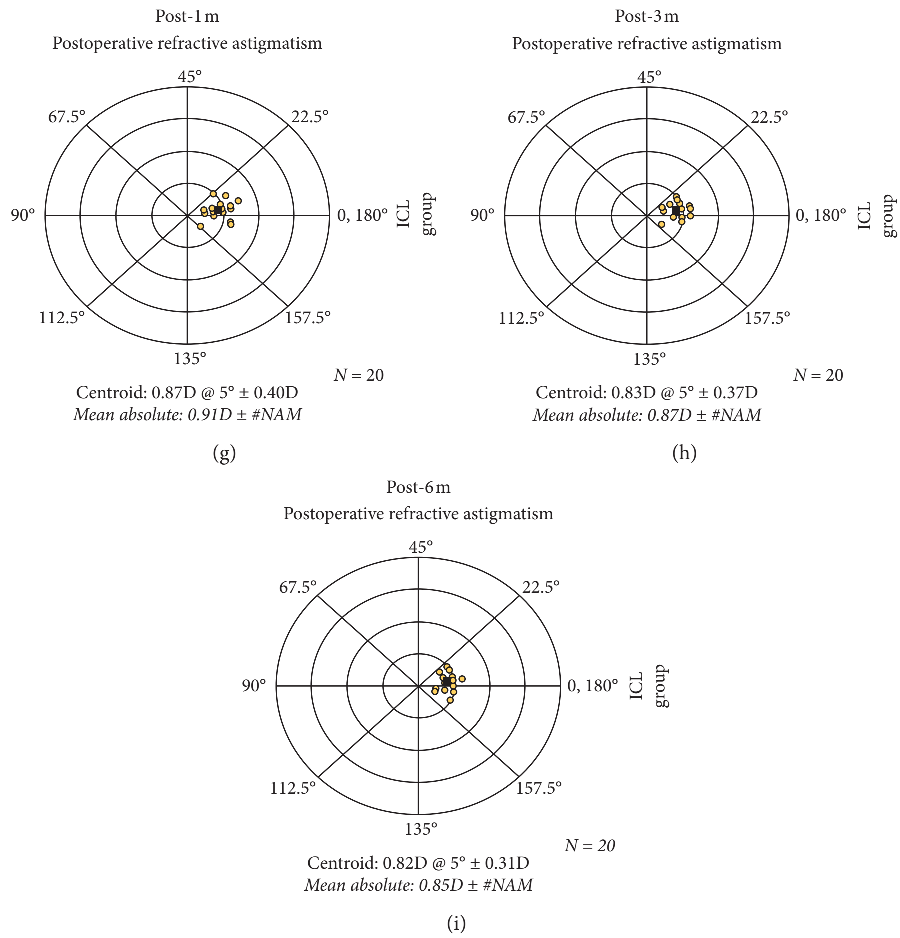

Figure 5: Double-angle plot vector analysis of postoperative residual astigmatism distribution in three groups at 1, 3, and 6 months (the figure shows the LenSx + ICL group, TICL group, and ICL group, respectively, each ring = 1.00 D). (a) Post-1 m postoperative refractive astigmatism. (b) Post-3 m postoperative refractive astigmatism. (c) Post-6 m postoperative refractive astigmatism. (d) Post-1 m postoperative refractive astigmatism. (e) Post-3 m postoperative refractive astigmatism. (f) Post-6 m postoperative refractive astigmatism.

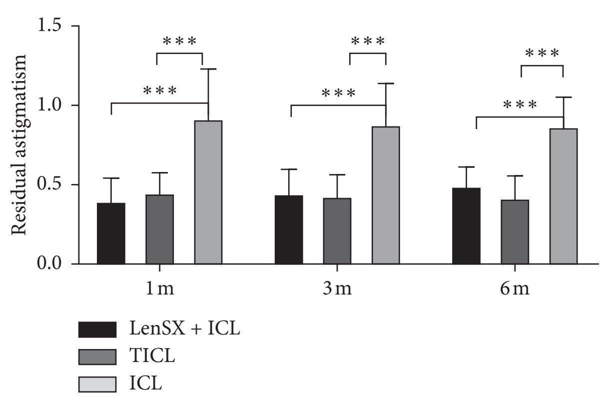

Figure 6: The comparison of postoperative residual astigmatism in three groups at 1, 3, and 6 months (the results are expressed as means ± SD and $^{***}P < 0.001$).

[13]. However, the traditional LRIs are performed manually, and it is difficult to achieve accurate length, position, and depth of the incision, often rendering the astigmatism correction effect unpredictable [4]. In cataract surgery, some scholars have attempted to solve corneal astigmatism with the help of femtosecond laser-assisted LRIs and they have achieved ideal results. This study compares traditional ICL implantation, TICL implantation, and femtosecond laser-assisted LRIs with ICL implantation to assess the safety, efficacy, and predictability of this new approach to treating astigmatism, and we hope to propose a new treatment for the correction of low to moderate astigmatism in ICL surgery.

This study found that the UDVA of the 3 groups improved compared with the preoperative CDVA. This result showed that the three methods could improve the visual acuity to a certain extent. In addition, the postoperative CDVA in all 3 groups was better than the preoperative CDVA, and the differences were statistically significant. This outcome showed that, regardless of traditional ICL implantation or femtosecond-assisted ICL implantation, there was no decrease in CDVA, reflecting the safety of the surgery and suggesting that, for some patients with amblyopia, this new method can correct visual acuity to a degree that is unobtainable with ordinary frame glasses, thus improving patient quality of life.

Compared with the ICL group, the residual astigmatism was smaller in the LenSx + ICL group and the TICL group

Table 3: CI in three groups after surgery.

	LenSx + ICL group	TICL group	ICL group	P value
1 month	0.66 ± 0.15	0.64 ± 0.12	0.25 ± 0.19	$P = 0.89$, $P < 0.001$
3 months	0.62 ± 0.16	0.66 ± 0.12	0.25 ± 0.20	$P = 0.69$, $P < 0.001$
6 months	0.59 ± 0.12	0.66 ± 0.12	0.27 ± 0.16	$P = 0.13$, $P < 0.001$

Note: the front P value in the column is the pairwise comparison result of LenSx + ICL group and TICL group and the latter one is the comparison of LenSx + ICL group and TICL group, respectively, with ICL group (means ± SD).

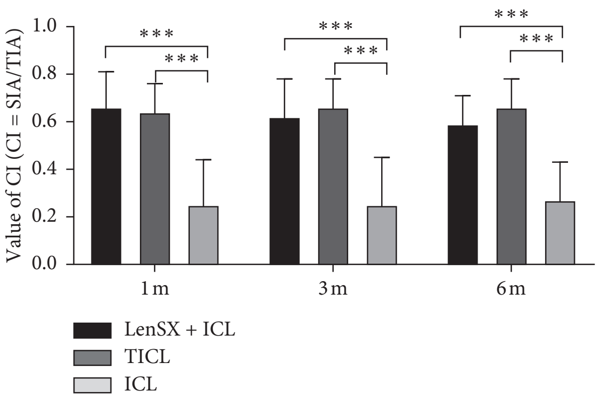

Figure 7: The comparison in astigmatism correction index among the three groups after surgery at 1, 3, and 6 months (the results are expressed as the means ± SD, $^{***}P < 0.001$).

after surgery, indicating that the LenSx + ICL group and TICL group experienced better astigmatism correction than the ICL group. Although the residual astigmatism between the LenSx + ICL and TICL group displayed some differences, these differences were not statistically significant. To compare the astigmatism correction capabilities of the three methods, CI values were compared with each group. CI=1 indicates that the expected astigmatism was completely corrected, CI <1 indicates undercorrection, and CI >1 indicates overcorrection. These CI values were less than 1 in all three groups, indicating that all three groups were undercorrected after surgery. Among the groups, the LenSx + ICL and TICL group had higher CI values than the ICL group, and, similar to residual astigmatism, there were no statistically significant differences between the LenSx + ICL and TICL groups. We found that the CI values in the LenSx + ICL group decreased with the operation time, just as the residual astigmatism values increased. It is considered that, during long-term corneal incision healing in the LenSx + ICL group, the diopter of the astigmatism is increased, indicating astigmatism regression and thus a possible slight decrease in visual acuity and visual quality. This outcome is consistent with the research by Tetikoğlu [14], which found that the healing process of the surgical incision directly affects corneal astigmatism and thus affects the change in corneal aberration. It also suggests that we can further explore the problem of astigmatism regression caused by corneal incision healing and adjust the nomogram to obtain a more stable and longer-term astigmatism correction effect.

In recent years, refractive surgeons have aimed not only to improve the visual acuity of patients but also to improve patients' visual quality through a series of personalized operations. Myopia and astigmatism are low-order aberrations (LOAs) and cannot truly reflect the visual quality of patients. Therefore, we collected and studied the HOAs of three methods to analyze the visual quality of postoperatively. We used the iTrace visual quality analyzer to analyze the patients' visual quality before and after surgery. The iTrace analyzer uses optical path tracing technology, and the visual quality of the patient can be simulated by computer software. The iTrace analyzer can convert the point spread function to a Fourier transformation to obtain the MTF curve. Currently, many scholars [15] use the iTrace analyzer to compare the visual quality of patients between femtosecond laser-assisted cataract surgery and traditional phacoemulsification surgery. We selected two major indicators of visual quality, total HOAs and MTF value. Lower HOAs and higher MTF values indicated better visual quality. This study collected patients' total HOAs and MTF values with pupil diameters of 3 mm and 5 mm before and after surgery. The total HOAs in the 3 groups before and 1, 3, and 6 months after surgery displayed no statistically significant differences, indicating that no new HOAs were introduced among the three methods. This outcome is consistent with some earlier research, including that of Zhou Xingtao et al. [16], who used the OQAS objective visual quality analysis system to compare the visual quality of wavefront aberration-guided LASIK surgery and ICL implantation and concluded that ICL implantation introduced no new aberrations and achieved better visual quality than LASIK. In another long-term comparative observation over 3 years, Zhou Chen et al. [17] also found that, compared with traditional refractive surgery, ICL implantation offered more stable visual acuity and smaller aberrations. This study found that the MTF values of the TICL group were always slightly higher than those of the LenSx + ICL group; however, the differences were not statistically significant. Compared to the ICL group, the LenSx + ICL and TICL groups had higher MTF values, except for the comparison between the LenSx + ICL and ICL groups under a 3 mm diameter pupil in 6 months after the surgery. The results showed that, compared with the ICL implantation, the visual acuity in the LenSx + ICL group was clearly superior, and the visual quality of the patients was better. In addition, the LenSx + ICL group achieved a similar effect to that with TICL implantation.

Postoperative follow-up found that only a short arc-length incision was left under the cornea in the LenSx + ICL group after surgery. There was no bleeding or infiltration of

Table 4: The total HOAs in three groups before and after surgery.

Groups	Parameter (mm)	Pre	Post-1 m	Post-3 m	Post-6 m	P value
LenSx + ICL group	3	0.189 ± 0.055	0.199 ± 0.063	0.189 ± 0.051	0.181 ± 0.060	0.789
	5	0.413 ± 0.173	0.390 ± 0.123	0.396 ± 0.119	0.410 ± 0.123	0.935
TICL group	3	0.154 ± 0.093	0.140 ± 0.080	0.138 ± 0.058	0.141 ± 0.063	0.888
	5	0.359 ± 0.181	0.372 ± 0.167	0.354 ± 0.146	0.349 ± 0.139	0.969
ICL group	3	0.237 ± 0.130	0.242 ± 0.098	0.250 ± 0.111	0.229 ± 0.103	0.948
	5	0.477 ± 0.171	0.500 ± 0.155	0.498 ± 0.117	0.486 ± 0.093	0.940

Pre = preoperative and Post- = postoperative. Means ± SD, comparison.

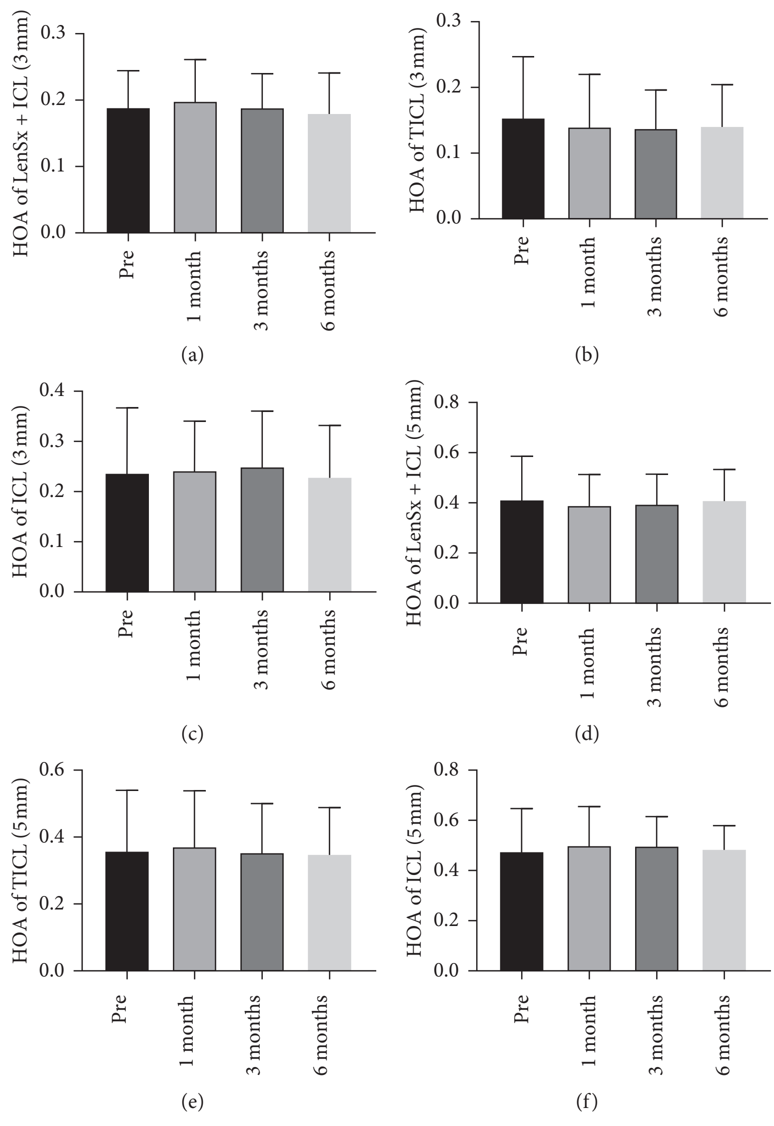

Figure 8: The total high-order aberrations in the three groups before and after surgery at 1, 3, and 6 months (the results are expressed as the means ± SD).

the incision, and the postoperative tightness was good. There were no complications, such as infection or poor healing of the incision. Masket et al. [18] also showed that femtosecond laser-assisted corneal incisions are much neater and tighter than manual corneal incisions. Studies by Chung et al. [19] also showed that femtosecond laser-assisted cataract phacoemulsification surgery yields good watertightness and neatness in the corneal incision. Traditional manual corneal incisions are relatively poorly sealed, and this inevitably resulting in edema of the surrounding tissues during the

Table 5: The MTF value among three groups.

Parameter		LenSx + ICL group	TICL group	ICL group	P value
Pre	3 mm	0.267 ± 0.067	0.282 ± 0.096	0.263 ± 0.065	0.722
	5 mm	0.211 ± 0.044	0.220 ± 0.079	0.212 ± 0.042	0.849
Post-1 m	3 mm	0.356 ± 0.063	0.374 ± 0.091	0.279 ± 0.077	0.0005
	5 mm	0.276 ± 0.041	0.287 ± 0.090	0.213 ± 0.053	0.0012
Post-3 m	3 mm	0.364 ± 0.079	0.391 ± 0.083	0.289 ± 0.072	0.0003
	5 mm	0.274 ± 0.078	0.295 ± 0.059	0.218 ± 0.047	0.0006
Post-6 m	3 mm	0.357 ± 0.074	0.381 ± 0.072	0.307 ± 0.071	0.0047
	5 mm	0.261 ± 0.081	0.284 ± 0.066	0.203 ± 0.033	0.0004

Pre = preoperative and Post- = postoperative. Means ± SD, comparison.

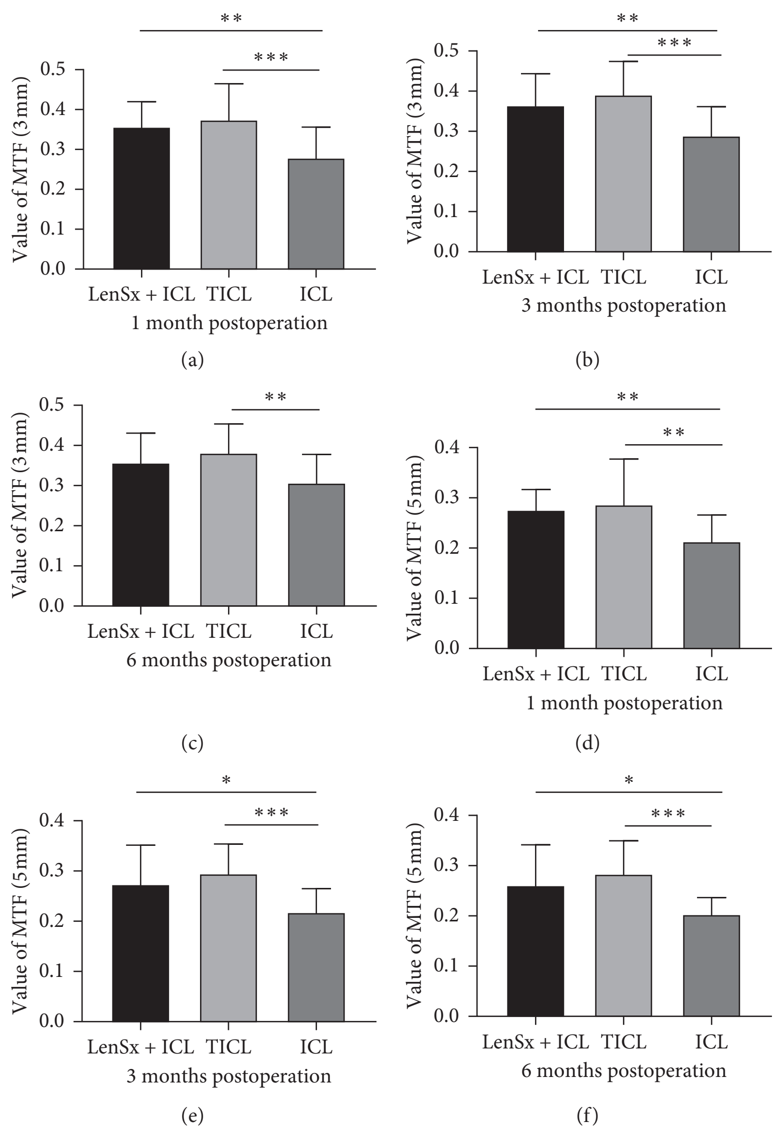

Figure 9: The comparison of modulation transfer function values among three groups after surgery at 1, 3, and 6 months at pupil diameters of 3 mm and 5 mm (the results are expressed as means ± SD, $^{*}P < 0.05$, $^{**}P < 0.01$, and $^{***}P < 0.001$).

postoperative period, causing an increase in high-order aberrations after surgery.

5. Conclusion

In summary, this study provided a new method to resolve high myopia combined with low to moderate astigmatism, and it preliminarily verified the safety, efficacy, and predictability of this method of astigmatism correction. Femtosecond laser-assisted LRI combined with ICL implantation could be an alternative because of time constraints or rotation of the TICL lens. In addition, it is probable that the femtosecond parameters (such as incision depth and arc length) can be further optimized to obtain a stable and long-term astigmatism correction. However, due to ethical considerations, this study did not establish a manual LRI combined with an ICL implantation group, and the numbers of patients included were limited. We plan to compare the manual LRI and femtosecond LRI in the next step. Therefore, larger samples and a longer follow-up time are needed in further studies to verify the surgical effects.

Data Availability

Data analyzed during the current study are available from the corresponding author on reasonable request.

Disclosure

A similar article has been submitted to other article in June of this year, and I may have unintentionally checked agree to publish the preprint version, so you can find the article on the website. But this article was not published by the journal in the end; the link is only a preprint version for reading. Although the titles of the two articles are same, the content of this article has been more meticulously revised and is different from the previous one. An e-mail was sent to the website to opt the previous article out.

Conflicts of Interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Acknowledgments

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