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Comparitive Study of Various Preloaded IOL Delivery Systems Currently Available

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Statements :

1. The authors certify that there are no financial interests.
2. The authors certify that the manuscript has been read and approved by them, the requirements for authorship have been met, and each author believes that the manuscript represents honest work.
3. The authors certify that they have obtained all appropriate patient consent forms. In the form the patient has given her consent for her images and other clinical information to be reported in the journal. The patient understands that her name and initials will not be published and due efforts will be made to conceal her identity, but anonymity cannot be guaranteed.

ABSTRACT: Purpose : Evaluation of implantation behavior of the following preloaded IOLs using corresponding IOL delivery systems : Alcon AcrySof IQ IOL using Acrysert C injector, Hoya 1 piece IOL using its injector system, & Zeiss CT Lucia IOL using its injector system.

Materials &Method : 150 eyes of 150 patients were operated for cataract via phacoemulsification and implanted with one of the following preloaded IOLs : Alcon AcrySof IQ using acrysert C injector, Hoya 1 piece IOL using iSert251 injector system, & Zeiss CT Lucia using ACCUJET injector system; 50 in each category.

Results: Hoya IOL delivery system was concluded to be superior in terms of highest predictability and least complications with the most cases of smooth passage of IOL through the cartridge and very few cases of sleeve override. Alcon AcrySof IQ IOL delivery system was associated with most complications, like adhesions between optic and haptic, overshoot, long unfolding time and sleeve override. It required the highest amount of manipulation to set the IOL in the bag. The only major disadvantage with Zeiss CT Lucia IOL was the excessive force required to release the IOL toward the end in most cases, which increased the implantation time

Conclusion : All intraocular lenses could be implanted without major complications. No damage to optics or haptics due to the implantation process occurred.

I. MANUSCRIPT

Introduction

Each step of cataract surgery has evolved over the decades. A wire vectis for nucleus removal was replaced by phacoemulsification, and femtosecond lasers appear to be replacing the knife for incision creation.[1-3] Similarly, the place of lens holding and folding forceps is increasingly being taken by myriad IOL insertion systems.

IOL injectors make only a brief appearance during cataract surgery, yet their impact on the safety and efficiency of the procedure is significant.[4] Injectors play a role in vision outcomes as well, as they aid surgeons in minimizing surgically induced astigmatism by delivering lenses through increasingly smaller and smaller incisions.[4] These important tools have improved incrementally over the years.

Prior to the introduction of injectors, problems during IOL implantation were common. Rigid PMMA lenses and some of the first foldable lenses had to be manually folded and placed in the eye with forceps. The use of forceps often damaged the IOL.[5] The procedure also required large incisions, which often had to be sutured.[5]

Manual holding, folding, and insertion techniques have, in recent years, been largely replaced by the use of novel IOL injection systems. The concept of dispensing an IOL as a prepackaged, ready-to-insert, preloaded IOL has been adopted by many manufacturers. The focus of these innovations is on development of simple, safe, and effective devices for IOL implantation through a relatively small incision.[6,7]

Most IOL injectors work with a disposable cartridge into which the IOL is loaded after it is removed from the packaging. The cartridge is then connected to a reusable handpiece with a plunger or screw mechanism that advances the IOL to its folded position and then into the eye. While today's injector systems share those same primary components, other aspects have been introduced or upgraded in different ways over the years. Screw-type mechanisms require two hands but safely limit the speed at which the IOL can advance.[4] Plungers advanced by thumb pressure may require only one hand, but the plunger can be advanced at difficult-to-control speeds, often resulting in damage to eye structures.[4]

Preloaded IOL systems must be surgeon-friendly and should offer safety, ease of insertion, and time-saving in the surgical procedure.[8] The characteristics of an ideal preloaded IOL injection system include the following: one-step, ready-to-insert implant package; optimized design for a small incision size; smooth passage of the IOL through the device with minimum friction; no risk of damage to IOL optic or haptics; smooth folding and unfolding of the IOL; optic-haptc non adhesion; and convenient and cost-effective use.[9,10,11]

The benefits of a good preloaded IOL injection system are several. First, the delivery system enables consistent, predictable, and controlled insertion with minimal incision size. Second, it eliminates the need for the postoperative cleaning and sterilization associated with reusable systems. Third, it saves time in the operating room, and, fourth, it eliminates handling and misloading of the IOL that can occur with a manual tucking mechanism.[11]

Purpose

1. Evaluation of implantation behavior of the following preloaded IOLs using corresponding IOL delivery systems : Alcon AcrySof IQ IOL using Acrysert C injector, Hoya 1 piece IOL using its injector system, & Zeiss CT Lucia IOL using its injector system.
2. Measurement of time taken for implantation of IOL using the various systems.
3. Check for complications during implantation.

Materials & Method

This was a single centre, prospective, interventional, double-blinded study.
It was conducted at our institute in the duration of six months from April 2019 to September 2019.
150 eyes of 150 patients were operated for cataract via phacoemulsification and implanted with one of the following preloaded IOLs : Alcon AcrySof IQ using acrysert C injector, Hoya 1 piece IOL using iSert251 injector system, & Zeiss CT Lucia using ACCUJET injector system; 50 in each category.
The phacoemulsification procedure was carried out by the same surgeon in all cases.
Video recordings of the IOL delivery stage were analyzed by a single observer. Of particular interests were the orientation of the leading haptic and optic on insertion, behavior of trailing haptic, the degree of intrawound manipulation of the injector, and ease of passage of IOL through cartridge. The time required to insert and satisfactorily deliver the IOL into the capsular bag in a correct orientation was measured. Other parameters assessed were : characterisitic of unfolding of IOL and predictability of IOL delivery. Problems of IOL delivery were like sleeve override, overshoot, requirement of excessive force in the end, IOL presenting inanterior chamber were also noted.
Statistical analysis was performed to determine the significance of differences between groups.

Inclusion criteria

Patients aged 50 to 70 years
Bilateral senile cataract
Co operative patients tolerating topical surgery

Exclusion criteria

Posterior polar cataract
Complicated /traumatic cataract
Any retinal pathology
Any co morbid systemic diseases

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II. RESULTS

Table 1. IOL Injector characteristics

IOL Injector characteristics					
IOL injection system type	Incision tip	IOL design	Optic material	Haptic material	Plunger
Hoya iSert251	Plastic	C-loop	Hydrophobic Acrylic	Hydrophobic Acrylic PMMA	Screw
Alcon acrySert C	Plastic	C-loop	Hydrophobic Acrylic	Hydrophobic Acrylic	Push
Zeiss injector	Silicone sleeve	C-loop	Hydrophobic Acrylic, heparin coated	Hydrophobic Acrylic	Push

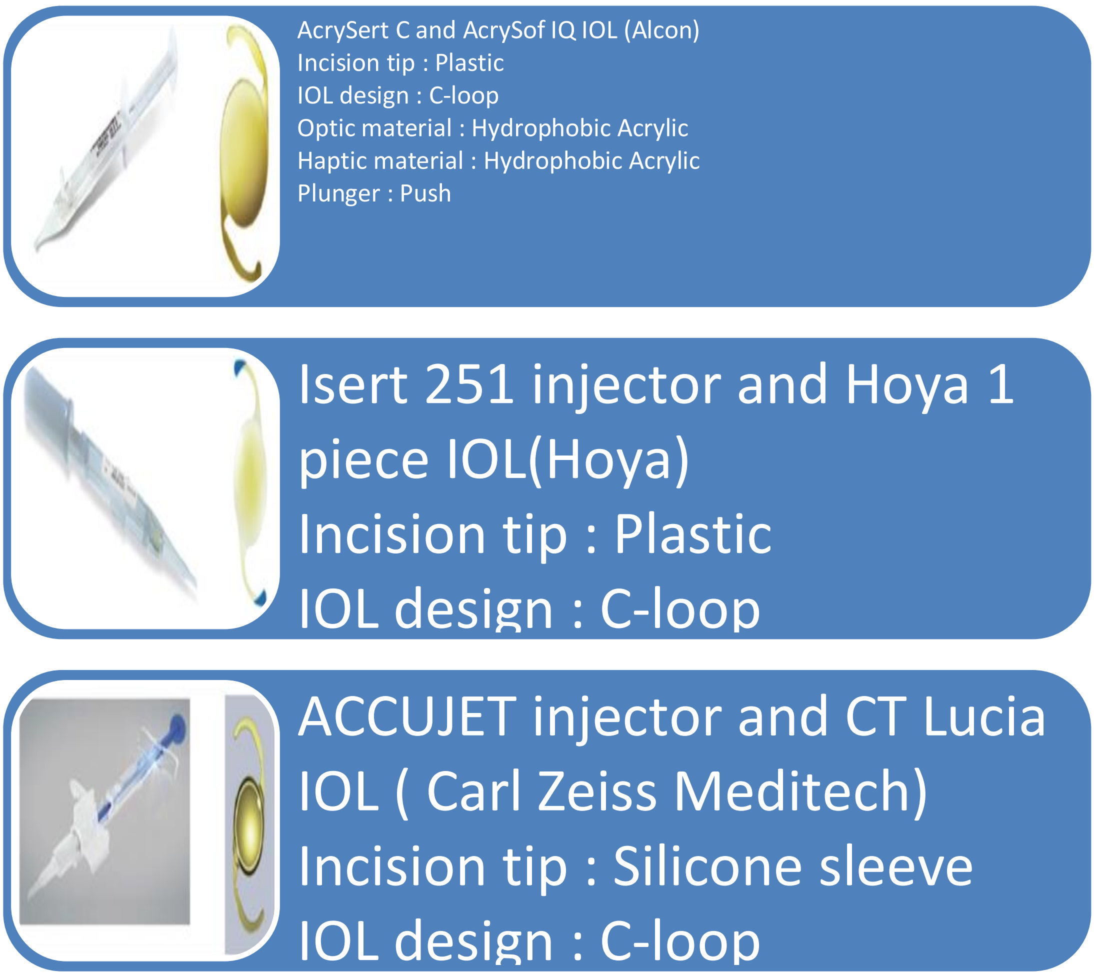

Figure 1. The three IOLs and their corresponding injectors in the study

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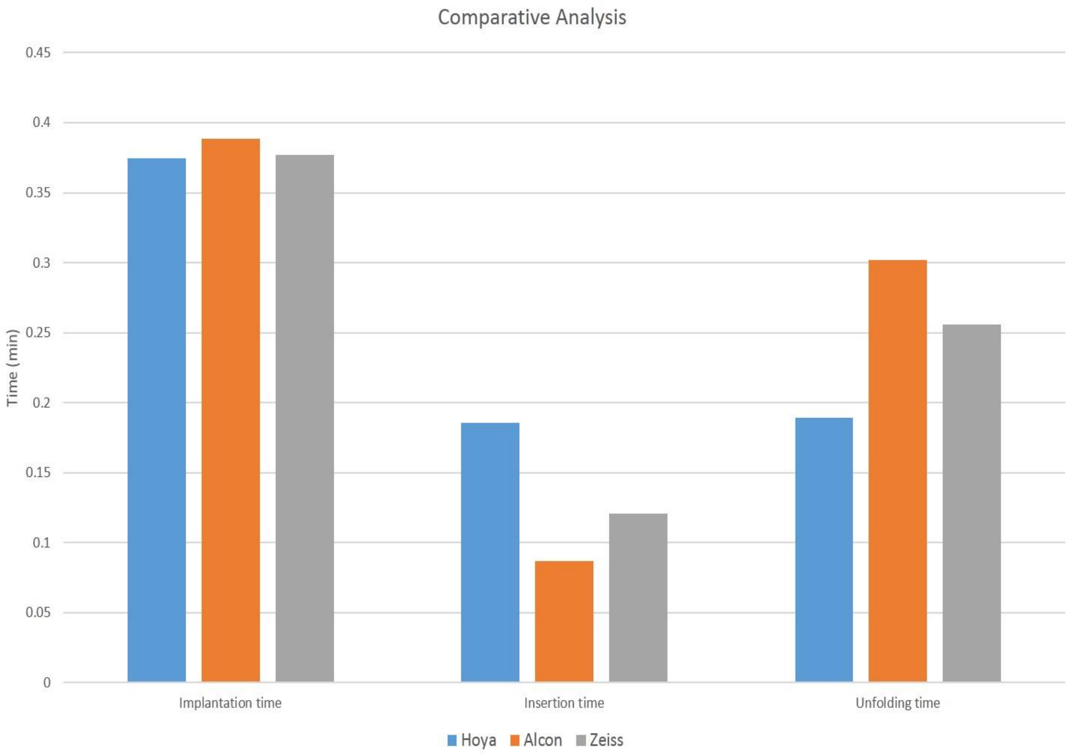
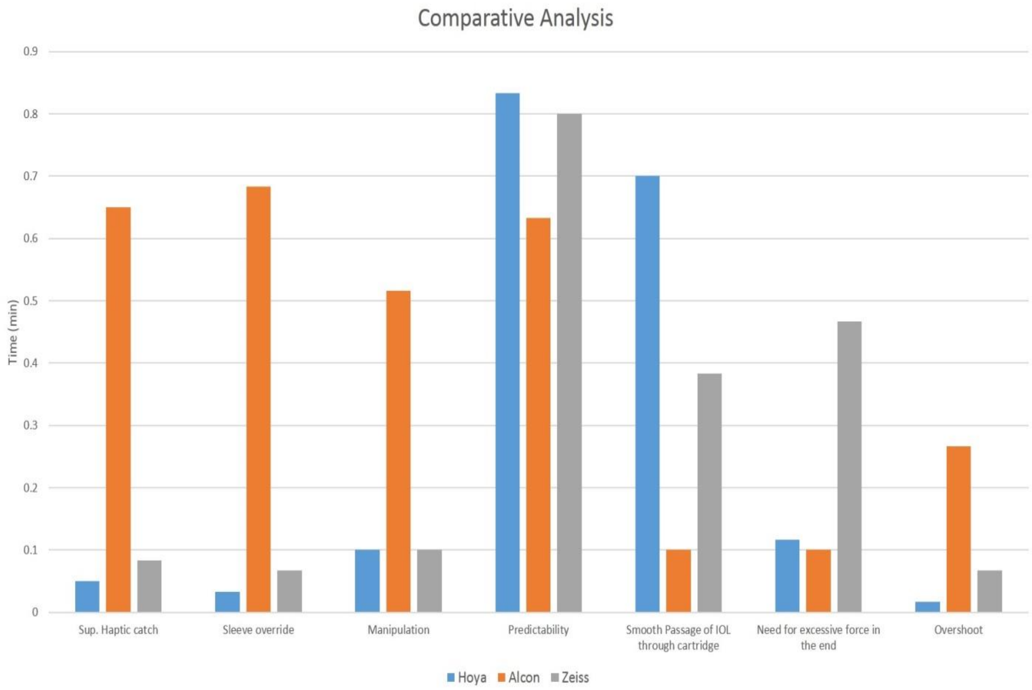
Table 2. Comparative analysis of IOL injector systems

Comparative analysis of IOL injector systems			
Characteristic	Hoya (n=50)	Alcon (n=50)	Zeiss (n=50)
Incision size	2.4 mm	2.4 mm	2.2 mm
Ease of opening & sterility of Package,	Satisfactory	Satisfactory	Satisfactory
Implantation time (sec)	22.47	23.31	22.61
Insertion time (sec)	11.13	5.2	7.26
Unfolding time (sec)	11.34	18.11	15.35
Sup. Haptic catch	3	39	5
Trailing haptic	Easily follows	Stuck to optic	Follows
Sleeve override	2	41	4
Manipulation	6	31	6
Predictability	50	38	48
OVD requirement	Yes	Yes	Yes
Passage of IOL through cartridge	Smooth in 42	Not smooth in 44	Not smooth in 27
Need for excessive force in the end	7	6	28
Overshoot	No	16	4
Unfolding	Smooth	Smooth	Smooth
IOL presenting in AC	No	No	No



Graph 1. Comparing timeline of IOL Implantation



Graph 2. Comparing complications in IOL delivery

Discussion

The study was aimed at comparing the various IOL delivery systems currently running in the market.

It was noted that all intraocular lenses could be implanted without major complications. No damage to optics or haptics due to the implantation process occurred.

Ease of opening and the sterility of package was found satisfactory for all delivery systems.

In our study, the implantation time ranged from 20 sec to 100 sec. Merz et al., in 2016, conducted a study to compare the implantation behavior of 4 preloaded IOL delivery systems: AcrySert with AcrySof SN60WF (Alcon), ACCUJET with CT Lucia (Zeiss), Itech with Tecnis PCB00 (AMO), and iSert with VivinexXY1 IOL (Hoya).[12] They observed the implantation time to range between 30 and 120 seconds. We concluded that the highest implantation time was required for Alcon IOLs(23.31 sec), followed by Zeiss(22.61 sec) and Hoya(22.47 sec). Our results were mirrored in the study by Merz et al.[12]

Insertion time was defined as the time between placing the injector tip at the incision and the exit of trailing haptic from the delivery system. It was maximum for Hoya injector (11.13 sec). This points to the longer time taken by screw-type injector, although it does provide a more controlled entry, as compared to the plunger-type injectors. This was followed by Zeiss (5.3 sec) and Alcon (5.2 sec) injectors.

Unfolding time was defined as the time between insertion of IOL into the bag and the point where the IOL haptics are o longer visible under the dilated pupil diameter. It was least for Hoya delivery system (11.34 sec), followed by Zeiss (17.35 sec) and Alcon (18.11 sec) delivery systems. Unfolding was smooth for all three categories.

In 2013, Ong HS et al[13] conducted a study to observe the intraocular lens delivery characteristics of the preloaded AcrySof IQ SN60WS/AcrySert injectable lens system. They recorded problems like trapped trailing haptic, haptic-optic adhesion, overriding of the plunger over the optic, and trauma to optic edge. These complications also surfaced in our study. Alcon AcrySof IQ IOL presented with adhesions of the haptics to the anterior/posterior surface of the optic and superior haptic catch. This was found to be one of the reasons for Alcon IOL to have the longest unfolding time.

Sleeve override was noted in 44 cases with Alcon delivery system, whereas it was only seen in 2 and 4 cases with Hoya and Zeiss delivery system respectively.

Ong HS etal., in their study found that forty-seven of the 85 eyes (55%) required additional rotational manipulation of IOL orientation.[13]Similarly in our study, manipulation was required in 31(62%) cases with Alcon injector. This was considerably higher as compared with the other two, with manipulation being done only in 6 cases of Hoya and Zeiss injectors. This explains the longest unfolding time for Alcon IOL.

Passage of IOL through cartridge was smooth in 42 cases for Hoya IOLs, whereas it was smooth for 23 cases for Zeiss delivery system. The number fell down considerably in the cases with Alcon delivery system; only 6 cases had a smooth passage of IOL through the cartridge.

Zia ul Mazhry, in 2015,[11] conducted a study to study the evolution of pre loaded IOL delivery systems. He also compared the AcrySert C inserter for the AcrySof IQ IOL (Alcon), the iSert for Hoya one- and three-piece IOLs (Hoya), and the inserter for the CT Lucia one-piece IOL (Carl Zeiss Meditec). He concluded that since the Zeiss CT Lucia system is designed to deliver the IOL through an incision of less than 2.2 mm, this narrows the cartridge markedly at its preinjection position. Thus excessive force is required toward the end of IOL delivery. This trend was apparent in our study as well.Only 7 and 6 cases of Hoya and Alcon respectively required excessive force toward the end to inject the IOL. However, excessive force was applied in 28 cases to inject the Zeiss IOL into the bag.

Predictability in IOL delivery was highest with Hoya IOL injectors, followed by Zeiss (48), then Alcon (38).

None of the IOLs opened in the anterior chamber.

To summarise, Hoya IOL delivery system was concluded to be superior in terms of highest predictability and least complications with the most cases of smooth passage of IOL through the cartridge and very few cases of sleeve override. These results were mirrored in the study by Zia ul Mazhry, in 2015, in which he concluded that the iSert received the best rating, owing to its easy handling and fail-safe delivery.[11]However, the plunger type injector led to longer insertion time.

Alcon AcrySof IQ IOL delivery system was associated with most complications, like adhesions between optic and haptic, overshoot, long unfolding time and sleeve override. It required the highest amount of manipulation to set the IOL in the bag. The passage of IOL through the cartridge was not smooth in most cases. These results are in tandem with the study conducted by Ong HS et al., in which they concluded that The AcrySof SN60WS/AcrySert system does not appear to meet the expectations of pro-viding a predictable means of IOL delivery.[13]

The only major disadvantage with Zeiss CT Lucia IOL was the excessive force required to release the IOL toward the end in most cases, which increased the implantation time.

In his study, Zia ul Mazhry, in 2015, concluded that the preloaded IOL insertion systems for hydrophobic C-loop one- and three-piece designs need more work to ensure fail-safe delivery;[11] however, these lenses definitely perform better in terms of long-term lens clarity and less PCO.[14,15,16] A longer follow up would be required for us to derive a similar conclusion.

III. CONCLUSION

IOL implantation may evolve in a variety of ways in the near future, but preloaded devices will continue to be a focus. It is expected that preloaded systems will ultimately become the preferred method of delivery because of the added convenience and efficiency associated with delivery, along with the reduced risk of damage to the IOL and elimination of handling errors that can occur during loading and folding of an IOL. The refractive outcomes of cataract surgery today are better than ever because of small incisions, high-quality IOL materials and optics and delivery systems that act in concert with them. Injectors are a critical piece of the procedure. The only product that stays with the patient is the IOL, and the delivery system is responsible for getting it there.

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