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Comparison of the effect of sodium hyaluronate (Ophthalin®) and hydroxypropylmethylcellulose (HPMC-Ophtal®) on corneal endothelium, central corneal thickness, and intraocular pressure after phacoemulsification

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PURPOSE. *To prospectively evaluate the effects of 2% hydroxypropyl-methylcellulose (HPMC-Ophtal®) and sodium hyaluronate 1% (Ophthalin®) on intraocular pressure, corneal thickness, and endothelial cell loss in small incision cataract surgery with implant.*

METHODS. *A total of 110 patients undergoing routine phacoemulsification with implant received either 2% hydroxypropylmethylcellulose or sodium hyaluronate 1% as ophthalmic viscosurgical device. Pre- and postoperative slit lamp examination, intraocular pressure measurement (preoperatively and at 1–4 hours, 1 day, and 7 days postoperatively), ultrasonic pachymetry (preoperatively and at 1 week, 4–6 weeks, and 12 weeks postoperatively), and corneal endothelial cell count (preoperatively and 12 weeks postoperatively) were performed. Data were analyzed using two-way analysis of variance.*

RESULTS. *All measurements were comparable between the two groups preoperatively. Intraocular pressure was significantly lower in the Ophthalin® group at 1 day postoperatively, while no significant difference was found between the two groups on the 1–4 hours and 7 days examination. The central corneal thickness was not significantly different between the two groups at any postoperative visit. However, the mean cell density demonstrated a significant fall of 11.76% for Ophthalin® and 4.27% for HPMC-Ophtal® at 12 weeks postoperatively, the difference between the two being significant (p=0.009).*

CONCLUSIONS. *2% Hydroxypropylmethylcellulose, compared with sodium hyaluronate 1%, is superior in protecting the corneal endothelial cells, has the same effect on central corneal thickness, and is associated with slightly higher intraocular pressure 1 day postoperatively. It compares favorably with sodium hyaluronate 1% and can be used as an effective and cheaper alternative in routine small incision cataract surgery with implant. (Eur J Ophthalmol 2006; 16: 239-46)*

KEY WORDS. *Hydroxypropylmethylcellulose, Ophthalmic viscosurgical devices, Phacoemulsification, Sodium hyaluronate*

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INTRODUCTION

The long-term health and clarity of the cornea is critically dependent upon the maintenance of a functional endothelial cell layer (1, 2). Corneal endothelial cells are incapable of cell division in humans and healing of corneal endothelial wound is dependent on enlargement and sliding of remaining cells (2, 3). The development of the specular microscope has permitted the in vivo study of corneal endothelial cells, such as the effect of surgery on cell density and morphology (2, 4).

Cataract extraction and lens implantation inevitably causes endothelial damage due to mechanical trauma from direct contact with instruments and intraocular lens (IOL), air bubble exposure, trauma from lens fragments, and also irrigation fluid turbulence (5, 6). However, ophthalmic viscosurgical devices (OVDs) protect the corneal endothelium during cataract operation by coating the endothelium and implant, thus avoiding direct contact (7). This cushions the endothelium from compression and shearing forces, and maintains space for manipulation by separating tissues and implant from the endothelium (7).

OVDs may be divided into two main groups. The first consists of cohesive and highly viscous materials, including sodium hyaluronate. They help to create space and stabilize the surgical microenvironment, for example by deepening the anterior chamber, enlarging small pupils, and dissecting adhesions. They are removed easily during surgery as a single mass. The second group consists of low viscosity dispersive materials, including hydroxypropylmethylcellulose. These tend to disperse in the anterior chamber and adhere to the corneal endothelium forming a visible coating, which remains there during phacoemulsification and protects the endothelium (7, 8).

Sodium hyaluronate 1% (Healon®) was the first OVD to be commercially available and its usefulness has been well documented (7, 9, 10). Other OVDs, including 1.4% sodium hyaluronate (Healon GV®), 4% chondroitin sulphate–3% sodium hyaluronate (Viscoat®), and 2% hydroxypropylmethylcellulose (HPMC-Ophtal®), have since been introduced (7). However, the newer substances are generally compared to sodium hyaluronate as the gold standard (7). Provisc® and Ophthalin® are similar to Healon® (sodium hyaluronate 1%).

Ophthalin® (sodium hyaluronate 1%) is a cohesive OVD. The literature has reported that it may occasionally be responsible for postoperative inflammation (11). In our department, over 7000 cataract operations are performed every year, and for the last 7 years the routinely used OVD has been Ophthalin®. We have throughout this period not observed any severe adverse effect (i.e., severe postoperative inflammation).

Two percent hydroxypropylmethylcellulose is a glucose related polymer that is chemically inert. It has been used in ophthalmic surgery since 1977, initially to coat IOLs before insertion and later as anterior chamber space maintainer (12). It has been shown to be a safe and efficient OVD material in clinical studies (8, 13). It is widely used in modern small incision cataract surgery (15).

The use of OVDs in ophthalmic surgery is safe but not free from complications. The main postoperative effect is rise in intraocular pressure (IOP). This poses a risk to all patients, and especially to those with ocular conditions that poorly tolerate elevations in IOP such as glaucoma and advanced vascular disease (14, 16-18).

The aim of this study was to prospectively evaluate and compare the effects of 2% hydroxypropyl-methylcellulose (HPMC-Ophtal®) and sodium hyaluronate 1% (Ophthalin®) on IOP, corneal thickness, and endothelial cell loss in small incision cataract surgery with posterior chamber lens implant. Our large experience with Ophthalin® has not shown any association of this OVD with severe side effects, hence the decision to consider Ophthalin® as a standard OVD with which HPMC-Ophtal® was compared.

METHODS

A total of 110 patients undergoing routine phacoemulsification and lens implantation by five experienced surgeons were randomly assigned to receive either sodium hyaluronate 1% (Ophthalin®) (Group 1, n=58) or 2% hydroxypropylmethylcellulose (HPMC-Ophtal®) (Group 2, n=52) as OVD. The surgeons did not have access to the randomization procedure of the patients. Masking of the surgeons to the OVD was not possible, as the different properties of the two used OVDs make them easily distinguishable by an experienced surgeon. However, all patients had the same surgical technique, including clear corneal incision and the implant placed in the capsular bag. An attempt was made to use similar amounts of OVD and to completely remove it from the anterior chamber at the end of surgery in both groups. More specifically, on completion of the irrigation/aspiration (I/A) the IOL optic was gently pushed down both centrally and at its periphery by the I/A tip, so as to express and aspirate the OVD

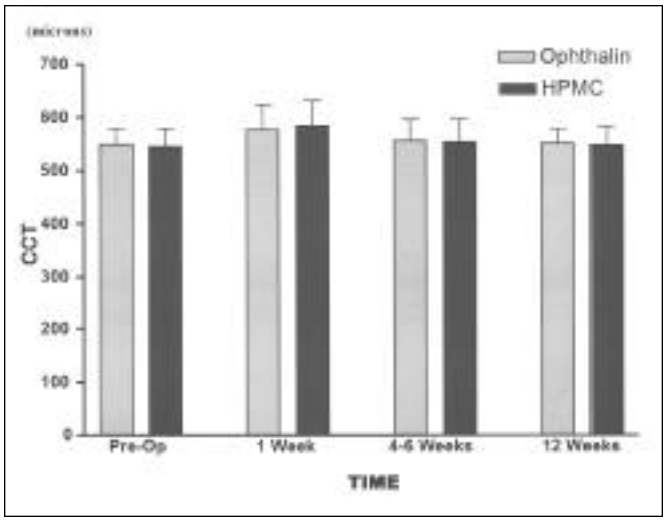

Fig. 1 - *Mean central corneal thickness measurements and standard deviations are shown over time from surgery.*

trapped behind the IOL. All patients were treated postoperatively with drops Betnesol-N® (betamethasone sodium phosphate 0.1% and neomycin sulphate 0.5%) four times per day, but no antiglaucoma drops were used.

We excluded patients with a previous history of ocular surgery, corneal disease, uveitis, ocular hypertension, or glaucoma, and also patients on any ocular medication or systemic steroids. Patients with systemic diseases likely to affect the eye (i.e., diabetes mellitus) were also excluded. Patients with peroperative complications such as capsular tear with or without vitreous loss and postoperative complications such as moderate or severe intraocular inflammation were also excluded from the analysis. Finally, we excluded all patients whose operation was converted from phacoemulsification to extracapsular cataract extraction (ECCE) due to a very hard cataract.

All patients had a complete eye examination preoperatively on the day of surgery including slit lamp examination, IOP measurement with a Goldman applanation tonometer, central corneal thickness (CCT) measurement using ultrasonic pachymetry (Advent, Mentor O&O, Norwell, MA), and central corneal endothelial cell count using the Konan noncontact specular microscope (NonCon Robo-CA, Konan Inc.) in the same sequence. All instruments were calibrated before use and the same equipment was used for all measurements. The mean value of three measurements for the IOP as well as for the corneal thickness were calculated and noted.

Postoperatively, IOP measurements were recorded at 1–4 hours, 24 hours, and 1 week; CCT was measured at 1 week, 4–6 weeks, and 12 weeks, and central corneal endothelial cell density and cell size variation (polymegethism) were examined at 12 weeks.

All measurements, pre- and postoperatively, were made by either of the same two observers, who were masked to the OVD used during surgery.

Data were analyzed using the t-test and the two-way analysis of variance (ANOVA). A value of $p<0.05$ was considered as significant.

RESULTS

Seven patients in the Ophthalin® group (n=58) were excluded from the study. In one patient the IOL haptic was broken during implantation, and had to be exchanged with a new implant. In two patients posterior capsule rupture occurred. One patient had zonule dehiscence and vitreous prolapse. One patient with a very dense cataract had a prolonged operation and developed postoperative uveitis which required slightly increased topical corticosteroid treatment. In two patients the operation was converted to ECCE due to an extremely dense cataract.

In the HPMC-Ophtal® group (n=52), two patients were excluded. One of these patients had posterior capsule rupture and in the other a very hard cataract necessitated conversion of phacoemulsification to ECCE. Phacoemulsification energy values were not noted in all cases. However, since the operations were performed by the same experienced surgeons and the same surgical technique was used, the authors believe that there were not significant differences between the two groups and certainly no bias. Three patients from each group failed to attend some of the postoperative appointments, but all of them were examined at least once either at 6 or at 12 weeks postoperatively. The difference in the number of complications between the two groups was not found to be statistically significant (Fisher's two-tailed test, p=0.18).

Both OVDs showed the anticipated increase in IOP after 1–4 hours. However, there is little difference in pressure rise between the two groups (Tab. I). At 1 day postsurgery a difference in the IOP was observed between the groups, with the mean IOP for the Ophthalin® group reducing significantly quicker than the HPMC-Ophtal® group. However, at 1 week postoperatively the IOP was down to preoperative levels in both groups. IOP higher than 30 mmHg was observed in a few patients of both groups only immediately (at 1–4 hours) postoperatively, but it was found

lower than 30 mmHg in all patients after 24 hours.

To assess the overall significances regarding IOP in relation to OVD and time factors, the data were tested using two-way ANOVA. Overall differences due to OVD were not significant (p=0.07); however, there were significant differences attributable to time (p<0.0001) (Tab. II).

In Figure 1, CCT is shown in relation to time from surgery. The most obvious feature is the increase in corneal thickness 1 week postoperatively, which was found to be highly significant in both the Ophthalin® (p=0.001) and HPMC-Ophtal® groups (p<0.0001). The difference between the two was not significant (p=0.88), a finding replicated at the 4–6 week and 12 weeks examinations, as compared to preoperative values.

TABLE I - PREOPERATIVE AND POSTOPERATIVE INTRAOCULAR PRESSURE (IOP) MEASUREMENTS

	Ophthalin®, IOP			HPMC-Ophtal®, IOP			
Time	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**p Value**
Preoperative	15.7	2.8	58	15.9	3.5	52	—
1–4 hours	23.6	9.5	51	24.0	11.4	50	0.86 (t=0.1781, df=94)
1 day	17.6	4.7	49	21.3	8.3	50	0.007 (t=2.767, df=77)
1 week	13.4	3.5	48	13.9	3.5	47	0.49 (t=0.6943, df=92)

SD = Standard deviation

TABLE II - TWO-WAY ANALYSIS OF VARIANCE (ANOVA) SHOWING THE DIFFERENCES IN INTRAOCULAR PRESSURES (IOP) IN RELATION TO OVD AND TIME FROM SURGERY

Source of variation	**df**	**Sum of squares**	**Mean square**	**F**	**p Value**
OVD	1	144.7	144.7	3.278	0.071
Time	3	5989	1996	45.24	<0.0001
Residual	397	17,520	44.13		

Values are two-way ANOVA of mean IOP; OVD = Ophthalmic viscosurgical devices

TABLE III - TWO-WAY ANALYSIS OF VARIANCE (ANOVA) SHOWING THE DIFFERENCES IN CENTRAL CORNEAL THICKNESS (CCT) IN RELATION TO OVD AND TIME

Source of variation	**df**	**Sum of squares**	**Mean square**	**F**	**p Value**
OVD	1	31.15	31.15	0.022	0.8831
Time	3	71,190	23,730	16.51	<0.0001
Residual	372	534,500	1437		

Values are two-way ANOVA of mean CCT; OVD = Ophthalmic viscosurgical devices

TABLE IV - PREOPERATIVE AND POSTOPERATIVE CORNEAL ENDOTHELIAL CELL DENSITY WITH CELL LOSS

	Ophthalin®				HPMC-Ophtal®				
Time	**Mean**	**SD**	**% Reduction**	**N**	**Mean**	**SD**	**% Reduction**	**N**	**p Value**
Preoperative	2211	350.30	—	58	2247	273.60	—	52	
12 weeks	1951	390.90	11.76	48	2151	334.20	4.27	47	0.009 (t=2.7, df=90)

SD = Standard deviation

Two-way ANOVA (Tab. III) confirms the differences of CCT in relation to time ($p<0.0001$), but shows no significant difference between OVDs.

The most significant observation of the study was regarding corneal endothelium cell density (Tab. IV). From similar preoperative levels, both treatment groups demonstrated a fall in cell density after 12 weeks, but to different degrees. Ophthalin® produced an endothelial cell loss of 11.76%, and HPMC-Ophtal® produced an endothelial cell loss of 4.27%; the difference between the two was highly significant ($p=0.009$).

The coefficient of variation (CV) (cell size) in the central cornea was found to be normal by 12 weeks in both groups.

Changes in surgical techniques have altered the requirements of OVDs (7). In phacoemulsification, performed in a closed system, a prime consideration is to select an ophthalmic viscosurgical device that will better protect the corneal endothelium.

DISCUSSION

Currently available OVDs for cataract surgery can be divided into two broad categories: those exhibiting high zero-shear viscosity and cohesive behavior in surgery, e.g., sodium hyaluronate, and those with lower zero-shear viscosity and dispersive properties, e.g., hydroxypropylmethylcellulose and Viscoat® (7, 8). Cohesive OVDs create and preserve space, but can sometimes leave the anterior chamber too quickly (7, 8). Dispersive OVDs remain in contact with the corneal endothelium during phacoemulsification, but are not as good in maintaining the anterior chamber space and are more difficult to remove at the end of the procedure. This may lead to postoperative IOP elevation (7, 8). Additionally, dispersive OVDs have a greater potential for trapping air bubbles and lens fragments, which may affect visibility during surgery (19). In our study, decreased visibility was not reported by any of the five surgeons.

The postoperative increase in IOP is a well-documented complication of surgery using OVDs (14, 16-18, 20). Increases in postoperative IOP are usually transient, occurring in the first 4–24 hours and typically resolving spontaneously within 72 hours (21-24). In our study, the IOP measured 4 hours after surgery was compared to the preoperative IOP, and it was found increased by 53% in the sodium hyaluronate group and by 49% in the HPMC-Ophtal® group. There was no significant difference between the two groups. However, at 24 hours postoperatively, there was a statistically significant difference between the IOP response in the two groups, with the IOP in the HPMC-Ophtal® remaining 29% higher compared to 9% higher in the sodium hyaluronate group. At 1 week postoperatively, the IOP had returned to preoperative levels in both groups. The difference in IOP at 24 hours could probably be explained by differences in the ease of removal of the OVDs from the anterior chamber. Berson and coworkers demonstrated significant (65%) decrease in outflow facility when sodium hyaluronate was left in the anterior chamber of enucleated eyes (25). The mechanism of postoperative increase in IOP is believed to be a mechanical obstruction of the trabecular meshwork resulting in a temporarily decreased outflow facility (13, 21, 25). Assia and colleagues studied the ease and rate of removal of OVDs in the postmortem eye using an automated irrigation/aspiration (I/A) device (26). Sodium hyaluronate was completely removed in 20 seconds. However, 3 to 3? minutes were needed for the complete removal of other agents, including hydroxypropylmethylcellulose, and this necessitated special maneuvers with the I/A cannula that would probably be too risky in non-experimental surgery (26). Due to the risk of a postoperative increase of IOP, an attempt at the end of surgery for as complete aspiration of the OVD as possible is advocated. The OVD trapped at the retrolental space should be removed during I/A, otherwise it can later dissipate into the anterior chamber and cause high IOP. The surgeon can tilt the IOL optic with the I/A tip and directly aspirate the trapped OVD, or express it by gently pressing with the I/A tip the center and the sides of the IOL optic posteriorly against the posterior capsule. Additionally, higher flow I/A could be used to aspirate dispersive OVDs, as their removal has been shown to be more difficult (7, 8, 26).

We found, at 1 week postoperatively, a comparable increase in CCT of 5% in the sodium hyaluronate group and 7% in the HPMC-Ophtal® group. Six weeks later, CCT had returned to preoperative levels. Davis and Lindstrom reported a significant increase of CCT in the first postoperative day in patients who had 1.6% sodium hyaluronate, 2% hydroxypropylmethylcellulose, or 4% chondroitin sulphate–3% sodium hyaluronate, but there was no difference in the percentage of CCT increase among the three groups (27). Kiss et al found that 3 months postoperatively the CCT returns to preoperative values (8). Most investigators have not found any difference in the effect of vari-

ous OVDs on CCT in the long term (27-30).

For an OVD to protect the endothelium it must be able to coat the endothelial cells and to remain in the anterior chamber during the operation. The ability of an OVD to coat the endothelium is independent of its viscosity or ability to maintain the anterior chamber, but is higher when its surface tension is low (7). Hammer and Burch demonstrated that a thin coating with a high viscosity substance was inadequate in preventing endothelial damage from compression and shear forces during surgery, while a thick layer of a high viscosity substance such as sodium hyaluronate was effective (9). It has been demonstrated that hydroxypropylmethylcellulose is retained in the anterior chamber more commonly than sodium hyaluronate in phacoemulsification (10, 19).

There is no agreement among investigators on the effect of various OVDs on the endothelial cell count. Glasser and coauthors found Viscoat® and Ocucoat® (2% hydroxypropylmethylcellulose) to cause less cell loss than Healon during phacoemulsification (10). Lane and coworkers found that Healon®, Viscoat®, and Ocucoat®, used in extracapsular cataract surgery, caused similar cell loss (31), while Kiss et al reported no difference between Ocucoat® and Viscoat® used in phacoemulsification (8). Dua and colleagues, using an experimental model, concluded that 2% hydroxypropylmethylcellulose is superior to sodium hyaluronate in protecting the endothelium from damage during I/A (32). In our study, 12 weeks postoperatively, the central corneal endothelial cell loss was 11.76% in the sodium hyaluronate group and 4.27% in the HPMC-Ophtal® group, the difference being highly significant (p=0.009).

Holzer and coauthors found that, when complete removal of OVD was attempted at the end of surgery, dispersive OVDs like hydroxypropylmethylcellulose and Viscoat were associated with a significantly higher endothelial cell loss than the cohesive OVDs like sodium hyaluronate (33). Hence, for dispersive OVDs that are known to be more difficult to remove from the anterior chamber, an attempt should be made to remove them as completely as possible, but prolonged removal time should be avoided as it can itself cause endothelial cell damage and further cell loss (34). Zetterstrom and Laurell demonstrated a mean central endothelial cell loss of 4% in phacoemulsification with sodium hyaluronate, and the change in cell density did not correlate with the total phacoemulsification energy used (29). In another study, no correlation was found between central corneal endothelial cell loss and CCT postoperatively, provided that the cell density remained within a physiologic limit, and the mean cell loss was found to be 16% (30).

The study design was limited in that only the central endothelial cells were examined. Cellular loss during cataract surgery is greatest in the superior part of the cornea (2, 35). Central corneal endothelial cells migrate and enlarge, but the maximum response concerning cell density and size is delayed until 12 weeks after surgery (35). Postoperative cell density does not completely reflect the endothelial cell damage or function; analysis of endothelial cell size and shape is a more sensitive indicator of the above (36).

Matsuda and coworkers found a rapid decrease in central endothelial cell density and disruption of normal morphology after intracapsular cataract extraction without implant in the first month (37). They noted a gradual recovery of the frequency of the hexagonal cells over 1 to 6 months postoperatively, and eventually cellular morphology returned to normal (37).

The CV is a non-dimensional index that can provide a good quantitative measurement of cell size variation (polymegethism) (38). In our study, there was no statistical difference between the preoperative and 3-month postoperative levels of CV of mean endothelial cell area in the central endothelium between the two groups.

The nature of the study did not allow for masking of the surgeons to the OVD. Although every attempt was made to standardize the procedure and to use similar amounts of OVDs in each patient, surgeons' personal preferences may have introduced bias. Additionally, we had to exclude from the outcome analysis those patients who had complications, as these complications could have a direct effect on the IOP, CCT, and central corneal endothelial cell count. This may have introduced bias.

In conclusion, our study showed that HPMC-Ophtal®, when used during phacoemulsification, was associated with lower endothelial cell loss than sodium hyaluronate. Both these OVDs caused similar transient increase in CCT. However, in the first postoperative day, HPMC-Ophtal® was associated with more significant increase in IOP when compared to sodium hyaluronate. HPMC-Ophtal® may be used in routine small incision cataract surgery with implant as an effective alternative to sodium hyaluronate, but should probably be avoided in patients with advanced glaucoma or diseases that predispose to retinal vascular occlusions or anterior ischemic optic neuropathy. Due to its dispersive property a thorough, though

not excessive, removal is recommended. New improved ophthalmic viscosurgical devices are needed and the search for the ideal OVD is ongoing.

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