Original Article

Comparative evaluation of an automated preloaded delivery system with a non-preloaded system

Rajesh S Joshi

Purpose: To evaluate a single surgeon's experience with an automated preloaded intraocular lens (IOL) delivery system and a nonpreloaded system. **Methods:** This was a prospective, observational case series. Phacoemulsification was performed under topical anesthesia by creating a temporal clear corneal incision. Patients were consecutively assigned to either the Clareon group (n = 50; the IOL was injected into the capsular bag by using an automated injector system) or the AcrySof group (n = 50; the IOL was injected into the capsular bag by using a conventional injector system). The main outcome measures were ease of implantation, intraoperative complications, postoperative centration, and visual acuity. **Results:** Additional manipulation in the anterior chamber was not required in 38 (74%) eyes in the Clareon group and 41 (82%) eyes in the AcrySof group. However, seven eyes in the Clareon group and one eye in the AcrySof group required trailing haptic dislodgement from the optic. Furthermore, two eyes in the Clareon group and five eyes in the AcrySof group required injector rotation (varying from 10° to 90°) in the wound. Moreover, in two eyes of the Clareon group, the silicon plunger of the injector system crossed over the optic. None of the patients developed iris trauma and PCR during IOL manipulation. All the IOLs were centered in the capsular bag. **Conclusion:** The automated IOL delivery system enables the controlled delivery of an IOL in the capsular bag. The effect of carbon footprints created by plastic generated from the delivery system and the implications of the CO_2 cylinder on the environment should be addressed.

Key words: Automated intraocular IOL delivery system, intraocular lens, phacoemulsification, preloaded intraocular IOL delivery system, semipreloaded IOL delivery system

Videos available on: www.ijo.in

Access this article online

Website: www.ijo.in

DOI: 10.4103/ijo.IJO_1635_22

Quick Response Code:

A foldable intraocular lens (IOL) can be implanted through a small incision by using modern phacoemulsification techniques. Foldable IOLs are recognized worldwide for their advantages, including a decrease in the use of forceps unlike in handling polymethylmethacrylate rigid IOLs, the risk of surgically induced astigmatism, and the entry of bacteria into the eye due to the lack of contact between the IOL and operative field. With advancements in phacoemulsification technology, the lens material and delivery system of IOLs have improved. Various injector systems are used to introduce IOLs, including the manual folding of the IOL by using forceps or unfolder cartridges mounted on either a reusable metallic or disposable injector. These injector systems involve the use of forceps for handling the IOL. Metallic injectors require maintenance (i.e., cleaning and autoclaving) before each use. Problems related to the use of these injector systems include forceps-induced scratch marks on IOL optics,[1] irregularities on the surface of the optics due to IOL compression during packaging,[2] stretch marks on the posterior surface of the IOL during injection,[3] cartridge shaft deformities leading to IOL protrusion through the cartridge shaft,[4] and optic reversal caused by human error in the holding and folding of the IOL.[1,5] To solve these problems, preloaded IOLs have been developed, and their benefits include decreased surgical time and uniformity in IOL loading.[6] However, the process of IOL injection in the capsular bag is the most crucial and involves exerting force to inject the IOL. The amount of force required to be applied depends on the IOL material, ophthalmic viscoelastic device, wound size, and IOL thickness. Cabeza *et al*.[7] examined the force exerted during IOL delivery through a syringe-type injection. They indicated that hydrophilic IOLs exhibit the lowest resistance force, hydrated C-loop hydrophobic IOLs present a higher force, and hydrophobic IOLs in a dry state produce the highest force.

A novel preloaded automated injector system has been developed for IOL introduction (Clareon CNA0T0; Alcon Laboratories, Inc., Fort Worth, TX, USA). This system involves CO_2-driven delivery. The IOL design is similar to that of AcrySof IOL (Alcon Laboratories, Inc., Fort Worth, TX, USA). However, a hydrophilic copolymer, 2-hydroxyethyl-methacrylate, is introduced instead of phenylethylmethacrylate. Therefore, the water content of Clareon IOLs is higher than that of AcrySof IOLs (1.5% vs. 0.4% at 35°C).

Clareon IOLs have been reported to have favorable optical characteristics, cause few glistening and chromatic aberrations, and result in excellent visual and refractive outcomes.[8-10]

Department of Ophthalmology, Government Medical College, Nagpur, Maharashtra, India

Correspondence to: Dr. Rajesh S Joshi, 77, Panchatara Housing Society, Manish Nagar, Somalwada, Nagpur - 440 015, Maharashtra, India. E-mail: jrajesh5@rediffmail.com

Received: 06-Jul-2022 Revision: 02-Aug-2022
Accepted: 16-Aug-2022 Published: 30-Nov-2022

Cite this article as: Joshi RS. Comparative evaluation of an automated preloaded delivery system with a non-preloaded system. Indian J Ophthalmol 2022;70:4307-11.

We believe that the use of an injector system requires some learning curve. The force with which an IOL must be pushed into the capsular bag can be accurately determined with experience. Complications such as the precipitate delivery of the IOL in the posterior chamber, reversal of optics, iris trauma, and posterior capsular rent may occur if the IOL is not injected properly.

The advantages of a preloaded IOL system have increased its use for IOL implantation after phacoemulsification. However, no study has explored the use of an automatic IOL delivery system (AutonoM) for IOL implantation in the Indian population. Clinical experience can help in evaluating a newly launched device. Therefore, the present study investigated the delivery characteristics and safety features of a newly launched automatic preloaded IOL system and compared them with those of the currently available injector system for the delivery of AcrySof IOLs (SN60WF) after cataract phacoemulsification.

Methods

Sample size

The sample size was calculated to detect a difference of 5% in the manipulation of IOL in the anterior chamber between two groups with an α level of 0.05 and power of 90% turned out to be 41. Considering 20% dropout, the sample size was approximately 47 in each group which was rounded up to 50 in each group.

This prospective observational study was performed in a tertiary eye care center in central India from March 2022 to May 2022. The study included patients who were operated on by using the phacoemulsification technique with IOL implantation performed using the automatic IOL delivery system (AutonoM) or routine injector system available for AcrySof IOL implantation (SN60WF). This study was approved by the ethical committee of the hospital.

Each patient provided written informed consent prior to participation in the study. The study adhered to the tenets of the Declaration of Helsinki. Patients with complicated, traumatic, or subluxated cataracts and vitrectomized eyes were excluded to ensure sample uniformity between the two groups.

A total of 100 patients (100 eyes) who underwent IOL implantation were included in the study. The patients were randomly allocated to receive IOL implantation by using either the automated injector system (Clareon group, n = 50) or a conventional injector system (AcrySof group, n = 50). A randomization schedule was generated using an online tool. In total, 100 eyes were randomized into two groups by using software available on the website (https://www.randomizer.org). The routine preoperative examination included visual acuity, slit-lamp biomicroscopy, and nucleus grading based on the Lens Opacities Classification System III, applanation tonometry for intraocular pressure, and IOL power calculation by using an optical biometer (Lens star LS900).

Preoperative mydriasis was achieved using phenylephrine (5%) and tropicamide (0.8%) eye drops. A single experienced surgeon operated on the patients. The patients were instilled with topical anesthetic drops (0.5% proparacaine hydrochloride) thrice at an interval of 5 min. A side port incision was created. A viscoelastic material (2% hydroxypropyl methylcellulose, Appavisc, Appasamy Ocular Devices, Puducherry, India) was injected to facilitate the creation of a 2.8-mm clear corneal temporal incision. Capsulorhexis was performed using Utrata forceps. Hydrodissection was performed, and the nucleus was freed through dialing. A standard quick chop was applied for endocapsular phacoemulsification (Oertli Swiss Tech, Switzerland). Cortical aspiration was completed using an irrigation/aspiration probe. The anterior chamber was filled with viscoelastic material.

IOL implantation in the Clareon group (AutonoMe)

An ocular viscoelastic device (OVD) was injected into the cartridge all the way to the nozzle tip. The lockout assembly was removed from the injector, and the speed controller was pressed. Upon activation of the CO_2 mechanism, a click was heard. Subsequently, the speed controller was continually pressed. We ensured the folding of leading and trailing haptics over each other, ensuring the readiness of the device for injection. The eye was stabilized using a second instrument, and the speed controller was slowly pressed to inject the IOL into the capsular bag [Video 1].

IOL implantation in the AcrySof group (SN60WF)

The cartridge was filled with an OVD, and the IOL was placed in the C cartridge. The cartridge was loaded into the injector system. The system was ready for IOL injection. With the help of a second instrument, the globe was stabilized, and the IOL was injected into the capsular bag. IOL delivery was achieved with further advancement of the leading haptic into the capsular bag. Subsequently, the trailing haptic was dialed into the bag by using a second manipulating instrument to achieve a well-centered IOL position [Video 2].

In both the groups, the incision size was measured before and after IOL implantation, and the surgeon determined the loading characteristics of the IOL. The characteristics of IOL implantation were further verified through video recordings of each case.

The patients were postoperatively followed up after 1 day, 1 week, 1 month, and 6 months.

Results

A total of 100 eyes of 100 patients were included in the study. The mean age of the participants at the time of surgery was 68.42 (± 12.05) years (range: 55–76 years). Among the total participants, 60 (60%) were women and 40 (40%) were men. The Clareon IOL was implanted in the right eye of 33 (60%) patients and in the left eye of 17 (34%) patients. The AcrySof SN60WF was implanted in the right eye of 30 (60%) patients and in the left eye of 20 (40%) patients.

The powers of the IOL in the Clareon group ranged from 6 to 28 D. In total, 38 (74%) patients did not require additional manipulation in the anterior chamber to place the IOL in the capsular bag. Among the remaining 12 patients, seven required trailing haptic dislodgement from the optic [Videos 3 and 4]. Two patients required injector rotation (varying from 10° to 90°) in the wound to place the leading haptic in the capsular bag. One patient required a partial anteroposterior rotation of the IOL [Video 5]. In two patients, the silicon plunger of the injector system crossed over the optic, causing difficulty in delivering the IOL into the capsular bag [Figs. 1 and 2]. In these

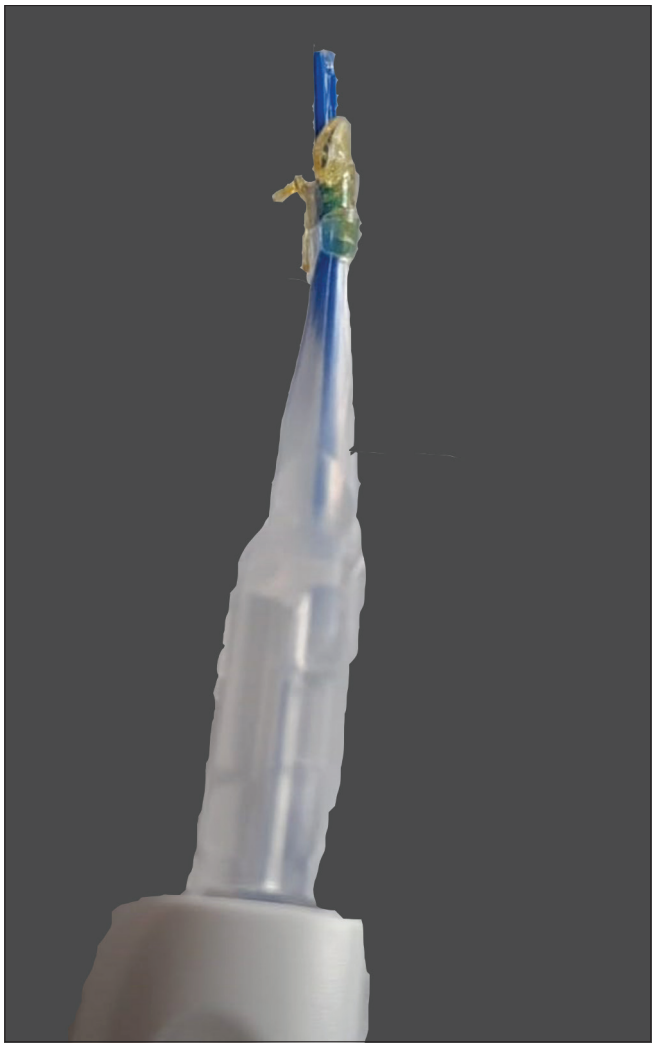

Figure 1: The silicon plunger of the injector system crossed over the optic, causing difficulty in the delivery of the IOL into the capsular bag

patients, the Clareon IOL with the same power was injected into the capsular bag. In one patient, the surgeon suspected improper folding of the leading haptic over the optic IOL. In this particular case, the implantation length was increased.

The IOL power of the AcrySof group ranged from 8 to 30 D. In the AcrySof group, 41 (82%) patients did not require additional manipulation in the anterior chamber to place the IOL in the capsular bag. One patient required trailing haptic dislodgement from the optic. Five patients required injector rotation (varying from 10° to 90°) in the wound to place the leading haptic in the capsular bag. Two patients required the anteroposterior rotation of the IOL. In one patient, the IOL experience a total posterior rotation, in which the anterior surface of the IOL was facing the posterior capsule. The IOL position was corrected in this patient.

In both the groups, after loading the IOL in the cartridge, the lens optic along with its folded haptics was noted.

None of the patients experienced iris trauma, posterior capsular rupture during IOL implantation and manipulation, or stretch marks on the IOL optics. All the IOLs were finally centered in the capsular bag.

Figure 2: The silicon plunger crossed over the optic and came out through the mouth of the cartridge

The mean incision size after the completion of phacoemulsification and IOL implantation was 2.81 (± 0.02) mm in the Clareon group and 2.83 (± 0.03) mm in the AcrySof group, which achieved sutureless closure.

During the postoperative period, all the patients had a stable IOL in the capsular bag and none exhibited posterior capsular opacification and glistening at 6-month follow-up. In total, 94 (94%) patients achieved the best-corrected visual acuity of 20/20 at 6-month follow-up. Four of the remaining six patients had a visual acuity of 20/80 and age-related macular degeneration, and two patients (20/60) had partial optic atrophy. None of the patients developed postoperative infection.

Discussion

The IOL technology and implantation system are being continually improved. A reduction in the incision size leads to improvement in IOL implantation. The development of a preloaded IOL delivery system has improved the safety of IOL insertion through a clear corneal incision. The use of this system prevents human error in IOL delivery. In their *in vivo* study, Shimizu *et al*.[6] demonstrated promising results of a preloaded IOL injection system without the use of OVDs.

AutonoMe is the first completely preloaded IOL with a CO_2-based injector system. To our knowledge, this is the first study to comprehensively compare a newly developed automatic IOL delivery system with a currently used conventional device for IOL implantation after phacoemulsification. The present study compared the safety and efficacy of these two systems for IOL implantation.

Based on our experience, 41 (82%) eyes that were operated upon by using the novel preloaded IOL injection system did not require additional manipulation in the anterior chamber to place the IOL in the capsular bag. Bedar *et al*.[11] implanted the Clareon IOL in 391 eyes and observed that IOL implantation occurred in only one patient. In this particular case, the trailing haptic was not loaded correctly, leading to the fracture of the haptic, which required IOL explantation. This mishap was caused by not following guidelines for IOL implantation. Acar *et al*.[12] reported that the Eyeceryl-sert preloaded system showed excellent ease of handling and injection of the IOL in the capsular bag. In their series on a single surgeon's experience of 200 cases of preloaded IOL implantation, Joshi *et al*.[4] reported that 94% of the IOLs could be implanted in the capsular bag in the first attempt. Ong *et al*.[13] used the AcrySert injection system for IOL delivery and reported that 45% of the eyes had correct delivery of the IOL in the capsular bag. Our results appear to be better than those of Ong *et al*. This proves the safety of the newly introduced preloaded injector system for IOL implantation.

We followed the manufacturers' instructions for the preparation and implantation of the Clareon IOL. During the delivery of the leading haptic inside the capsular bag, the following characteristics were noted in the Clareon group: the anteroposterior rotation of the IOL wherein the IOL edge was facing anteriorly (n = 1), the rotation of the injector at the incision site varying from 10° to 90° (n = 2), an increased length of implantation due to the inappropriate loading of the IOL (n = 1), and IOL trapping in the injector system (n = 2). Furthermore, the plunger crossed over the IOL, causing difficulty in retrieving the IOL in these two cases. Another IOL (Clareon) of the same power was implanted. Joshi *et al*.[4] reported similar observations in their study on preloaded IOL systems.

In the AcrySof group in this study, 82% (41/50) of the patients did not require additional manipulation to place the IOL in the capsular bag. This could be attributed to the initial learning curve required to master IOL injection in the Clareon group. However, varying degrees of rotation of the injector (10°–90°) were required (n = 5). The high rotation rate of the injector in the AcrySof group could be ascribed to the varying position of IOL placement in the cartridge. Uncontrolled or precipitate delivery of the IOL injection or inappropriate loading of the IOL can cause the anteroposterior rotation of the IOL or the reversal of the optic where the anterior surface of the IOL faces the posterior capsule. Two patients had anteroposterior rotation, and one patient had a total posterior rotation of the IOL. The IOL position was corrected by introducing dialers through the side port and main incision. None of the patients developed iris trauma or posterior capsular rupture during implantation or required IOL manipulation.

The attachment of the trailing haptic to the optic (n = 7) was a common observation in the Clareon group. This finding is in contrast to the AcrySof group, where one patient had such adhesion. In their experience of the Clareon injector system with a series of cases, Bedar et al. did not observe such adhesion.[11] However, Ong *et al*.[13] noted one case of haptic adhesion among the patients who were operated on using the AcrySert injector system. We did not observe a high adhesion rate in the Clareon group. The low adhesion rate in the AcrySof group could be due to the usual practice of rinsing the IOL with a balanced salt solution and laying over the OVD on the top of the IOL optic before being folded in the cartridge. The adhesion of the haptic to the optic did not affect IOL placement in the bag. However, it required IOL manipulation inside the anterior chamber after unfolding.

None of the patients in the Clareon group experience optic reversal. One patient in the AcrySof group developed optic reversal. Such reversal may occur due to the inappropriate loading of the IOL in the cartridge and the uncontrolled delivery of the IOL inside the anterior chamber. The reversal did not affect the postoperative visual outcome in the particular case.

Studies have reported haptic entrapment within the cartridge during implantation.[4,14-18] In our study, none of the eyes in the AcrySof group had entrapped haptic. However, the Clareon group had two eyes that developed trailing haptic entrapment in which the pusher overpassed the haptic. No such incident has been reported in the literature. In a preloaded system, the removal of the entrapped IOL is difficult. The exact reason for this entrapment could not be elucidated. Joshi *et al*.[4] explained the mechanism underlying the entrapment of trailing haptic in their study on a preloaded IOL system. They indicated that the loose proximal end of the plunger may overpass the stiff trailing optic haptic junction.

In the Clareon group, the length of IOL implantation was increased (n = 1). In this group, the leading haptic did not fold over the optic. The surgeon has to additionally manipulate the injector at the wound site to place the leading haptic inside the capsular bag. The reloading of the IOL in the same preloaded injector system was not possible because the system was intended for single use. The passage of the IOL during implantation does provide a clue regarding IOL delivery in the capsular bag. In both the groups, the passage of IOL was visible through the cartridge during IOL implantation.

The powers of IOLs inserted in the Clareon and AcrySof groups were 6–28 D and 8–30 D, respectively. The thickness of the IOLs increase with their power. Because the cartridge size is identical, the hypermetropic power of the IOL poses a problem during implantation. A study reported the presence of postoperative stretch lines on the optic.[4] However, none of the patients with hypermetropic power in either of the groups had stretch marks on the optic.

The contact of the IOL with surgical instruments increases the risk of bacterial contamination. Studies have reported delayed-onset postoperative infection after the implantation of preloaded IOL.[17,18] A preloaded IOL system eliminates contact with surgical instruments, reducing the risk of postoperative infection. None of the patients in either of the groups developed postoperative infection in the 6-month follow-up period. However, a strict sterilization protocol and the use of intracameral antibiotics can help prevent bacterial contamination.

An ideal IOL injector system should have minimal or no rotation during implantation to prevent damage to the architecture of the corneal wound. Negishi *et al*.[19] reported that wound repair after the implantation of the Clareon IOL required 1 month. However, no significant difference was observed in the postoperative visual acuity. The cartridge used for Clareon IOL implantation is compatible with a 2.4-mm

clear corneal incision. The recommended size of the incision is 2.2 mm. Wound construction requires suturing at the incision site. None of the patients in both the groups required sutures at the incision site. The incision size remained unchanged after the implantation of IOL.

Concerns exist regarding the preloaded system generating numerous plastic wastes, which might be harmful to the environment. A nonpreloaded system generates only the cartridge and lens case as waste. The effect of the discarded CO_2 cylinder on the environment remains unknown.

A limitation of this study is the involvement of only a single surgeon; this did not allow the comparison of IOL implantation techniques among different surgeons. Furthermore, this study did not examine other available preloaded systems available in the market.

The compatibility of the newly introduced automatic injected system with IOL injection performed without an OVD should be examined.

Conclusion

The newly developed automated IOL delivery system enables the controlled delivery of the IOL in the capsular bag. The system does not have added advantages over the available nonpreloaded system for IOL delivery. The effect of carbon footprints created by plastic generated from the delivery system will be apparent in the coming years.

Acknowledgments

We would like to thank Dr. Avinash Turankar, Associate professor, Department of Pharmacology, Government Medical College, Nagpur, Maharashtra, and Dr. Rohit Khanna, Consultant Ophthalmologist, LV Prasad Eye Institute, Hyderabad, India for the statistical assistance.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Vrabec MP, Syverud JC, Burgess CJ. Forceps-induced scratch- ing of a foldable acrylic intraocular lens. Arch Ophthalmol 1996;114:777.
2. Nguyen DQ, Saleh TA, Pandey SK, Bates AK. Irreg- ularities on the surface of single-piece AcrySof SA60AT intraocular lenses. J Cataract Refract Surg 2006;32:495-8.
3. Faschinger CW. Surface abnormalities on hydrophilic acrylic intraocular lenses implanted by an injector. J Cataract Refract Surg 2001;27:845-9.
4. Joshi RS. Descemet's tear due to injector cartridge tip deformity: Cartridge shaft deformity. Indian J Ophthalmol 2013;61:82-3.
5. Rao SK, Leung AT, Lam DS, Padmanabhan P. *In situ* tumbling of the AcrySof intraocular lens. J Cataract Refract Surg 2000;26:177-9.
6. Shimizu K, Kobayashi K, Takayama S, Zhaobin G. Preloaded injector for intraocular lens implantation without the use of ophthalmic viscosurgical devices. J Cataract Refract Surg 2008;34:1157-60.
7. Cabeza-Gil I, Ríos-Ruiz I, Calvo B. Experimental evaluation of the injection force exerted in intraocular lens delivery with syringe-type injectors. J Mech Behav Biomed Mater 2021;124:104793. doi: 10.1016/j.jmbbm.2021.104793.
8. Maxwell A, Suryakumar R. Long-term effectiveness and safety of a three-piece acrylic hydrophobic intraocular lens modified with hydroxyethyl-methacrylate: An open-label, 3-year follow-up study. ClinOphthalmol 2018;12:2031-7.
9. De Giacinto C, Porrelli D, Turco G, Pastore MR, D'Aloisio R, Tognetto D. Surface properties of commer- cially available hydrophobic acrylic intraocular lenses: Comparative study. J Cataract Refract Surg 2019;45:1330-4.
10. Hillenmayer A, Wertheimer CM, Kassumeh S, von Studnitz A, Luft N, Ohlmann A, *et al*. Evaluation of posterior capsule opacification of the Alcon Clareon IOL vs the Alcon Acrysof IOL using a human capsu- lar bag model. BMC Ophthalmol 2020;20:77.
11. Bedar MS, Kellner U. Klinische Erfahrung mit der Clareon®-IOL und dem AutonoMe®-Implantationssystem. Der Ophthalmologe 2020;117:1100-4.
12. Acar B, Torun IM, Acar S. Evaluation of preloaded IOL delivery system and hydrophobic acrylic intraocular lens in cataract surgery. Open Ophthalmol J 2018;12:94-103.
13. Ong HS, Subash M, Sandhu A, Wilkins MR. Intraocular lens delivery characteristics of the preloaded AcrySof IQ SN60WS/ AcrySert injectable lens system. Am J Ophthalmol 2013;156:77-81.
14. Ng DT, Francis IC, Schumacher RS, Alexander SL. Prospective study of 1 surgeon's experience with 115 cases using the Unfolder lens injection system. J Cataract Refract Surg 2001;27:1437-9.
15. Hagan JC 3rd. Initial experience with the MONARCH IOL delivery system for insertion of the 5.5 mm. ACRYSOF intraocular lens. Mo Med 1999;96:561-2.
16. Moreno-Montañés J, Maldonado MJ, García-Layana A, Aliseda D, Munuera JM. Final clear corneal incision size for AcrySof intraocular lenses. J Cataract Refract Surg 1999;25:959-63.
17. Hayashi Y, Eguchi H, Miyamoto T, Inoue M, Mitamura Y. A Case of delayed-onset propionibacterium acnes endophthalmitis after cataract surgery with implantation of a preloaded intraocular lens. Case Rep Ophthalmol 2012;3:291-7.
18. Kokuzawa S, Suemori S, Mochizuki K, Hirose Y, Yaguchi T. Aspergillus tubingenesis endophthalmitis after cataract surgery with implantation of preloaded intraocular lens. Semin Ophthalmol 2014;29:218-21.
19. Negishi K, Masui S, Torii H, Nishi Y, Tsubota K. Refractive stability of a new single-piece hydrophobic acrylic intraocular lens and corneal wound repair after implantation using a new automated intraocular lens delivery system. PLoS One 2020;15:e0238366.