

Near binocular visual function after SMILE surgery for myopia

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Research article

Keywords: Near heterophoria; Near point convergence; Small incision lenticule extraction (SMILE); Visual fatigue

Posted Date: February 25th, 2020

DOI: <https://doi.org/10.21203/rs.2.24502/v1>

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Abstract

Purpose: To analyze the changes of near binocular vision function after small incision lenticule extraction and association with asthenopia. **Methods:** This was a retrospective study. Twenty-five myopic patients who underwent small incision lenticular extraction (SMILE) surgery from Tianjin Eye Hospital were included in this study. The values of parameters of near binocular vision function were measured at preoperative, 1 week, 1 month and 3 months postoperatively including near heterophoria, near point convergence (NPC), horizontal base-in fusional reserves (BIFR) and base-out fusional reserves (BOFR). The patients were grouped by the preoperative symptoms scores. The comparisons among different follow-up periods were conducted by the repeated measures analysis of variance. The Pearson correlation coefficient (r) was used to evaluate the linear fit of the relationship between variables. Multiple linear regressions were used to analyze the relationship between asthenopia and parameters of binocular and accommodative function. **Results:** The NPC significantly increased at 1 week and 1 month after SMILE and then get back to the level of preoperatively in 3 months postoperatively. Near heterophoria significantly decreased at 1 week after SMILE and then remained stable in 3 months postoperatively. In the regression analysis, there was no significant association between the values of the fatigue questionnaire at different stages after SMILE operation and the parameters of near binocular visual function ($P > 0.05$). However, there was significant positive correlation among each visit with the preoperative visual fatigue questionnaire ($P < 0.05$). There was no significant difference in the parameters of binocular visual function between the normal group and the fatigue group. For the visual fatigue group, there was positive correlation between the score of visual fatigue questionnaire 1 week after SMILE surgery and the difference in near horizontal phoria between 1w postoperative and that preoperative ($r = 0.523$, $P = 0.046$), and significant negative correlation with the recovery point of BOFR at 1 week ($r = -0.581$, $P = 0.023$). **Conclusion:** SMILE surgery wouldn't influence the binocular vision in the short term. Since there was no significant association between binocular vision function and visual fatigue, factors of asthenopia in the early period of SMILE surgery should be further studied.

Background

The relationship between ametropia and binocular vision can be critical to the successful, asymptomatic outcome of any refractive correction. Several studies have evaluated the effects of refractive surgery on fusional vergence amplitudes and ocular alignment; however, the results remain controversial [1-4]. Furthermore, all of these studies were limited to Laser in-situ keratomileusis (LASIK), the flap of cornea grinding with (laser epithelial keratectomy, LASEK) and refractile corneal surface cutting (photorefractive keratectomy, PRK), none of them was observed after the new novel corneal refractive surgery, small incision lenticule extraction (SMILE) procedure.

Compared with traditional refractive surgery, SMILE procedure shows the same safety, effectiveness, predictability, and stability, as well as better protection of corneal nerves and less impact on corneal biomechanics and other advantages[5]. Since the principle of SMILE surgery is different from that of traditional corneal refraction surgery, the early postoperative refraction state and wound healing degree is

different, and the postoperative visual recovery time is longer than that of traditional LASIK, which may be reasons for the abnormal changes in SMILE collection and regulation function after surgery [6,7].

Hence, this study was performed to undertake a retrospective analysis of clinical records to determine if there are any changes in near binocular vision function after SMILE surgery for myopes and to explore its relationship with early visual fatigue.

Methods

Patients

This is a retrospective case series study. We reviewed the clinical charts of the subjects who underwent SMILE surgery in the refractive surgery center of Tianjin Eye Hospital. The study was approved by the Ethics Committee of Tianjin Eye Hospital and strictly followed the tenets of the Declaration of Helsinki. Written Informed consent to use any clinical data for analysis and publication was obtained from all patients.

Twenty-five patients who were included in this present study were myopia, age from 20 to 35 years, corrected distance visual acuity (CDVA) of better than 20/25, and having follow-ups at 1 week, 1 month, 3 months postoperatively with all examinations. Exclusion criteria were the presence of manifest tropia, a history of strabismus surgery, anisometropia greater than 1.5 D, previous strabismus or intraocular surgery, absence of binocular vision, and anterior segment pathologic condition. All patients were surveyed by visual symptom questionnaire, and according to which, the patients were divided into two groups, the normal group and the visual fatigue group. Visual fatigue was defined as the questionnaire score more than a mean+0.5 standard deviation [8].

SMILE procedure

All the patients involved in the study were performed by the same surgeon, who had rich experience in SMILE surgery. Preoperatively, 0.3% thalibitol eye drops were used 4 times/day for 3 consecutive days. Conventional conjunctival sac irrigation and periocular disinfection were performed during the operation, followed by local anesthesia with 0.4% oxybuprocaine hydrochloride eye drops (Santen, Japan), which were performed twice. The corneal flap and stromal lens were made by VisuMax[®] femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany). The patient was required to fix the red spot in the fixation instrument, and the suction was applied when the center of the pupil was centered on the contact lenses. After that, the femtosecond laser was used for scanning to complete the fabrication of microlens. First, the posterior surface of the refractive lens was made with femtosecond laser from the peripheral to the center of the cornea. The anterior surface of the refractive lenticules was created from the center to the periphery, and finally the small incision was created at the 12 o'clock position with the cordial length ranging from 2 to 5 mm. After femtosecond laser treatment, a blunt spatula was used to break the remaining tissue bridges and loosen the stromal lenticules, which were then grasped with a pair of forceps and removed.

Preoperative assessment

The patients had eye examinations including the manifest refraction, uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), history of refractive stability, slit-lamp evaluation, dilated funduscopy and corneal topography using a rotating Scheimpflug Camera (Pentacam HR, Oculus, Wetzlar, Germany), binocular visual function using phoropter, preoperatively and visual symptoms were measured by a questionnaire [8].

Near horizontal heterophoria (phoria) was measured by the Von Graefe method. Horizontal base-in fusional reserves (BIFR) and base-out fusional reserves (BOFR) were determined using the smooth method with a phoropter, with a 20/25 acuity target at 40cm. The break point was the prism value at which a single vision was no longer maintained, and the recovery point was the prism value at which a single vision was regained through fusion. Measurements of near point convergence (NPC) were repeated 3 times, and the mean of the measurements was considered to be the representative value. All preoperative measurements were performed with spectacle correction.

Postoperative assessment

The postoperative follow-up was scheduled at 1 day, 1 week, 1 month and 3 months. Visual acuity, manifest refraction, slit-lamp and tonometry examination were included in the routine examination at all follow-ups. Near binocular visual function including phoria, BIFR and BOFR, and NPC were assessed 1 week and 1 and 3 months after surgery. All postoperative measurements were performed without residual refraction error correction. The target refractive error after surgery was emmetropia in all cases.

Statistical analysis

Statistical analysis was performed using Stata software (SPSS, version 24.0, Chicago, USA). Each data set was evaluated for normality of distribution using Kolgov-Smirnov testing. The results were normally distributed and expressed as mean±standard deviation. Repeated measures ANOVA was used to compare preoperative results and postoperative results at each follow-up; Pairwise comparison between groups was analyzed by the LSD test. An independent sample t-test was used to compare the differences of parameters between groups at different follow-up times. Pearson or Spearman linear correlation analysis was used to studying the correlation between parameters, represented by r ; a P value of 0.05 or less was considered statistically significant. A P-value of 0.05 or less was considered statistically significant.

Results

The study involved a total of 25 patients, including 14 males and 11 females. In the present study, the mean±SD patient age was 24.00±2.92 years, ranging from 20 to 35 years. The preoperative manifest refraction spherical equivalent (MRSE) was -5.44 ± 2.04 D in the right eye and the left eye, ranging from -1.50 to -9.25 D.

Near binocular visual function

Table 1 shows the near binocular vision function over time. There were no statistically significant differences in the break point, recovery point either BIFR or BOFR at different stages after SMILE surgery (F=-0.162, P=0.841; F=2.223, P=0.093; F=0.049, P=0.986; F=0.813, P=0.496).

Table 1. Comparison of parameters of near binocular visual function before and after SMILE surgery (mean±standard deviation)

Parameters	Preoperative	Postoperative			F	P-Value
		1Week	1 Month	3 Months		
Horizontal heterophoria	-6.04±6.38	-4.16±4.56	-3.88±4.06	-3.88±4.17	3.351	0.024*
PC	5.62±2.41	6.60±2.54	6.79±2.36	5.78±1.86	3.893	0.012*
Break Point□BIFR□	21.12±6.42	20.64±4.69	20.60±4.14	20.44±4.0	0.162	0.841
Recovery Point□BIFR□	14.68±6.60	12.72±5.84	11.68±5.06	12.56±4.32	2.223	0.093
Break Point□BOFR□	18.48±9.12	18.09±7.37	18.54±6.10	18.14±6.85	0.049	0.986
Recovery Point□BOFR□	7.34±6.15	6.95±4.47	8.54±6.10	8.73±6.86	0.813	0.496

There was a decreased trend 1 week after surgery compared with that before surgery failing to reach significance ($p = 0.105$). However, it was significantly reduced 1 month and 3 months after surgery compared with that before surgery ($P=0.036$, $P=0.029$; respectively). (Fig 1).

As for the NPC after SMILE surgery, there were significant increasing 1 week after surgery and 1 month after surgery compared with that before surgery ($P=0.032$, $P = 0.006$; respectively). There was no statistically significant difference 3 months after surgery compared with that before surgery ($P=0.728$). (Fig 2)

Visual fatigue

In the regression analysis, there was no significant association between the values of the fatigue questionnaire at different stages after SMILE operation and the parameters of near binocular visual function ($P>0.05$). However, there was significant positive correlation among each visit with the preoperative visual fatigue questionnaire ($r=0.710$, $P=0.000$; $r=0.487$, $P=0.015$; $r=0.591$, $P=0.003$).

There was no significant difference in the parameters of binocular visual function between the normal group and the fatigue group. For the visual fatigue group, there was positive correlation between the score of visual fatigue questionnaire 1 week after SMILE surgery and the difference in near horizontal phoria between 1w postoperative and that preoperative ($r=0.523$, $P=0.046$), and significant negative correlation with the recovery point of BOFR at 1 week ($r=-0.581$, $P=0.023$). (Fig 3, Fig 4)

Discussion

Normal binocular visual function, accommodation, and their coordination ability are important factors for maintaining eye comfort. Some patients who underwent corneal refractive surgery complained of visual fatigue symptoms such as blurred vision and short time of working distance in the early postoperative period, which affected the visual quality. Currently, studies have confirmed that the changes of binocular visual function and accommodation in the early postoperative period after LASIK, LASEK or PRK may be related to the early postoperative visual fatigue, due to the changes of refractive state, prism effect, wound healing, residual refractive error and other factors [4,9-11]. As a new type of corneal refractive surgery that has emerged in recent years, and studies have found that the postoperative vision recovery time is longer than that of traditional LASIK because of different principles and operative techniques, and which may affect on binocular vision [6,7]. Therefore, the purpose of this study was to observe the change characteristics of binocular visual function after SMILE surgery and to explore the relationship between binocular visual function and postoperative visual fatigue.

The present study found near horizontal heterophoria decreased postoperatively may be caused by the change of the refractive state of the eye after refraction surgery. The previous study showed accommodative lag decreased after SMILE surgery. As the quality of accommodation effort improves with adjustment to the new emmetropic state, the amount of convergence probably increases [12]. Chung et al. found more than half of their patients with exodeviation preoperatively had an improvement postoperatively [13]. Nemet et al. and Rajavi et al. also observed a decreased amount of exotropia after two anisometropia patients with exotropia performed LASIK [14,15]. Our results are in line with them.

Although, Snir et al. and Gómez de Liaño-Sánchez et al. studies showed the amount of heterophoria increases significantly in patients with preoperative exophoria after LASIK, and some patients even have persistent diplopia or strabismus [3,16]. Among the Snir study, the selected subjects were patients with strabismus after refraction surgery, and the refraction was moderate and high myopia with a large amount of exotropia. And also, in Gómez de Liaño-Sánchez's study, the patients had a previous binocular pathology. Considering the selection conditions of the observed subjects, the results were more inclined to individual cases, and could not represent the postoperative change characteristics of the normal myopia population.

It was also indicated that the changed eye alignment state was mostly due to the hypermetropic residual refraction either due to myopic hypercorrection or regression of the hypermetropic correction [3]. Even it was thought that hypermetropic residual refraction state in the early postoperative period when the amount of accommodative response increased at the near task, the accommodative convergence increased as well, then the near phoria decreased. However, if the patients had a previous binocular pathology, the balance of accommodation and convergence would be disturbed [3]. It was showed that in the early stage after refractive surgery, the spherical equivalent of residual refraction is lowest hypermetropic refraction in SMILE, followed by LASIK, and PRK had the highest [17,18]. Different residual refraction may induce different characters of phoria changed by different strategies of surgery. Similar to previous studies, in this present study the residual spherical equivalent in this study was -0.030.18 D 1

week postoperative, 0.03 ± 0.17 D 1 month postoperative, and 0.01 ± 0.20 D 3 months postoperative. There were over-correction and no significant difference between the three follow-up times.

In this study, we didn't find any difference in BIFR or BOFR before and after SMILE surgery. However, Han et al., together with Rajavi et al. observed that the break point and recovery point of BOFR decreased 1 week after refractive surgery, and returned to normal level 3 months after surgery [4,15]. Holland D and Kushner indicated persistent diplopia was observed in patients with high anisometropia preoperative. As we described in inclusion criteria, anisometropia diopter needed to be less than 1.5 D, and that's why the study showed different results [1,19].

The present study showed the NPC had significantly moved away 1 week after the surgery, and it recovered to the same level as that before the surgery, which was similar to the results of previous studies [4,14]. For myopia, minus glasses can produce a certain amount of base in prismatic effect when near task. After refractive surgery, the prismatic effect caused by glasses disappears, and patients' demand for near convergence increases. Although the NPC moved away after SMILE surgery and the difference was also statistically significant, there was only 1 cm difference between 1 week after surgery and that before surgery. Han Jinu et al. observed that the NPC moved 0.57cm away after 3 months compared with that before surgery, which had no significant clinical significance and was not enough to cause blur at near or visual fatigue [4].

In visual fatigue group, we found that the value of visual fatigue questionnaire at 1 week postoperative was positively correlated with the difference in near horizontal phoria between 1w postoperative and that preoperative, indicating that the greater the change of near phoria after surgery, the more severe the degree of visual fatigue. As mentioned above, the reason for the decrease in the amount of postoperative near phoria may be related to the change in the refractive state and the distance of the lens after the surgery. Therefore, it could be seen that the change of near phoria is the result of the combined effect of accommodation and binocular vision, especially the result of this coordination instability in the early stage after SMILE surgery. Besides, people with myopia usually wear traditional glasses. One of the characteristics of glasses is that a certain amount of prismatic effect with the bottom facing outward will be produced when the eyes are near, and the prismatic effect is related to the diopter. After SMILE, the prismatic effect produced by the glasses will disappear, and the demand for the convergence will increase. Hence, theoretically, people with high myopia may have a greater change in the amount of heterophoria, which is more likely to cause visual fatigue. However, this study has not confirmed this hypothesis, which may be related to the sample size and selected subjects, and further studies are needed.

The recovery point indicates that after binocular diplopia, the ability of binocular monocular vision can be regained. The larger the recovery point value is, the faster the patient can recover binocular monocular vision. According to 1:1 rule, when the recovery point of BIFR is smaller than the esophoria, eye discomfort is likely to occur. This current study also found that for the visual fatigue group, the value of visual fatigue questionnaire 1 week after SMILE surgery was negatively correlated with the recovery point

of BOFR 1 week after surgery, indicating that the smaller the recovery point value was, the more severe the visual fatigue was.

A limitation of the current study was that the follow up period of the study was not long enough to judge about the course of binocular vision function changes after surgery. Longer follow-up may provide more evidence on whether near phoria and vergence change after SMILE surgery.

Conclusions

SMILE surgery would not have adverse effects on near binocular visual function for normal myopia patients since the near horizontal phoria gradually tended to be stable and point convergence return to the preoperative level at 3 months after the surgery. The patient with a higher value of visual fatigue questionnaire should be paid more attention since it would be easier to get visual symptoms after surgery. No evidence was found a relationship between binocular visual function between visual fatigue at the early stage, and the reason why visual fatigue at the early stage after SMILE surgery still needs to be further studied.

Abbreviations

SMILE: Small incision lenticule extraction; LASIK: Laser in-situ keratomileusis; LASEK: Laser epithelial keratectomy; PRK: Photorefractive keratectomy; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; NPC: Near point convergence; BIFR: Base-in fusional reserves; BOFR: Base-out fusional reserves; MRSE: Manifest refraction spherical equivalent; SE: Spherical equivalence

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Committee of Tianjin Eye Hospital and adhered to the tenets of the Declaration of Helsinki. Written informed consent to use any clinical data for analysis and publication was obtained from all patients prior to surgery.

Consent for publication

Not applicable.

Availability of data and material

Available upon request from the first author: Dr. Xiaoqin Chen.

Competing interests

The authors do not have any conflict of interest to report and have no proprietary interest in any of the materials mentioned in this article.

Funding

This work was supported by a grant from the National Natural Science Foundation of China (No. 81873684).

Authors' contributions

Study concept and design were performed by CXQ and WY. Preparation of the first draft was done by CXQ and revised by WY. Data was analyzed and interpreted by CXQ and LLH. Data collection was performed by CXQ. Review and approval of the manuscript was performed by WY. All authors read and approved the final manuscript.

Acknowledgment

None.

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Figures

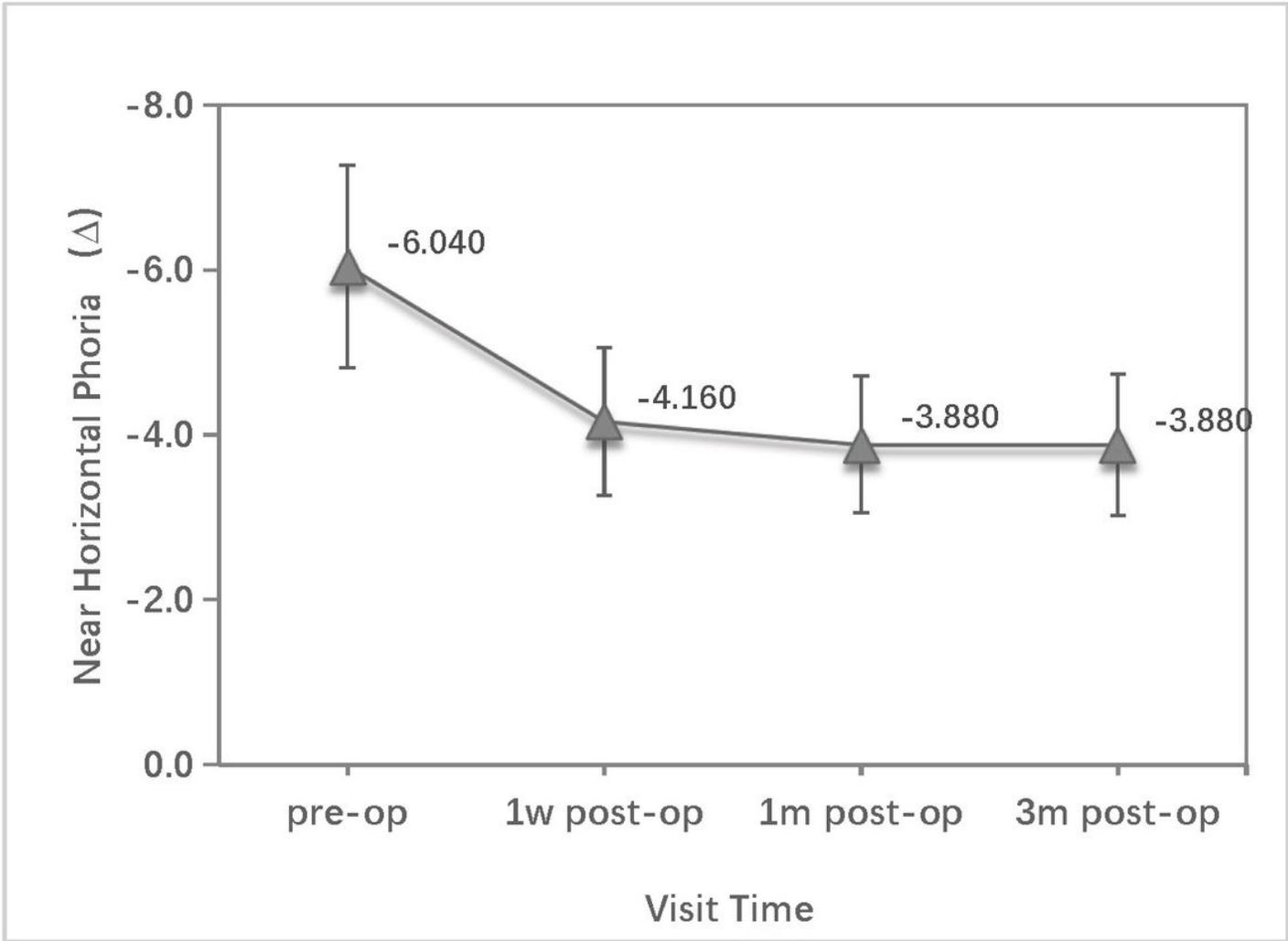


Figure 1

The changes of the near horizontal phoria with time

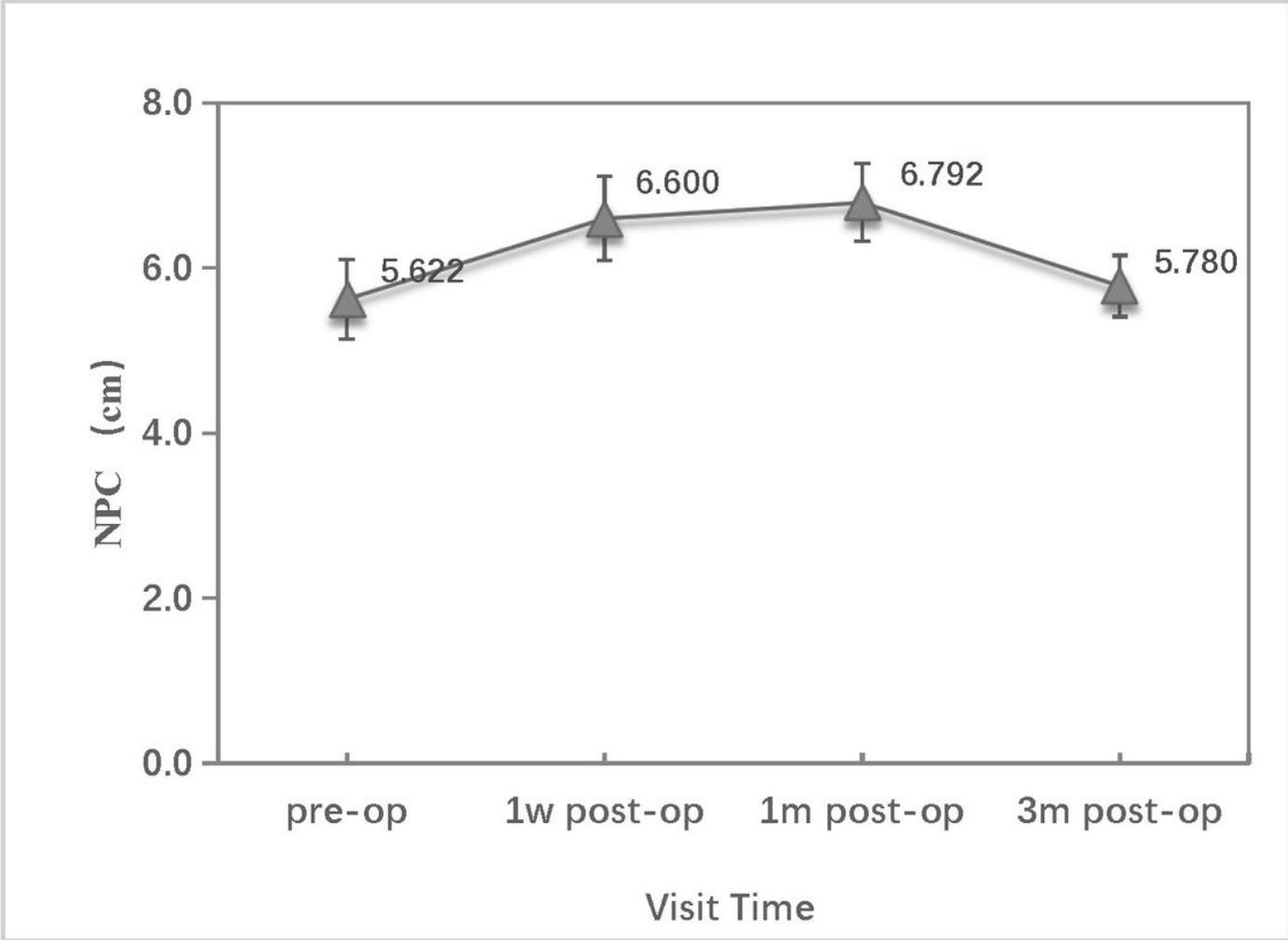


Figure 2

The changes of near point convergence with time

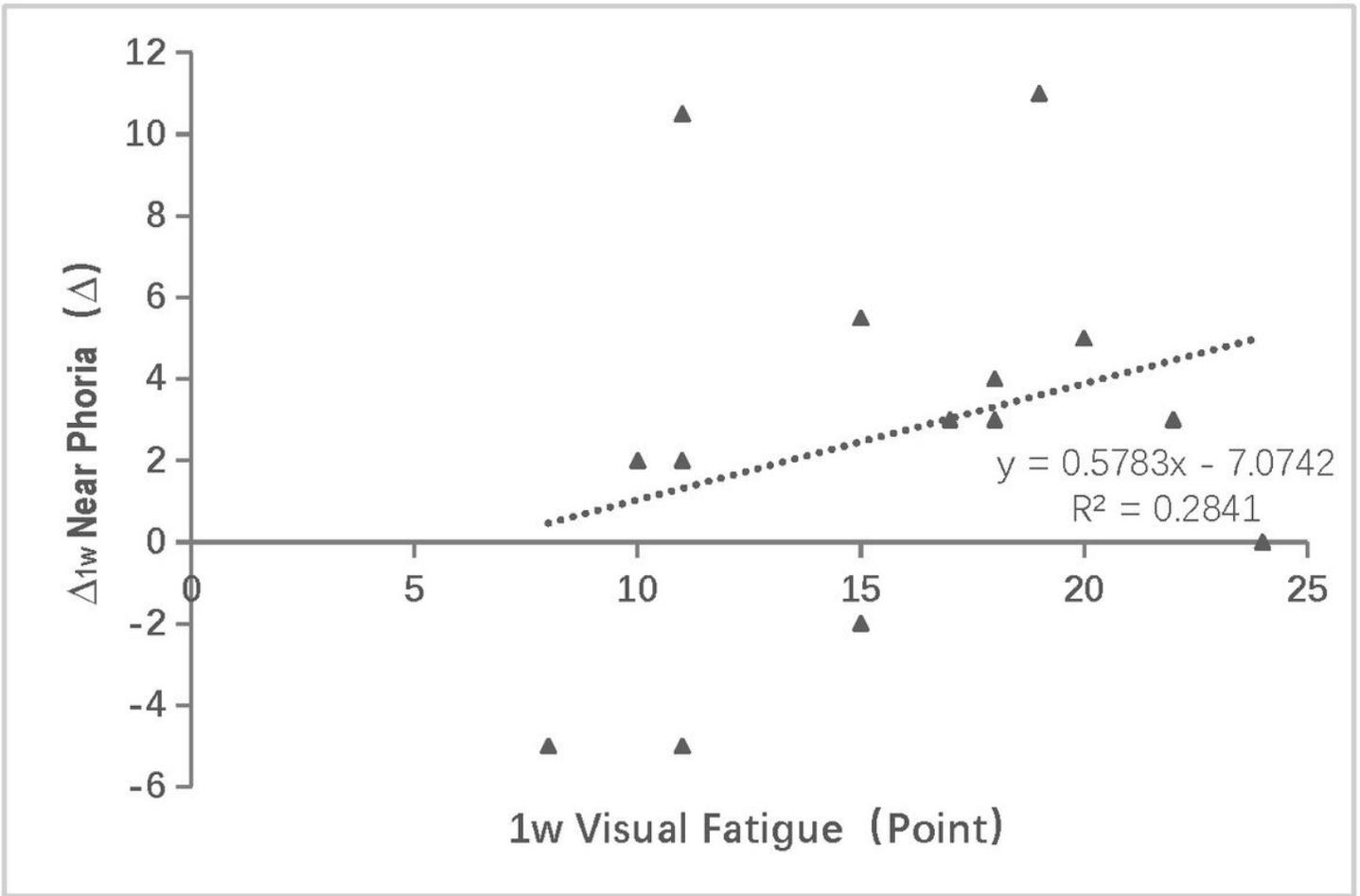


Figure 3

The correlation between visual fatigue symptoms and the difference of near horizontal phoria between 1 week postoperatively and preoperatively.

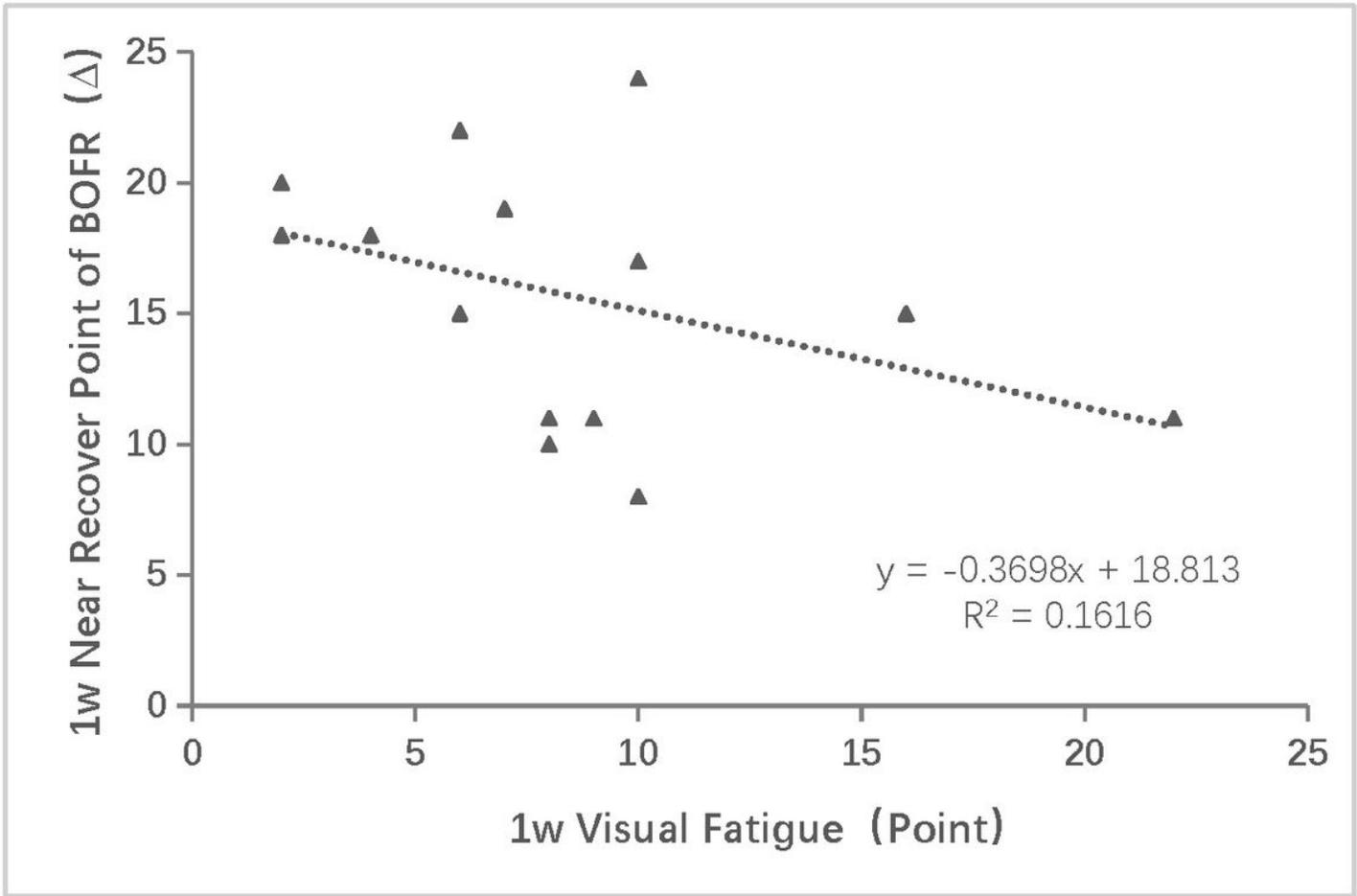


Figure 4

The correlation between visual fatigue symptoms and the recovery point of BOFR at 1 week postoperatively.