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Comparison of clinical results between heparin surface modified hydrophilic acrylic and hydrophobic acrylic intraocular lens

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PURPOSE. *To compare the clinical results of heparin surface modified (HSM) hydrophilic acrylic intraocular lens (IOL) with those of hydrophobic acrylic IOL.*
METHODS. *One hundred patients with cataract were randomized to receive one of acrylic foldable IOLs after phacoemulsification: HSM hydrophilic acrylic IOL (n=50) BioVue3® (BioVue, OII, Ontario, CA, USA) and hydrophobic acrylic IOL (n=50) Sensar® (AR40e, AMO, Santa Ana, CA, USA). Best-corrected visual acuity and refractive error were measured at 1 week, 2 months, 6 months and 12 months after surgery in both IOL groups. To assess posterior capsular opacification (PCO), digital retroillumination image of posterior capsule was analyzed at 12 months using POCOman software.*
RESULTS. *Best-corrected visual acuity (log MAR) was 0.032±0.082 in BioVue3® group and 0.034±0.077 in Sensar® group at 12 months. There was no statistically significant difference between the two groups (p=0.554). Refractive error was -0.247±0.821 diopter in BioVue3® group and -0.264±0.808 diopter in Sensar® group at 12 months. There was no statistically significant difference of refractive error between the two groups (p=0.909). At 12 months, BioVue3® IOL group had a lower percentage area and severity of PCO than Sensar® group. However, it was not statistically significant (p=0.349, p=0.288). No Nd:YAG capsulotomy was performed in BioVue3® group while it was required in two eyes (4.0%) in Sensar® group.*
CONCLUSIONS. *There was no statistically significant difference of postoperative visual acuity, refractive error and degree of PCO between HSM hydrophilic acrylic IOL and hydrophobic acrylic IOL. (Eur J Ophthalmol 2008; 18: 377-83)*

KEY WORDS. *Heparin surface modified, Hydrophilic acrylic intraocular lens, Hydrophobic acrylic intraocular lens*

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INTRODUCTION

Since the initiation of cataract surgery with intraocular lens (IOL) by Ridley in 1949, polymethyl methacrylate (PMMA) has been used most frequently as the IOL material until recently. It has long been considered to be biologically inert. However, studies have shown that PMMA is not as inert as previously believed and is associated with postoperative inflammation (1, 2). In the search for better biocompatibility, research has been conducted resulting in the development of hydrophilic IOL by coating the surface of previous PMMA IOL with heparin.

The binding of heparin to PMMA IOL surface makes the IOL more hydrophilic. Its surface is changed to have negative charge to have the effect of preventing the attachment of not only bacteria, protein, and corneal endothelial cells but also lens epithelial cells.

The superiority of heparin surface modified (HSM) PMMA IOL has been proven in numerous studies. HSM PMMA lens reduced postoperative inflammation in both routine and complicated cataract cases when compared with non-HSM PMMA lens (3-5). The efficacy of HSM IOL on

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reducing aqueous flare and protein concentration in aqueous humor is confirmed in patients with high risk factors for blood–aqueous barrier impairment such as diabetes mellitus, glaucoma, pseudoexfoliation, and uveitis (6, 7). Inflammatory cellular deposits on IOL surface were significantly lower in HSM PMMA IOL compared with unmodified PMMA IOL (8). Acrylic IOL was first implanted into the human eye in 1990 in an effort to find more biocompatible IOL materials and began to be used in 1994. A number of clinical and experimental studies showed that acrylic IOL has superior biocompatibility over various IOL types. Lens epithelial cell reaction was the lowest in acrylic IOL among several different IOLs evaluated (9). Acrylic IOLs were associated with a significantly reduced degree of anterior and posterior capsular opacification (10, 11). Furthermore, acrylic IOL has been reported to be superior to PMMA IOL coated with heparin (12). Therefore, if the surface of acrylic IOL that has superior biocompatibility was coated with heparin, theoretically, it could be considered to be an ideal IOL.

In our study, the clinical performance of HSM hydrophilic acrylic IOL BioVue3® (BioVue, OII, Ontario, CA, USA), which is the first acrylic foldable lens with heparin surface modification, was compared with that of hydrophobic acrylic IOL Sensar® (AR40e, AMO, Santa Ana, CA, USA).

MATERIALS AND METHODS

This single-center prospective study was conducted at the Department of Ophthalmology and Visual Science, The Catholic University of Korea. This study comprised 100 eyes with cataract in 100 patients who had phacoemulsification. Cases with past history of diabetes mellitus, glaucoma, uveitis, other ocular diseases, and ocular trauma were excluded from the study.

Fifty eyes (50 patients) had BioVue® IOL implantation and 50 eyes (50 patients) had Sensar® AR40e IOL implantation. All patients were admitted to Kangnam St. Mary's Hospital for cataract surgery. All surgeries were performed by an experienced surgeon (C.K.J.) using the same technique from February 2004 through February 2006. Informed consent was obtained from all patients and ethics committees approved all protocols.

BioVue3® is a HSM acrylic hydrophilic IOL which is a three-piece IOL with an optic diameter of 6.0 mm and an overall length of 12.5 mm. The IOL's biconvex optic has square edge design and is made of HEMA and MMA acrylic polymer with refractive index of 1.46. The haptics of the lens are composed of blue polyvinyldine fluoride and have an angulation of five degrees. Heparin is coated on whole IOL surface, including optic and haptic. The Sensar® AR40e is an acrylic hydrophobic IOL which is a foldable three-piece IOL with an optic of EA, EMA, TFEMA, and EGDMA acrylic polymer and haptics of PMMA. The optic diameter is 6.0 mm and an overall length is 13.0 mm. The lens has posterior squared optic edge. It has refractive index of 1.47. The haptics have an angulation of five degrees (Tab. I).

All patients underwent ocular biometry with manual keratometry and axial length. The SRK II formula was routinely used to calculate the actual IOL power.

All patients received topical anesthesia before surgery. A

TABLE I - INTRAOCULAR LENS CHARACTERISTICS

	BioVue3®	Sensar®
Model	BioVue 3 Three-piece	AR 40e Three-piece
Optic		
Diameter	6.0 mm	6.0 mm
Shape	Equal biconvex	Equal biconvex
Materials	Hydrophilic acrylic polymer (HEMA/MMA)	Hydrophobic acrylic polymer (EA/EMA/TFEMA/EGDMA)
A-constant	118.2	118.4
Edge design	Squared anterior edge, squared posterior edge	Round anterior edge, squared posterior edge
Refractive index	1.46	1.47
Haptic		
Length	12.5 mm	13.0 mm
Materials	poly vinylidene fluoride	PMMA
Angle	5 degrees	5 degrees

HEMA = 2-hydroxyethyl methacrylate; MMA = Methyl methacrylate; EA = Ethyl acrylate; EMA = Ethyl methacrylate; TFEMA = 2,2,2-trifluoroethyl methacrylate; EGDMA = Ethylene glycol dimethacrylate

3.00 mm clear corneal temporal incision by diamond knife was made and Healon® was injected. Continuous curvilinear capsulorhexis (CCC) approximately 5.5 mm in diameter was created. The CCC size was intended to be slightly smaller than the IOL optic size in all cases. Healon® was used to reform surgical space and protect corneal endothelium. After hydrodissection and hydrodelineation using balanced salt solution (BSS®), the phacoemulsification of the nucleus was performed and residual cortex were cleared by irrigation/aspiration system. The wound was enlarged to 3.2 mm for IOL implantation. Lens capsule was inflated with Healon® and then IOL was placed in the capsular bag with a Naviglider for BioVue® lens and a Sapphire injector for Sensar® lens. After IOL insertion, the viscoelastic material was thoroughly evacuated. Stitch wound was not sutured. Any surgical complications were excluded. Following surgery, levofloxacin 0.1% and prednisolone acetate 1% were used four times daily for 4 weeks. All patients were examined at the slit lamp by the surgeon the day after surgery, 1 week, 2 months, 6 months, and 12 months after surgery. Best-corrected visual acuity was recorded at each visit and it was changed into a logarithm of minimal angle of resolution (logMAR) scale for comparing them. Refraction was also measured in every visit and refraction error was calculated. Refractive error was defined as subtraction of preoperative desired refraction from postoperative spherical equivalent.

To evaluate PCO, digital retroillumination photography of posterior capsule was taken 12 months after surgery. The image was analyzed using POCOman software, giving the percentage of PCO by area within the whole capsulorhexis and a score for PCO severity. POCOman is semiobjective assessment of PCO in which the observer, assisted by the computer software, determines the percentage area of PCO and assigns a severity of PCO (13). The incidence of neodymium:YAG laser posterior capsulotomy in both IOL groups was also examined throughout the follow-up period.

For statistical Analysis, the Mann-Whitney *U* test was used for comparison between the two IOL groups of logMAR visual acuity, refraction error, and PCO value. Any differences with a p value less than 0.05 were considered to be statistically significant.

RESULTS

Of 100 eyes in 100 patients in this study, 50 eyes of 50 patients received a BioVue® IOL and another 50 eyes of 50 patients implanted a Sensar® AR40e IOL. The mean age of the patients in BioVue® and Sensar® group was 69.5 years (range 42 to 85) and 66.5 years (range 42 to 88), respectively. The male:female ratio was 21:29 in BioVue® and 23:27 in Sensar® lens. The differences of age, gender, axial length, the inserted IOL power, and preoperative visual acuity converted to logMAR between the two IOL groups were not statistically significant (Tab. II).

Figure 1 shows the mean best-corrected visual acuity in each IOL group. In BioVue® group, 80% of cases achieved 20/20 or better and 90% achieved 20/25 or better best-corrected visual acuity at postoperative 12 months. In Sensar® group, 78% of cases achieved 20/20 or better and 92% achieved 20/25 or better best-corrected visual acuity at postoperative 12 months. When comparing the BioVue® and Sensar® groups, no significant difference was found in mean visual acuity throughout the follow-up period (Tab. III).

In BioVue® group, refractive error was –0.247±0.821 diopters at 12 months after surgery. In Sensar® group, refractive error was –0.264±0.808 diopters at 12 months af-

TABLE II - PATIENT CHARACTERISTICS OF THE TWO INTRAOCULAR LENS (IOL) GROUPS

Characteristic	IOL group		
	BioVue3®	Sensar®	p value*
No. of eyes (patients)	50 (50)	50 (50)	
Age, yr, mean ± SD	69.5±8.8	66.5±11.1	0.086
Gender (M/F)	21/29	23/27	0.840†
Preoperative axial length (mm), mean ± SD	23.31±0.79	23.19±0.88	0.453
Inserted IOL power (diopter), mean ± SD	20.60±1.57	20.27±2.30	0.463
Preoperative corrected visual acuity (logMAR), mean ± SD	0.592±0.407	0.582±0.366	0.909

*Statistical significance was tested by the Mann-Whitney U test.
†Pearson chi-square test

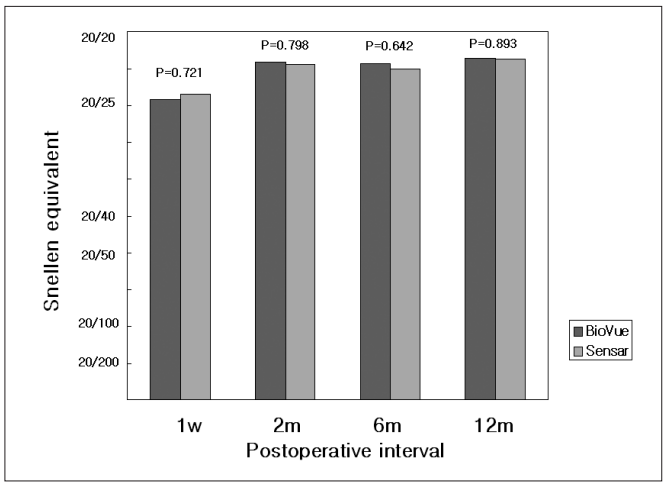

Fig. 1 - *Mean best-corrected visual acuity in the BioVue3® and Sensar® groups. When comparing groups, no significant difference was found in mean visual acuity between the BioVue3® and Sensar® groups throughout the follow-up period.*

ter surgery. The difference of refractive error between the two IOL groups was not statistically significant at any follow-up point (Tab. IV).

There was no significant difference in PCO between the two IOL groups (Figs. 2 and 3). At 12 months after surgery, in BioVue® group, the mean POCOman PCO percentage and mean PCO severity were 4.32% and 0.041, respectively. In Sensar® group, the mean POCOman PCO percentage and mean PCO severity were 5.75% and 0.076, respectively. No neodymium:YAG capsulotomy was performed in BioVue® group. Two patients who complained of deterioration of visual acuity in Sensar® group required a neodymium:YAG capsulotomy within 1 year of the study (Tab. V).

In all 50 eyes with BioVue® IOL and 50 eyes with Sensar® IOL, during the 12-month follow-up period, complications such as the decentration of IOL, endophthalmitis, intraocular pressure elevation, and posterior synechia were not observed.

TABLE III - BEST-CORRECTED VISUAL ACUITY AT FOLLOW-UP VISIT (LOGMAR)

	BioVue3®	Sensar®	p value*
Preop	0.592±0.407	0.582±0.366	0.909
Postop 1 day	0.271±0.467	0.235±0.381	0.593
Postop 1 week	0.088±0.154	0.081±0.074	0.721
Postop 2 months	0.037±0.060	0.040±0.057	0.798
Postop 6 months	0.039±0.062	0.046±0.086	0.642
Postop 12 months	0.032±0.082	0.034±0.077	0.893

Values are mean ± SD.

*Statistical significance was tested by the Mann-Whitney U test

TABLE IV - MEAN REFRACTIVE ERROR AT EACH FOLLOW-UP (DIOPTERS)

	BioVue3®	Sensar®	p value*
Post op 1 week	–0.222±0.819	–0.205±0.734	0.898
Post op 2 months	–0.196±0.774	–0.222±0.749	0.843
Post op 6 months	–0.215±0.833	–0.259±0.732	0.766
Post op 12 months	–0.247±0.821	–0.264±0.808	0.909

*Statistical significance was tested by the Mann-Whitney U test

TABLE V - ND:YAG RATE AND POCOMAN VALUE AT THE 1-YEAR FOLLOW-UP

Parameter	BioVue 3® (n = 50)	Sensar® (n = 50)	p value*
No. of Nd:YAG (%)	0 (0)	2 (4)	0.153
Mean POCOman PCO, %	4.32	5.75	0.349
Mean POCOman PCO severity score	0.041	0.076	0.288

*Statistical significance was tested by the Mann-Whitney U test.
Nd:YAG = Neodymium:YAG; PCO = Posterior capsular opacification

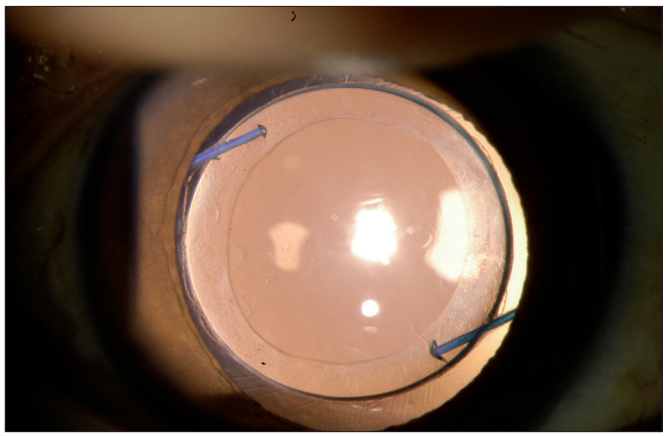

Fig. 2 - *Retroillumination photograph showing an eye with BioVue3® intraocular lens at 12 months after surgery.*

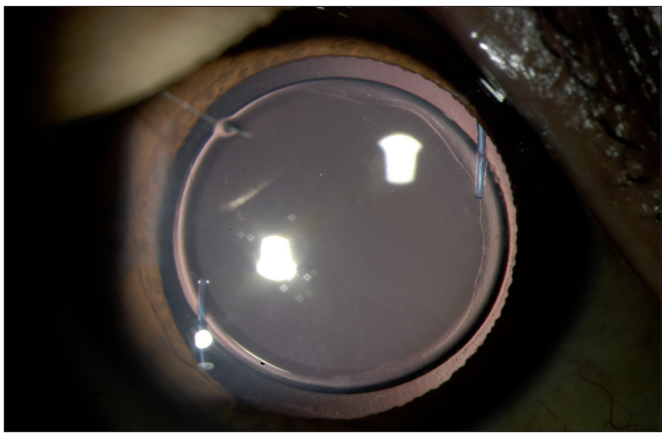

Fig. 3 - *Retroillumination photograph showing an eye with Sensar® AR40e intraocular lens at 12 months after surgery.*

DISCUSSION

Many reports documenting the benefits of heparin surface modification (HSM) have been about the assessment of PMMA IOL. To our knowledge, there are few studies about HSM acrylic IOL, especially in the clinical setting. In our study, the clinical performance of the first heparin surface coated acrylic foldable IOL, BioVue3®, was compared with that of another acrylic foldable IOL, Sensar®, which has been used widely and thus its safety has been proven.

Oshika and associates have reported their experience of postoperative visual acuity after acrylic IOL implantation in 64 patients. A total of 86.9% of patients had corrected visual acuity of 20/20 at 6 months, 82.8% had 20/20 at 1 year, and 86.3% had 20/20 at 2 years (14).

Jeon et al reported the clinical results of 814 patients who had been implanted with acrylic IOL and showed an excellent visual prognosis with acrylic IOL (15). They reported that best-corrected visual acuity over 20/40 was obtained in 92% and over 20/25 in 83% at 6 months after surgery. In our study, at 6 months after surgery, 78.0% of patients implanted with Sensar® lens had best-corrected visual acuity of 20/20 and 92.0% had 20/25 or better. In BioVue3® group, 80% of patients implanted with BioVue3® lens had 20/20 and 90% had 20/25 or better. As repeatedly shown in our results, a good prognosis of postoperative visual acuity of acrylic IOL was validated. In BioVue3® group, there were three patients whose best-corrected visual acuity was lower than 20/40 at 12 months. Those three patients had branched retinal vein occlusion, cystoid macular edema, and unknown cause. If these patients are excluded, all patients with BioVue3® had visual acuity of 20/25 or better. There was no statistically significant difference of postoperative visual acuity (log MAR) between BioVue® and Sensar® lenses implanted in the bag after phacoemulsification. Therefore, heparin-surface-modified acrylic IOL (BioVue3®) also proved excellent visual outcome.

Modern cataract surgery is performed not only to remove a crystalline lens opacification but also as a refractive surgery with the purpose of correcting refractive errors. Thus, it is important for patients to obtain postoperative refractive goals as well as to improve their best-corrected vision. In BioVue3® group, postoperative mean refractive error at 12 months was –0.247± 0.821 diopter. Patients who showed refractive error within 0.5 diopter from the target refraction value were 63% and patients showing refractive error within 1.0 diopter were 93%. The mean refractive error in Sensar® group was –0.264 ± 0.808 diopter at 12 months. Patients who showed refractive error within 0.5 diopter from the target refraction value were 57% and patients showing the refractive error within 1.0 diopter were 90%. During the 12 months follow-up, the slight myopic shift of target refraction was shown in both IOL groups (–0.247 diopter in BioVue3® group and –0.264 diopter in Sensar® group). Therefore, we recommend preoperative target refraction of BioVue3® lens should be set to be hyperopic by 0.24 diopter.

With the tremendous advances in surgical techniques and the improvement of IOL, the incidence of PCO has been reduced greatly. However, PCO remains one of the most common complications of cataract surgery. In order to prevent the occurrence of PCO, surgical techniques, pharmacologic methods, and IOL material and design

have been investigated. It is reported that there are two factors to minimize PCO, one associated with surgery and the other associated with IOL itself. As factors associated with IOL, the importance of square-edged optic design which creates a sharp bend in the posterior capsule, preventing lens epithelial cell migration, has been pointed out by Nishi and coauthors (16). Ursell et al emphasized the importance of IOL material in the pathogenesis of PCO and showed that IOLs made from acrylic polymer were associated with a significantly reduced degree of PCO compared with those from PMMA and silicone (17). Acrylic IOL was also known for its strong adhesiveness to a collagen membrane (18). This leads to increase the contact of IOL to posterior or anterior capsules and can be another possible reason why it may cause less PCO. For these reasons, Sensar® IOL is now considered to be one of the most preferred IOLs with regard to PCO.

Both IOLs used in our study are three-piece shape with a square-edged optical area. However, BioVue3® is a HSM hydrophilic acrylic IOL and Sensar® is a non-HSM hydrophobic acrylic IOL. Each cataract operation was performed by a single experienced surgeon using same surgical technique. Therefore, heparin surface modification and the difference of hydrophilic/phobic IOL material appear to be decisive factors on evaluation of PCO in our study.

Heparin is a well-known traditional anticoagulant without any serious side effects. It was found that heparin can suppress lens epithelial cell and fibroblast proliferation and reduce deposition and adhesion of platelets, macrophage, and fibroblasts on posterior capsular surface (19, 20). One laboratory investigation showed a high free heparin level in aqueous humor ensured adequate inhibition of lens epithelial cell and fibroblast proliferation and alleviated postoperative inflammatory reaction in rabbit eyes (21). In addition, the optical area of hydrophilic acrylic lens is thicker than hydrophobic acrylic lens due to the difference of water content, thus the probability of contacting with lens capsules is high and it is more suitable to the “no space no cells” theory. Therefore, we anticipated that the incidence of PCO would be much lower in BioVue3® group.

In our study, however, the HSM hydrophilic acrylic IOL did not show that it is associated with a lower PCO rate than the hydrophobic acrylic IOL 12 months after surgery. Although the difference between two IOL groups was not statistically significant, BioVue3® group showed a lower percentage and PCO severity score. In addition, the Nd:YAG laser capsulotomy was performed on two patients who used only Sensar® lens.

In older generation hydrophilic IOLs, lens epithelial cell proliferation on IOL surface and the loss of IOL transparency had been a problem (22). However, recently developed hydrophilic IOLs induce less lens epithelial cell proliferation than older models (23). HSM hydrophilic acrylic IOL used in our study also show the low incidence of lens epithelial cell proliferation, which is at least equal to that of hydrophobic acrylic IOL or slightly superior to that of hydrophobic acrylic IOL. Moreover, any significant lens epithelial cell ongrowth into anterior IOL surface was not observed through the study and no single lens opacification or loss of transparency occurred in the IOL groups.

BioVue3® has several IOL-related factors in lowering the incidence of PCO. First, heparin surface modification provides IOL with more biocompatible nature. It reduces the stimulation of cell proliferation. Secondly, its bioadhesive biomaterial induces maximal IOL optic-posterior capsule contact, which plays a role as effective barrier, and the space where residual lens epithelial cells grow and migrate was able to be reduced. The last PCO preventive effect comes from its square optic edge design. In our study, however, the superiority of BioVue3® with these PCO preventive conditions has not been proven.

However, additional research is required to determine the benefit of HSM hydrophilic acrylic IOL to prevent PCO in complicated cataract surgery at risk for post-surgical complications, such as uveitis, glaucoma, pseudoexfoliation syndrome, and diabetes mellitus.

As shown above, during 12 months after surgery, no difference was noted in the comparison of best-corrected visual acuity, refractive error, and PCO of HSM hydrophilic acrylic IOL, BioVue3®, with the clinical outcome of the hydrophobic acrylic IOL, Sensar®. Therefore, the findings of our study indicate that heparin surface modification of IOL might be unnecessary in uncomplicated cataract operation.

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