

# Implantable collamer lens with a central hole for residual refractive error correction after corneal refractive surgery

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## Research article

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# Abstract

**PURPOSE:** To assess the visual and refractive outcomes of an implantable collamer lens with a central hole (ICL V4c) for residual refractive error correction after corneal refractive surgery in individuals with myopia. **DESIGN:** Prospective, nonrandomized observational case series (self-controlled). **METHODS:** We investigated 16 eyes of eight consecutive patients with myopia undergoing ICL V4c implantation after corneal refractive surgery. The uncorrected visual acuity (UCVA) and best-corrected visual acuity (BCVA) were examined before surgery and 1 month, 3 months, and 6 months after surgery. We quantitatively assessed the postoperative values of the modulation transfer function (MTF) cutoff frequency, Strehl ratio, objective scattering index (OSI), and OQAS values (OVs) by using an Optical Quality Analysis System. **RESULTS:** At 6 months after surgery, the mean uncorrected logMAR VA was  $0.06 \pm 0.10$ , and the values had improved in 100% of the eyes. The mean MTF cutoff frequency, Strehl ratio, OSI, OV 100%, OV 20%, and OV 9%, were  $31.29 \pm 4.32$  cycles/degree (c/d),  $0.18 \pm 0.04$ ,  $1.469 \pm 0.47$ ,  $0.97 \pm 0.26$ ,  $0.75 \pm 0.29$ , and  $0.51 \pm 0.23$  at 6 months after ICL V4c implantation, respectively. **CONCLUSION:** ICL V4c implantation was safe and effective for the correction of residual refractive error after corneal refractive surgeries, and it had excellent optical performance.

## Introduction

The Visian Implantable Collamer Lens (ICL™, STAAR Surgical, Switzerland) was applied to the correction of high myopia more than ten years<sup>[1-4]</sup>. Especially in recent years, with the improvement of surgical techniques and the update of ICL design, it has been applied more and more widely. As this surgical procedure is largely reversible, allowing the lens to be exchanged, when refractive changes and unexpected complications occur after surgery. The currently used approaches for the correction of residual refractive error after corneal refractive surgeries mainly include corneal enhancement surgeries and relaxing corneal incisions<sup>[5-8]</sup>. Considering the thinner corneal thickness after corneal refractive surgery, it is unsafe to perform corneal laser surgery again. Especially in patients with large residual refractive error, the application of ICL shows unique advantages.

Previous studies have demonstrated that ICL V4c implantation for correcting moderate to high myopia has good safety, efficacy, predictability, and stability after long-term follow-up<sup>[9-11]</sup>. Recently, ICL implantation has also been confirmed to perform well for low and moderate myopia<sup>[12-13]</sup>. These provide theoretical support and guidance for the use of ICL to correct residual refractive errors after corneal refractive surgery.

In addition, in order to evaluate the visual quality after ICL implantation, we used an Optical Quality Analysis System (OQAS; Terrassa, Spain), which was a device that uses the double-pass technique to assess the quality of retinal imaging. Previously, it has been generally used to evaluate the visual quality after ICL implantation<sup>[14-16]</sup>.

The current study mainly evaluated the safety and efficacy of ICL implantation for residual refractive errors after corneal laser surgery by observing the visual acuity and visual quality.

## Materials And Methods

The study was approved by the ethics committee of The Ninth Hospital of Jiao Tong University. It followed the tenets of Declaration of Helsinki. Written consent was obtained from all patients after the possible consequences of the study were explained.

This study included a total of 16 eyes from eight patients (three men and five women) who underwent implantation of a phakic posterior chamber ICL V4c for residual refractive error after corneal refractive surgeries between August 10, 2015 and February 19, 2018 at Shanghai Ninth Hospital Affiliated with Jiao Tong university.

All patients underwent full ophthalmic evaluation at the refractive surgery center preoperatively and met the surgical requirements. An anterior chamber depth of 2.80 mm or more and an endothelial cell density >2,000 cells/mm<sup>2</sup> were included in the inclusion criteria in this study. It was required that patients had a reasonable expectation of surgical outcomes, and patients with keratoconus, cataract, or glaucoma and systemic disease were excluded.

All surgeries were performed by the same experienced surgeon. The ICL model used in this study was ICL V4c with a 0.36-mm central artificial hole (ICL V4c™, STAAR Surgical). For ICL V4c implantation, the patients did not undergo preoperative or intraoperative peripheral iridotomies, which was different from the V4 operation process. On the day of surgery, the pupil of the patients was enlarged first. After topical anesthesia, a model V4c ICL was inserted through a 3-mm temporal clear corneal incision after injection of 1% sodium hyaluronate into the anterior chamber. The ICL V4c was placed in the posterior chamber, and the viscoelastic surgical agent was washed out of the anterior chamber. Especially I/A tip should be aimed at the central hole to aspirate the viscoelastic surgical agent behind ICL and to ensure it completely cleared. Postoperative medications included antibiotic eye drops, steroidal eye drops, and artificial tear drops. All surgeries were uneventful, and no intraoperative complications occurred.

Before and 6 months after surgery, the uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refractive error, and visual quality (OQAS, Spain) were evaluated. By the optical quality parameters, the objective scattering index (OSI), MTF cutoff frequency, Strehl ratio, and Optical Quality Analysis System value (OV), the OQAS was used to evaluate the visual performance. The meanings and calculations of the parameters have been shown in several previous studies<sup>[20-22]</sup>.

## Statistical analysis

All statistical analyses were performed in SPSS version 20.0 (SPSS Inc., IBM, USA), and the results are expressed as mean ± SD. Preoperative parameters were analysed by using the paired *t*-test, and the

postoperative p value was determined by using repeated measurement analysis of covariance. A p value < 0.05 was considered statistically significant.

## Results

All surgeries were uneventful, and no postoperative complications were observed during the 6 month follow up. The preoperative logMAR UCVA and BCVA were  $0.48 \pm 0.23$  and  $0.09 \pm 0.08$ , respectively. After the operations, the logMAR UCVA and BCVA improved significantly, to  $0.06 \pm 0.10$  and  $-0.02 \pm 0.07$  (Wilcoxon signed rank test,  $p < 0.001$ ). The manifest refractive spherical equivalent (MRSE) changed from  $-4.26 \pm 2.89$  D preoperatively to  $-0.53 \pm 0.31$  D at 1 month and  $-0.37 \pm 0.29$  D at 6 months after ICL implantation (Table 1).

Six months after surgery, none of the examined eyes had lost one line or more of BCVA. Four eyes did not change after surgery, eight eyes gained one line, and four eyes gained two lines of BCVA (Figure 1). The safety indices (postoperative CDVA/preoperative CDVA) and the efficacy indices (postoperative UDVA/preoperative CDVA) at 6 months were  $1.26 \pm 0.21$  and  $1.19 \pm 0.24$ , respectively.

There were no statistically significant differences in the Strehl ratio and OVs at contrasts of 9% in the stage around the ICL implantation. However, there were significant differences in the MTF cutoff frequency, OSI, and OVs at contrasts of 100% and 20%, preoperatively and postoperatively (Wilcoxon signed rank test,  $p=0.000$ ). The results are summarized in Table 2 and Figure 2.

The deviation of the achieved MRSE from the calculated MRSE was determined. At 6 months, all eyes were within 0.50 D of the target refractive change (Figure 3;  $R = 0.944$ ).

## Discussion

Posterior chamber pIOL implantation is a safe and effective refractive surgery that has been widely accepted. Previous studies have demonstrated that ICL implantation is better than corneal refractive surgery for the correction of moderate and high myopia, especially reduced disturbance of night vision<sup>[17-19]</sup>. However, very scarce data are available regarding the consequences of implantable collamer lenses with a central hole for residual refractive error correction after corneal refractive surgery. The aim of the present study was to evaluate the efficacy, safety, predictability and optical quality in patients who underwent posterior chamber ICL V4c implantation for residual refractive error after corneal refractive surgery.

In present study, there was an improvement in UCVA after ICL V4c implantation for residual refractive error correction after corneal refractive surgeries, 6 months after surgery, all of the eyes gained a UCVA of 20/20 or better (Figure 1). The efficacy index (mean postoperative UDVA/mean preoperative CDVA) was 1.19 at 6 months postoperatively, which was good, with a BCVA of  $-0.02 \pm 0.07$ . The safety index (mean postoperative CDVA/mean preoperative CDVA) was 1.26; In our study, most eyes maintained the BCVA, and some gained more lines of BCVA, results consistent with findings from previous case reports<sup>[18,19]</sup>. In

the follow-up period, no eyes lost more than 1 line of BCVA. The predictability was also high: 100% of eyes were within  $\pm 0.50$  D of the predicted refractive change (Figure 3). The manifest spherical equivalents (MRSE) 6 months after surgery of all patients were shown in Figure 3, which was near emmetropia ( $R = 0.944$ ) (Figure 3).

In agreement with findings from previous reports<sup>[20,21]</sup>, our research demonstrated good results and a contribution to accurate preoperative optometry. In the case of pIOL implantation, the calculation is less dependent on corneal refractive power but more dependent on precise subjective refraction. The reliability of autorefractometry after corneal refractive surgery is influenced by the preoperative amount of myopia and the laser optic ablation zone<sup>[22]</sup>. Increasing the positive spherical aberration after corneal refractive surgery, higher refractive power and retinal image form are encountered in the pupil area by the peripheral imaging rays, and the results of subjective refraction seem to be more myopic<sup>[22]</sup>. In view of the inherent measurement of refractive errors in the eyes after corneal refractive surgery, in our study, the preoperative subjective refraction was assessed under the same illumination conditions by two experienced residents trained and measured by a comprehensive refractometer. The patient underwent small pupil refraction and cycloplegia refraction. In addition, considering the relatively advanced age of the patients, the diopters were low to moderate and could be easily overcorrected after corneal refractive surgery; therefore, emmetropia was usually selected as the target refraction in the dominant eye and we adjusted the target diopter to keep  $-0.50$  D in the non-dominant eye when the patients were more than 45 years old.

Furthermore, our study indicated that there were no significant differences shown on the Strehl ratio and the OVs among the optical quality parameters, at contrasts of 9%, preoperatively and postoperatively. However, the significant changes of the MTF cutoff frequency were shown in our study, respectively, OSI, and OVs at contrasts of 100% and 20%, before and after-operation. In our study, all patients had undergone corneal refractive surgeries a few years earlier, and had increased cornea spherical aberration, which partly contributed to the changes in OSI after ICL implantation. All preoperative data suggested that the preoperative total HOAs and spherical aberration of all patients increased and led to greater postoperative intraocular scattering and affected the visual quality at contrasts of 9%. OVs at contrasts of 9% simulate night vision, which can be disturbed after corneal laser refractive surgery, including PRK or LASIK; which is reported to be the main factor affecting night vision due to increased spherical aberration<sup>[23]</sup>.

Compared with the previous study<sup>[24]</sup>, we used a new type of ICL with a central hole, without preoperative peripheral iridotomies, and also obtained good results. In addition, to evaluate the objective visual quality postoperatively, we used OQAS, an advanced tool for quantitatively evaluating optical quality changes after refractive surgeries. In our study, there were significant differences in the MTF cutoff frequency and OVs at contrasts of 100% and 20%, thus indicating that ICL implantation for correction residual myopia contributed to the good visual quality, mainly during daytime. ICL implantation does not involve surgical tissue abstraction and leaves the central cornea untouched; therefore, the visual quality was essentially

improved postoperatively. However, the night vision loss due to corneal refractive surgery cannot be improved.

Studies by Kamiya K and Liu HT have demonstrated that ICL implantation results in nearly no disturbance to the optical quality, because there was no statistically significant change in the OSI after the operation<sup>[14,18]</sup>. However, in our study, the OSI increased postoperatively. Two reasons may account for this phenomenon. First, all patients had prior corneal refractive surgery, which might have induced corneal spherical aberration and made the OSI increase postoperatively<sup>[25,26]</sup>. Second, the optical quality of the eye decreases with aging<sup>[27]</sup>. In our research, the average age of the subjects was  $39.16 \pm 7.52$ , older than previously reported subjects<sup>[28,29]</sup>. We postulated that the crystal density increases with age, and the intraocular scattering index also increases.

There were several limitations to this study. One was that the sample size of this study was relatively small from a statistical standpoint, and the follow-up time was short. However, patients with this kind of demand after corneal refractive surgery were uncommon. Another limitation was that we did not assess the preoperative and postoperative total corneal HOAs and spherical aberration, which were important factors for evaluating vision quality. In addition, we did not comprehensively evaluate the subjective vision quality, such as by administering a patient questionnaire for night vision.

In conclusion, our study demonstrated significantly improved optical quality parameters, such as the MTF cutoff frequency, Strehl ratio, OSI, and OVs at contrasts of 100%, 20%, and 9%, of patients after corneal refractive surgery undergoing ICL implantation. These results suggested that ICL implantation could result in good refractive outcomes for retreated eyes with residual refractive error after corneal refractive surgery. Further studies are needed to evaluate patient satisfaction and follow subjects for longer postoperative follow-up periods to confirm the safety of the procedure.

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## Tables

Due to technical limitations, Table 1 is only available as a download in the supplemental files section.

Table 2. Optical quality parameters in eyes undergoing implantable collamer lens (ICL) implantation after corneal refractive surgery

OQAS	Preoperative	post 1 mo	post 3 mo	post 6mo	P value
MTFcutoff	28.739	30.274	30.738	31.294	0.000
OSI	1.399	1.613	1.516	1.469	0.049
SR	0.183	0.171	0.175	0.187	0.130
OV100	0.890	1.021	1.048	1.066	0.000
OV20	0.654	0.701	0.723	0.748	0.005
OV9	0.483	0.509	0.507	0.509	0.121

## Figures

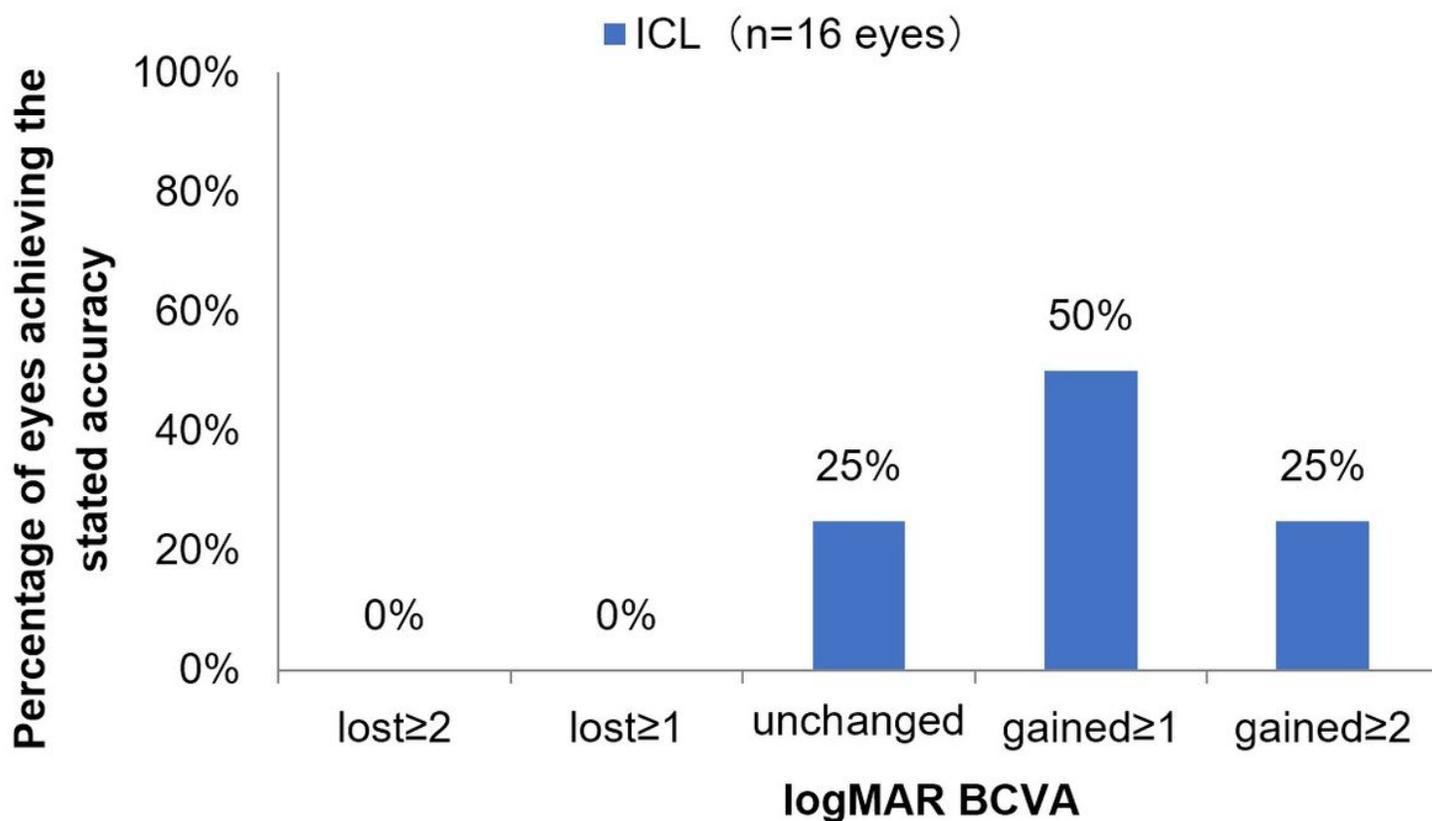


Figure 1

The changes in BCVA six months after ICL implantation

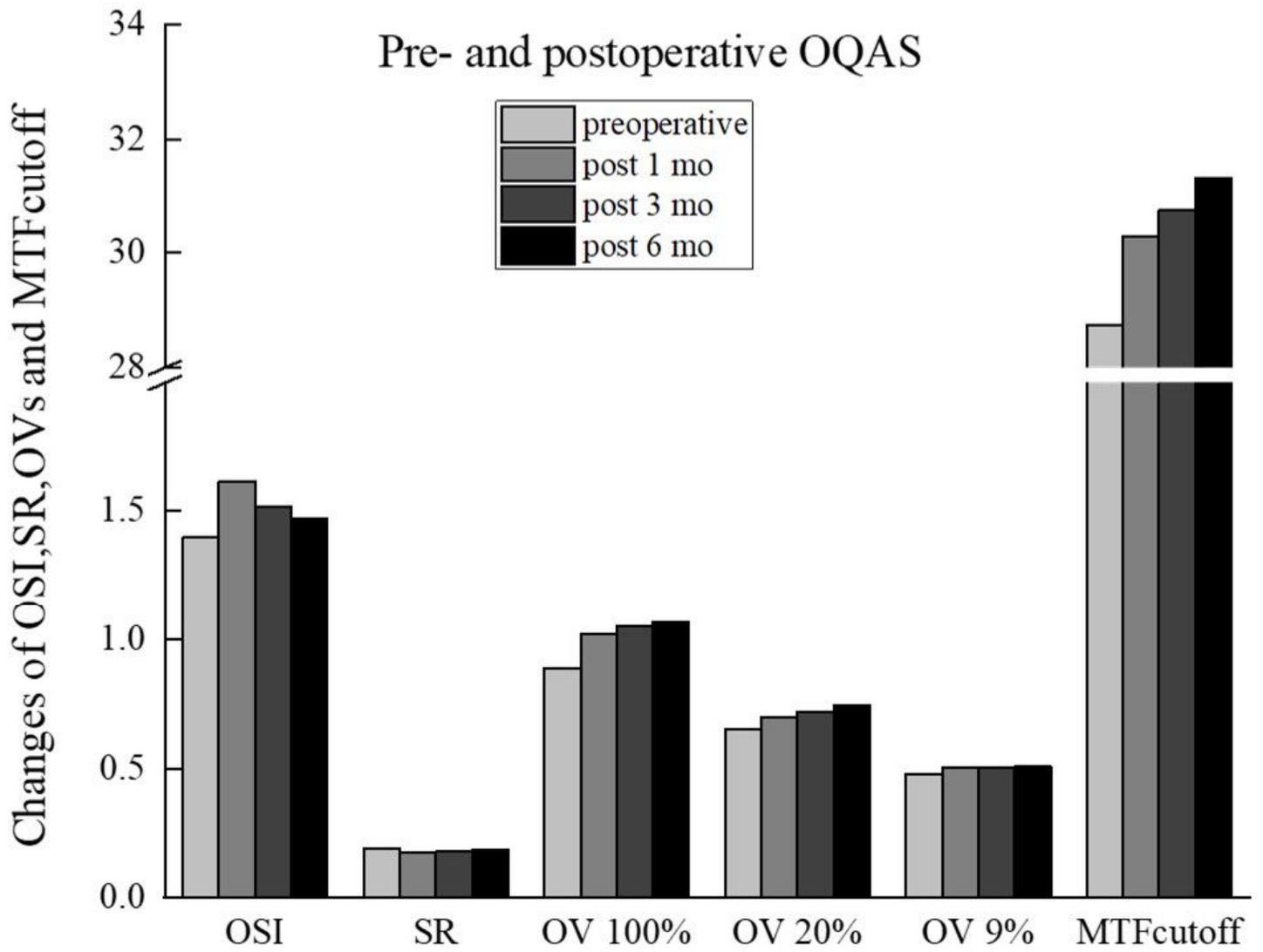


Figure 2

Pre- and postoperative optical quality parameters

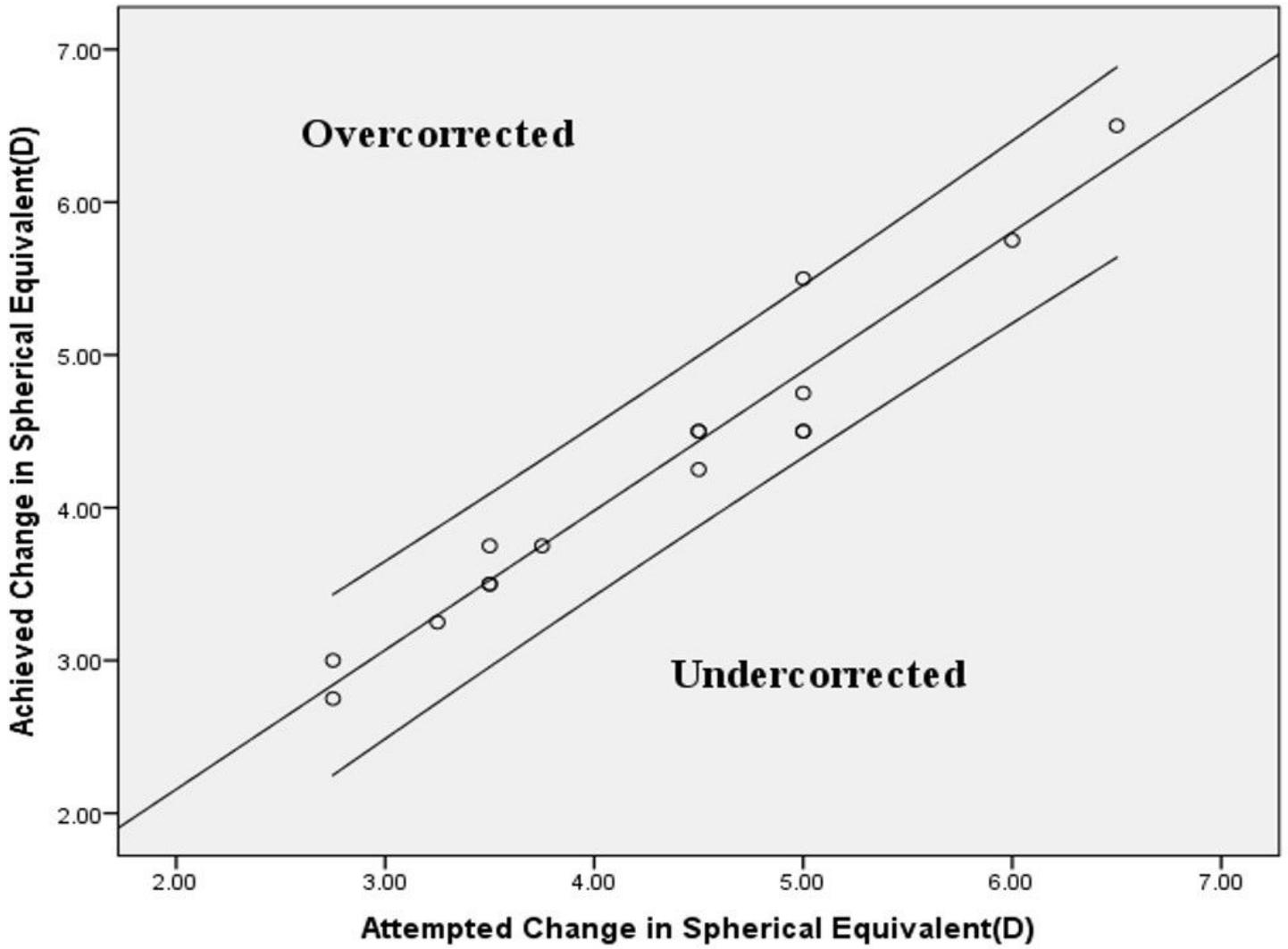


Figure 3

Scatterplot demonstrating the attempted vs achieved correction (predictability) six months after ICL implantation  $R = 0.944$ ,  $y = 0.33 + 0.91 \cdot x$ . D=diopeters

### Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Table1.jpg](#)