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To Compare The Effect Of Cohesive And Dispersive Viscoelastic Substances In Protecting The Corneal Endothelium During In-The-Bag Phacoemulsification With Implantation Of A Foldable Lens

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Abstract
Purpose*: To compare the effect of cohesive and dispersive viscoelastic substances in protecting the corneal endothelium during in-the-bag phacoemulsification with implantation of a foldable lens. These effects were measured in terms of: endothelial cell count, Hexagonality frequency , The central corneal thickness.*
Design*: Hospital based randomized interventional study*
Method*: Study was conducted on 60 patients (30 patients in group A and 30 patients in group B) who underwent phacoemulsification with IOL implantation. Group A- Patients who underwent phacoemulsification and IOL implantation using cohesive viscoelastic. (30 eyes of 30 patients) ,Group B- Patients who underwent phacoemulsification and IOL implantation using dispersive viscoelastic. (30 eyes of 30 patients). These effects were measured in terms of: endothelial cell count, Hexagonality frequency , The central corneal thickness*
Result*: We assessed the endothelial cell count, post-operatively at intervals of 1 month and 3 months and noted that, In Group A, the mean endothelial cell count dropped to 2135.97 ± 222.6/mm2 at 1 month and 2077 ± 228/mm2 at 3 months.(P<0.001)*
In Group B, the mean endothelial cell count dropped to 2393.17±279.75/mm2 at 1 month and 2332 ± 281.4/mm2 at 3 months.(P<0.001) still the mean endothelial cell loss was significantly higher in group A as compared to group B at each follow up. (P<0.001)
Postoperatively, the mean CCT in group A increased to 528.9 ± 8.97 microns at 1 month and then reduced to 515 ± 11 microns at 3 months postoperatively. Similarly, in group B the mean CCT increased to 517.87 ± 9.44 microns at 1 month and then reduced to 511.3 ± 9.05 at 3 months postoperatively
The difference in the mean CCT between the groups was not significant preoperatively as well as at 3 months postoperatively. (P=0.12)
Conclusion*: At the end of 3 months we found that the mean endothelial cell loss was more in group A than group B suggesting that the dispersive viscoelastics have a role in protecting the corneal endothelium during cataract surgery in comparison to cohesive viscoelastics. Though the mean central corneal thickness and hexagonality did not alter much and the values shift towards the preoperative status at the end of 3 months, and the difference was not statistically significant at the end of 3 months.*
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Keywords: *cohesive viscoelastics, dispersive viscoelastics, post-operative corneal edema*

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I. Introduction

The development of new surgical phaco techniques is aimed at restoring visual acuity (VA) in order to secure a fast return to normal social life and work. However, postoperative VA can still be seriously compromised by transient or permanent corneal oedema caused by a decrease in endothelial pump function. Corneal endothelial cell loss has been documented as one of the complications of phacoemulsification surgery. However, the incidence of variable degree of endothelial decompensation in patients after cataract surgery remains around 17%.4 To decrease postoperative endothelial cell loss, different ocular viscoelastic devices (OVDs) have been proposed to facilitate: surgical manoeuvres, maintain space during surgery, protect the endothelial cells. The introduction of viscoelastic agents (now termed ophthalmic viscosurgical devices (OVD) by the International Standards Organization (ISO) for uses in ophthalmic intraocular procedures had a significant impact on the practice of ophthalmology. OVD possess a unique set of properties, based on their chemical structure, that enable them to protect the corneal endothelium from mechanical trauma and to maintain an intraocular space, even in the face of an open incision. Maintenance of corneal transparency is an important

aspect of successful cataract surgery. In this context evaluation of corneal endothelial cell function after cataract surgery assumes great significance

II. Aims And Objectives

To compare the effect of cohesive and dispersive viscoelastic substances in protecting the corneal endothelium during in-the-bag phacoemulsification with implantation of a foldable lens. These effects were measured in terms of:

1. Endothelial cell loss, based on endothelial cell count
2. Hexagonality frequency (the frequency of hexagonal cells)
3. The central corneal thickness

III. Materials And Methods

Setting/Tertiary care: Upgraded Department of Ophthalmology, SMS Medical College & Hospitals, Jaipur.
Study design: Hospital based randomized interventional study
Study Duration: 1 Year
Sample size- Study was conducted on 60 patients (30 patients in group A and 30 patients in group B) who underwent phacoemulsification with IOL implantation. After explaining the study, surgical procedures and possible complications, an informed consent was obtained and patients were assigned into two groups.
Group A- Patients who underwent phacoemulsification and IOL implantation using cohesive viscoelastic. (30 eyes of 30 patients)
Group B- Patients who underwent phacoemulsification and IOL implantation using dispersive viscoelastic. (30 eyes of 30 patients)

IV. Eligibility Criteria

-INCLUSION CRITERIA

1. All patients undergoing cataract surgery during study period,
2. Age greater than 40 years, 3. Pre operative endothelial cell count > 1500/mm2 cells.

-EXCLUSION CRITERIA

- Traumas or previous intraocular surgery,
- Preoperative pupil dilatation < 4 mm,
- Age less than 40 years,
- Surgical complications.
- All patient not giving consent to participate in the study

Those who are not able to come on follow up.

V. Methodology

PRE OP EVALUATION

Ophthalmic evaluation:

- UCVA (Uncorrected Visual Acuity) and BCVA (Best Corrected Visual Acuity)
- Intraocular pressure (Applanation Tonometry)
- Slit lamp examination
- Fundus examination (indirect ophthalmoscopy)
- Keratometry, A scan and IOL Power calculation.
- Specular microscopy study with Topcon SP-3000 P specular microscope

1. Endothelial cell count per mm2
2. Central corneal thickness in microns
3. Hexagonality

PREOPERATIVE INVESTIGATIONS:

- Blood sugar (Fasting or Random)
- Urine complete
- ECG
- Blood pressure

PREOPERATIVE MEDICATION

- Ciprofloxacin eye drops 2 hourly one day prior to surgery in the eye to be operated
- Tab. Ciprofloxacin 500mg B.D. for 5 days

VI. Surgical Technique

• All surgeries were performed by the same surgeon under topical anaesthesia using proparacaine 0.5% eye drops after pupillary dilation with tropicamide 0.8% and phenylephrine 5% eye drop.
• A single 0.9mm side port was created according to the main port site.
• After injecting dye Anterior Chamber (AC) was formed with ophthalmic viscoelastic device (OVD).
• Main biplanar clear corneal incision was created temporally using a 2.8mm keratome.
• A continuous curvilinear capsulorrhexis was performed using a capsulorrhexis forceps.
• After hydrodissection/ hydrodelineation, phacoemulsification (divide and conquer) was performed using Alcon Laureate with kelman-type microtip (30 degree) and for the pulse mode program (vacuum 360mmHg; max 60% US power; bottle height 135cms). Cortical matter was removed with irrigation/aspiration (I/A) ultrasleeve tip.
• After filling the AC with OVD, foldable IOL with the recommended injector system was implanted into the eye. Finally OVD was removed with the I/A tip and the stromal wound was hydrated.

POSTOPERATIVE MEDICATION

Tobramycin 0.3% + Dexamethasone 0.1% eye drops 2 hourly for 6 weeks in tapering doses.

FOLLOW UP

The follow up examination was conducted 1 day, 1 week, 1 month and 3 months postoperatively with specular microscopy done at 1st and 3rd month postoperatively.

These effects were measured in terms of:
1. Endothelial cell loss, based on endothelial cell count
2. Hexagonality frequency (the frequency of hexagonal cells)
3. The central corneal thickness.

VII. Observations And Results

-STASTICAL ANALYSIS

Tests for difference among groups in demographic and clinical characteristics were carried out using chi-square tests for categorical variables and student T test tables for continuous variables. Normality of the data was checked by use of the Kolmogorov–Smirnov tests. Similar p-values were obtained using non-parametric tests.(data not shown). To evaluate whether there was a statistically significant difference withingroup, repeated measurements were evaluated by using paired t test was used. Probability was considered to be significant if less than 0.05.

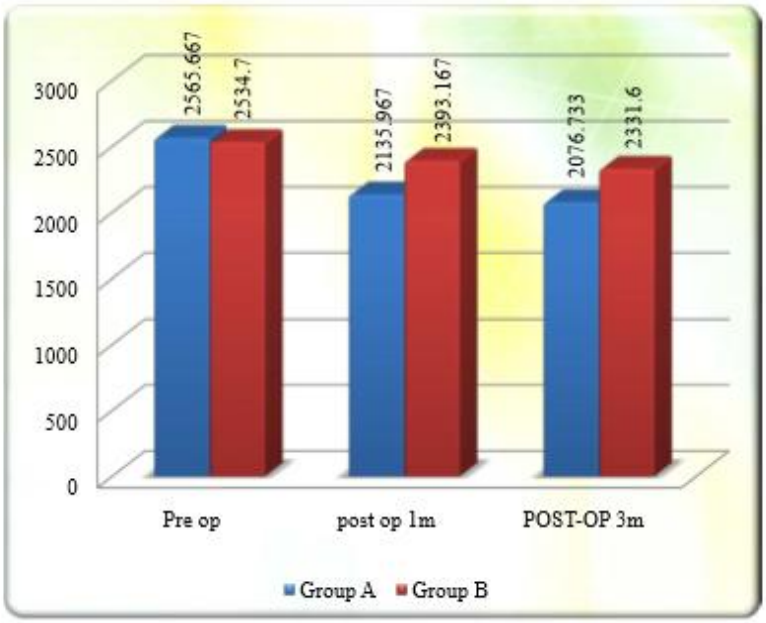
			Pre op			POST-OP 1MONTH			POST-OP 3 MONTH		
		Age	Cell Density (per sq.mm)	C.C.T (μm)	Hexagonality %	Cell Density (per sq.mm)	C.C.T (μm)	Hexagonality %	Cell Density (per sq.mm)	C.C.T (μm)	Hexagonality %
Most Extreme Differences	Absolute	.132	.143	.198	.247	.454	.491	.316	.489	.229	.178
	Positive	.132	.040	.057	.036	.454	0.000	.034	.489	0.000	.071
	Negative	-.121	-.143	-.198	-.247	0.000	-.491	-.316	0.000	-.229	-.178
Kolmogorov-Smirnov Z		.508	.547	.759	.949	1.743	1.885	1.214	1.876	.878	.684
Asymp. Sig. (2-tailed)		.959	.925	.612	.329	.005	.002	.105	.002	.423	.737

Table 11: Comparative analysis of CELL DENSITY (per sq.mm)

during follow up period

Group		Pre Op	Post Op 1m	POST-Op 3m
Group A	N	30	30	30
	Mean	2565.667	2135.967	2076.733
	Std. Deviation	271.1938	222.5964	228.0558
Group B	N	30	30	30
	Mean	2534.700	2393.167	2331.600
	Std. Deviation	277.5501	279.7554	281.4010
Total	N	60	60	60
	Mean	2550.183	2264.567	2204.167
	Std. Deviation	272.5028	282.2078	284.6061
		0.664NS	<0.001S	<0.001S

This table shows the Comparative analysis of CELL DENSITY (per sq.mm) follow up period. No significant difference was observed among the groups at pre-op findings. Significant difference was found at 1 month and 3 months of follow up period, as the mean CELL DENSITY (per sq.mm) was significantly lower in group A as compared to group B.

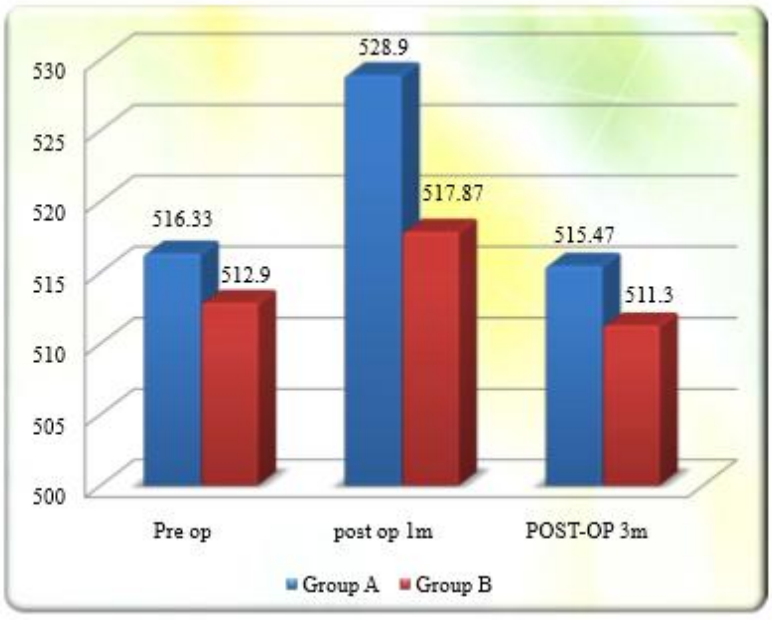


Graph 1: Comparative analysis of CELL DENSITY (per sq.mm) during follow up period

Table 2: Comparative analysis of C.C.T (µm) during follow up period

Group		Pre Op	Post Op 1m	Post-Op 3m
Group A	N	30	30	30
	Mean	516.33	528.90	515.47
	Std. Deviation	12.25	8.98	11.30
Group B	N	30	30	30
	Mean	512.90	517.87	511.30
	Std. Deviation	11.26	9.45	9.05
		0.26NS	<0.001S	0.12NS

This table shows the Comparative analysis of C.C.T (µm) during follow up period and no significant difference was observed among the groups at preop findings, at 1 month and 3 months of the follow up period.

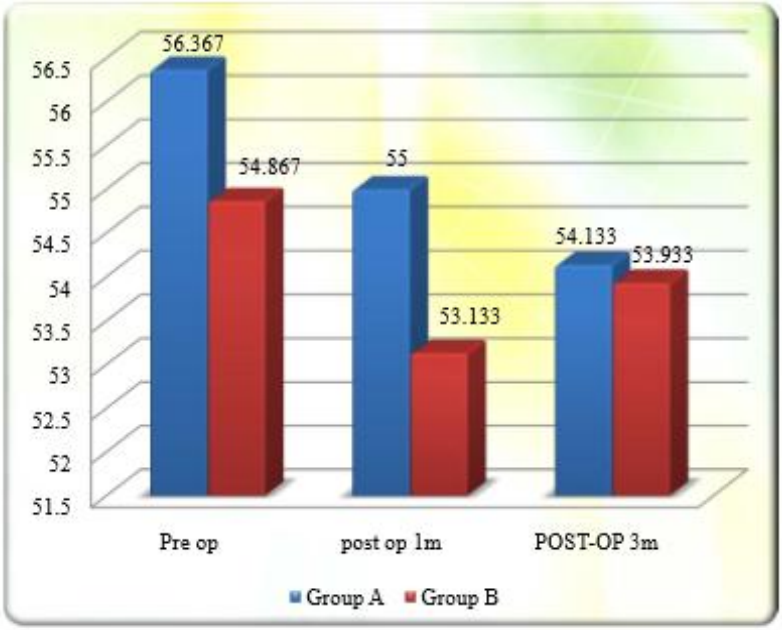


Graph 2: Comparative analysis of C.C.T(µm) during follow up period

Table 3: Comparative analysis of HEXAGONALITY% during follow up period

Group		Pre Op	Post Op 1m	Post-Op 3m
Group A	N	30	30	30
	Mean	56.367	55.000	54.133
	SD	3.5084	3.2163	3.1484
Group B	N	30	30	30
	Mean	54.867	53.133	53.933
	SD	4.0491	3.6268	3.7502
Total	N	60	60	60
	Mean	55.617	54.067	54.033
	SD	3.8316	3.5265	3.4345
		0.13NS	0.39NS	0.82NS

This table shows the Comparative analysis of HEXAGONALITY% during follow up period and no significant difference was observed among the groups at pre-op findings. No significant difference was observed in the mean HEXAGONALITY% among the groups at 1month and 3 month of the follow up period.



Graph 3: Comparative analysis of HEXAGONALITY% during follow up period

VIII. Discussion

60 eyes of 60 patients were evaluated in our study with the aim to study and assess the corneal endothelial cell density, central corneal thickness and hexagonality in patients undergoing phacoemulsification and IOL implantation with cohesive viscoelastics (Group A-30) and with dispersive viscoelastics (Group B-30).

Our study reports postoperative status of the corneal endothelium after cataract surgery and compares the status of the 2 groups. In our study, the mean age in group A was 62.20 ± 7.13 years and in group B was 62.45 ± 5.78 years. The difference was not statistically significant.(P value is 0.424). No significant difference was observed in gender. Thus, we did not observe any difference in both the groups. The mean Endothelial Cell Counts (ECC) in group A, preoperatively was 2565.67 ± 271.194/mm2 and in group B was 2534.7 ± 277.55/mm2.(P=0.664). Thus, there was no difference in endothelial cell count pre-operatively. We assessed the endothelial cell count, post-operatively at intervals of 1 month and 3 months and noted that, In Group A, the mean endothelial cell count dropped to 2135.97 ± 222.6/mm2 at 1 month and 2077 ± 228/mm2 at 3 months.(P<0.001)

In Group B, the mean endothelial cell count dropped to 2393.17±279.75/mm2 at 1 month and 2332 ± 281.4/mm2 at 3 months.(P<0.001) It was observed that pre-operatively there was no significant difference in the endothelial cell counts between the two groups, still the mean endothelial cell loss was significantly higher in group A as compared to group B at each follow up. (P<0.001)

IX. Summary And Conclusion

Our study entitled The effect of viscoelastic substances in protecting corneal endothelial cell population during cataract surgery: a prospective study of cohesive and dispersive viscoelastics was conducted in the upgraded Department of Ophthalmology, S.M.S. Medical College, Jaipur. This study included a total of 60 patients: 30 patients in group A and 30 patients in group B. Group A- 30 patients who underwent phacoemulsification and IOL implantation with cohesive viscoelastics. Group B- 30 patients who underwent phacoemulsification and IOL implantation with dispersive viscoelastics. Phacoemulsification was done by a single surgeon. No difference was observed in the pre-operative and intra-operative parameters. We assessed corneal endothelial cell count, central corneal thickness, and hexagonality. Follow up was done at 1st postoperative day, 1 week, 1 month and 3 months with specular microscopy done at 1 month and 3 months. At the end of 3 months we found that the mean endothelial cell loss was more in group A than group B suggesting that the dispersive viscoelastics have a role in protecting the corneal endothelium during cataract surgery in comparison to cohesive viscoelastics.

Though the mean central corneal thickness and hexagonality did not alter much and the values shift towards the preoperative status at the end of 3 months, and the difference was not statistically significant at the end of 3 months. Despite no corneal abnormalities before surgery, the endothelium is vulnerable to surgical trauma and these findings should be considered when planning cataract surgery.

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