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Original Article

Ophthalmology Section

To Compare the Changes in the Corneal Endothelium Post Phacoemulsification Surgery with Balanced Salt Solution vs. Viscoelastic Device

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ABSTRACT

Introduction: The corneal endothelial layer cannot regenerate. During phacoemulsification, it is exposed to damage. It is necessary to determine the causes of endothelial damage and replace them with less damaging alternatives.

Aim: To compare the endothelial cell density and morphology in patients undergoing phacoemulsification with and without the use of viscoelastic device.

Materials and Methods: This was a hospital based prospective interventional study. Fifty patients with cataract were included, who underwent cataract extraction by phacoemulsification. Among 25 patients viscoelastic device (Group I) was used. In the other 25 (Group II) the Anterior Chamber (AC) was maintained using continuous infusion of Balanced Salt Solution (BSS). Specular microscopy was done preoperatively and on 14th postoperative day. Student's paired and Unpaired t-test was done. SPSS 24.0 version was the software used and $p<0.05$ was considered as level of significance.

Results: The endothelial cell density reduced from 2346.16±237.04 cells/mm^2 to 2327.88±234.93 cells/mm^2 in Group I and from 2347.96±215.55 cells/mm^2 to 2320.28±220.82 cells/mm^2 in Group II on 14th postoperative day. The percentage of hexagonal cells reduced by 8.33% in Group I and 8.37% in Group II on the 14th postoperative day.

Conclusion: Implantation of IOL using BSS infusion seems to be a faster alternative to use of viscoelastic device in experienced hands without higher endothelial cell loss rates since there was no significant difference in corneal density or morphology between the two groups on the 14th postoperative day.

Keywords: Anterior chamber maintainer, Endothelial cell density, Endothelial morphology, Specular microscopy

INTRODUCTION

The loss of corneal endothelial cells is compensated for by the enlargement and migration of surrounding cells. This, in turn, leads to loss of the normal morphology of the cells [1]. The dysfunctional endothelial pump mechanism causes increased stromal hydration, results of which are an increased corneal thickness and decreased corneal transparency [2]. Ophthalmic viscoelastic devices are used to maintain the anterior chamber and also to coat the ocular structures during cataract surgery [3]. Some ocular viscoelastic devices have caused corneal endothelial cell loss by increased thermal damage [4]. If the viscoelastic device is not washed properly from the anterior chamber, it could cause an inflammatory response accompanied by a raised intraocular pressure. This could have a depletory effect on the corneal endothelial cells [5]. Furthermore, it is not easy to completely remove the viscoelastic device from certain areas such as the ciliary sulcus and from behind the IOL which in the worst case scenario causes capsular distension syndrome. The removal of viscoelastic device increases the overall operation time. If one does manage to remove all the viscoelastic devices, the overall operation time increases which can also adversely affect the corneal endothelial health [6]. Anterior Chamber Maintainer (ACM) prevents the collapse of the anterior chamber during cataract surgery and thus reduces endothelial cell loss [7]. Both balanced salt solution and air can be used to maintain the anterior chamber during intraocular lens implantation, but both of them can also escape easily resulting in the collapse of the anterior chamber [8]. The corneal endothelial cell count and morphology are parameters for assessing the health of the corneal tissue [9,10].

In 2005, Chang DF and Campbell JR, suggested that excessive injection of OVD forms a risk factor for floppy iris syndrome [11]. Bianchi GR, described a method of phacoemulsification without the use of viscoelastic. They concluded that the endothelial cell count must be evaluated pre and postoperatively [12].

Thus the present study aimed to compare the effect of phacoemulsification with the use of BSS via anterior chamber maintainer vs. the use of ocular viscoelastic device, on the corneal endothelium.

MATERIALS AND METHODS

This was a hospital based prospective interventional study conducted over a period of 6 months (March 2019 to August 2019) and was conducted in the Department of Ophthalmology at Acharya Vinobha Bhave Rural Hospital, Sawangi, Wardha, Maharashtra.

This study was approved by the Institutional Ethics Committee of the University (Ref. DMIMS (DU)/IEC/01/7892) and was carried out in accordance with the declaration of Helsinki. 25 patients were in Group I (ocular viscoelastic device used) and 25 patients were in Group II (balanced salt solution via anterior chamber maintainer used).

All patients with cataract, attending the Ophthalmology Outpatient Department at Acharya Vinobha Bhave Rural Hospital were selected for the study after taking the inclusion and exclusion criteria into consideration.

Inclusion criteria: Patients presenting with cataract (Nuclear sclerosis grade II) during the study period; Age-50-70 years.

Exclusion criteria: Patients having other pre-existing corneal conditions (dystrophies, degenerations, scars) that might independently decompensate corneal endothelium. Patients with inflammatory diseases such as iritis. Patients with any retinal pathology (exudative age-related macular degeneration, proliferative diabetic vitreoretinopathy, retinal ischemic diseases). Patients with

glaucoma (open angle, secondary). Patients with floppy iris syndrome and patients on Tamsulosine.

Samplling Procedure

Patients who fulfilled the inclusion criteria and were not eliminated under the exclusion criteria were admitted to the Ophthalmology ward. After explaining the details of the study, written informed consent was taken from them. A single experiences surgeon performed all the surgeries.

Data collection tools and process: The patients age, sex and ocular history were noted. Visual acuity pre and post surgery as well as post operative complications, if any, were documented.

Surgical Procedure

Preoperative: Written consent was taken from the patients willing for and fit for cataract extraction. Endothelial cell density and the % of hexagonal endothelial cells was measured at the central cornea using a noncontact specular microscope at a resolution of 640×480 pixels (TOPCON SP 1P08). All measurements were done by one person at a single clinical site.

Steps of surgery: The eye was fully dilated using E/D Tropicamide 0.8% + Phenylephrine 5%. Topical anaesthesia was given using E/D Proparacaine 5%. The eye speculum was then placed. Two clear corneal incisions of 1.1 mm were made with 15-degree lance tip near to the limbus. Two incisions were made- at 2'o'clock and at 10'o'clock. An anterior chamber maintainer of 1.1 mm diameter connected to a balanced salt solution bottle (80-95 cm above the patients head level) was introduced though the 2'o'clock incision and the irrigation was turned on in order to maintain a deep anterior chamber. The anterior chamber maintainer fit in the 2'o'clock incision such that there was no leakage.

In 25 patients (Group I) capsulorhexis was performed using viscoelastic device (OVD) to maintain a stable and safe space to work while in 25 (Group II) patients BSS circulation in the anterior chamber by means of the irrigation cannula which produced a positive pressure, was used for the same.

A 2.8 mm keratome was used to make a clear corneal incision at 12 'o'clock. After that, hydrodissection was performed with hydro cannula until a complete rotation of the nucleus was observed Then, phacoemulsification, aspiration and mass extractions were performed. Only foldable One-piece Intraocular Lens (IOLs) model with injector was used. Balanced salt solution flowed out of the anterior chamber when the intraocular lens cartridge was introduced though the incision. This resulted in a momentary shallowing of the anterior chamber. As the IOL injection began, the leakage stopped. The anterior chamber depth was maintained and the positive pressure expanded the capsule. As the IOL unfolded, a cannula was used to fix it in place. Corneal hydration was done followed by placing an eye pad and bandaging the eye.

Postoperative: The pad and bandage were opened the next day and vision was assessed using Snellen's chart. Port operatively the following medications were prescribed- T. Ciprofloxacin 500 mg BD for 3 days, T. Ibuprofen 400 mg BD for 3 days, T Ranitidine 150 mg BD for 3 days, E/D Moxifloxacin 0.5 % + E/D Dexamethasone 0.1% 1 hourly for 2 weeks followed by QID for 2 months and E/D Homatropine 2% BD for 1 week. Patients were followed-up on 14th postoperative day for assessment of corneal endothelium using specular microscopy.

STATISTICAL ANALYSIS

Statistical analysis was done by using descriptive and inferential statistics using Student's paired and Unpaired t-test and software used in the analysis was SPSS 24.0 version and $p<0.05$ was considered as level of significance.

RESULTS

Overall mean phacoemulsification time, phacoemulsification energy, phacoemulsification suction time was similar in all the patients and all surgeries were conducted by a single surgeon. Mean surgical time and irrigation-aspiration suction time were marginally similar in both the groups [Table/Fig-1].

Parameters	Group I	Group II	p-value
Mean surgical time (minutes)	10.2±1.4	11±1.6	0.001
Mean phacoemulsification time (seconds)	47.0±17.3	47.3±13.0	0.576
Phacoemulsification energy (Joules)	146±114.4	151.4±83.2	0.220
Phacoemulsification suction time (seconds)	53.1±20.5	53.3±15.1	0.480
Irrigation-aspiration suction time (seconds)	40.3±17.7	46.3±15.6	0.001

[Table/Fig-1]: Surgical parameters of Group I and Group II.

Out of the 25 patients in Group I 15 (60%) were male and 10 (40%) were female. Out of the 25 patients in Group II 13 (52%) were male and 12 (48%) were females. The mean age of the patients was 61.35±1.23 years. There were no intraoperative or postoperative complications.

The preoperative and 14th day postoperative corneal endothelial cell count is depicted in [Table/Fig-2]. Both the groups showed a significant decrease in corneal endothelial cell count (p-value=0.001). The difference between the mean decrease in corneal endothelial cell count of the two groups was not significant (p-value=0.10) [Table/Fig-3].

		Mean	N	Std. deviation	Std. error mean	Mean difference	t-value
VISCO (Group I)	Pre-op	2346.16	25	237.04	47.40	18.28±19.85	4.60 p=0.001,S
	Post-op	2327.88	25	234.93	46.98		
AC maintainer (Group II)	Pre-op	2347.96	25	215.55	43.11	27.68±20.09	6.80 p=0.001,S
	Post-op	2320.28	25	220.82	44.16		

[Table/Fig-2]: Comparison of Cell count in VISCO and AC Maintainer group at pre and post test.
Student's Paired t-test

	N	Mean	Std. deviation	Std. error mean	t-value
VISCO (Group I)	25	18.28	19.85	3.97	1.66 p=0.10,NS
AC maintainer (Group II)	25	27.68	20.09	4.01	

[Table/Fig-3]: Comparison of mean difference in Cell count in VISCO and AC Maintainer groups.
Student's Unpaired t-test

The preoperative and 14th day postoperative hexagonality of the corneal endothelial cells showed a significant decrease in percentage of hexagonal cells (p-value- 0.001) [Table/Fig-4].

		Mean	N	Std. deviation	Std. error mean	Mean difference	t-value
VISCO (Group I)	Pre t/t	57.08	25	6.36	1.27	4.76±1.09	21.81 p=0.001,S
	Post t/t	52.32	25	5.68	1.13		
AC maintainer (Group II)	Pre t/t	53.52	25	6.21	1.24	4.48±0.87	25.69 p=0.001,S
	Post t/t	49.04	25	5.87	1.17		

[Table/Fig-4]: Comparison of Hexagonality in VISCO and AC Maintainer group at pre and post test.
Student's Paired t-test

The difference between the mean decrease in percentage of hexagonal cells of the corneal endothelium of the two groups was not significant (p-value=0.32) [Table/Fig-5].

DISCUSSION

As compared to preoperative values, Group I and Group II showed a significant decrease in corneal endothelial cell count and

	N	Mean	Std. deviation	Std. error mean	t-value
VISCO group (Group I)	25	4.76	1.09	0.21	1.00 p=0.32,NS
AC maintainer group (Group II)	25	4.48	0.87	0.17	

[Table/Fig-5]: Comparison of mean difference in Hexagonality in VISCO and AC Maintainer groups.
Student's Unpaired t-test

percentage of hexagonal cells postoperatively (p=0.001). There was no significant difference between the two groups in terms of the decrease in cell count and percentage of hexagonal cells caused postoperatively (p-value=0.01).

Erden Y et al., in their study concluded that although the postoperative differences in CECs were similar in the visco as well as the BSS study groups, the surgical time was significantly shorter in the BSS Group. This would result in the added advantage of shorter surgical time and the possibility of performing a greater number of operations and thus a more cost-effective use of the operating room [13]. The difference in surgical time could be due to the fact that in their study all grades of cataract were included. In our study only cataracts with Grade II nuclear sclerosis were used to maintain uniformity.

Oksuz H et al., described a technique to perform capsulorhexis without viscoelastic, but IOL implantation was done with the use of viscoelastic and they concluded that this was an easy, safe and cheap alternative to using Viscoelastic. They achieved a complete capsulorhexis. They compared the IOP pre and postoperatively (day 1) and found a significant increase (p-value <0.05). The IOP reduced to preoperative levels by one week [14].

Studeny P et al. reported a 1 month and 6 month post-operative reduction in endothelial cell density of 9.76%±13.5%, 10.7%±12.6%, respectively in the OVD group and 9.07%±12.7%, 9.13%±13.7%, respectively in the hydroimplantation group. The difference between the two were insignificant [15]. This was similar to the findings seen in the present study which also showed no significant difference between the two groups.

Techniques of using viscoelastic only during continuous curvilinear capsulorhexis or only during IOL implantation have been described. In the index study, the corneal endothelium of the patients in Group II was not exposed to visco throughout the procedure as both continuous curvilinear capsulorhexis and IOL implantation were performed with continuous infusion of BSS via AC maintainer.

The corneal endothelial cell density and the percentage of hexagonal cells are indices to assess the quantity and quality of the corneal endothelium respectively, which is why we have chosen to study these two parameters.

The present authors have included only patients with Grade II nuclear sclerosis in the present study to ensure uniformity, so that the grade of cataract does not influence the surgical time and energy used which in turn might influence the endothelial cell count and hexagonality.

Minor complications like mild corneal epithelial oedema and mild aqueous flare can interfere with the assessment of the corneal endothelium. The cornea was assessed on the 14th postoperative day so that in case these minor complications occurred postoperatively, they would settle by the 14th postoperative day. Furthermore, the present authors did not want other confounding factors (such as age related loss of corneal endothelial cells) to influence our results, which is why we have chosen a single and shorter follow-up date.

The study by Lee HY et al., had similar results to this study, but they compared the high viscosity OVD Amvisc Plus™ (Bausch & Lomb Incorporated, Bridgewater, NJ, USA) with BSS during hydrophilic acrylic IOL implantation and found a decrease of ~3% after 3 months without significant differences between both groups [16].

Milla E et al. reported the difference between phacoemulsification with and without AC infusion. The anterior chamber was maintained during phacoemulsification using the continuous irrigation option through the phaco probe. OVD was used in both groups and it was found that the endothelial cell density was significantly reduced on day 7 in the continuous infusion group. By day 30 there was no statistically significant difference between the two groups. In the present study, authors found no statistically significant difference on day 14 in endothelial cell loss [17].

Nayak BK and Jain EK, found no statistically significant difference in the corneal endothelial cell loss between the ACM without OVD's (7.38%) and the OVD (7.47%) group measured one month post-surgery. This was similar to the findings of the index study [18].

In a study conducted by Wang H et al., it was found that at 1 week, 1 month, and 6 months after surgery, the percentage of corneal endothelial cell loss of the group with no viscoelastic device was significantly lower than that of conventional viscoelastic device group and at each postoperative time point, the corneal endothelial hexagonal cell density was significantly greater in the former than the later. In their study, they used Viscoelastic in both groups during the continuous curvilinear capsulorhexis step and IOL implantation was done by a viscoless technique in one of the groups. This was different from the method used in this study, where all steps of the surgery were done without visco in Group II. This might have caused a difference in the results [19].

Schulze SD et al., found no additional benefit in the use of OVDs during IOL implantation using a single-hand injector and a hydrophilic acrylic IOL. They found no significant difference in the decrease in corneal endothelial cell count between their two study groups [20].

LIMITATION

A bigger sample size and a longer follow-up period is required to study any delayed implications of the use of OVD and BSS on the corneal endothelial morphology and cell count. This study included patients having Grade II nuclear sclerosis and so the results might not stand true for other grades of cataract and complicated cataract.

CONCLUSION

Phacoemulsification with the use of continuous balanced salt solution infusion via anterior chamber maintainer is an efficient alternative to ocular viscoelastic device. We can also conclude that when an experienced surgeon performs the surgery, there isn't a significant difference in endothelial cell count or change in cell morphology when surgery is done with the use of continuous infusion with balanced salt solution as compared to when it is done with ocular viscoelastic device.

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