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Prä- und postoperativer Winkel Kappa bei Patienten mit multifokaler Intraokularlinse (MIOL) nach Touch-up-Laser-in-situ-Keratomileusis (LASIK)

Dissertation

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Meiner Familie, die mich auf diesem Weg stets unterstützt und ermutigt hat

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Zusammenfassung

Winkel Kappa (κ) beschreibt die Distanz zwischen der visuellen und der pupillaren Achse im optischen System des Auges. In der refraktiven Chirurgie wird κ in Zusammenhang mit der Zentrierung der Intraokularlinse (IOL) verwendet und hat somit einen potenziellen Einfluss auf das endgültige Sehergebnis nach einem chirurgischen Linsenaustausch. In der wissenschaftlichen Literatur wird ein großer κ mehrfach als möglicher Risikofaktor für postoperative IOL-Dezentrierung und visuelle Phänomene wie *Halos* und *Glares* diskutiert, welche zu einer verminderten Sehqualität bei Patienten führen können. In dieser Studie wurde untersucht, ob ein großer κ bei Patienten nach Implantation einer multifokalen IOL (MIOL) und nachfolgender Laser-in-situ-Keratomileusis (LASIK), auch bekannt als Bioptik-Verfahren (engl. *Bioptics*), ein Risikofaktor für ein schlechtes postoperatives Ergebnis ist. Ziel der Arbeit war es, den möglichen Einfluss des κ in dieser besonderen Patientenkohorte zu evaluieren, um seine Eignung als Risikoprädiktor für visuelle Phänomene zu prüfen. Insgesamt wurden 548 Augen eingeschlossen, die nach einem refraktiven Linsenaustausch (RLA) eine keratorefraktive Behandlung zur Korrektur ihrer Restfehlsichtigkeit erhalten haben. Im ersten Eingriff erhielten die Patienten eine hydrophile diffraktive MIOL und anschließend eine *Touch-Up*-LASIK. Der κ wurde prä- und postoperativ mittels eines auf Scheimpflug-Technologie basierenden Bildgebungssystems ermittelt. Dabei wurde der Abstand zwischen der visuellen Achse und dem Pupillenzentrum gemessen, welcher klinisch als *Chord mu* (μ) bezeichnet wird. Weiterhin wurden der unkorrigierte und korrigierte Fernvisus (*UDVA* und *CDVA*), die Präzision und der Sicherheitsindex (SI) der Behandlung bestimmt. Es gab eine signifikante Abnahme der κ-Magnitude nach MIOL-Implantation und LASIK. Der absolute κ-Wert der hyperopen Augen war größer als der der myopen Augen. Jedoch zeigte sich weder in der Gesamtkohorte noch in den Subgruppen eine signifikante Korrelation zwischen κ und dem Fernvisus bzw. dem SI. Eine solche postoperative Abnahme von κ und die Verteilung zwischen myopen und hyperopen Augen sind in der Literatur vorbeschrieben. Ein großer κ wird teilweise mit erhöhtem Blendungsrisiko nach der Operation und verminderter Sehqualität assoziiert. Unsere Ergebnisse zeigen jedoch, dass κ nicht als klinischer Prädiktor für das postoperative Ergebnis bei Bioptik-Patienten geeignet ist. Weitere Untersuchungen von potenziell bedeutsamen Einflussfaktoren sind notwendig, um postoperative Komplikationen zu minimieren und die individuelle Vorhersage zu verbessern.

Summary

Angle kappa (κ) describes the distance between the visual and pupillary axis within the optical system of the eye. In refractive surgery, κ is associated with the centration of the intraocular lens (IOL) and therefore has a potential influence on the final visual outcome after refractive lens exchange (RLE). In literature, large κ is often discussed as a potential risk factor for postoperative IOL decentration and visual phenomena such as halos and glares, which can reduce visual quality. This study investigated whether a large κ is a risk factor for unfavorable postoperative outcomes in patients who have received multifocal IOL (MIOL) implantation and subsequent laser-in-situ-keratomileusis (LASIK), also known as Bioptics. The aim of this work was to assess the potential impact of κ in this particular patient group and determine its suitability as a predictor for visual phenomena. A total of 548 eyes were included that underwent keratorefractive treatment following RLE to correct residual refractive errors. In the first procedure, patients received a hydrophilic diffractive MIOL followed by touch-up LASIK. The κ was determined both pre- and postoperatively using an ocular imaging system based on Scheimpflug technology. Here, the distance between the visual axis and the pupil center was measured, which is clinically referred to as the chord mu (μ). Additionally, the uncorrected and corrected distance visual acuity (UDVA and CDVA), the accuracy, and the safety index (SI) of the treatment were calculated. There was a significant decrease in κ magnitude after MIOL implantation and LASIK. The absolute κ value was greater in hyperopic eyes than in myopic eyes. There was no significant correlation found between κ and distance visual acuity or SI in either the overall cohort or the subgroups. In the literature, the postoperative decrease in κ is described, along with the distribution between myopic and hyperopic eyes. In some publications, a large κ is associated with increased risk of glare after surgery and reduced visual quality. However, our study results reveal that κ is not clinically predictive of postoperative outcome in Bioptics patients. Further investigation of potentially significant influencing factors is needed to minimize postoperative complications and enhance individual outcome prediction.

Abkürzungsverzeichnis

CDVA	*corrected distance visual acuity* (dt. korrigierter Fernvisus)
IOL	Intraokularlinse (engl. *intraocular lens*)
κ	Winkel Kappa
LASIK	Laser-in-situ-Keratomileusis
MIOL	multifokale Intraokularlinse (engl. *multifocal intraocular lens*)
PRK	Photorefraktive Keratektomie (engl. *photorefractive keratectomy*)
RLA	Refraktiver Linsenaustausch (engl. *refractive lens exchange*)
SI	Sicherheitsindex (engl. *safety index*)
UDVA	*uncorrected distance visual acuity* (dt. unkorrigierter Fernvisus)

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1 Einleitung

1.1 Verfahren in der Refraktiven Chirurgie

Die refraktive Chirurgie hat in den letzten Jahren aufgrund ihrer signifikanten Entwicklung in Bezug auf Sicherheit und Effektivität weltweit an Bedeutung gewonnen. Sie zählt mittlerweile zu den häufigsten operativen Eingriffen am Auge und wird zur Korrektur von Fehlsichtigkeiten (Ametropie), wie Myopie oder Hyperopie, eingesetzt (Kim et al., 2019).

Es gibt zwei Hauptkategorien refraktiv-chirurgischer Eingriffe: keratorefraktive und intraokulare Verfahren, bei denen entweder das Hornhautprofil oder die intraokulare Brechkraft modifiziert wird. Zur ersten Kategorie gehören photoablative Verfahren, wie die Laser-in-situ-Keratomileusis (LASIK). Dabei wird nach Bildung eines „Hornhautdeckels" (engl. *Flap*) die Abtragung eines individuellen Hornhautprofils mittels eines *Excimer*-Lasers durchgeführt. Die zweite Kategorie umfasst künstliche Intraokularlinsen (IOL), die entweder als Zusatz zur körpereigenen Linse (phake IOL) oder als Ersatz für diese (pseudophake IOL) implantiert werden können. Diese Verfahren sind insbesondere für Patienten mit Altersweitsichtigkeit (Presbyopie) geeignet, bei denen die natürliche Akkommodationsfähigkeit nicht mehr vorhanden ist. Der refraktive Linsenaustausch (RLA) ist ein Verfahren, bei dem die noch klare körpereigene Linse durch eine IOL ersetzt wird.

Die Kombination aus keratorefraktiver und IOL-basierter refraktiver Chirurgie wird als Bioptik bezeichnet und kann bei komplexen oder hohen Refraktionsfehlern eingesetzt werden. Dabei erfolgt in der Regel zuerst die Implantation der IOL, gefolgt von einem refraktiven Eingriff an der Hornhaut. Bei Patienten nach einer RLA-Behandlung und einer Restfehlsichtigkeit (Restametropie) kann ein keratorefraktiver Eingriff diesen Fehler korrigieren. Dieser Eingriff findet frühestens drei Monate nach dem ersten statt und wird als *Touch-Up*-Prozedur bezeichnet.

1.2 Prä- und postoperative Patientenevaluation

Eine umfangreiche präoperative Beurteilung der Patienten vor refraktiven Eingriffen ist von großer Bedeutung, um eine möglichst präzise Korrektur zu erzielen. Diese umfasst unter anderem die exakte Bestimmung des Refraktionsfehlers mittels subjektiver Refraktion sowie eine Hornhauttomografie mittels Scheimpflug-Technologie zur Analyse der vorderen und hinteren Hornhautfläche. Weitere Untersuchungen zur Wellenfrontanalyse oder Hornhautdickenmessung sind ebenfalls notwendig, um möglicherweise Risikopatienten rechtzeitig auszuschließen.

Ein wichtiger Parameter bei den Untersuchungen ist κ, welcher den Winkel zwischen der Pupillenachse (Verbindungslinie zwischen Pupillenzentrum und Hornhautscheitel) und der visuellen Achse (Verbindungslinie zwischen Fixierobjekt und Fovea) bezeichnet. κ beschreibt somit die Abweichung des Pupillenzentrums von der visuellen Achse und kann in der klinischen Praxis als *Chord mu* bestimmt werden. Die bei der Hornhauttomographie ermittelten Koordinaten können in einen Vektor umgewandelt werden, um die Distanz in μm auszudrücken.

Patienten, bei denen postoperativ eine Über- oder Unterkorrektur festgestellt wird, erhalten nach drei Monaten und nach Stabilisierung der Sehleistung eine umfassende Untersuchung zur Bestimmung der Ursache der Restametropie. Dabei werden unter anderem der korrigierte und unkorrigierte Visus (*CDVA* und *UDVA*) erhoben. Diese Untersuchung bildet die Grundlage für einen möglichen Zweiteingriff im Rahmen einer Bioptik-Behandlung.

Im Rahmen von Studien und zur Qualitätskontrolle werden für die Berechnung des Sicherheitsindex (SI) die prä- und postoperativen Visuswerte verwendet. Der SI gibt das Verhältnis zwischen dem postoperativen *CDVA* und präoperativem *CDVA* an.

1.3 Vorherige Arbeiten

Die Bedeutung von κ wurde bereits in verschiedenen Studien untersucht. Sowohl im Zusammenhang mit der Zentrierung der Ablationszone bei keratorefraktiven Eingriffen (Chan and Boxer Wachler, 2006, Reinstein et al., 2013) als auch auf die Positionierung der MIOL bei einem Linsenaustausch (Bonaque-González et al., 2021, Cervantes-Coste et al., 2022) wird die klinische Bedeutung von κ unterschiedlich diskutiert.

In einer vorherigen Studie hat unsere Arbeitsgruppe die Veränderung von κ bei hyperopen Augen vor, während und nach einer LASIK-Behandlung untersucht und festgestellt, dass es einen Unterschied von prä- zu intraoperativ gab, jedoch keinen signifikanten Unterschied von prä- zu postoperativ (Frings et al., 2019). Die vorliegende Arbeit behandelt eine weiterführende Fragestellung und schließt auch myope Augen ein, wobei alle Augen eine Bioptik-Behandlung erhalten haben. Hierbei untersuchen wir den Zusammenhang zwischen κ und verschiedenen prä- und postoperativen Parametern, um eine mögliche Korrelation zu evaluieren.

1.4 Ziele der Arbeit

Das Ziel dieser Arbeit besteht darin, die Rolle von κ bei der präoperativen Evaluation von Patienten vor einem RLA-Eingriff und anschließender *Touch-up*-LASIK näher zu untersuchen. Es soll insbesondere untersucht werden, ob ein hoher κ-Wert ein relevanter Risikofaktor für ein suboptimales postoperatives Ergebnis darstellt, insbesondere bei Patienten mit hohen Refraktionsfehlern, die häufiger einen Zweiteingriff im Rahmen einer Bioptik-Prozedur benötigen (Leccisotti, 2006). Die Ergebnisse dieser Arbeit könnten wichtige Informationen zur präoperativen Entscheidungsfindung und verbesserten Patientenauswahl vor einem Bioptik-Eingriff liefern.

1.5 Ethikvotum

Diese Studie wurde von der Ethikkommission der Heinrich-Heine-Universität in Düsseldorf genehmigt (Studien-ID 2020-1150).

PLOS ONE

RESEARCH ARTICLE

Pre- and postoperative angle kappa in MIOL patients after touch-up LASIK

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Data Availability Statement: We are unable to share the de-identified data set due to ethical and legal restrictions. The decision not to share the data was made by our local ethics committee, which has imposed these restrictions due to the sensitivity of the patient information contained in the data set. The contact details of our local ethics committee below for your reference: Ethics Committee at the Medical Faculty of the HHU Düsseldorf; Moorenstr. 5, D-40225 Düsseldorf; E-Mail: ethikkommission@med.uni-duesseldorf.de.

Abstract

Purpose

To study the influence of angle kappa (κ) on visual acuity after implantation of a multifocal intraocular lens (MIOL) and consecutive "touch-up" corneal refractive surgery with Laser-in-situ-Keratomileusis (LASIK).

Methods

This retrospective multicenter study included patients who underwent MIOL surgery and consecutive LASIK (= Bioptics) in the period from 2016 to 2020 at Care Vision Refractive Centers in Germany. Our study was approved by the local ethics committee at the University in Duesseldorf (approval date: 23.04.2021) and conducted according to the tenets of the Declaration of Helsinki and Good Clinical Practices Guidelines. The pre- and post-operative κ of 548 eyes were measured using a Scheimpflug-based imaging system. Corrected distance visual acuity (CDVA) and the safety index (SI) were analyzed in relation with κ. For a more detailed analysis, the cohort was divided into pre-operative hyperopic and myopic patients to show group-specific differences.

Results

There was a significant decrease ($p<0.001$) in the magnitude of κ after MIOL implantation and Bioptics. However, there was almost no significant correlation of κ on CDVA and SI, pre- and postoperatively.

Conclusion

A large κ is not a significant risk factor for poor visual acuity. Therefore, it is not a suitable clinical predictor of postoperative outcomes after a Bioptic procedure.

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Introduction

With the invention of corneal tomography, the measured parameters have become much more important in refractive surgery, as they provide accurate values of corneal curvatures [1]. Angle kappa (κ) is one of these parameters, which is defined as the difference between two optical axes of the eye: the pupillary axis and visual axis. First one, the pupillary axis, passes perpendicular to the cornea and intersects the center of the entrance pupil. Second one, the visual axis, is an imaginary line that connects the fixated object and the center of the fovea. Thus, it is also called the foveal-fixation axis [2]. The chord distance between the intersection of the pupillary axis with the cornea and the corneal light reflex (vertex normal) makes the practical measurement of the angle κ as a distance between the intersections of both axes with the corneal surface. Pentacam® systems (Oculus Optikgeräte GmbH, Wetzlar, Germany) can identify the distance in the x and y directions in the first Purkinje image. This Scheimpflug-based imaging system proved to be a reliable measurement method [3].

In the last years multifocal intraocular lenses (MIOL) popularity increased strongly. With a wide range of lenses available, individual needs can be addressed and patients' quality of life can be positively influenced [4]. In cataract surgery and in the correction of refractive errors, the importance of MIOL centration regarding the quality of visual outcomes has been discussed numerously. Because a decentration of MIOL among other reasons is associated with postoperative optic phenomena such as glare and halos, quality of life may suffer accordingly. Next to blurred vision, reduced contrast sensitivity is also a common side effect after MIOL implantation [5–7]. Angle κ might be a possible predictor of such phenomena. Some studies suggest large angle κ greater than 0.4 mm has a negative impact on the postoperative outcome [8, 9]. Velasco-Barona et al. could not prove any relationship [10].

Residual ametropia, especially for intermediate vision, is also a reason for poor patient satisfaction [9, 11, 12]. One possible approach to this problem is a touch-up procedure which is an Excimer laser enhancement after MIOL implantation. It showed reliable refractive outcomes and high patient satisfaction, because LASIK is known to be a successful procedure offering reasonably accurate results [13]. However, rainbow glare and halos are possible side effects of femtosecond laser procedure [14].

According to current research, there is little evidence of the relationship between κ and the visual outcome in MIOL patients. Besides, only few eyes were involved in most of previous studies and none of them included patients underwent a touch-up procedure. Based on the latest state of studies, it is still unclear if there is a higher risk due to large κ [10, 15].

The goal of our study is first, to examine if there is a significant change in κ pre- to postoperatively. Second, we want to determine the relationship between κ and CDVA and the safety index (SI). Our aim is to show whether angle κ is a parameter to be considered avoiding negative effects in clear lens refractive surgery (MIOL surgery). This would play an important role in patient selection.

Materials and methods

Clear lens extractions performed in 548 presbyopic eyes (235 male and 313 female) without previous surgeries or pathologies, from 45 to 76 years of age (mean: 53.8 ± 5 years) were included in our study. The eyes (patients) were divided into pre-operative myopic and hyperopic groups. All eyes had gone through a touch-up LASIK to correct a residual ametropia. Only non-complicated eyes were included. A common complication such as secondary cataract, macular edema or severe dry eye after LASIK which reduces the corrected visual acuity below SI of 0.8, reduces the ability to focus on the tomograph and visual test target and does not allow reproducible visual acuity and angle κ values. Hence, we excluded eyes with SI < 0.8.

Analyzing only eyes with good SI, excludes this bias and improves the resolution of the correlation between angle κ and SI to clinically meaningful range.

Our multicenter retrospective study included data retrieved from the Care Vision Refractive Database (R&D Department of CARE Vision company, Germany). Our study adhered to the tenets of the Declaration of Helsinki and the GDPR (General Data Protection Regulation). All patients voluntarily provided written informed consent for data analysis during the surgery recruitment process.

The implanted MIOL types were hydrophilic refractive diffractive MIOLs (PhysIOL, Liege, Belgium). Pre-operative corneal cylinder of 2 diopter or more indicated a toric MIOL (Model FineVision Pod F toric) which was implanted in 49 eyes (8.9%). In all other eyes non-toric MIOLs (FineVision Pod F in 282 eyes (51.5%) and FineVision Micro F in 217 eyes (39.6%)) were implanted. The surgical procedures were carried out according to an internal standard protocol under topical anesthesia. All implanted MIOLs were centered at the pupil center. The power of the trifocal MIOL was computed using a laser interferometer (IOL Master 500, Zeiss, Germany) and the Haigis formula.

To estimate the angle κ values, the distance between the pupilar center and corneal light reflex was determined using a Scheimpflug-based imaging system (Pentacam®, Oculus Optikgeräte GmbH, Wetzlar, Germany). The values of angle κ were presented not in degrees of angle but as κ magnitude. The offset of the pupil center image on the corneal surface from the corneal apex is given by the Pentacam as "x" and "y" values and was converted to a nasal offset in a polar (Vector) value of "κ magnitude" measured in micrometer (μ), the κ magnitude of the left eyes was converted to a standard right eye reference in which more nasal means more minus x value. Angle κ is referred as "κ", "angle κ" or "κ magnitude" interchangeably. CDVA was measured at a viewing distance of 6 meters (20 feet) to a Snellen Visual Chart [16]. SI was calculated as the relation between the post-operative corrected distance visual acuity (CDVA) and the pre-operative CDVA [17]. Angle K, SI and CDVA were taken pre-operatively and after the final LASIK. Generally, preoperative measurements were made 4 to 6 weeks before surgery and touch-up LASIK was performed on average 3 months after MIOL surgery. No decentering of the ablation zone occurred. Preoperative angle κ was compared with the postoperative measurement at follow-up, which was performed at least 3 months after Bioptics (final treatment). Because this is a multicenter retrospective study, we only analyzed data that had been consistently and completely documented in all eyes.

The correlation between angle κ and continuous variables CDVA and SI was estimated using linear regression. A p value less than 0.05 was considered statistically significant. All analysis was performed with R [18].

Results

The statistical analysis showed that pre- and postoperative angle κ of our cohort (548 eyes) were homogenously distributed around the mean values. It further showed that the κ values of the hyperopic eyes were larger than those of the myopic eyes.

Refractive outcomes

Since all patients received two consecutive treatments, the visual outcomes of two different intervals were examined. First, the preoperative visual acuity (VA) is compared with the postoperative VA after MIOL implantation (Fig 1). Second, preoperative VA is compared with VA after touch-up LASIK (Fig 2). The reported refractive outcomes are in accordance with the Standard Reporting in Refractive Surgery [19].

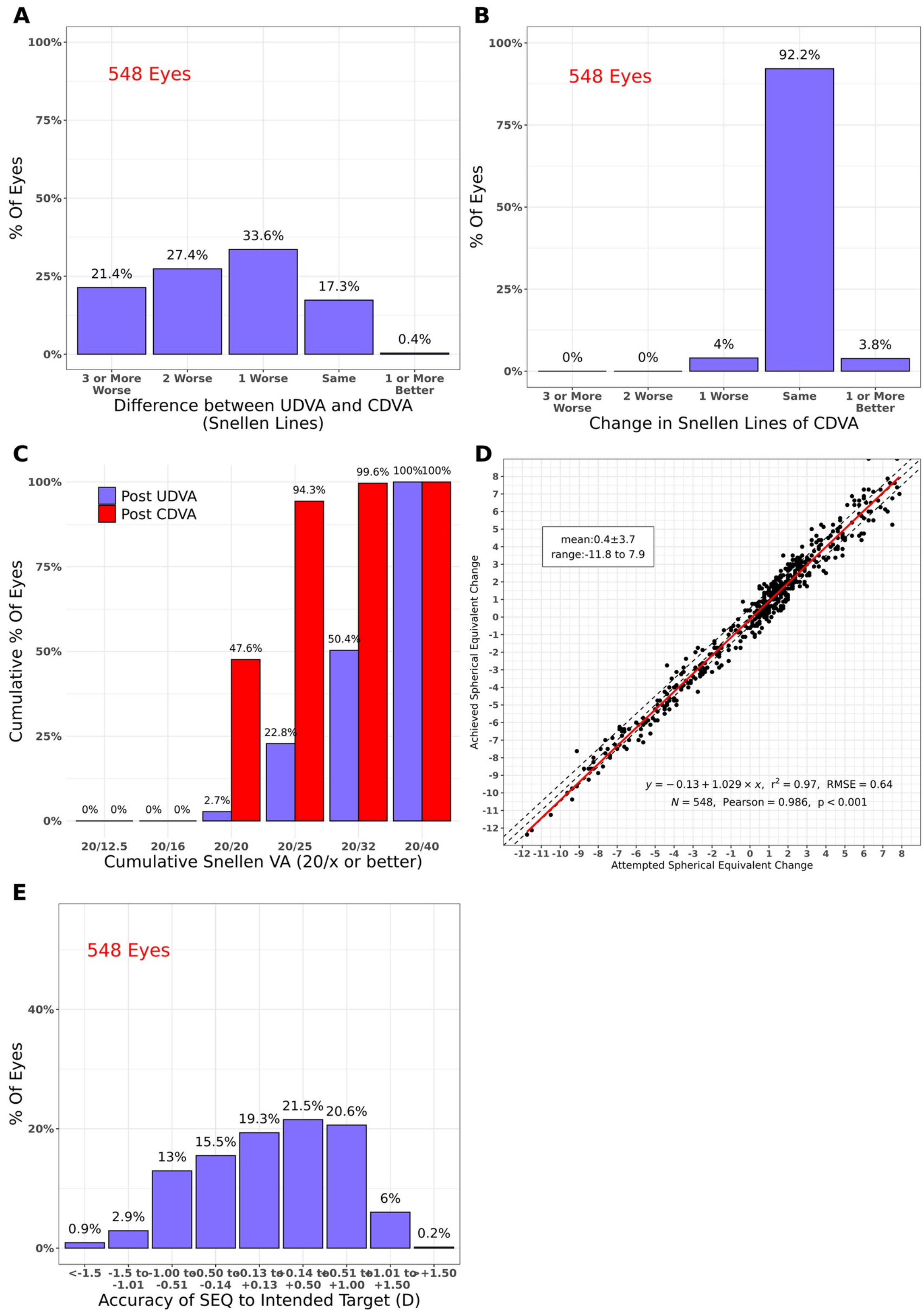

Fig 1. Standard graphs reporting visual outcomes: Preoperative vs postoperative (MIOL implantation). UDVA: uncorrected distance visual acuity, CDVA: corrected distance visual acuity, VA: visual acuity, SEQ: spherical equivalent, D: diopter(s), r^2: coefficient of determination, RMSE: root mean squared error, N: number of eyes, Pearson: Pearson Correlation Coefficient.

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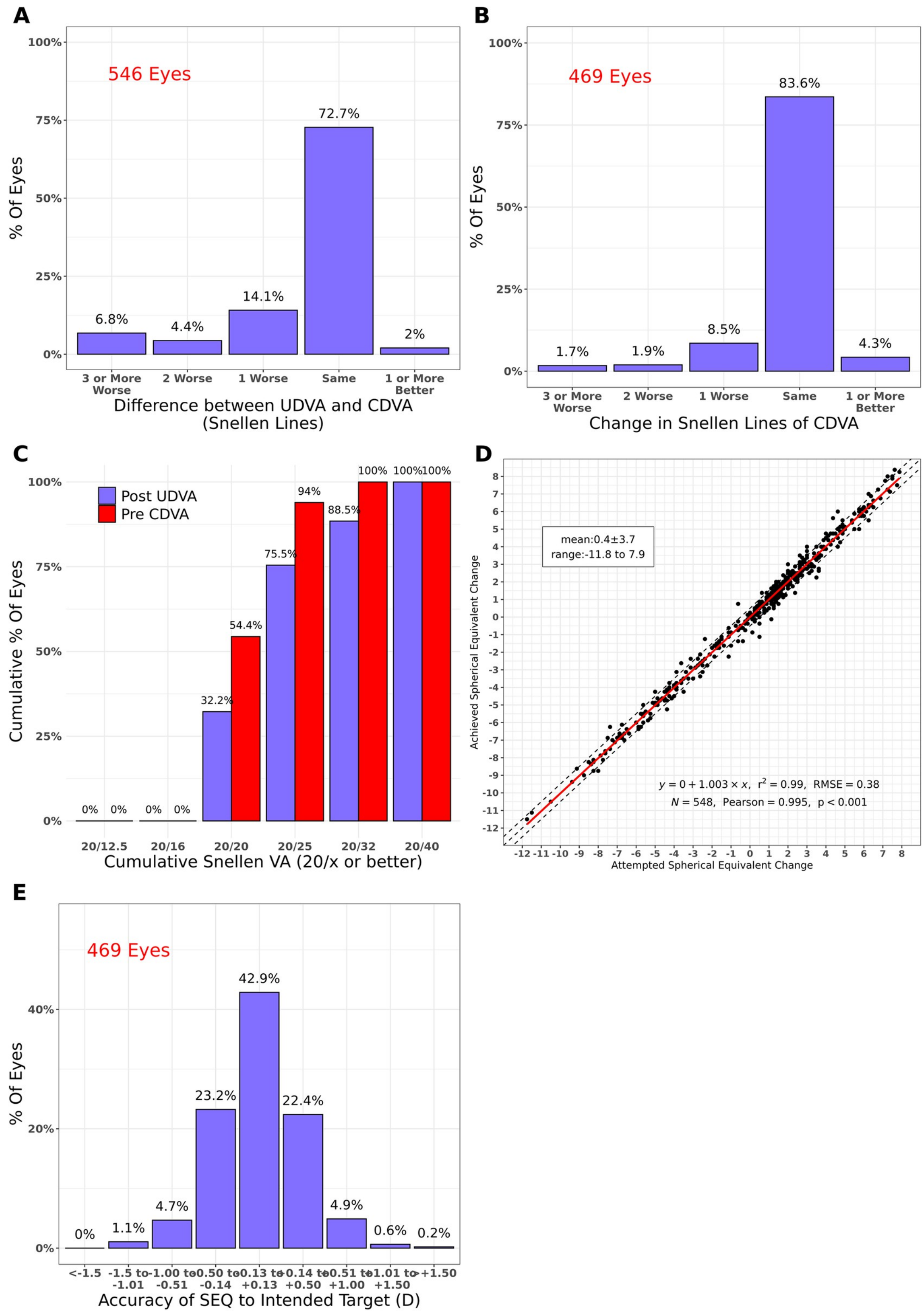

Fig 2. Standard graphs reporting visual outcomes: Preoperative vs postoperative (touch-up LASIK). UDVA: uncorrected distance visual acuity, CDVA: corrected distance visual acuity, VA: visual acuity, SEQ: spherical equivalent, D: diopter(s), r^2: coefficient of determination, RMSE: root mean squared error, N: number of eyes, Pearson: Pearson Correlation Coefficient.

https://doi.org/10.1371/journal.pone.0283578.g002

Graphs A and C respectively show the efficacy of the treatments. Graph B shows the safety, graph D the predictability as a correlation between attempted and achieved spherical equivalent (SEQ), and graph shows the accuracy of SEQ regarding the intended target.

After MIOL implantation UDVA was equal to or better than CDVA in 17.7% of eyes, while this proportion increased to 74.7% after LASIK (Figs 1A and 2A).

All eyes were within 1 Snellen Line of CDVA after MIOL implantation, but only 96.4% after LASIK (Figs 1B and 2B).

After MIOL surgery, only 2.7% of eyes had UDVA of 20/20 compared with 47.6% that had CDVA of 20/20 (Fig 1C). On the other hand, 32.2% of eyes achieved UDVA of 20/20 after LASIK compared with 54.4% CDVA in the preoperative condition (Fig 2C).

A strong correlation between attempted and achieved SEQ was observed in both intervals (Pearson = 0.986 and 0.996, $p<0.001$, Figs 1D and 2D).

Postoperative SEQ was within ±0.5 D of emmetropia in 56.3% of eyes after MIOL implantation and in 88.5% of eyes after LASIK (Figs 1E and 2E).

Change of angle κ

The mean angle κ was 277 μm ± 142 preoperatively and 217 μm ± 121 postoperatively in the overall group. The mean value of the hyperopic group was 307 μm ± 149 preoperatively and 238 μm ± 125 postoperatively while in the myopic group it was 208 μm ± 92 and 172 μm ± 94, respectively. This decrease in κ magnitude means that the line of sight was more nasal to the pupil center pre-operatively and still nasal but closer to the pupil center post-operatively. Fig 3 shows this shift in angle κ in horizontal and vertical axis (x and y direction), whereby the change in the mean horizontal axis was larger. This change in magnitude of κ was significant ($p < 0.001$; Fig 4).

Correlation angle κ and CDVA

The correlation between angle κ and CDVA was analyzed pre- and postoperatively. There was no significant relationship in the overall group preoperatively ($p = 0.979$). The hyperopic group showed a significant correlation between κ and CDVA postoperatively but not preoperatively, even though κ was higher preoperatively. The myopic group did not show any correlation between κ and CDVA (Table 1).

Correlation angle κ and SI

The relationship between angle κ and SI pre- and post-operatively showed no significant differences in the subgroups or in the whole group. Thereby, all associations here were not statistically or clinically significant (Table 2).

Correlation angle κ magnitude change and SI or CDVA

Finally, the change of the angle κ magnitudes also showed no significant correlation to neither SI nor CDVA ($p = 0.869$ and $p = 0.226$, respectively, Figs 5 and 6). No significance was found in the subgroups either.

Discussion

In the current study we first examined the distribution of angle κ magnitudes in eyes before a clear lens extraction. Next, we set out to investigate the change in angle κ magnitude after MIOL and LASIK surgery. Finally, we discussed the correlation of angle κ on the postoperative

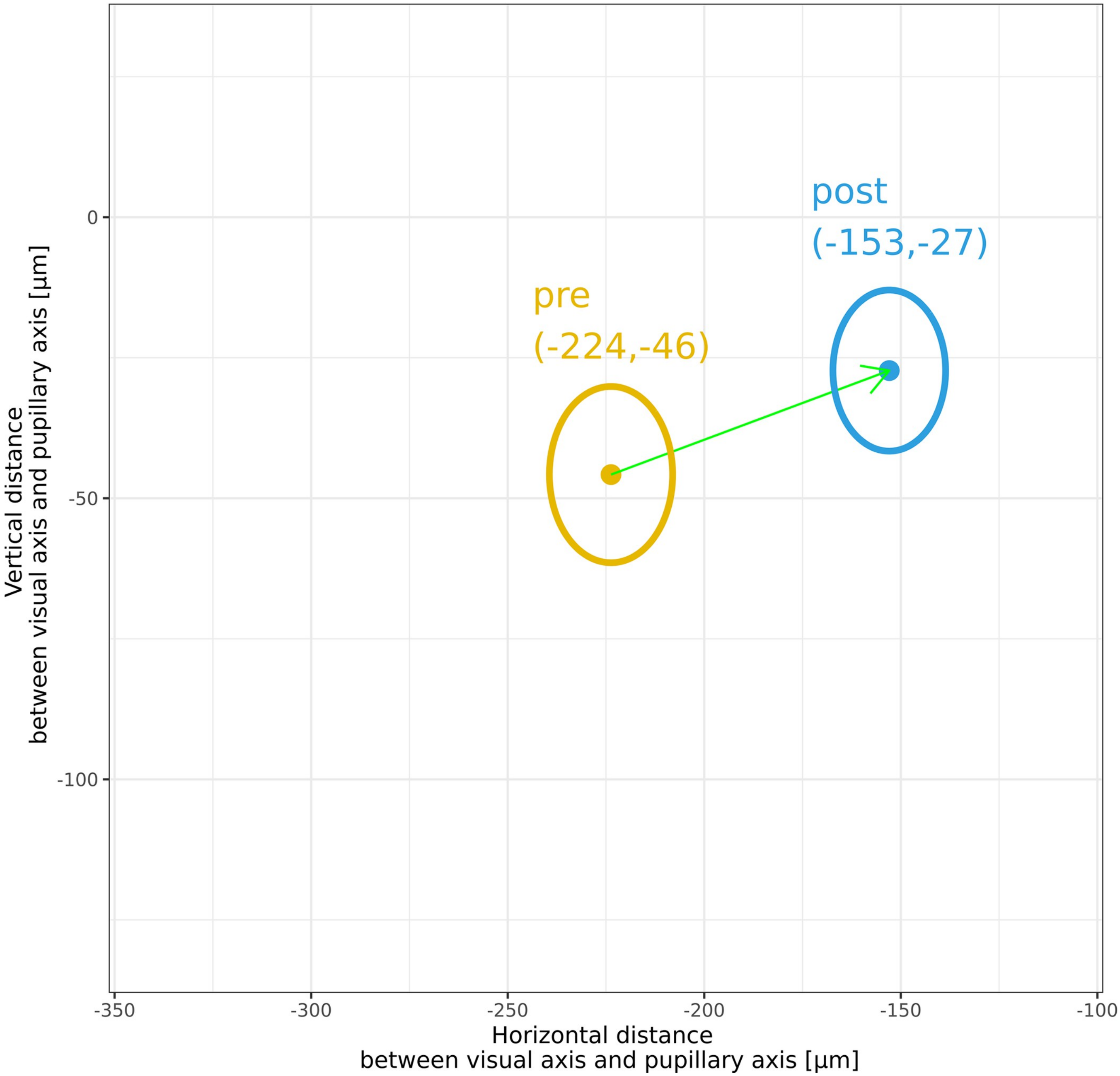

Fig 3. Change of angle kappa magnitudes: Difference vector in terms of preoperative and postoperative visual axis (overall group). pre: preoperative, post: postoperative.

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outcome after both procedures. Our study would be the largest among published studies of angle κ after MIOL.

A decrease of angle κ after phacoemulsification and MIOL implantation was presumed by *R. Wang et al.* and *Garzón et al.* [20, 21]. *S. Zarei-Ghanavati et al.* showed no change of angle κ after refractive surgery (PRK) [22] while our group showed in a previous study a change in its magnitude even intraoperatively during Excimer Laser vision correction compared to

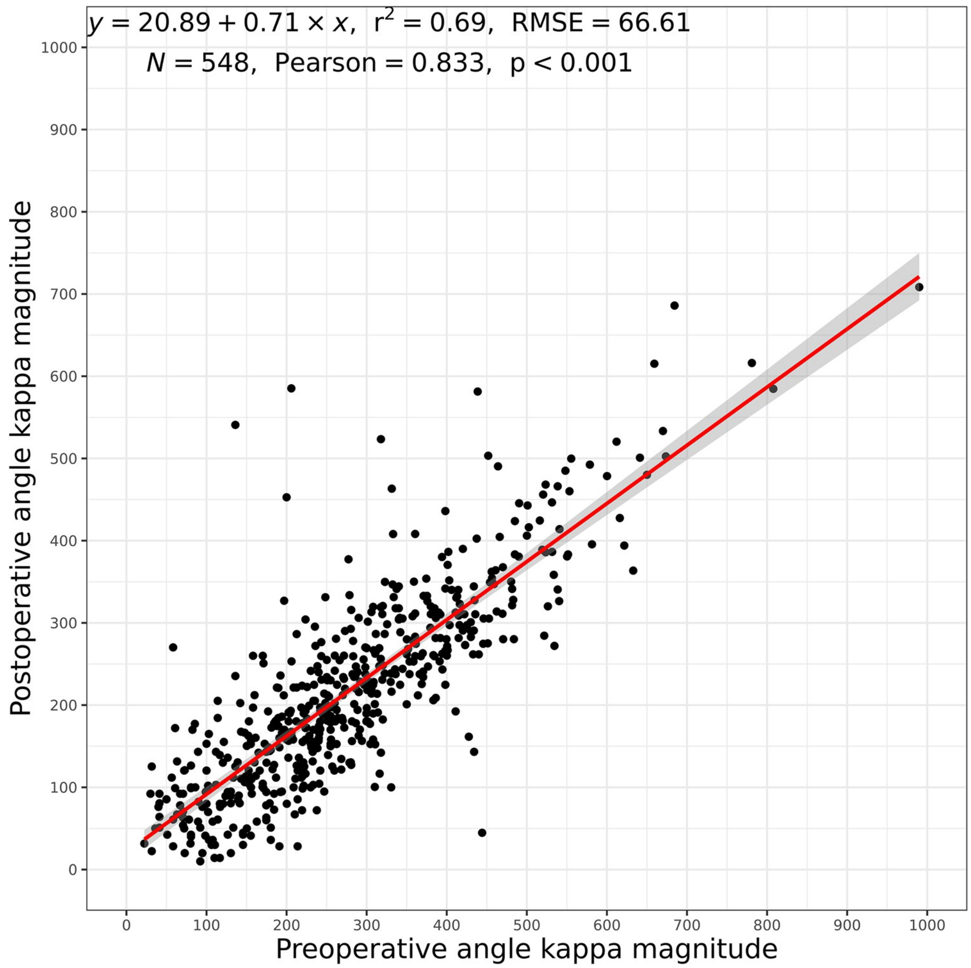

Fig 4. Correlation plot: Change of angle kappa magnitudes (overall group). r^2: coefficient of determination, RMSE: root mean squared error, N: number of eyes, Pearson: Pearson Correlation Coefficient.

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preoperative κ values [23]. Our expectation of a significant change in angle κ magnitude after MIOL and Bioptic procedure was confirmed by this study.

The analysis of angle κ distribution in an Iranian population investigated by *H. Hashemi et al.* showed that hyperopic eyes have a larger angle κ then myopic eyes and that emmetropic eyes hold the greatest values [24]. Others proved a similar occurrence [25, 26]. Factors associated with larger angle κ include shallower anterior chamber depth and older age [27]. Our study supports the findings of these studies and showed higher angle κ magnitudes in hyperopic and myopic eyes amounting to 99 μm preoperatively and 66 μm postoperatively.

The results of some studies suggest a correlation between large angle κ and unfavorable results occurring postoperatively [8]. Others could not find any significance of this suggested relationship. *Moshirfa et al.* summed up from previous studies that large angle κ could be a

Table 1. Correlation between angle κ and CDVA in all three groups, pre- and postoperatively (p-values).

	overall group	hyperopic group	myopic group
preoperative	0.979	0.238	0.948
postoperative	0.05	0.042	0.762

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Table 2. Correlation between angle κ and SI in all three groups, pre- and postoperatively (p-values).

	overall group	hyperopic group	myopic group
preoperative	0.336	0.550	0.184
postoperative	0.215	0.377	0.713

https://doi.org/10.1371/journal.pone.0283578.t002

factor leading to a decentration of MIOL and consequently to vision dysphotopsias. A possible explanation is that with larger angle κ, central light rays would pass through the multifocal rings at the edge causing glare. But this correlation is not clearly proved [15, 28]. Our study does not analyze the centration of the MIOL compared to pupil center. Since the MIOL is centered on the circumference of the capsular bag one may suggest that higher distance between pupil center and line of sight may be related to discrepancy between capsular bag center and one of these anatomic centers. This question may be relevant to the performance of the MIOL but is beyond the scope of our current study.

Karhanová et al. showed in a more differentiated approach that at positive angle κ (pupillary axis is nasal compared to visual axis), temporal decentration of the MIOL has a worse effect regarding photic phenomena then does nasal decentration [15]. Some recommend

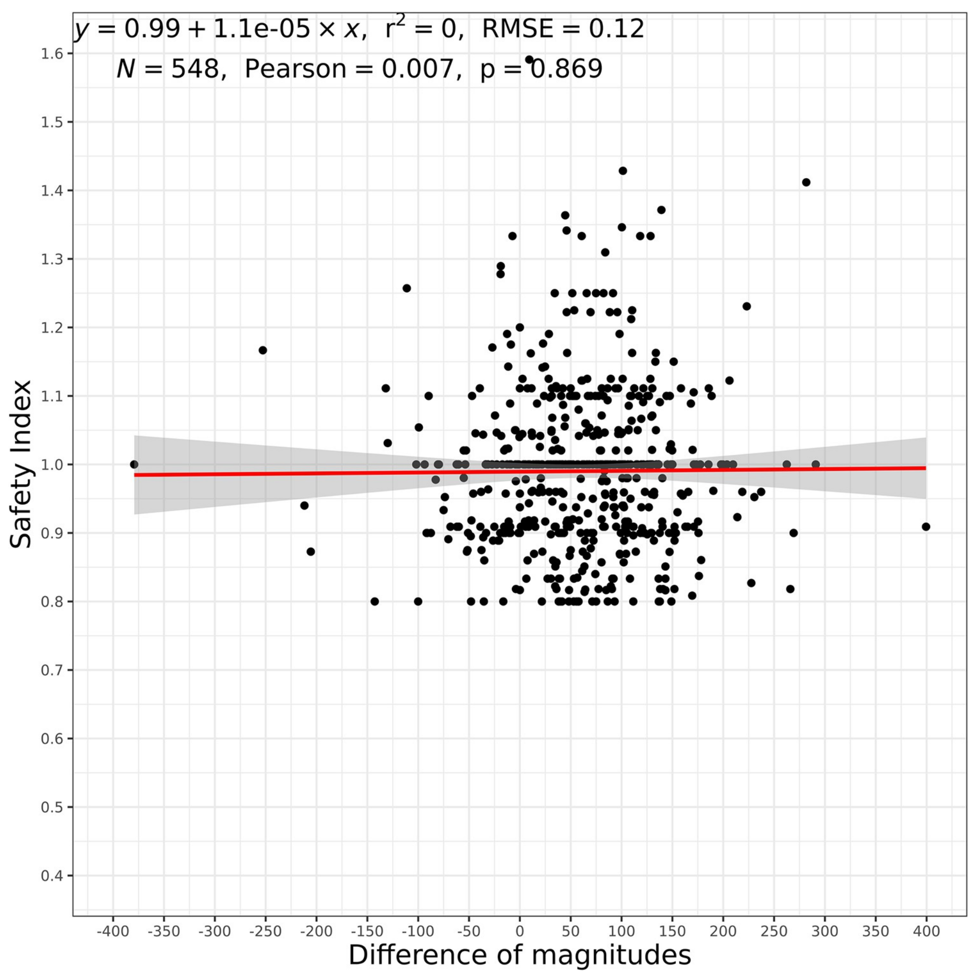

Fig 5. Difference in angle κ magnitudes in relation to SI (overall group). r^2: coefficient of determination, RMSE: root mean squared error, N: number of eyes, Pearson: Pearson Correlation Coefficient.

https://doi.org/10.1371/journal.pone.0283578.g005

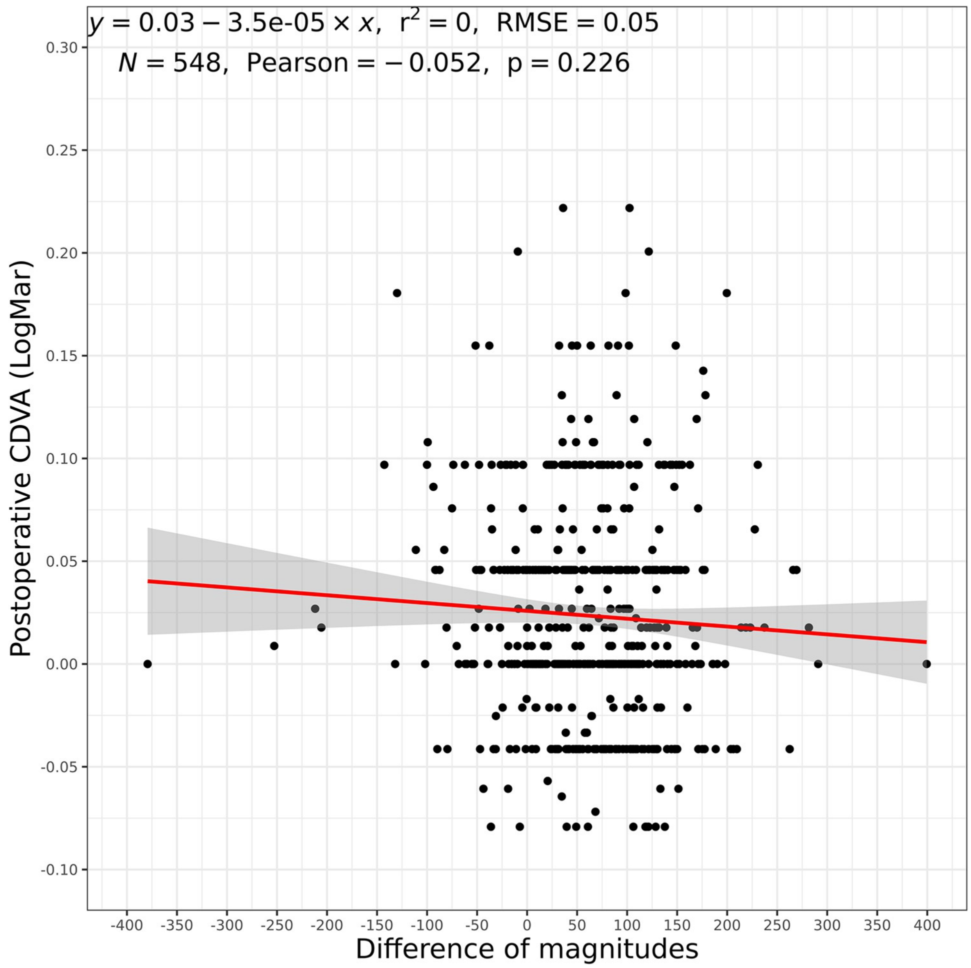

Fig 6. Difference in angle κ magnitudes in relation to CDVA (overall group). CDVA: corrected distance visual acuity, r^2: coefficient of determination, RMSE: root mean squared error, N: number of eyes, Pearson: Pearson Correlation Coefficient.

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considering angle κ when selecting patients for MIOL implantation and ruling out surgery, if applicable [11]. Angle κ larger than 400μm before MIOL implantation is related to more dysphotopsias, larger than 500μm with decreased visual quality [9, 29]. *H. Basmak et al.* also assume a negative effect of large angle κ on the postoperative result of laser treatment [26]. However, the data proving this relationship is very poor and partially demonstrated on an eye model only.

C. Velasco-Barona et al. and *Garzón et al.* could not find any significant association between angle κ and higher-order aberrations in their clinical trial. Furthermore, the visual acuity of the three different trifocal MIOLs does not seem to be affected by angle κ [10, 21]. *Cobo-Soriano* et al also excluded angle K as a negative factor influencing CDVA in bioptics patients, although they underwent corneal refractive surgery before lens replacement [30]. In our study, no negative effects were evident in CDVA or SI even in MIOL patients with high angle κ magnitudes after LASIK enhancement. Therefore, our findings go in line with previous data of *C. Velasco-Barona et al.* However, postoperative photic phenomena appear to have multifactorial causes (biometrical parameters such as shallow anterior chamber), making it difficult to identify a significant relationship to angle κ [15].

Centration of corneal ablation in laser refractive surgery has been widely discussed as it can affect the visual outcome. While centering over the pupillary center was previously assumed to be safe [31], more recent studies have prioritized the corneal light reflex (or visual axis) in this procedure [32–35]. This enhancement of safety and efficacy is more pronounced in hyperopic eyes because, as previously mentioned, they have a larger angle κ. This is negligible in myopic eyes since they commonly have small angle κ and therefore, a small distance between both points [36]. Accordingly, *M. Moshirfar et al.* recommend selecting the half distance between corneal light reflex and pupillary center [28]. Since angle κ changes intraoperatively, *Frings et al.* recommend centering the ablation based on the intraoperative measurements [23]. Moreover, the ametropia corrected in touch-up LASIK is normally very small and might be less sensitive to angle κ related to decentration of the excimer ablation.

Analyzing the role of angle κ in combination of clear lens extraction, MIOL implantation and a touch-up procedure (Bioptics) makes our study a unique research subject. According to the high variability of factors, our results show that at least angle κ does not need to be routinely evaluated in MIOL eyes receiving a laser enhancement surgery. Due to the current unclear published literature and disagreements, further studies are needed to support our findings.

Author Contributions

Conceptualization: Andreas Frings, Vasyl Druchkiv, Toam Katz.

Data curation: Amr Saad.

Formal analysis: Amr Saad, Vasyl Druchkiv.

Investigation: Andreas Frings, Toam Katz.

Methodology: Andreas Frings, Toam Katz.

Project administration: Andreas Frings, Vasyl Druchkiv, Toam Katz.

Resources: Amr Saad.

Software: Vasyl Druchkiv.

Supervision: Andreas Frings, Toam Katz.

Validation: Amr Saad.

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3 Diskussion

In der vorliegenden Studie wurde die Verteilung der κ-Magnitude in der Patientengruppe untersucht und es konnte gezeigt werden, dass größere κ-Werte bei hyperopen Augen im Vergleich zu myopen Augen häufiger beobachtet wurden (Hashemi et al., 2010). Nach Implantation einer MIOL bei RLA-Patienten und konsekutiver *Touch-up*-LASIK konnte ebenfalls eine signifikante Abnahme der κ-Werte beobachtet werden und entspricht damit den Ergebnissen früherer Studien (Wang et al., 2020, Garzón et al., 2020).

Der Zusammenhang zwischen κ und dem postoperativen Ergebnis bei Bioptik-Patienten war in dieser Studie von besonderem Interesse. Unsere Ergebnisse zeigen, dass es keine signifikante Korrelation zwischen einem hohen κ und einem schlechten bestkorrigierten Fernvisus (*CDVA*) gibt. Diese Korrelation war weder prä- noch postoperativ nachweisbar. Ebenso konnte kein signifikanter Zusammenhang zwischen κ und dem SI nachgewiesen werden.

Es wurden bereits mehrere Studien zur Rolle von κ in der refraktiven Chirurgie durchgeführt. *Moshirfar et al.* haben in einem Review-Artikel die publizierten Ergebnisse zu κ in PRK-, LASIK- und MIOL-Patienten zusammengefasst (Moshirfar et al., 2013). Eine Zentrierung der Ablationszone über dem Hornhautreflex bei LASIK-Patienten führt nachweislich zu besseren Visusergebnissen (Basmak et al., 2007, Kanellopoulos et al., 2012). Ebenso wird angenommen, dass ein hoher κ-Wert und die damit verbundene potenzielle Dezentrierung einer MIOL zu *Halos* und *Glares* führen können (Karhanová et al., 2013, Karhanová et al., 2015, Park et al., 2012, Fu et al., 2019). Ein κ-Wert größer als $400\mu m$ wird hierbei als möglicher Risikofaktor für solche Dysphotopsien diskutiert (Qi et al., 2018, Prakash et al., 2011, Montrimas et al., 2023). Dies könnte durch den Einfall von Lichtstrahlen auf die Ringstruktur bei einer dezentrierten refraktiven MIOL erklärt werden. *Garzón et al.* haben in ihrer Studie keine Korrelation zwischen einem großen κ und einem schlechten visuellen Ergebnis bei Patienten mit der in unserer Studie verwendeten diffraktiven MIOL (POD F, PhysIOL, Belgien) festgestellt (Garzón et al., 2020). *Cervantes-Coste et al.* konnten ebenfalls keinen signifikanten Zusammenhang mit κ nachweisen (Cervantes-Coste et al., 2022). Die Evidenz für eine eindeutige Korrelation zu visuellen Phänomenen bleibt jedoch diskutabel (Liu et al., 2020, Bonaque-González et al., 2021, Tchah et al., 2017, Umesh et al., 2023). Insgesamt sind die Ergebnisse der verschiedenen Studien nicht eindeutig signifikant (Kermani et al., 2009, Soler et al., 2011) und aufgrund ihres unterschiedlichen Settings sowie der unterschiedlichen Patientenpopulationen, des Studiendesigns, der Operationsmethode, des MIOL-Modells und der statistischen Ansätze schwer vergleichbar.

3.1 Relevanz unserer Studienergebnisse

Wir haben mit unserer Studie erste Ergebnisse zur Rolle von κ bei Bioptik-Patienten publiziert, was die Neuartigkeit unserer Arbeit auszeichnet. Im Gegensatz zu anderen Arbeiten haben wir eine Studienpopulation mit gemischten Ametropien untersucht, bei denen sowohl myope als auch hyperope Augen inkludiert waren. Die Analyse einer großen Anzahl von Augen erhöht die Aussagekraft unserer Ergebnisse. Unsere Arbeit leistet einen wichtigen Beitrag dazu, dass refraktive Chirurgen bei der Vorbereitung ihrer Eingriffe auf evidenzbasierte Informationen zurückgreifen können und somit eine fundierte klinische Entscheidung treffen können.

Aufgrund des retrospektiven Studiendesigns ist eine Analyse der photopischen Phänomene nicht möglich, da dies eine vollständige und lückenlose Dokumentation bei allen untersuchten Augen erfordern würde. Bei einer so großen Anzahl an Patienten ist dies nicht praktikabel. Somit lässt sich ein Zusammenhang zu κ nicht mit Sicherheit ausschließen. Darüber hinaus kann das retrospektive Setting möglicherweise zu Einschränkungen bei der Kontrolle potenzieller Einflussfaktoren geführt haben kann, was ebenfalls nicht ausgeschlossen werden kann.

3.2 Schlussfolgerungen

Zusammenfassend zeigen unsere Studienergebnisse größere κ-Werte bei hyperopen Augen, eine postoperative Abnahme der κ-Magnitude und keinen signifikanten Zusammenhang mit der endgültigen Sehleistung bei Patienten nach einer Bioptik-Behandlung. Das postoperative Ergebnis nach refraktiven Eingriffen scheint nach wie vor multifaktoriell beeinflusst zu sein. Weitere umfangreiche Studien, welche andere Patientengruppen und zusätzliche Einflussfaktoren berücksichtigen, sind notwendig, um potenzielle prädiktive Parameter für ein ungünstiges postoperatives Ergebnis zu identifizieren.

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