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Comparison of Two Separate Folding Methods Applied to Intraocular Lenses Used in Cataract Surgery in Terms of Mechanical Damage to the Lens and Causing Complications

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ABSTRACT
Objective: The aim of this study was to compare two different folding techniques recommended by companies and applied by scrub nurse to foldable intraocular lenses used in cataract surgery in terms of mechanical damage to the lens and the occurrence of lens-related intraocular surgical complications during surgery. **Materials and Methods:** The study was conducted as a non-randomized clinical trial with a control group. 150 patients who received surgical indication as a result of senile cataract were included in the study. The X-folding technique was applied to the first group (n=75), and the Y-folding technique was applied to the second group (n=75). Data were recorded on the data collection form at the end of each surgery. Chi-square test was used for statistical significance between two qualitative variables. Statistical significance was accepted as p <0.05. **Results:** While mechanical damage to the lens was less common in the patient group using the X technique, lens-related intraocular surgical complications were less common in the patient group using the Y technique. The differences between the two techniques were not found to be statistically significant (p>0.05). **Conclusion:** It can be said that the effects of both lens folding techniques on the mechanical damage of the lens and the formation of lens-related intraocular surgical complications during surgery are similar.
Keywords: Intraocular Lens, Implantation, Cataract, Surgery.

Katarakt Cerrahisinde Kullanılan Göz İçi Lenslerde Uygulanan İki Ayrı Katlama Yönteminin, Lensin Mekanik Hasara Uğraması ve Komplikasyon Oluşturması Açısından Karşılaştırılması

ÖZ
Amaç: Bu çalışmada, katarakt ameliyatlarında kullanılan katlanabilir göz içi lenslere, firmalarca önerilen ve scrup hemşirenin uyguladığı iki ayrı katlama tekniğinin; lenste mekanik hasar oluşumu ve ameliyat sırasında lense bağlı göz içi cerrahi komplikasyon oluşumu açısından karşılaştırılması amaçlanmıştır. **Yöntemler:** Bu çalışma randomize olmayan kontrol gruplu klinik bir çalışmadır. Senil katarakt sonucu cerrahi endikasyon alan 150 hasta çalışmaya alınmıştır. İlk gruba (n=75) X katlama tekniği, ikinci gruba (n=75) Y katlama tekniği uygulanmıştır. Her ameliyat sonunda veriler veri toplama formuna kaydedilmiştir. İki nitel değişken arasında istatiksel olarak anlamlılık için Ki-kare testi kullanılmıştır. İstatiksel anlamlılık p <0.05 kabul edilmiştir. **Bulgular:** Lensin mekanik hasara uğraması durumu X tekniği kullanılan hasta grubunda daha az tespit edilirken, ameliyat esnasında lense bağlı göz içi cerrahi komplikasyon oluşumu Y tekniği kullanılan hasta grubunda daha az tespit edilmiştir. İki teknik arasında oluşan farklar istatistiksel olarak anlamlı bulunmamıştır (p>0.05). **Sonuç:** Her iki lens katlama tekniğinin, lensin mekanik hasara uğraması ve ameliyat esnasında lense bağlı göz içi cerrahi komplikasyon oluşumu üzerine etkilerinin benzer olduğu söylenebilir.
Anahtar Kelimeler: Göz içi lens, İmplantasyon, Katarakt, Cerrahi.

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INTRODUCTION

Cataract, defined as the progressive loss of transparency of the eye lens, is known as the most common cause of vision loss and blindness in the world. According to World Health Organization (WHO) data, it is estimated that 15 million people worldwide are blind due to cataracts (WHO, 2022). Cataract surgery is one of the most frequently performed and oldest surgeries in the world (Davis, 2016; Lindstrom, 2015; Zhang, Ji, Tan, Yu, & Guan, 2023). Today, the most commonly used surgical method in cataract treatment is phacoemulsification (Tekin, Çıtırık, Üzel, & İlhan, 2016) The phacoemulsification method was first used by Dr. Charles Kelman in 1967. (Kelman, 1994). In this method, first the anterior lens capsule is opened in a round shape and the lens nucleus is emulsified and aspirated with the help of a high-frequency ultrasonic needle. After this stage, the cortex is cleaned using the aspiration method. Finally, viscoelastic material is injected into the remaining capsular bag and an artificial foldable intraocular lens (IOL) is placed through the surgical incision (Gözüm, 2012). One of the most important factors in the transition to the phacoemulsification method, especially after 1992, was the development of foldable IOLs with a quality higher than in 1984 (Leaming, 1999). IOL material gained foldable properties in the 1990s by using first silicone and then acrylic materials by folding them with forceps, and then in the 2000s, surgeries could be performed with minimal incisions by injecting and inserting IOLs with cartridge-injector systems (Oshika et al., 1998). Recent developments in IOL design have increased the expectations of patients and doctors from cataract surgery (Halkiadakis et al., 2023). While the IOL folding method was initially done manually with the help of a surgical instrument, the cartridge and injector system was developed over time. As a result of increased manipulation during the insertion stage of the IOL into the cartridge, the IOL may be damaged. This is especially true for hydrophilic acrylic IOLs, which have been reported to be damaged by up to 28% during intraocular implantation with the injector system (Myers & Olson, 1999). Looking at the history of injection systems, it is known that they have some problems as well as their benefits. Even if it is not traumatic, it causes unpredictable placement (Aslan & Gücükoğlu, 2005). Folding styles applied to the IOLs for cartridge implantation may cause mechanical damage to the IOL. An intraocular lens that is not placed correctly in the cartridge may suffer mechanical damage during advancement by pushing the injector mechanism (Singh, Fang, & Rath, 1999). However, as with other rigid conventional IOL, some complications may occur, which may require foldable IOL to be removed from the eye again (Singh, Fang, & Rath, 1999). Having a mechanically damaged IOL removed from the eye causes surgical stress for the surgeon and scrub nurse. At the same time, removing the IOL from the eye and replacing it with a second IOL also increases the costs.

The aim of this study was to compare two different folding techniques recommended by companies and applied by scrub nurse to foldable intraocular lenses used in cataract surgery in terms of mechanical damage to the lens and the occurrence of lens-related intraocular surgical complications during surgery. As a result of the study, it is thought that determining the superior one of two different folding methods and adopting only the superior method in lens folding will reduce the rate of developing lens-related complications in patients and accordingly, accelerate recovery and shorten the hospital stay. If it is determined with the study that both techniques carry similar risks without providing superiority to each other, it is thought that it will help reduce the surgical stress experienced by surgical nurses when deciding on the lens folding technique. The result of the study is expected to contribute to the literature with the information that there is or is not a difference in terms of complication formation between the two folding techniques recommended by the companies.

MATERIALS AND METHODS

Study type

The study was conducted as a non-randomized clinical trial with a control group. Patients who underwent a cataract surgery in a state hospital operating room between April 2021 and December 2021 were included in the study. In order to find a significant difference between the two different methods to be applied in the study, the minimum sample size was 144 (n= 72 for each group), type I error was 0.05, and the power of the test was 0.90 (α= 0.05, β = 0.10). The study included 150 patients, with 75 patients in group X and 75 patients in group Y. In the study using sequential technique, the x technique was applied to the first 75 patients who met the inclusion criteria among the patients admitted to the operating room, and the y technique was applied to the next 75 patients. The research was limited to patients who underwent a surgery in the state hospital where the study was conducted and the two different lens folding methods used. A data collection form was designed specifically for the study, and the form included demographic information such as age, gender, and quantitative data such as IOL diopter and axial length. Quantitative data and demographic characteristics based on the measurements taken by the patients during the preparation for the surgery were taken from the patient cards and recorded in the data collection form. Data obtained from the lens folding technique used were taken from the operative report written by the surgeon on the patient's chart after the case, as determined independently from the study.

Procedures

Two separate lens folding techniques suggested by the companies were named X and Y methods specifically for the study.

A sequential technique was used for the research, and the X-folding technique was applied to the first group of 75 patients and the Y-folding technique was applied to the second group of 75 patients. One-piece, hydrophilic acrylic structure, foldable lenses with an optical diameter of 6.00 mm were used in the study. The IOL was prepared under sterile conditions and was removed from its bottle filled with the appropriate liquid and checked macroscopically for mechanical integrity before being placed in the cartridge. It was folded according to the X or Y technique and placed in the injector system. After making sure that the IOL moved easily inside the cartridge by gently pressing the injector plunger, it was delivered to the surgeon for implantation. In all cases included in the study, the folding technique was determined and applied by the research nurse.

X technique: After sufficient viscoelastic material was placed in the lens cartridge, the intraocular lens was placed in an inverted S shape. The front haptic of the IOL was placed flat on the front of the cartridge, and the rear haptic was moved closer to the body of the optic. X technique is shown in Figure 1.

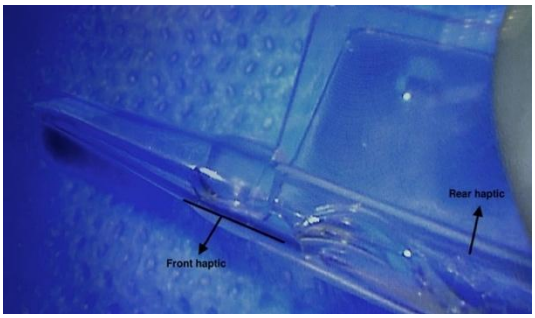

Figure 1. X technique

Y technique: After sufficient viscoelastic material was placed in the lens cartridge, the intraocular IOL was placed in an inverted S shape. Both the front haptic and rear haptic of the IOL are folded towards the optic. Y technique is shown in Figure 2.

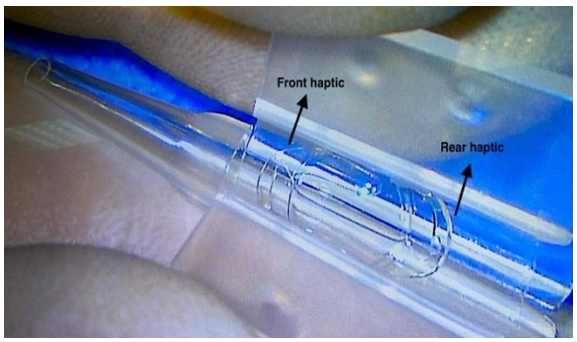

Figure 2. Y technique

Purposeful sampling selection technique was used in the study. To ensure that the only meaningful difference among the patients included in the study is the IOL folding technique, their other characteristics were planned to be within a similar range.

The exclusion and inclusion criteria of the study were established by consulting to experienced surgeons and determining appropriate parameters for the study. Especially since the IOL becomes thinner as the IOL diopter decreases and the IOL becomes thicker as the IOL diopter increases, the extra thin and the extra thick lenses were excluded from the study (EyeCyrl Plus, 2022).

Research inclusion criteria

- Being over 40 years old, under 80 years old.
- Axial length should be between 20-26 mm.
- Intraocular lens size between 14-26 diopters.
- The cataract that occurs in the patient is only age-related.
- No eye disease other than cataracts.
- No history of any eye-related surgery.
- The patient is literate.

Research exclusion criteria

- Being under the age of 40, over the age of 80.
- Axial length is not between 20-26 mm.
- Intraocular lens size is not between 14-26 diopters.
- The cataract that occurs in the patient is not only age-related.
- Having an eye disease other than cataracts.
- Having eye surgery before.
- The patient is illiterate.
- Patient's wish to withdraw from the study.

Statistical analysis

The data collected in the study was analyzed by creating a database in IBM SPSS 24.0 program. Chi-square test and independent groups t-test were used in statistical analysis. Statistical significance was accepted as $p<0.05$.

Ethical approval

Ethics Committee approval numbered 2021/80 and written consent from patients were obtained from Haydarpaşa Numune Training and Research Hospital Clinical Research Ethics Committee for this research. Verbal and written consent was obtained from each participant before the study, and they were asked to fill in the informed consent form, and only the participants who gave consent were included in the study. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

RESULTS

In this study, the effect of two different IOL folding methods on jam formation in the lens-injector system, mechanical damage to the IOL, use of a second IOL, and lens-related complications were investigated. A total of 62 female patients (38 in group X and 24 in group Y) and 88 male patients (37 in group X and 51 in group Y) were included in the study. There were no significant differences between the two groups for the variables specified in the inclusion criteria: age/ axial length/ IOL size ($p>0.05$). It was assumed that the gender variable indicating demographic characteristics would not affect the study results. The preoperative characteristics and test values of the groups are shown in Table 1.

Jam occurred in the lens-injector system used in a total of 44 patients, 18 of 75 patients (24%) using the X technique and 26 of 75 patients (34.6%) using the Y technique.

When the jamming results in the lens-injector system were examined according to the applied technique, it was seen that there was no statistically significant difference between the two techniques (X^2=2.058, p>0.05). The distribution of these data and the chi-square analysis results are shown in Table 2.

Table 1. Preoperative characteristics and test values of patients who underwent X and Y techniques.

		X		Y		
		n	%	n	%	p[a]
Gender	Male	37	49.3	51	68.0	X^2=5.389 p=0.015
	Female	38	50.7	24	32.0	
		Mean	sd	Mean	sd	p[b]
Age		68.910	8.197	67.230	8.359	0.216
Axial Length		23.564	1.356	23.834	1.089	0.180
IOL Size		20.453	3.496	19.757	2.633	0.171

[a] Chi-square Test-Fisher Exact; [b] Independent Groups T-Test χ^2: Chi-square Test sd: Standard deviation.

Table 2. Comparison of the number of jams occurring in the lens-injector system.

Groups		Techniques		X^2	df	p
		X	Y			
Lens-injector system jam	Yes	18 (%24)	26 (%34.7)	2.058	1	0.151
	No	57 (%76)	49 (%65.3)			
	Total	75	75			

χ^2: Chi-square Test df: degrees of freedom.

While the IOL was not damaged as a result of jamming in 34 (77.2%) of the 44 cases where jamming occurred in the lens-injector system, mechanical damage to the IOL occurred as a result of jamming in 10 (22.7%) of them. Of the 10 patients with mechanical damage to the IOL, the lens was used with the X technique in 3 (30%) and with the Y technique in 7 (70%).

When the results of mechanical damage to the IOL were examined according to the technique used, it was seen that there was no statistically significant difference between the two techniques (X^2=1.714, p>0.05). The distribution and analysis results of these data are shown in Table 3.

Table 3. Comparison of the number of mechanical damages to the IOL.

Groups		Techniques		X^2	df	p
		X	Y			
Mechanical damage to the IOL	Yes	3 (%4)	7 (%9.3)	1.714	1	0.190
	No	72 (%96)	68 (%90.7)			
	Total	75	75			

χ^2: Chi-square Test df: degrees of freedom.

A second IOL using occurred in a total of 10 patients within the study, due to mechanical damage to the IOL. In 3 of 10 patients (30%) who underwent second IOL placement, the IOL was folded using the X technique, and in 7 (70%) patients it was folded using the Y technique.

When the number of times a second IOL was used as a result of the applied technique was examined, it was seen that there was no statistically significant difference between the two techniques (X^2=1.714, p>0.05). The distribution and analysis results of these data are shown in Table 4.

Table 4. Comparison of the number of times a second IOL was used.

Groups		Techniques		X^2	df	p
		X	Y			
Using a Second IOL	Yes	3 (%4)	7 (%9.3)	1.714	1	0.190
	No	72 (%96)	68 (%90.7)			
	Total	75	75			

χ^2: Chi-square Test df: degrees of freedom.

Lens-related complications occurred in a total of 3 cases, 2 in patients using the X technique and 1 in the patients using the Y technique. As a result of chi-square analysis performed with complication data based on the technique used, the minimum expected count was found to be 1.49.

For this reason, the interpretation was based on Fisher's exact test value and there was no significant difference between the techniques (Fisher's=1.000, p>0.05). The distribution and analysis results of these data are shown in Table 5.

Table 5. Comparison of the number of complications resulting from the X and Y techniques.

Groups		Techniques		X^2	df	p
		X	Y			
Complication as a result of X and Y technique	Yes	2 (%2.7)	1 (%1.3)	0.327	1	1.00
	No	73 (%97.3)	74 (%98.7)			
	Total	75	75			

χ^2: Chi-square Test df: degrees of freedom

In the study, the complications that developed separately in the 2 patients in whom the X technique was used as the IOL folding technique were posterior capsule perforation and iris trauma. The complication that occurred in 1 patient in whom the Y technique was used as the IOL folding technique was Descemet's detachment.

DISCUSSION

Today, the most commonly used surgical method in cataract treatment is phacoemulsification. In this method, the lens of the eye that has lost its transparency is emulsified and aspirated with an ultrasonic hand device, and an artificial intraocular lens is placed in its place (Singh, Fang, & Rath, 1999). In this study, the rates of jamming in the lens-injector system, mechanical damage to the IOL, and lens-related complications of one-piece foldable intraocular lenses used in cataract surgeries as a result of two separate folding techniques applied and recommended by the scrub nurse were investigated. The two main methods of implanting a foldable lens are insertion by folding with folding forceps or insertion with a cartridge-injector system.

Folding the IOL with forceps can cause surface abnormalities, stress fractures, and fine tear lines in the IOL (Singh, Fang, & Rath, 1999). At the same time, the folding technique with forceps poses a risk of bacterial contamination. Injecting the lenses with a cartridge rather than folding them with forceps prevents the risk of bacterial contamination by preventing the IOL from coming into contact with the wound (Shimizu, Kobayashi, Takayama, & Zhaobin, 2008). In injection systems, complications such as IOL jamming and not being delivered, IOL damage or cartridge damage may occur (Singh, Fang, & Rath, 1999). One reason why injection systems cause such complications is the unpredictable insertion process that results from manual folding of IOLs. According to Shimizu's data, the rate of IOL damage observed after application was 0.14% in IOLs implanted using the ready-made injector system in which the IOL was placed by the company, while the damage after application with the manual cartridge-injector system was found to be 2.99%. It was suggested that the reason why IOLs pre-placed in the injector system were preferred was that they shortened the surgical time, but it was determined that it shortened the time compared to surgeries using the manual cartridge-injector system, which did not show statistical significance (Shimizu, Kobayashi, Takayama, & Zhaobin, 2008). The cause of IOL damage may be

various. Studies have shown that this can be due to poor packaging (Nguyen, Saleh, Pandey, & Bates, 2006), handling with forceps (Milazzo, Turut, & Blin, 1996), improper loading (Hesse, Freissler, & Lang, 2001), overloaded injector pistons (Singh, Fang, & Rath, 1999), friction during passage through the injector nozzle (Myers & Olson, 1999), quality and shape of the injector tip (Kleinmann, Marcovich, Apple, & Mamalis, 2005; Stefaniu et al., 2003). Before this study, when the issue of IOL damage was discussed with the manufacturer, it was argued by the manufacturer that the most likely cause was a poor loading technique, which caused the haptics to get stuck when closing the loading chamber, resulting in the haptics breaking during the injection attempt, as a result of the intraocular IOL not being fully placed in the cartridge groove. This possibility was eliminated by the fact that all IOLs used in the study were folded and prepared for implantation only by an experienced research nurse. IOL damage may occur due to the folding person or folding technique, or due to a manufacturing error in the IOL or cartridge-injector system. Even in highly accepted products from companies with excellent quality control systems, defects can develop as a result of changes in the manufacturing process or packaging process. Therefore, the IOL should always be examined under an operating microscope before preparing for implantation (Milazzo, Turut, & Blin, 1996). There have been a few reports of damage to certain IOLs when using injector systems, possibly during implantation. Reported damages include scratches, stress fractures, cracks, and tear lines (Kleinmann & Apple, 2007). In this study, folding techniques were used when placing the lens into the injector system. They were compared in terms of jamming in the lens-injector system, mechanical damage to the IOL, using a second IOL when necessary, and complications during the operation. The effect of the X and Y methods used in IOL folding on the formation of jamming in the lens-injector system was found to be 24% in the X technique and 34.6% in the Y technique. Although the jamming rate is higher in the Y technique, this rate does not present a statistically significant difference between the techniques. If excessive resistance is detected to the forward movement of the IOL when it is injected into the eye from the injector system, other maneuvers should be stopped and the IOL should be re-inserted into a new cartridge after being examined under the microscope for damage. When damage to the IOL is detected due to jamming in the injector system, a second IOL is used instead of the damaged IOL, and the case is continued. Under these circumstances, it can be said that there is an increase in surgical time and cost in cases where the Y technique is used. A second IOL was used as a result of mechanical damage to the IOL occurred in 3 cases in the X technique and in 7 cases in the Y technique. In cases where damage to the IOL is detected after the IOL is inserted into the eye, the damaged IOL in the anterior chamber must first be cut with the help of micro scissors and removed from the eye in order to place a new IOL. The possibility of other complications increases depending on the maneuvers performed during such procedures and the positions taken by the IOL as a result of these maneuvers. When the IOL is removed from the incision site, complications such as wound enlargement, iris or descemet membrane damage, and associated anterior chamber hemorrhage may occur, which may require suturing when the case is finalized. At the same time, it is known that each new intervention in the surgical field increases the risk of infection, along with the increase in cost in each case where a new IOL is replaced with a damaged IOL. It has been stated that the IOL requires significant manipulation after being removed from the sterile packaging and before being placed in the eye, and such manipulations may increase the risk of bacterial contamination (Bainbridge et al., 1998). Considering that cataract surgeries are routinely performed under local anesthesia; it can be said that all these situations prolong the surgical time and increase both the operation-related stress on the patient and the surgical stress experienced by the surgeon and the scrub nurse. During the implantation stage, when the lens exits the cartridge and unfolds in the anterior chamber, complications related to the folding technique were compared. In one patient using the X technique, posterior capsule perforation occurred due to the anteriorly positioned lens haptic pressing against the capsule, while another patient experienced iris trauma caused by the haptic passing through the iris. In contrast, in one patient using the Y technique, Descemet's membrane detachment occurred due to the lens.

In IOLs folded with the X technique; by not folding the front haptic towards the optical part and releasing it to the front of the cartridge, the passage of the IOL through the lumen in the cartridge becomes easier and it can be said that less jamming occurs in the lens-injector system. While in the Y technique, the IOL becomes thicker as a result of folding both the front and rear haptics onto the optic. Due to this situation, it can be said that as it becomes more difficult for the IOL to pass through the lumen, more jamming occurs in the lens-injector system, and as the jamming rate increases, the possibility of mechanical damage to the IOL and the possibility of a second IOL using as a result of mechanical damage increases. In a similar study, it was proven that cracks may form on the cartridge after the IOL passes through the lumen, depending on the density of the viscoelastic agents used during IOL loading into the cartridge-injector system (Singh, Fang, & Rath, 1999).

CONCLUSION

The results obtained from the research are summarized below:

- Jamming in the lens-injector system and mechanical damage to the IOL were detected less in the patient group using the X technique than in the patient group using the Y technique.
- A second IOL using occurred less frequently in the patient group using the X technique than in the patient group using the Y technique.
- Lens-related complications were detected less in the patient group using the Y technique than in the patient group using the X technique.

Within these results, the differences between the two groups in terms of jamming in the lens-injector system, mechanical damage to the IOL, and lens-related complications were not found to be statistically significant. In conclusion, our study revealed that there was no significant difference between X and Y IOL folding techniques.

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Conflict of Interest
All the authors of this article declare that they have no conflicts of interest.

Author Contributions
Plan, design: AD; **Material, methods and data collection:** AD; **Data analysis and comments:** AD, SY; **Writing and corrections:** AD, SY.

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Ethical Approval
Institution: Haydarpasa Numune Training and Research Hospital Clinical Research Ethics Committee
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