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KORELACIJA VREDNOSTI FRAKCIONOG KLIRENSA I OPTIČKOG ISHODA KOREKCIJE KRATKOVIDOSTI LASIK METODOM

Sažetak: Pulsevima excimer lasera LASIK metodom vrši se ablatiranje strome rožnjače, čime se postiže njeno remodelovanje do željenih optičkih karakteristika. Pored korigovanja ametropije, poželjno je svesti indukciju optičkih aberacija višeg reda (HOA) na najmanju moguću meru, jer one utiču na pojavu zablještenja i zamagljenja u uslovima noćnog gledanja. Frakcioni klirens (FC) predstavlja odnos dijametra tretirane optičke zone (OZ) i zenice u skotopskim uslovima osvetljenja. Cilj ovog rada je da se ispita povezanost proširenja dijametra tretirane OZ i povećanja indeksa FC na postoperativni nivo HOA. Prospektivna studija obuhvatila je 37 ispitanika (74 oka) sa miopijom, koji su tretirani LASIK metodom. Oko sa većom vrednošću rezidualnog stromalnog ležišta tretirano je dijametrom OZ 7,0 mm, a drugo oko istog pacijenta dijametrom OZ 6,5 mm. Nakon 6 meseci izvršena je objektivna evaluacija optičkog ishoda Analyzer aparatom. Srednja vrednost FC u grupi očiju tretiranih sa OZ 6,5 mm iznosi 2,138 (SD 0,30), a u grupi tretiranoj OZ 7,0 mm iznosi 2,325 (SD 0,37), sa statistički visoko značajnom razlikom ($t = 3,64$; $p < 0,001$). Utvrđena je manja indukcija svih izmerenih HOA kada je tretirana šira OZ od 7,0 mm, pri čemu je statistički najznačajnije smanjenje uočeno kod indukcije sferne aberacije. Povećanje indeksa FC je proporcionalno proširenju dijametra tretirane OZ. Sa povećanjem vrednosti FC smanjuje se nivo svih HOA nakon LASIK procedure, a najznačajnije smanjenje se uočava kod indukcije sferne aberacije. Proširenje

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OZ na 7,0 mm, kada to strukturne karakteristike rožnjače dozvoljavaju, poboljšava postoperativni optički ishod.

Ključne reči: frakcioni klirens, optička zona, LASIK, optičke aberacije višeg reda

UVOD

LASIK (Laser-Assisted in Situ Keratomileusis) predstavlja jedan od najčešće primenjivanih metoda refraktivne hirurgije za korekciju ametropija (1, 2). Pored miopije, LASIK se primenjuje i za korekciju drugih refraktivnih anomalija, uključujući hipermetropiju i astigmatizam, sa značajnim kliničkim uspehom (3). Primenom pulseva excimer lasera vrši se precizna ablacija strome rožnjače, čime se postiže njeno remodelovanje i korekcija postojećeg refraktivnog defekta. Kvalitet postoperativnog vida ne zavisi samo od postizanja željene refrakcije, već i od minimiziranja neželjenih optičkih efekata.

Pored korekcije osnovne ametropije, jedan od ključnih ciljeva LASIK procedure je minimiziranje indukcije optičkih aberacija višeg reda (Higher Order Aberrations – HOA), koje direktno utiču na pojavu subjektivnih smetnji, kao što su zablještenje (glare) i halos fenomeni u uslovima noćnog gledanja (4, 5). Pacijenti sa većim nivoom HOA često izražavaju nezadovoljstvo kvalitetom vida uprkos dobroj vidnoj oštrini merenoj u standardnim dnevnim uslovima osvetljenja (6).

Optička zona (OZ) predstavlja dijametar centralne površine rožnjače koja se tretira tokom LASIK procedure. Standardno preporučeni dijametar OZ iznosi 6,5 mm (7). Međutim, izbor dijametra OZ ima direktan uticaj na postoperativni optički ishod, naročito u uslovima slabijeg osvetljenja kada je zenica šira (8, 9). Šira OZ omogućava bolju korelaciju između tretirane površine rožnjače i dijametra zenice u skotopskim uslovima gledanja, što je od posebnog značaja za kvalitet noćnog vida. Proširenje dijametra tretmana OZ zahteva veću potrošnju tkiva strome rožnjače tokom ablacije, pa stoga odluka o dijametru OZ mora biti zasnovana na pažljivoj preoperativnoj evaluaciji strukturnih karakteristika rožnjače.

Frakcioni klirens (FC) predstavlja matematički odnos između dijametra tretirane optičke zone i dijametra zenice u skotopskim uslovima osvetljenja (10). Prema dosadašnjim istraživanjima, vrednost FC treba da iznosi najmanje 1,17, odnosno dijametar tretirane OZ treba biti veći za najmanje 17% od dijametra skotopske zenice kako bi se smanjila indukcija postoperativnih HOA (10). Ovaj odnos se pokazao kao realniji pokazatelj postoperativnog optičkog kvaliteta nego pojedinačne vrednosti dijametra OZ ili zenice, jer homogenost dijametra zenice na oba oka istog pacijenta ukazuje da na vrednost FC presudni značaj ima primenjeni dijametar OZ (10, 11).

Savremeni dijagnostički sistemi, kao što su Scheimpflug rotaciona kamera (Oculyzer) i softverski sistemi excimer lasera (Wavelight Allegreto Q 400), omogućavaju preciznu predikciju postoperativne centralne pahimetrije, utroška volumena

strome i debljine rezidualnog stromalnog ležišta (RSB – Residual Stromal Bed), što čini osnovu za bezbedno proširenje OZ kod odabranih pacijenata (2, 12). Individualizovani pristup, koji uzima u obzir specifične karakteristike rožnjače, kao što su njena zakrivljenost i morfologija, pokazao se kao ključan za postizanje optimalnih rezultata (12). Na osnovu ovih prediktivnih parametara moguće je doneti odluku o proširenju dijametra tretmana sa standardnih 6,5 mm na 7,0 mm kod pacijenata kod kojih strukturne karakteristike rožnjače to dozvoljavaju, čime se postiže veća vrednost indeksa FC i, sledstveno tome, bolji postoperativni optički ishod.

Cilj ovog rada je da se ispita povezanost između proširenja dijametra tretirane optičke zone (sa standardnih 6,5 mm na 7,0 mm) i sledstvenog povećanja indeksa frakcionog klirensa na postoperativni nivo optičkih aberacija višeg reda nakon LASIK tretmana miopije.

MATERIJAL I METODE

Prospektivna klinička studija izvedena je na Klinici za oftalmologiju Vojnomedicinske akademije u Beogradu. U studiju je uključeno 37 pacijenata (74 oka) kojima je LASIK metodom izvršena korekcija postojeće ametropije Wavelight Allegreto Q 400 Hz excimer laserom. U studiju su uključene oči sa miopijom i miopnim astigmatizmom. Refraktivni sferni ekvivalent očiju uključenih u studiju bio je od -1,75 Dsph do -10,0 Dsph, pri čemu je vrednost astigmatske komponente bila do -2,75 Dcyl.

Kriterijumi za uključivanje u studiju bili su životna dob od 18 do 45 godina, stabilna refrakcija tokom prethodnih 12 meseci (promena manja od 0,50 Dsph), refraktivni sferni ekvivalent od -1,75 do -10,0 Dsph sa astigmatskom komponentom do -2,75 Dcyl, centralna pahimetrija rožnjače najmanje 480 μm, predviđena postoperativna debljina rezidualnog stromalnog ležišta (RSB) najmanje 300 μm, nekorigovana vidna oštrina najmanje 0,1 i najbolje korigovana vidna oštrina najmanje 0,8 po Snellenu. Kriterijumi za isključivanje bili su: keratokonus ili sumnja na keratokonus, progresivna miopija, znaci sindroma suvog oka (Schirmer test <10 mm/5 min), prisustvo katarakte ili drugih oboljenja prednjeg ili zadnjeg segmenta oka, sistemske bolesti, terapija sistemskim kortikosteroidima, trudnoća ili dojenje.

Preoperativna evaluacija obuhvatala je kompletan oftalmološki pregled, uključujući vidnu oštrinu, subjektivnu i objektivnu refrakciju, biomikroskopiju prednjeg segmenta, aplanacionu tonometriju, funduskopiju u midrijazi i snimanje rožnjače Scheimpflug rotacionom kamerom (Oculyzer). Dijametar zenice u skotopskim uslovima izmeren je pupilometrom pri niskom nivou osvetljenja od 0,04 cd/m² tokom preoperativnog pregleda.

Oculyzer analizom izvršena je evaluacija centralne i periferne pahimetrije, prednje i zadnje elevacije rožnjače, kao i simulacija ablativnog profila za oba dijametra optičke zone (6,5 mm i 7,0 mm), sa predikcijom postoperativne debljine RSB, utroška

volumena strome i progresije kornealnog istanjenja. Na osnovu ovih podataka doneta je odluka o primeni dijametra optičke zone (OZ) za svako oko.

LASIK procedura izvođena je u lokalnoj topikalnoj anesteziji (Tetracaine 0,5%). Kornealni flap debljine 100 μm kreiran je femtosecond laserom. Nakon podizanja flapa, izvršena je ablatija strome rožnjače Wavelight Allegreto Q 400 excimer laserom sa frekvencom od 400 Hz. Zona prelaza iznosila je dodatnih 1,5–2,0 mm izvan dijametra tretirane OZ.

Oči su podeljene u 2 grupe zavisno od dijametra korišćene optičke zone (OZ) prilikom tretmana excimer laserom:

1. Oči tretirane korišćenjem OZ 6,5 mm (n = 37)

2. Oči tretirane korišćenjem OZ 7,0 mm (n = 37)

Kriterijum za izbor dijametra OZ donet je na osnovu evaluacije softvera excimer lasera o predviđenoj postoperativnoj debljini rezidualnog stromalnog ležišta (RSB) za svako oko simuliranjem tretmana OZ sa 6,5 ili 7,0 mm. Kod istog pacijenta, oko sa većom postoperativnom debljinom RSB tretirano je sa OZ 7,0 mm, a oko sa manjom vrednošću RSB sa OZ 6,5 mm.

Frakcioni klirens (FC) za svako oko izračunat je prema formuli:

FC = dijametar tretirane optičke zone (OZ) / dijametar skotopske zenice

Vrednost FC > 1,17 smatrana je optimalnom prema publikovanim preporukama u literaturi.

Kontrolni pregled vršen je nakon 24 časa, 7 dana, 1 mesec, 6 meseci i godinu dana nakon operacije. Pregled je obuhvatao ispitivanje vidne oštrine (korigovane i nekorigovane) za svako oko, snimanje prednjeg očnog segmenta i analizu na aparatima Oculyzer i Analyzer. Nakon 6 meseci izvršena je objektivna evaluacija optičkog ishoda koristeći wavefront aberometar (Analyzer), kojim su merene vrednosti optičkih aberacija višeg reda, uključujući totalnu aberaciju (RMS – Root Mean Square), sfernu aberaciju (SPHA), defokalnu aberaciju (DFOK), astigmatizam višeg reda (ASTIG) i komu (COMA).

Statistička analiza podataka izvršena je korišćenjem Studentovog t-testa za poređenje kontinuiranih varijabli između grupa. Pearsonov koeficijent korelacije korišćen je za ispitivanje korelacije između frakcionog klirensa i postoperativnih HOA. Statistička značajnost definisana je kao $p < 0,05$.

REZULTATI

Srednja vrednost FC u grupi očiju tretiranih sa OZ 6,5 mm iznosi 2,138 (SD 0,30), a u grupi tretiranoj OZ 7,0 mm iznosi 2,325 (SD 0,37). Studentov t-test je pokazao statistički visoko značajnu razliku između grupa ($t = 3,64$; $p < 0,001$) (Tabela 1).

Tabela 1. Prikaz frakcionog klirensa – odnosa dijametra optičke zone i zenice

Grupe	Srednja vrednost	Standardna devijacija	Studentov test (t)	Verovatnoća (p)
6,5 mm	2,13	0,30	3,64	p < 0,001
7 mm	2,32	0,37		

Frakcioni klirens (odnos dijametra optičke zone i zenice) je statistički visoko značajno veći u grupi gde je dijametar OZ iznosio 7,0 mm u odnosu na grupu sa dijametrom 6,5 mm. Tabela 2 prikazuje korelaciju između frakcionog klirensa i različitih parametara optičkih aberacija pre i nakon operacije u grupi tretiranoj sa OZ 6,5 mm.

Tabela 2. Korelacija frakcionog klirensa i drugih parametara (pre i posle operacije; 6.5)

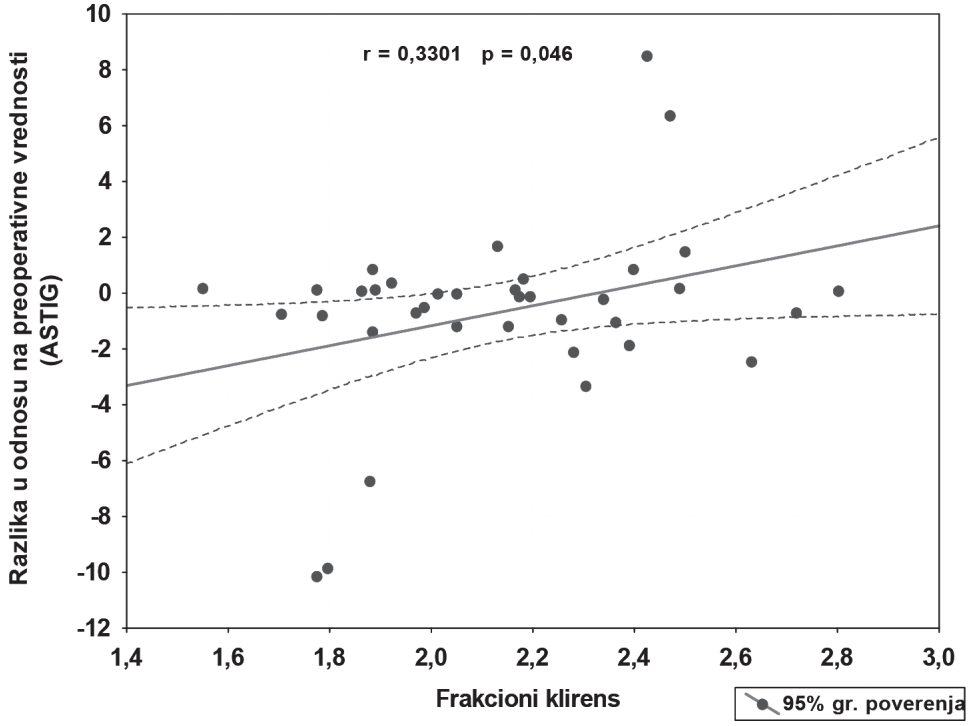
Parametar (x)	Parametar (y)	Koeficijent korelacije (r)	Značajnost
Frakcioni klirens	SPHA		
	Pre	0,0607	p = 0,721
	Posle	-0,0943	p = 0,579
	RMS		
	Pre	0,2860	p = 0,086
	Posle	0,1482	p = 0,381
	DFOK		
	Pre	0,2485	p = 0,138
	Posle	-0,0048	p = 0,977
	ASTIG		
	Pre	-0,1111	p = 0,513
	Posle	0,2245	p = 0,182
	COMA		
	Pre	0,1425	p = 0,400
	Posle	0,1290	p = 0,447

Ne postoji statistički značajna korelacija između frakcionog klirensa i pojedinih HOA u grupi tretiranoj sa OZ 6,5 mm. Korelacioni trend (relativno blizak statističkoj značajnosti) postoji samo između frakcionog klirensa i vrednosti RMS pre operacije.

Poređenje postoperativne indukcije HOA između grupa pokazalo je da je u grupi tretiranoj sa širom OZ od 7,0 mm došlo do manje indukcije svih izmerenih HOA. Najznačajnije smanjenje uočeno je kod indukcije sferne aberacije (SPHA), gde je razlika između grupa bila statistički značajna. Indukcija komarnih aberacija,

astigmatizma višeg reda i defokalne aberacije takođe je bila manja u grupi sa OZ 7,0 mm, iako razlike nisu dostigle statističku značajnost.

Regresionom analizom utvrđena je statistički značajna pozitivna korelacija između vrednosti frakcionog klirensa i uspeha operacije merenog razlikom preoperativnih i postoperativnih vrednosti astigmatizma višeg reda (ASTIG) (r = 0,3301; p = 0,046) (Grafikon 1). Veće vrednosti frakcionog klirensa povezane su sa manjim promenama u astigmatizmu višeg reda nakon LASIK procedure, što ukazuje na bolji postoperativni optički ishod.



Grafikon 1. Korelacija frakcionog klirensa i uspeha operacije (razlika numeričkih vrednosti ASTIG pre u odnosu na posle operacije)

DISKUSIJA

Ova prospektivna studija pokazuje da proširenje dijametra tretirane optičke zone sa standardnih 6,5 mm na 7,0 mm tokom LASIK procedure za korekciju miopije dovodi do statistički značajnog povećanja indeksa frakcionog klirensa i redukcije postoperativne indukcije optičkih aberacija višeg reda, naročito sferne aberacije.

Frakcioni klirens predstavlja klinički relevantan parametar koji kvantifikuje odnos između dijametra tretirane optičke zone i dijametra zenice u skotopskim uslovima (10). Naši rezultati pokazuju da se proširenjem OZ sa 6,5 mm na 7,0 mm postiže statistički značajno povećanje FC sa 2,138 na 2,325 ($p < 0,001$), što predstavlja povećanje od približno 9%. Prema preporukama u literaturi, vrednost FC treba da bude najmanje 1,17 kako bi se minimizirala indukcija HOA (10). Obe grupe u našoj studiji prevazilaze ovaj prag, što ukazuje da je standardna OZ od 6,5 mm adekvatna za većinu pacijenata. Međutim, naši rezultati sugerišu da dodatno proširenje na 7,0 mm kod pacijenata sa odgovarajućim strukturnim karakteristikama rožnjače može doneti dodatne koristi u smislu smanjenja HOA.

Obe grupe u našoj studiji postigle su vrednosti FC značajno iznad minimalno preporučene vrednosti od 1,17, što objašnjava zašto nismo našli značajnu korelaciju između FC i pojedinih HOA u grupi sa OZ 6,5 mm. Ovo sugeriše da postoji prag efekat – dok je kritično dostići minimalnu vrednost FC od 1,17, dodatno povećanje iznad ovog praga može imati manje izražen, ali i dalje klinički značajan efekat na smanjenje HOA.

Naši rezultati pokazuju da proširenje OZ dovodi do redukcije svih merenih HOA, pri čemu je najizraženije smanjenje uočeno kod sferne aberacije. Ovo je klinički značajan nalaz jer je sferna aberacija najčešća HOA koja se indukuje tokom LASIK procedure i direktno utiče na kvalitet vida u mezopskim i skotopskim uslovima osvetljenja (4, 5). Pacijenti sa većom postoperativnom sfernom aberacijom često izražavaju nezadovoljstvo kvalitetom noćnog vida, zablještenje od jakih izvora svetlosti i smanjenu kontrastnu osetljivost (4, 6).

Mehanizam kojim šira OZ redukuje indukciju HOA je multifaktorijalan (8, 9, 11). Prvo, šira OZ omogućava da pacijent gleda kroz tretirani deo rožnjače čak i kada je zenica maksimalno proširena u skotopskim uslovima, čime se izbegava prelazak svetlosnih zraka kroz tranzicionu zonu između tretirane i netretirane rožnjače. Drugo, šira OZ omogućava glađi prelaz između centralne tretirane zone i periferne netretirane rožnjače, što smanjuje indeks pregiba i time redukcije nepravilne refrakcije na periferiji ablativne zone. Treće, šira OZ smanjuje efekat mikrostrukturnih promena u stromalnom tkivu, koje nastaju tokom procesa zarastanja nakon ablacije, koje mogu doprinositi indukciji HOA.

Međutim, važno je napomenuti da proširenje OZ nije bez ograničenja. Veća OZ zahteva dublju ablaciju strome i veću potrošnju tkiva, što može ograničiti primenu kod pacijenata sa većim refraktivnim defektima ili tanjom rožnjačom (2, 12, 13). U našoj studiji, odluka o proširenju OZ je donošena individualno za svako oko na osnovu prediktivne analize softvera excimer lasera, čime je obezbeđeno da postoperativna debljina rezidualnog stromalnog ležišta ostane iznad sigurnosnog praga od 300 μm. Ovaj pristup omogućava maksimiziranje koristi od šire OZ, uz održavanje strukturne sigurnosti rožnjače.

Naši nalazi su u skladu sa prethodnim studijama koje su ispitivale uticaj dijametra OZ na postoperativni optički ishod (7, 10, 14). Bühren i saradnici su uveli koncept frakcionog klirensa kao prediktor optičkog kvaliteta nakon LASIK procedure, naglašavajući da je odnos između OZ i zenice značajniji prediktor nego pojedinačne vrednosti ovih parametara (10). Naša studija potvrđuje ovaj koncept, pokazujući da je fokus na postizanju odgovarajuće vrednosti FC praktičniji pristup u planiranju LASIK procedure nego jednostavno korišćenje standardnog dijametra OZ za sve pacijente.

Značaj dugoročnog praćenja postoperativnih rezultata pokazan je u studijama kod topografski vođenih LASIK procedura, koje su demonstrirale stabilnost postignutih rezultata u periodu od godinu dana (14). Slični pozitivni ishodi postignuti su i kod primene LASIK metode u različitim refraktivnim anomalijama, uključujući hipermetropiju i prezbiopiju, što potvrđuje široku primenljivost ove tehnike (3, 16).

Individualizovani pristup u planiranju LASIK procedure, koji uzima u obzir specifične karakteristike rožnjače, kao što su njena zakrivljenost (ravna, normalna ili strma), pokazao se kao ključan faktor za postizanje optimalnih rezultata (12). Ova saznanja su posebno važna u kontekstu kompleksnih kliničkih situacija, kao što su pacijenti nakon prethodnih refraktivnih procedura, gde je potreban izuzetno precizan pristup (15, 17, 18).

Studije su pokazale da je potrebno da dijametar OZ bude bar za 17% širi od zenice pacijenta u skotopskim uslovima kako bi se indukcija HOA smanjila za 50% (10). U našoj studiji, obe grupe su postigle FC vrednosti značajno iznad ovog praga (prosečno 2,138 i 2,325), što objašnjava relativno nizak nivo postoperativnih HOA u obe grupe.

Naša studija ima nekoliko važnih kliničkih implikacija. Prvo, ona potvrđuje da proširenje OZ sa 6,5 mm na 7,0 mm kod pacijenata sa adekvatnim strukturnim karakteristikama rožnjače dovodi do merljivog poboljšanja optičkog ishoda u smislu redukcije HOA (1, 2). Ovo se može odraziti na poboljšanje subjektivnog kvaliteta vida, naročito u noćnim uslovima gledanja, što je od velike važnosti za zadovoljstvo pacijenata (6). Drugo, rezultati naglašavaju važnost individualizovanog pristupa u planiranju LASIK procedure (12). Umesto primene standardnog dijametra OZ za sve pacijente, odluka treba biti zasnovana na preoperativnoj evaluaciji strukturnih karakteristika rožnjače, veličine refraktivnog defekta i dijametra skotopske zenice. Savremeni dijagnostički i softverski sistemi omogućavaju preciznu prediktivnu analizu, što čini individualizovani pristup realnim i bezbednim (13). Treće, studija potvrđuje vrednost koncepta frakcionog klirensa kao kliničkog pokazatelja (10, 11). Kalkulacija FC vrednosti je jednostavna i može lako biti integrisana u rutinsku preoperativnu evaluaciju. Fokusiranje na postizanju optimalne FC vrednosti (>1,17, idealnije >2,0) može pomoći hirurzima u donošenju odluke o dijametru OZ.

Ova studija ima nekoliko ograničenja koje treba uzeti u obzir pri interpretaciji rezultata. Prvo, relativno mali uzorak od 37 pacijenata ograničava statističku snagu

za detekciju manjih razlika između grupa. Bile bi potrebne studije sa većim brojem učesnika da bi se potvrdili ovi nalazi i ispitale dodatne varijable koje mogu uticati na postoperativni optički ishod. Drugo, period praćenja od 6 meseci je relativno kratak. Dugoročne studije, kao što je pokazano u istraživanjima sa jednogodišnjim praćenjem kod topografski vođenih procedura (14), su potrebne da bi se ispitala stabilnost rezultata i utvrdilo da li se koristi od šire OZ održavaju tokom vremena ili se smanjuju zbog procesa kornealnog remodelovanja i adaptacije. Treće, studija nije uključila subjektivne mere kvaliteta vida, kao što su upitnici o zadovoljstvu pacijenata ili testovi kontrastne osetljivosti (6). Iako objektivna redukcija HOA sugeriše poboljšanje vizuelnog kvaliteta, direktna korelacija sa subjektivnim iskustvom pacijenata bi ojačala kliničku relevantnost nalaza. Četvrto, studija je dizajnirana tako da je svaki pacijent dobio različit dijametar OZ na svakom oku, što omogućava direktno poređenje unutar istog pacijenta. Međutim, ovaj dizajn ne dozvoljava procenu da li pacijenti subjektivno primećuju razliku između očiju u svakodnevnom životu.

ZAKLJUČAK

Rezultati ove studije pokazuju da proširenje dijametra tretirane optičke zone sa 6,5 mm na 7,0 mm tokom LASIK procedure za korekciju miopije dovodi do statistički značajnog povećanja indeksa frakcionog klirensa i redukcije postoperativne indukcije optičkih aberacija višeg reda, posebno sferne aberacije. Povećanje vrednosti indeksa frakcionog klirensa proporcionalno je proširenju dijametra tretirane optičke zone. Veća vrednost frakcionog klirensa korelira sa manjim nivoom optičkih aberacija višeg reda nakon LASIK tretmana miopije, pri čemu je ta korelacija najizraženija u pogledu nivoa sferne aberacije.

Kada postoje odgovarajuće strukturne karakteristike rožnjače, koje omogućavaju bezbedno proširenje dijametra optičke zone, proširenje sa 6,5 mm na 7,0 mm postiže bolji postoperativni optički ishod. Odluka o proširenju dijametra optičke zone treba biti zasnovana na individualnoj preoperativnoj evaluaciji ablativnog profila i predikciji postoperativnog rezidualnog stromalnog ležišta korišćenjem savremenih softverskih sistema excimer lasera. Postizanje optimalne vrednosti frakcionog klirensa treba biti jedan od ciljeva u planiranju LASIK procedure, uz održavanje strukturne sigurnosti rožnjače sa rezidualnim stromalnim ležištem od najmanje 300 μm.

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CORRELATION BETWEEN FRACTIONAL CLEARANCE AND OPTICAL OUTCOMES OF LASIK MYOPIA CORRECTION

Abstract: Excimer laser pulses using the LASIK method ablate the corneal stroma, achieving its remodeling to the desired optical characteristics. Besides correcting ametropia, it is desirable to minimize the induction of higher-order optical aberrations (HOA), as they affect the occurrence of glare and halos in night vision conditions. Fractional clearance (FC) represents the ratio of the treated optical zone (OZ) to the pupil diameter in scotopic lighting conditions. This study aims to examine the relationship between the enlargement of the treated OZ diameter and the increase in FC index on postoperative HOA levels. A prospective study included 37 subjects (74 eyes) with myopia treated with the LASIK method. The eye with a higher residual stromal bed value was treated with an OZ diameter of 7.0 mm, and the other eye of the same patient with an OZ diameter of 6.5 mm. After 6 months, an objective evaluation of optical outcomes was performed using an Analyzer device. The mean FC value in the group of eyes treated with OZ 6.5 mm is 2.138 (SD 0.30), and in the group treated with OZ 7.0 mm is 2.325 (SD 0.37), statistically significant ($t=3.64$; $p<0.001$). A smaller induction of all measured HOA was found when a wider OZ of 7.0 mm was treated, with the statistically significant reduction observed in spherical aberration induction. The increase in FC index is proportional to the enlargement of the treated OZ diameter. With an increase in FC value, the level of all HOA decreases after the LASIK procedure, with the most significant reduction observed in spherical aberration induction.

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Enlargement of OZ to 7.0 mm, when corneal structural characteristics allow it, improves postoperative optical outcomes.

Keywords: fractional clearance, optical zone, LASIK, higher-order optical aberrations

INTRODUCTION

LASIK (Laser-Assisted in Situ Keratomileusis) represents one of the most frequently performed refractive surgical procedures for the correction of ametropias (1,2). In addition to myopia, LASIK is applied in the correction of other refractive anomalies, including hyperopia and astigmatism, with considerable clinical success (3). Through the application of excimer laser pulses, precise ablation of the corneal stroma is performed, thereby achieving corneal remodeling and correction of the existing refractive error. The quality of postoperative vision depends not only on achieving the desired refraction, but also on minimizing unwanted optical effects.

Beyond the correction of the underlying ametropia, one of the primary objectives of the LASIK procedure is the minimization of induced higher-order aberrations (HOA), which directly contribute to subjective visual disturbances such as glare and halo phenomena under scotopic conditions (4,5). Patients with elevated levels of HOA frequently report dissatisfaction with visual quality despite achieving satisfactory visual acuity as measured under standard photopic illumination conditions (6).

The optical zone (OZ) refers to the diameter of the central corneal surface treated during the LASIK procedure. The standard recommended OZ diameter is 6.5 mm (7). However, the selection of OZ diameter exerts a direct influence on postoperative optical outcomes, particularly under conditions of reduced illumination when the pupil is dilated (8,9). A larger OZ facilitates better correspondence between the treated corneal surface and the pupil diameter under scotopic viewing conditions, which is of particular relevance for the quality of night vision. Expanding the treatment OZ diameter requires greater consumption of corneal stromal tissue during ablation; consequently, the decision regarding OZ diameter must be grounded in careful preoperative evaluation of the structural characteristics of the cornea.

The fractional clearance (FC) represents the mathematical ratio between the diameter of the treated optical zone and the scotopic pupil diameter (10). According to existing research, the FC value should reach a minimum of 1.1, that is, the treated OZ diameter should exceed the scotopic pupil diameter by at least 17, in order to reduce the induction of postoperative HOA (10). This ratio has demonstrated greater validity as an indicator of postoperative optical quality than the individual values of OZ or pupil diameter in isolation, given that the homogeneity of pupil diameter between both eyes of the same patient indicates that the applied OZ diameter is the decisive determinant of the FC value (10,11).

Contemporary diagnostic systems, such as the Scheimpflug rotating camera (Oculyzer) and the excimer laser software platform (Wavelight Allegretto Q 400), allow for precise prediction of postoperative central pachymetry, stromal volume consumption, and residual stromal bed (RSB) thickness, forming the basis for the safe expansion of OZ in selected patients (2,12). An individualized approach that accounts for the specific structural characteristics of the cornea, including its curvature and morphology, has proven essential for achieving optimal outcomes (12). On the basis of these predictive parameters, it becomes possible to make an informed decision to expand the treatment diameter from the standard 6.5 mm to 7.0 mm in patients whose corneal structural characteristics permit such expansion, thereby achieving a higher FC index and, consequently, improved postoperative optical outcomes.

This study aims to examine the association between expansion of the treated optical zone diameter (from the standard 6.5 mm to 7.0 mm) and the resultant increase in the fractional clearance index on postoperative levels of higher-order aberrations following LASIK treatment of myopia.

MATERIALS AND METHODS

A prospective clinical study was conducted at the Department of Ophthalmology of the Military Medical Academy in Belgrade. The study enrolled 37 patients (74 eyes) who underwent LASIK refractive correction using the Wavelight Allegretto Q 400 Hz excimer laser. Eyes with myopia and myopic astigmatism were included. The refractive spherical equivalent of the enrolled eyes ranged from −1.75 Dsph to −10.0 Dsph, with an astigmatic component of up to −2.75 Dcyl.

Inclusion criteria were as follows: age between 18 and 45 years, stable refraction over the preceding 12 months (change of less than 0.50 Dsph), refractive spherical equivalent between −1.75 and −10.0 Dsph with an astigmatic component not exceeding −2.75 Dcyl, central corneal pachymetry of at least 480 μm, predicted postoperative residual stromal bed (RSB) thickness of at least 300 μm, uncorrected visual acuity of at least 0.1, and best-corrected visual acuity of at least 0.8 on the Snellen scale. Exclusion criteria included: keratoconus or suspected keratoconus, progressive myopia, signs of dry eye syndrome (Schirmer test <10 mm/5 min), presence of cataract or other anterior or posterior segment pathology, systemic disease, systemic corticosteroid therapy, pregnancy, or breastfeeding.

Preoperative evaluation comprised a complete ophthalmological examination including visual acuity assessment, subjective and objective refraction, anterior segment biomicroscopy, applanation tonometry, funduscopy under mydriasis, and corneal imaging with a Scheimpflug rotating camera (Oculyzer). Scotopic pupil dia-

meter was measured using a pupillometer under low-luminance conditions of 0.04 cd/m² during the preoperative assessment.

Oculyzer analysis was performed to evaluate central and peripheral pachymetry, anterior and posterior corneal elevation, and to simulate the ablation profile for both optical zone diameters (6.5 mm and 7.0 mm), with prediction of postoperative RSB thickness, stromal volume consumption, and corneal thinning progression. Treatment decisions regarding the optical zone (OZ) diameter were made for each eye individually on the basis of these data.

The LASIK procedure was performed under topical local anesthesia (Tetracaine 0.5%). A corneal flap of 100 μm thickness was created using a femtosecond laser. Following flap elevation, stromal ablation was carried out with the Wavelight Allegretto Q 400 excimer laser operating at a frequency of 400 Hz. The transition zone extended an additional 1.5–2.0 mm beyond the treated OZ diameter.

Eyes were divided into two groups according to the OZ diameter applied during excimer laser treatment:

- Eyes treated with OZ 6.5 mm (n = 37)
- Eyes treated with OZ 7.0 mm (n = 37)

The criterion for OZ diameter selection was based on excimer laser software evaluation of the predicted postoperative RSB thickness for each eye, simulated for both 6.5 mm and 7.0 mm OZ treatments. In each patient, the eye with the greater predicted postoperative RSB thickness was treated with OZ 7.0 mm, while the eye with the lesser RSB value was treated with OZ 6.5 mm.

Fractional clearance (FC) for each eye was calculated according to the following formula:

- FC = treated optical zone diameter (OZ) / scotopic pupil diameter

An FC value >1.17 was considered optimal in accordance with published recommendations in the literature.

Follow-up examinations were conducted at 24 hours, 7 days, 1 month, 6 months, and 12 months postoperatively. Each examination included assessment of corrected and uncorrected visual acuity for each eye, anterior segment imaging, and analysis using the Oculyzer and Analyzer platforms. At the six-month follow-up, objective evaluation of optical outcomes was performed using a wavefront aberrometer (Analyzer), which measured higher-order aberration values including total aberration (RMS - Root Mean Square), spherical aberration (SPHA), defocus aberration (DFOK), higher-order astigmatism (ASTIG), and coma (COMA).

Statistical analysis was performed using Student's t-test for the comparison of continuous variables between groups. Pearson's correlation coefficient was used to assess the correlation between fractional clearance and postoperative HOA values. Statistical significance was defined as $p < 0.05$.

RESULTS

The mean FC value in the group of eyes treated with OZ 6.5 mm was 2.138 (SD 0.30), while in the group treated with OZ 7.0 mm, it was 2.325 (SD 0.37). Student's t-test demonstrated a statistically highly significant difference between the groups ($t = 3.64$; $p < 0.001$) (Table 1).

Table 1. Fractional clearance - ratio of optical zone diameter to pupil diameter

Group	Mean Value	Standard Deviation	Student's t-test (t)	Probability (p)
6,5 mm	2,13	0,30	3,64	p < 0,001
7 mm	2,32	0,37		

Fractional clearance (the ratio of optical zone diameter to pupil diameter) was statistically highly significantly greater in the group in which the OZ diameter was 7.0 mm compared to the group with a diameter of 6.5 mm. Table 2 presents the correlation between fractional clearance and various optical aberration parameters before and after surgery in the group treated with OZ 6.5 mm.

Table 2. Correlation between fractional clearance and other parameters (pre- and postoperative; OZ 6.5 mm group)

Parameter (x)	Parameter (y)	Correlation Coefficient (r)	Significance
Fractional Clearance	SPHA		
	Pre-operative	0,0607	p = 0,721
	Post-operative	-0,0943	p = 0,579
	RMS		
	Pre-operative	0,2860	p = 0,086
	Post-operative	0,1482	p = 0,381
	DFOK		
	Pre-operative	0,2485	p = 0,138
	Post-operative	-0,0048	p = 0,977
	ASTIG		
	Pre-operative	-0,1111	p = 0,513
	Post-operative	0,2245	p = 0,182
	COMA		
	Pre-operative	0,1425	p = 0,400
	Post-operative	0,1290	p = 0,447

No statistically significant correlation was identified between fractional clearance and individual HOA parameters in the group treated with OZ 6.5 mm. A correlational trend approaching but not reaching statistical significance was observed solely between fractional clearance and preoperative RMS values.

Comparison of postoperative HOA induction between groups demonstrated that the group treated with the larger OZ of 7.0 mm exhibited lower induction of all measured HOA parameters. The most notable reduction was observed in the induction of spherical aberration (SPHA), where the difference between groups reached statistical significance. Induction of coma aberration, higher-order astigmatism, and defocus aberration was also lower in the OZ 7.0 mm group, although these differences did not attain statistical significance.

Regression analysis revealed a statistically significant positive correlation between fractional clearance values and surgical outcome as measured by the difference between preoperative and postoperative higher-order astigmatism values ($r = 0.3301$; $p = 0.046$) (Figure 1). Higher fractional clearance values were associated with smaller changes in higher-order astigmatism following the LASIK procedure, indicating a more favorable postoperative optical outcome.

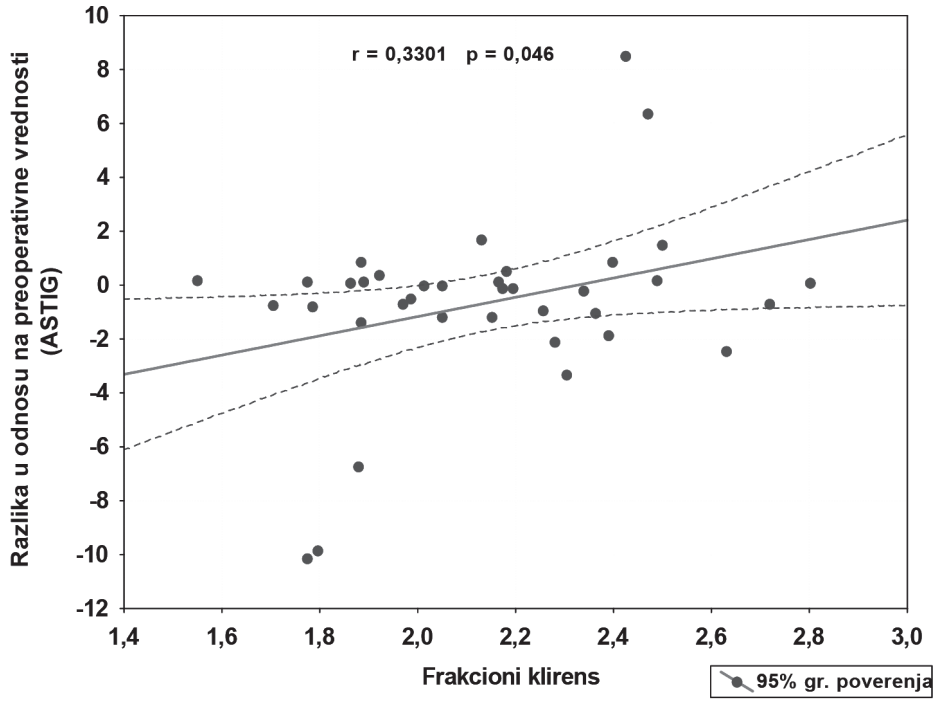


Figure 1. Correlation between fractional clearance and surgical outcome (difference between preoperative and postoperative numerical values of higher-order astigmatism)

DISCUSSION

This prospective study demonstrates that expanding the treated optical zone diameter from the standard 6.5 mm to 7.0 mm during LASIK correction of myopia results in a statistically significant increase in the fractional clearance index and a reduction in postoperative induction of higher-order aberrations, most notably spherical aberration.

Fractional clearance represents a clinically relevant parameter that quantifies the relationship between the treated optical zone diameter and the scotopic pupil diameter (10). Our results demonstrate that expanding the OZ from 6.5 mm to 7.0 mm yields a statistically significant increase in FC from 2.138 to 2.325 ($p < 0.001$), representing an increase of approximately 9%. According to recommendations, the FC value should reach a minimum of 1.17 in order to minimize HOA induction (10). Both groups in our study exceeded this threshold, suggesting that the standard OZ of 6.5 mm is adequate for the majority of patients. Nevertheless, our results indicate that further expansion to 7.0 mm in patients with appropriate corneal structural characteristics may confer additional benefits in terms of HOA reduction.

Both groups achieved FC values substantially above the minimum recommended threshold of 1.17, which accounts for the absence of a significant correlation between FC and individual HOA parameters in the OZ 6.5 mm group. This suggests the existence of a threshold effect. While achieving the minimum FC value of 1.17 is critical, further increases beyond this threshold may exert a less pronounced yet still meaningful effect on HOA reduction.

Our results demonstrate that OZ expansion leads to a reduction in all measured HOA parameters, with the most pronounced decrease in spherical aberration. This is a significant finding, as spherical aberration is the most commonly induced HOA during LASIK and directly affects visual quality under mesopic and scotopic illumination conditions (4,5). Patients with elevated postoperative spherical aberration frequently report dissatisfaction with night vision quality, glare from intense light sources, and reduced contrast sensitivity (4,6).

The mechanism by which a larger OZ reduces HOA induction is multifactorial (8,9,11). First, a larger OZ ensures that the patient views through the treated portion of the cornea even when the pupil is maximally dilated under scotopic conditions, thereby preventing light rays from passing through the transition zone between the treated and untreated corneal surfaces. Second, a larger OZ facilitates a smoother transition between the central treated zone and the peripheral untreated cornea, reducing the refractive index gradient and thereby minimizing irregular refraction at the periphery of the ablation zone. Third, a larger OZ attenuates the effect of microstructural changes in the stromal tissue that arise during the post-ablation healing process, which may contribute to HOA induction.

It is important to note, however, that OZ expansion is not without limitations. A larger OZ necessitates deeper stromal ablation and greater tissue consumption, which may preclude its application in patients with higher refractive errors or thinner corneas (2,12,13). In our study, the decision to expand the OZ was made individually for each eye based on predictive software analysis of the excimer laser system, ensuring that postoperative residual stromal bed thickness remained above the safety threshold of 300 μm. This approach allows the benefits of a larger OZ to be maximized while maintaining corneal structural integrity.

Our findings are consistent with those of previous studies examining the influence of OZ diameter on postoperative optical outcomes (7,10,14). Bühren et al. introduced the concept of fractional clearance as a predictor of optical quality following LASIK, emphasizing that the ratio between OZ and pupil diameter is a more meaningful predictor than the individual values of these parameters in isolation (10). Our study corroborates this concept, demonstrating that focusing on achieving an appropriate FC value represents a more practical approach to LASIK treatment planning than the uniform application of a standard OZ diameter across all patients.

The importance of long-term postoperative follow-up has been demonstrated in studies of topography-guided LASIK procedures, which have shown stability of achieved outcomes over one year (14). Similarly favorable outcomes have been reported following LASIK for other refractive anomalies, including hyperopia and presbyopia, confirming the broad applicability of this technique (3,16).

An individualized approach to LASIK treatment planning that accounts for the specific structural characteristics of the cornea, including its curvature profile (flat, normal, or steep), has proven to be a critical determinant of optimal outcomes (12). These findings are particularly relevant in the context of complex clinical scenarios, such as patients with prior refractive procedures, where a highly precise approach is required (15,17,18).

Studies have demonstrated that the OZ diameter must be at least 17% wider than the patient's scotopic pupil diameter to reduce HOA induction by 50% (10). In our study, both groups achieved FC values substantially above this threshold (means of 2.138 and 2.325, respectively), which accounts for the relatively low level of postoperative HOA observed across both groups.

Our study carries several important clinical implications. First, it confirms that expanding the OZ from 6.5 mm to 7.0 mm in patients with adequate corneal structural characteristics yields a measurable improvement in optical outcome in terms of HOA reduction (1,2). This may translate into an improvement in subjective visual quality, particularly under night-time viewing conditions, which is of considerable importance for patient satisfaction (6). Second, the findings underscore the importance of an individualized approach to LASIK treatment planning (12). Rather than applying a standard OZ diameter uniformly across all patients, the decision should be grounded

in preoperative evaluation of corneal structural characteristics, the magnitude of the refractive error, and scotopic pupil diameter. Contemporary diagnostic and software systems enable precise predictive analysis, rendering an individualized approach both feasible and safe (13). Third, the study affirms the clinical utility of the fractional clearance concept (10,11). Calculation of the FC value is straightforward and can readily be integrated into routine preoperative assessment. Focusing on achieving an optimal FC value (>1.17, ideally >2.0) may assist surgeons in determining the appropriate OZ diameter.

This study has several limitations that should be considered when interpreting the results. First, the relatively small sample of 37 patients limits the statistical power to detect smaller inter-group differences. Studies with larger participant cohorts would be required to confirm these findings and to examine additional variables that may influence postoperative optical outcomes. Second, the six-month follow-up period is comparatively short. Long-term studies, as demonstrated in research with a one-year follow-up of topography-guided procedures (14), are needed to assess the stability of outcomes and to determine whether the benefits of a larger OZ are sustained over time or diminish as a result of corneal remodeling and adaptation processes. Third, the study did not incorporate subjective measures of visual quality such as patient satisfaction questionnaires or contrast sensitivity testing (6). Although objective HOA reduction suggests an improvement in visual quality, direct correlation with patients' subjective experience would strengthen the clinical relevance of the findings. Fourth, the study was designed so that each patient received a different OZ diameter in each eye, enabling direct within-patient comparison. However, this design does not permit assessment of whether patients subjectively perceive a difference between their eyes in the course of daily activities.

CONCLUSION

The results of this study demonstrate that expanding the treated optical zone diameter from 6.5 mm to 7.0 mm during LASIK correction of myopia leads to a statistically significant increase in the fractional clearance index and a reduction in postoperative induction of higher-order aberrations, particularly spherical aberration. The increase in the fractional clearance index is proportional to the expansion of the treated optical zone diameter. Higher fractional clearance values correlate with lower levels of higher-order aberrations following LASIK treatment of myopia, with this correlation being most pronounced with respect to spherical aberration.

When the structural characteristics of the cornea are adequate to permit safe expansion of the optical zone diameter, expansion from 6.5 mm to 7.0 mm yields a more favorable postoperative optical outcome. The decision to expand the optical zone diameter should be grounded in individualized preoperative evaluation of the

ablation profile and prediction of postoperative residual stromal bed thickness using contemporary excimer laser software systems. Achieving an optimal fractional clearance value should be regarded as one of the primary objectives in LASIK treatment planning, alongside maintenance of corneal structural safety with a residual stromal bed of no less than 300 μm.

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