LITERATURE REVIEW

Visual Outcomes Following Diffractive-Refractive Multifocal Intraocular Lens Implantation : Literature Review

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ABSTRACT

Purpose: To evaluate the result of diffractive-refractive multifocal intraocular lens (IOL) implantation, regarding the visual acuity, spectacle independency, and also related disturbing visual pnenomenon such as halo and glare.
Methods: Seventeen articles collected from multiple sources including Pubmed, Clinical Key, and Ophthalmology Advance were reviewed. Visual acuity. Five types of diffractive-refractive multifocal IOL were found including ReSTOR SA60D3, SN60D3, SA6AD3, SA6DA1, and AT Lisa 809M. Uncorrected and corrected visual acuity, spectacle independency and undesired visual phenomenon data of each IOL were analyzed.
Results: For binocular uncorrected distance and intermediate vision, ReSTOR SN6AD1 is better than other IOL. Meanwhile, in binocular uncorrected near visual acuity category, ReSTOR SA60D3 is superior. Highest percentage of patients reporting spectacle independency found in ReSTOR SA60D3 group. Halo was found in each IOL group, ranged from 32 to 65 percent patients. Glare was found in a smaller percentage, ranged from 25 to 61 percent patients.
Conclusion: The best option for patients aiming for best visual acuity in distance to intermediate activity without spectacle use is ReSTOR SN6AD1. Meanwhile, the best option for patients aiming for best near visual acuity is ReSTOR SA60D3. Comprehensive preoperative education is crucial, considering the cost and benefit aspects of multifocal IOL implantation.

Keywords: diffractive-refractive multifocal, intraocular lens

Natural reduction of lens flexibility due to aging process, causes gradual decrease of accommodation.[1] Moreover, lens extraction procedure itself, either in cataract surgery or clear lens extraction also causing loss of accommodation ability, thus causing difficulty in near and intermediate task.

Advancement of technology in cataract and refractive surgery in recent

decades accompanied by raise of patient's expectation. Best visual performance without spectacle in all-distance task is expected. Multifocal intraocular lenses (IOL) were designed to divide light into more than one focal point for providing high perfomance in near, intermediate and distance vision, thus promising spectacle independence vision.[2-4] Various optical design of multifocal IOLs have been developed, including refractive design, diffractive design, and the latest is hybrid or diffractive-refractive design which combine both concept of previous multifocal IOLs.[1,5,6]

Despite the excelency, these newest multifocal IOLs are not without limitations. Some drawbacks reported include blurry vision and post-operative dissatisfaction caused by halo and glare.[5,6] Surgeons should know the efficacy and disadvantages of these IOLs based on evident literatures, thus knowing when to use or not to use these IOLs and could provide proper explanation to their patient.

Glucocorticoid (GC) have been used for treatment of moderate to severe GO due to their anti-inflammatory and immunosuppressive actions during the active phase of GO. It can be administered orally and intravenously. Intravenous GC was associated with significantly greater efficacy and was better tolerated than oral route in the treatment of patients with moderate to severe and active GO.[8] Intravenous GC has a variation cumulative dose and protocols, meanwhile the optimal treatment is still undefined. Lack of study investigated treatment effect and safety of different cumulative doses and also there were less research about protocols of IVGC for moderate to severe and active GO.

METHODS

Literature search was conducted through electronic databases including PubMed, Clinical key, and Ophthalmology advance. Inclusion criteria were all studies which reported implantation of multifocal intraocular lens (IOL) with diffractive-refractive design in senile cataract or clear lens extraction surgery with phacoemulsification technique, with specified detail outcomes including visual acuity, subjective visual symptoms such as glare and halo, and spectacle independency. Studies were excluded if there were differences in subjects (high myopia or hyperopia) or outcome parameter, if IOLs were implanted unilaterally, or if full text was unavailable.

RESULTS

Nineteen studies were included in this systematic review. Widely used diffractive-refractive multifocal IOLs were manufactured by two companies; Alcon and Zeiss. Alcon produced four series of AcrySof ReSTOR (SA60D3, SN60D3, SN6AD1 and SN6AD3). The earliest is SA60D3, Food and Drug Administration (FDA)-approved on 2005.[5] Still in the same year, SN60D3 was then produced with addition of Ultraviolet and blue light filter. In 2009, the latest diffractive-refractive IOLs, SN6AD1 and SN6AD3 were approved and marketed, with addition of aspherical properties.[3] Difference between SN6AD1 and SN6AD3 is only in the near-addition diopter, +3.00 and +4.00 respectively.[3] Diffractive-refractive multifocal IOL by Zeiss is AT Lisa 809M, with near addition diopter of +3.75, formerly called Acri Lisa 366D, produced in 2006.[3]

Spectacle independency is undoubtly linked to binocular uncorrected visual acuity. Mean binocular uncorrected visual acuity in each distance range extracted from articles were combined and calculated in this review (Table 1).

Table 1. Mean binocular uncorrected visual acuity results from all studies (in LogMAR)

IOL Name	UDVA Mean (no.of patients / no.of study)	UIVA Mean (no.of patients / no.of study)	UNVA Mean (no.of patients / no.of study)
ReSTOR SA60D3	0.06 (397/3)	0.32 (50/1)	0.02 (397/3)
ReSTOR SN60D3	0.07 (428/3)	0.16 (72/1)	0.06 (428/3)
ReSTOR SN6AD1	-0.02 (224/4)	0.09 (187/2)	0.05 (207/3)
ReSTOR SN6AD3	0.05 (19/1)	N/R	0.28 (19/1)
AT Lisa 809M	0.04 (196/3)	0.10 (94/1)	0.06 (196/3)

UDVA = Uncorrected distance visual acuity; UIVA = Uncorrected intermediate visual acuity; UNVA = Uncorrected near visual acuity; N/R = not reported

ReSTOR SN6AD1 is superior in achieving spectacle-freedom in distance and intermediate vision. Asphericity and lower near-addition power of ReSTOR SN6AD1 (+3.00) may contribute to these results. In UNVA category, ReSTOR SA60D3 is superior than other IOLs. Higher near-addition power of this IOL (+4.00) may be one contributing factor in achieving best near visual acuity.

Binocular corrected visual acuity results expected to represent best possible visual acuity that may be achieved in patients that tolerate spectacle use. Intermediate and near acuity measured with distance-vision correcting lens. These results showed in table 2.

Table 2. Mean binocular distance-corrected visual acuity results from all studies (in LogMAR)

IOL Name	CDVA Mean (no.of patients / no.of study)	DCIVA Mean (no.of patients / no.of study)	DCNVA Mean (no.of patients / no.of study)
ReSTOR SA60D3	0.03 (397/3)	0.23 (375/2)	0.03 (397/3)
ReSTOR SN60D3	0.02 (417/3)	0.27 (335/1)	0.04 (335/1)
ReSTOR SN6AD1	-0.06 (173/5)	0.12 (143/3)	0.03 (131/3)
ReSTOR SN6AD3	0.00 (19/1)	N/R	N/R
AT Lisa 809M	-0.03 (206/4)	0.10 (94/1)	0.05 (175/2)

CDVA = Corrected distance visual acuity; DCIVA = Distance-corrected intermediate visual acuity; DCNVA = Distance-corrected near visual acuity; N/R = not reported

Highest mean binocular CDVA achieved by implantation of ReSTOR SN6AD1. Meanwhile, highest mean binocular DCIVA reached after implantation of AT Lisa 809M, followed by ReSTOR SN6AD1 for the second best. Best mean DCNVA showed in implantation of ReSTOR SA60D3 and SN6AD1.

Regardless the visual acuity as the objective measure, subjectively-reported spectacle independency is an important outcome since it may represent functional success of multifocal IOL implantation. Incidence and percentage of spectacle independency extracted from articles was combined and calculated in this review (Table 3).

Highest percentage of patients reporting spectacle independency found in ReSTOR SA60D3 group. Superiority of ReSTOR SA60D3 in near task visual acuity may be contributing factor for this result.

Side effect regarding all multifocal IOL implantation was undesired visual phenomenon arising from nature of IOL's multifocality. Halo or glare were found in each IOL group, ranged from 25 to 65 percent patients. Despite the high percentage, only small number of patients

reporting related functional difficulties such as difficulty in night-driving.

Table 3. Incidence and percentage of spectacle independency

IOL Name	Spectacle independency % (n/total sample , no.of studies)
ReSTOR SA60D3	88.3 (106/120, 3)
ReSTOR SN60D3	80.6 (58/72, 1)
ReSTOR SN6AD1	78.0 (138/177 ,2)
ReSTOR SN6AD3	N/R
AT Lisa 809M	82.1 (69/84 ,1)

DISCUSSION

Diffractive-refractive or hybrid multifocal IOL combined both concept of diffractive and refractive multifocal IOL to increase the range of functional vision with a smooth transition between the distance and near zones to maximize image quality. Multifocal IOLs adopting this concept include Alcon AcrySof ReSTOR and Zeiss AT Lisa.

AcrySof ReSTOR is a single-piece IOL, with double-C loop haptic design. The refractive part is occupied 2.4 mm outer-ring area of the optic, while the diffractive part is in 3.6 mm area on the center part with apodization between each of the twelve concentric steps.[7] AcrySof ReSTOR IOL characteristics can be seen in Figure 1.

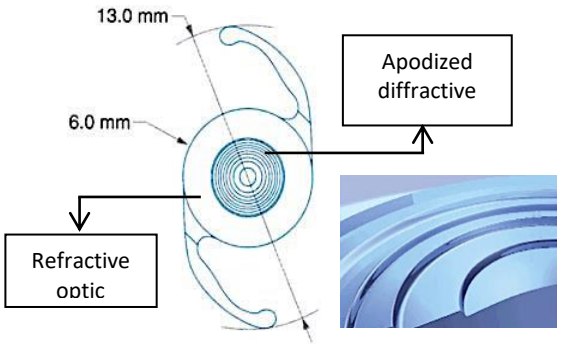

Fig 1. Alcon AcrySof ReSTOR IOL design

AT Lisa 809M is a bifocal biconvex diffractive-refractive single-piece IOL with a 6.0 mm foldable acrylate aspherical optic and overall diameter of 11.0 mm (Figure 2).[8] This surface is divided into main zones and phase zones; the phase zones assume the function of the steps of diffractive IOLs.[8-10] The diffractive structure has a soft transition of the phase zones between the main zones.[8-10] The IOL power responsible for distance vision comes from both refractive and diffractive origins, simultaneously.

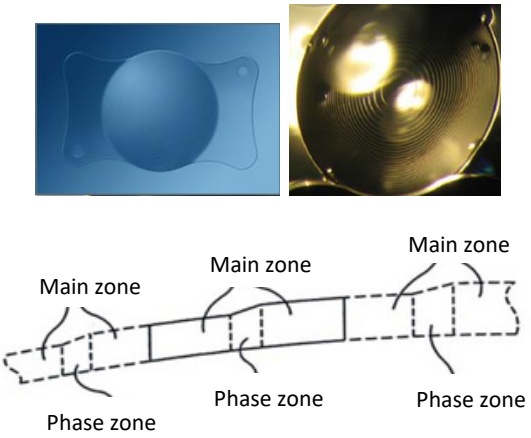

Fig 2. Zeiss AT Lisa 809M IOL design

Diffractive-refractive multifocal IOLs may be used either in cataract surgery or clear lens extraction. Montes-mico[11] included only patient underwent clear lens extraction. Mean monocular UDVA and UNVA in his study were better than result of other studies with the same IOL on cataract patients. However, patient with clear lens extraction tend to report lower levels of satisfaction and higher incidence visual discomfort.[1]

ReSTOR SN6AD1 showed superiority in distance visual acuity. Apodization design improves the crispness of vision and reduces light scatter, aberrations and visual disturbances. The refractive peripheral region is directing light to a distance focal point thus dedicated to distance vision. Asphericity compensates for positive corneal spherical

aberration, thus enhances image quality compared to spherical lenses. However, mean uncorrected binocular distance visual acuity for all groups is better than 6/7.5 in Snellen acuity (6/6.9 to 6/5.7 in Snellen acuity).

Differ from AT Lisa, all ReSTOR IOLs are pupil-dependent. In bright light, with constricted pupils, the lens sends light energy simultaneously to both near and distant focal points. In low light, with dilated pupils, the lens sends a greater amount of energy to distance vision thus theoretically minimize visual disturbances.[12] On the other hand, visual outcomes of pupil-dependent IOLs would be more sensitive to centration than pupil independent IOLs.[13]

ReSTOR SN6AD1 and AT Lisa 809M were superior than other IOLs in intermediate visual acuity. The lower addition power of both IOLs may contribute to improvement of intermediate vision. Alfonso et al[7] also found significantly better intermediate visual acuity of ReSTOR SN6AD1 than other IOLs with higher near-addition power.

For near vision, ReSTOR SA60D3 reached the highest mean visual acuity. Near addition power of +4.00 may be one of contributing factors. However, all of the IOLs reviewed in this study showed a good binocular uncorrected near acuity, ranged from 0.02 to 0.06 logMAR (6/6.9 to 6/6.3 in Snellen acuity), except for ReSTOR SN6AD3 due to lack of supporting articles.

In practical, it is important to consider patient's preference reading distance in choosing appropiate multifocal IOL. Multifocal IOL with +4.00 near-addition theoretically achieved best near acuity at distance of 33 to 36 cm.[14] Meanwhile, focal point for the clearest near vision in multifocal IOL with +3.00 near-addition is farther out than the ReSTOR +4.00 D, which is approximately 41 to 43 cm.[14]

Regarding the applicability, no previous articles reporting technical difficulties in implantation of both IOLs. Both IOLs are able to be injected through small incision size. Both ReSTOR and AT Lisa are single-piece IOL, only with different haptic shape. It is important to be considered that flawless surgery and good IOL centration are needed to achieve best result.

For the availability, both ReSTOR and AT Lisa lenses are available in Indonesia. However they are relatively costly. Price of multifocal IOLs in United States are approximately 895 USD for ReSTOR and 800 USD for AT Lisa,[10] and it might even higher in Indonesia. Clinician and patient should have all the consideration, regarding cost and benefit.

Limitation of this systematic review includes lack of supporting literature to conclude some outcome comparisons, lack of head-to-head and randomized clinical trial (RCT) study and heterogeneity of measurement methods for some outcomes such as halo and glare.

CONCLUSION

Both ReSTOR and AT Lisa provide excellent binocular uncorrected distance visual acuity, above 6/7.5 in each group. The best option for patients aiming for best visual acuity in distance to intermediate activity without spectacle use is ReSTOR SN6AD1, followed by AT Lisa 809M. Meanwhile, the best option for patients aiming for best near visual acuity is ReSTOR SA60D3.

Halo and glare are unavoidable, even though tends to be tolerated. Comprehensive preoperative education is crucial, considering the cost and benefit aspects of multifocal IOL implantation. Further RCT studies with uniformity in outcome measurement are needed.

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