Original Article

Partial versus Full Thickness Limbal Relaxing Incisions for Treating With-the-Rule Astigmatism: A Randomized Trial

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Abstract

Purpose: To compare the efficacy of partial thickness versus full thickness limbal relaxing incisions performed during phacoemulsification for the treatment of with-the-rule astigmatism in elderly cataract patients.
Design: Prospective randomized controlled trial.
Participants: Eighty-eight patients aged 65 years or older with senile cataract and with-the-rule astigmatism greater than 1.25 diopters were included. Patients were randomly allocated to either the partial thickness limbal relaxing incision group or the full thickness limbal relaxing incision group.
Methods: All participants underwent phacoemulsification with intraocular lens implantation. In the partial thickness group, limbal relaxing incisions were made with a guarded stainless-steel knife preset at 550 microns according to ASCRS guidelines. In the full thickness group, paired limbal incisions were created with a 2.8 mm MANI phaco knife. Postoperative follow-ups were conducted at one, three, and six months, assessing best-corrected visual acuity, uncorrected visual acuity, residual astigmatism, spectacle independence, photophobia, foreign body sensation, and patient satisfaction.
Main Outcome Measures: Best-corrected visual acuity, uncorrected visual acuity, corneal astigmatism, spectacle independence, patient satisfaction, and complications.
Results: At one month, the partial thickness group achieved significantly better uncorrected visual acuity ($P = 0.011$) and best-corrected visual acuity ($P = 0.012$) than the full thickness group, but these differences were not significant at six months. Residual astigmatism was slightly lower in the partial thickness group, though not statistically significant. Spectacle independence, foreign body sensation, and patient satisfaction were similar between groups. Photophobia occurred more often in the full thickness group (22.7% vs. 9.1%), but the difference was not statistically significant ($P = 0.080$). No surgical complications, including leakage or infection, were observed.
Conclusions: Full thickness limbal relaxing incisions do not provide superior correction of with-the-rule astigmatism compared with partial thickness incisions. Although technically simpler, faster, and more cost-effective, their penetrating nature carries potential risks. Partial thickness limbal relaxing incisions remain the safer and more effective technique during cataract surgery.
Keywords: Cataract; Partial; Full Thickness; Limbal Relaxing; Incision; Astigmatism.

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Introduction

Cataract is a common eye condition characterized by lens opacification, which leads to a decrease in visual acuity [1]. It is the leading cause of vision loss blindness worldwide in old and is also [2,3]. The prevalence of cataracts increases significantly with age; it is estimated that more than half of all individuals aged 80 and above have experienced some degree of cataract formation [4].

A combined cataract and refractive error occurs when the clouding of the lens of the lens coexists with a refractive error such as myopia, hyperopia, or astigmatism, which impairs the eye's ability to focus accurately. This combination significantly affects vision, causing blurriness from the cataract compounded by focusing issues from the refractive error [5].

Combined cataract and refractive errors such as astigmatism are increasingly being addressed in a single surgical session [6]. Combined cataract and astigmatism correction surgery is designed to simultaneously address the lens opacity and astigmatism among cataract patients [7]. The most common approach involves phacoemulsification for the removal of the cataract-affected lens, followed by the implantation of a toric intraocular lens (IOL) tailored to correct the specific astigmatic error of the patient [8].

In addition to the use of toric intraocular lenses (IOLs) for the correction of astigmatism during cataract surgery, several other methods can effectively address astigmatic errors [9]. These methods include laser refractive surgeries, such as laser-assisted in-situ keratomileusis (LASIK) or photorefractive keratectomy (PRK), either before or after cataract surgery, limbal relaxing incisions (LRIs), and corneal relaxing incisions (CRIs) [10-12].

The LRI method aids in improving vision in patients with low to moderate astigmatism below 3 D, protecting them from the high costs associated with other surgical methods for treating astigmatism (such as toric lenses) [13-16]. In these patients, LRI is performed in the same session after the Phacoemulsification, eliminating the need for a second preparation for the operating room and saving time and costs for the patient. Compared to similar methods, LRI results in more stable outcomes after surgery and reduces post-surgical complaints like glare, vision loss, and discomfort [14-16].

The classical LRI method includes a partial thickness incision, thinner than the corneal thickness, opposite the phaco surgical cut site, which requires the use of a special knife different from the one used in phaco surgery [17]. Another method named full thickness or penetrating limbal relaxing incision has been also suggested introduced [18]. In this method, a full thickness incision is made after the phaco surgery cut, opposite to it, which can be performed using the same knife used in phaco surgery [18]. The advantages of this method over the classical approach for the surgeon include easier surgical techniques, less experience needed, shorter operation time due to the shorter length of the incision compared to the LRI method, and no need to check the incision thickness after making it, which involves using fewer tools and reducing costs in both surgeries [18]. The disadvantages of this method compared to the classical approach include an increased risk of intraocular infections (endophthalmitis) and increased risk of leakage of intraocular contents [18]. Although these complications are rarely reported, there is a possibility of their occurrence.

There is a very limited body of evidence regarding the use of full thickness LRI in correction of astigmatism among patients undergoing cataract surgery. In our search of the English literature we only found one similar study comparing the partial thickness and full thickness LRIs methods in correction of astigmatism. The purpose of the present study was to compare the outcomes of partial thickness and full thickness LRIs in the correction of astigmatism among patients undergoing cataract surgery regarding visual acuity and refractive stability as well as patient satisfaction and report the probable post surgical complications.

Patients and Methods

Patients

This randomized controlled trial included 88 patients at the Vanak Eye Surgery Center, Tehran, Iran, from May 2022 to April 2023. The study protocol was approved by the ethics committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran, and all patients provided written informed consent before participating in the study. Patients were eligible if they were 65 years or older, were candidates for phacoemulsification surgery, and had with-the-rule astigmatism with a cylinder greater than 1.25 diopters. Patients were excluded if they had any other ocular pathology, a history of previous ocular disease or surgery, or any systemic disease. Randomization was used to allocate participants into either the full-thickness limbal relaxing incision (FTLRI) group as the case group or the partial thickness limbal relaxing incision (LRI) group as the control group.

Before surgery, patient medical history was collected using a standardized questionnaire and medical records were reviewed to minimize recall bias. A comprehensive ophthalmic examination, including an assessment of astigmatism and measurement of cylinder values as baseline data, was performed and recorded.

Surgical Methods

All surgical procedures were conducted in a controlled operating room setting using identical surgical instruments and conditions. The surgical incision area (surgically induced astigmatism) was considered in the preoperative planning for phacoemulsification. A single experienced surgeon (N.N) performed all phacoemulsification surgeries using an Alcon Infiniti device (Alcon Laboratories, Fort Worth, TX). At the beginning of surgery, the target eye was anesthetized with 0.5% tetracaine drops, adjusted based on the patient's sensitivity. After inducing anesthesia, the steepest meridian of the operated eye was marked at the 3, 6, and 9 o'clock positions using a Mendoza ring, slit lamp, and specialized markers.

During the surgical procedure, the main phacoemulsification incision was made using a 2.8 mm MANI knife at the 10 o'clock position on the cornea in the limbus. Subsequently, the side port incision was performed using the same knife at the 2 o'clock position on the limbus. Next, the lens was first fragmented and then removed, followed by the implantation of a monofocal intraocular lens (IOL) of the Alcon IQ SN60 model into the eye. To protect the endothelial layer of the cornea, a viscoelastic material was injected into the eye. At the final stage, an astigmatism-correcting incision was performed.

The astigmatism-correcting incision differed between the two groups. In the LRI group, a partial-thickness incision was performed using a preset guarded stainless steel knife with preset guards of 550 microns (Oasis Medical, CA, USA), as described by Hosny et al., [18] and according to the nomogram and guidelines of the American Society of Cataract and Refractive Surgery (ASCRS). The incision was made at the steepest corneal meridian in the limbal area.

In the FTLRI group, two full-thickness LRI incisions were performed in the limbal area of the cornea along the steepest meridian of the cornea. These incisions were created using the same 2.8 mm MANI knife that was used for phacoemulsification. If leakage complications occurred during surgery, a hydration plan was prepared as a precaution.

After the surgical procedure, 1 cc of Cefazolin solution and 1 cc of 1% Betamethasone solution were mixed and injected into the conjunctiva of the patients. Additionally, 2% Betamethasone eye drops were prescribed and applied every 4 hours during the first five days, every 6 hours during the second five days, every 8 hours during the third five days, every 12 hours during the fourth five days, and every 24 hours during the fifth five days. Moreover, 0.5% Chloramphenicol antibiotic eye drops were prescribed and applied every 4 hours with 2 drops during the first five days and every 6 hours with 2 drops during the second five days.

Postoperative follow-ups were scheduled at one, three, and six months after surgery. At each visit, a comprehensive ophthalmic examination was performed, including visual acuity assessment and measurement of changes in corneal astigmatism. Data were recorded in standardized forms by a designated examiner who was blinded to group allocation.

Sample Size Calculation and Statistical Analysis

For statistical analysis, descriptive statistics were presented as means, standard deviations, medians, ranges, frequencies, and percentages. Nominal, ordinal, and continuous variables were compared between the two groups using the Chi-square test, Mann-Whitney U test, and t-test, respectively. To account for potential correlation between eyes, a generalized estimating equation (GEE) model was applied where necessary. Statistical significance was set at a p-value of less than 0.05. Sample size calculation was based on the expected difference in corneal cylinder changes, based on the results of a previous study [18] with an alpha level of 0.05 and a power of 95%. All statistical analyses were conducted using SPSS version 26 (IBM Corp., Armonk, NY, USA).

Results

A total of 88 patients (56 females and 32 males) were included in the study, with a mean age of 65 ± 12 years. The demographic characteristics of the two groups, including baseline best-corrected visual acuity (BCVA), uncorrected visual acuity (UCVA), and astigmatism cylinder values, were comparable, with no statistically significant differences between them (Table 1).

Visual Acuity Outcomes

Postoperative BCVA and UCVA improvements were observed in both groups. At one month post-surgery, the mean BCVA was slightly better in the LRI group (0.04 ± 0.07 logMAR) compared to the FTLRI group (0.01 ± 0.05 logMAR), with a statistically significant difference (P = 0.012). However, at six months, the difference between the two groups was no longer significant (P = 0.392). Similarly, UCVA at one month showed significantly better improvement in the LRI group

Table 1: Comparison of baseline demographics and clinical features between LRI and FTLRI groups

Parameter		Total	Group		P
			LRI	FTLRI	
Sex	Female	56 (63.6 %)	27 (61.4 %)	29 (65.9 %)	0.531*
	Male	32 (36.4%)	17 (38.6 %)	15 (34.1 %)	
Age	Mean ± SD	65 ± 12	65 ± 12	65 ± 12	0.772†
	Median (range)	66 (21 to 93)	65 (39 to 93)	68 (21 to 84)	
BCVA (logMAR)	Mean ± SD	0.21 ± 0.26	0.24 ± 0.3	0.19 ± 0.2	0.410‡
	Median (range)	0.15 (0 to 1.5)	0.15 (0 to 1.5)	0.15 (0 to 1)	
UCVA (logMAR)	Mean ± SD	0.41 ± 0.4	0.47 ± 0.46	0.35 ± 0.31	0.114‡
	Median (range)	0.3 (0 to 2.6)	0.3 (0 to 2.6)	0.22 (0 to 1.5)	
AC Value	Mean ± SD	-1.27 ± 1.14	-1.49 ± 1.33	-1.06 ± 0.85	**0.043**‡
	Median (range)	-1 (-7 to -0.25)	-1 (-7 to -0.25)	-0.75 (-6 to -0.25)	

DCVA: best corrected visual acuity; UCVA: uncorrected visual acuity; logMAR: logarithmic minimum angle of resolution; SD: standard deviation; LRI: limbal relaxing incision; FTLRI: full thickness limbal relaxing incision; AC: Anterior Chamber
* Based on Chi-square test.
† Based on t-test.
‡ Based on GEE method.

(P = 0.011), but this difference was not sustained at six months (P = 0.302) (Table 2).

Astigmatism Correction

Preoperative astigmatism cylinder values were -1.49 ± 1.33 D in the LRI group and -1.06 ± 0.85 D in the FTLRI group. At one month postoperatively, the reduction in astigmatism was greater in the LRI group (-0.81 ± 1.05 D vs. -0.47 ± 0.65 D), but this difference was not statistically significant (P = 0.548). Similarly, at six months, the mean residual astigmatism was slightly lower in the LRI group (-0.76 ± 1.1 D) compared to the full-thickness group (-0.48 ± 0.66 D), but the difference remained non-significant (P = 0.541) (Table 2).

Surgical Outcomes and Patient Satisfaction

No significant differences were observed

Table 2: Comparison of visual acuity and asigmatism between LRI and FTLRI groups

Variable	Time	Group		Difference	Adjusted	95% CI		P‡
		LRI	FTLRI		Difference‡	Lower	Upper	
BCVA (logMAR)	Pre	0.24 ± 0.3	0.19 ± 0.2	0.05				
	M1	0.04 ± 0.07	0.01 ± 0.05	0.03	0.02	0.00	0.04	**0.012**
	Change (Pre-M1)	0.2 ± 0.28	0.18 ± 0.18	0.02				
	M6	0.02 ± 0.05	0.01 ± 0.04	0.01	0.00	-0.01	0.02	0.392
	Change (Pre-M6)	0.22 ± 0.28	0.18 ± 0.19	0.04				
UCVA (logMAR)	Pre	0.47 ± 0.46	0.35 ± 0.31	0.12				
	M1	0.17 ± 0.2	0.09 ± 0.13	0.08	0.04	0.01	0.07	**0.011**
	Change (Pre-M1)	0.3 ± 0.32	0.26 ± 0.22	0.04				
	M6	0.08 ± 0.13	0.04 ± 0.09	0.04	0.01	-0.01	0.04	0.302
	Change (Pre-M6)	0.39 ± 0.37	0.3 ± 0.25	0.09				
Astigmatism Cylinder (D)	Pre	-1.49 ± 1.33	-1.06 ± 0.85	-0.43				
	M1	-0.81 ± 1.05	-0.47 ± 0.65	-0.34	-0.03	-0.13	0.07	0.548
	Change (Pre-M1)	-0.67 ± 0.45	-0.59 ± 0.42	-0.08				
	M6	-0.76 ± 1.1	-0.48 ± 0.66	-0.28	0.03	-0.07	0.13	0.541
	Change (Pre-M6)	-0.72 ± 0.48	-0.58 ± 0.41	-0.14				

DCVA: best corrected visual acuity; UCVA: uncorrected visual acuity; logMAR: logarithmic minimum angle of resolution; SD: standard deviation; LRI: limbal relaxing incision; FTLRI: full thickness limbal relaxing incision; pre: preoperative; M1: one month postoperative; M6: six month postoperative
‡ Adjusted for the baseline values, based on marginal model by GEE method.
M1: Month one post surgery; M6: Month six post surgery

between the groups regarding spectacle independence (P = 0.446), foreign body sensation (FoBoS) scores (P = 0.861), or subjective patient satisfaction scores (P = 0.861). The incidence of photophobia was higher in the full-thickness LRI group (22.7%) compared to the LRI group (9.1%), but this difference did not reach statistical significance (P = 0.080) (Table 3).

Discussion

Our study demonstrated that both LRI and FTLRI techniques effectively improved visual acuity and reduced astigmatism in patients undergoing cataract surgery. The mean BCVA improved significantly in both groups one month after surgery. Although the LRI method initially showed superior improvement (P < 0.05), this advantage diminished over

Table 3: Comparison of surgical outcomes and patients' satisfaction between in LRI and Penetrating LRI Groups

Variable	Parameter	Group		Difference	95% CI		P
		LRI	FTLRI		Lower	Upper	
Photophobia	No	40 (90.9 %)	34 (77.3 %)				
	Yes	4 (9.1 %)	10 (22.7 %)	-13.6%	-29.0 %	1.8 %	0.080*
Complications	No	44 (100.0 %)	44 (100.0 %)	0	-	-	1*
Leakage	No	44 (100.0%)	44 (100.0 %)	0	-	-	1*
Spectacle Independence	No	45 (51.1 %)	39 (44.3 %)				
	Yes	43 (48. 9%)	49 (55.7 %)	-6.8%	-21.7 %	8.1 %	0.446‡
FoBoS	Mean ± SD	2.3 ± 1	2.2 ± 1	0.1	-0.3	0.5	0.861**
	Median (range)	2 (0 to 4)	2 (0 to 4)				
SL	Mean ± SD	8 ± 0.8	7.8 ± 1	0.3	-0.1	0.6	0.861**
	Median (range)	8 (6 to 9)	8 (6 to 9)				
Postoperative Residual Refractive Astigmatism	Mean ± SD	-0.76 ± 1.1	-0.48 ± 0.66	-0.28	-0.60	0.04	0.082‡
	Median (range)	-0.37 (-5.5 to 0.5)	-0.25 (-5 to 0.5)				

SL: Patients' satisfaction level; FoBoS: Foreign Body Sensation; LRI: limbal relaxing incision; FTLRI: full thickness limbal relaxing incision
* Based on Chi-square test.
‡ Based on marginal logistic regression by GEE method.
** Based on Mann-Whitney test.

time, with no significant difference observed at the six-month follow-up. A similar trend was seen in UCVA, where the LRI group initially exhibited greater improvement, but the difference between the two groups was no longer statistically significant after six months. Similar to our finding Mohammad-Rabei et al., [19] have reported a statistically significant improvement in UCVA from the baseline among patients with astigmatism correction using the LRI method with no difference between weeks 1, 4 and 8 after surgery. Also Bayramlar et al., [20] have reported a significant improvement in postoperative UCVA and BSCVA compared to baseline reading among patients with astigmatism correction using the LRI method during cataract surgery.

The reduction in astigmatic cylinder was comparable between the two groups. Despite a higher preoperative astigmatism in the LRI group, both techniques resulted in a significant reduction in cylinder power after one month, with no statistically significant difference between the groups at six months (P = 0.548). This suggests that both techniques were equally effective in reducing astigmatism over the long term. In a similar study by Hosny et al.,[18] the authors compared limbal relaxing incisions and penetrating limbal relaxing incisions in the management of astigmatism during cataract surgery. Contrary to our findings they reported that LRI results in better axis correction one month post surgery as compared to the FTLRI method.

One of the primary objectives of this study was to assess the postoperative independence from glasses. While a slightly higher percentage of patients in the FTLRI group achieved spectacle independence (55.7% vs. 48.9% in the LRI group), the difference was not statistically significant (P = 0.446). This indicates that neither technique offers a distinct advantage in reducing dependence on corrective eyewear. A key concern regarding the safety profile of FTLRI stems from its penetrating incisions, which could theoretically increase the risk of complications. However, in this study, no cases of surgical complications, including keratitis, endophthalmitis, or anterior chamber fluid leakage, were reported in either group. We also observed no significant differences between the two methods regarding foreign body sensation, or subjective patient satisfaction scores. This supports the notion that FTLRI might be a safe and viable alternative to LRI when performed correctly. From a practical standpoint, FTLRI offers several advantages, including ease of execution, reduced surgical time, lower costs, and no requirement for specialized equipment. These benefits make FTLRI an attractive option for surgeons seeking a simpler and more efficient approach to astigmatism correction during cataract surgery. However, concerns about its penetrative nature which potentially can increase the chance of endophthalmitis and potential long-term effects warrant further investigation.

A major strength of this study was its randomized, prospective design, which enhances the reliability of the findings. However, the relatively short follow-up period and the limited sample size may have restricted the ability to capture long-term differences.

Conclusion

FTLRI does not result in superior astigmatism correction compared to LRI and may lead to complications such as leakage and endophthalmitis because of its full thickness penetration of the cornea. From a practical standpoint, FTLRI offers several advantages, including ease of execution, reduced surgical time, lower costs, and no requirement for specialized equipment.

Conflict of interest:

The authors have no conflict of interest with the subject matter of the present study.

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