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COMPARATIVE SPECULAR MICROSCOPIC STUDY OF CORNEAL ENDOTHELIAL CELLS IN PHACOEMULSIFICATION VERSUS SUTURELESS MANUAL SMALL INCISION CATARACT SURGERY

By

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ABSTRACT

Background: Low socio-economic group patients from rural areas often opt for free cataract surgeries offered by public hospital. Cataract surgery can be performed by or phacoemulsification or sutureless manual small Incision cataract surgery. Manual small incision cataract surgery is more cost effective

Objective: Comparing the morphological (cell density, coefficient of variation and standard deviation) endothelial changes after phacoemulsification versus manual small-incision cataract surgery (MSICS).

Patients and Methods: Patients were randomly allocated to undergo phacoemulsification (Group A, *n* = 40) or MSICS (Group B, *n* = 40). The patients underwent complete ophthalmic evaluation and specular microscopy preoperatively, and after 1 and 6 months postoperatively. Morphological endothelial evaluation was done using Topcon SP- 2000 specular microscope. Phacoemulsification was performed by stop and chop technique. MSICS was performed by the irrigating vectis technique.

Results: On comparing between the phacoemulsification and MSICS groups regarding the endothelial cell density, the **P** value after 1 month and 6 months postoperatively were not statistically significant. The difference in mean endothelial cell density between groups at 1 week and 6 weeks was statistically significant. The mean coefficient of variation and mean standard deviation between groups were not statistically significant.

Conclusion: Both groups showed comparable endothelial cell loss in the post-operative period. As SICS was economical and less dependent on technology than phacoemulsification, it may be the appropriate surgical procedure for treatment of cataract in the developing world.

Keywords: Specular Microscopy, Corneal Endothelial Cells, Phacoemulsification, Sutureless Manual Small Incision Cataract Surgery.

INTRODUCTION

Age-related cataract remains a major cause of blindness throughout the world, and more so in developing countries. Because of the increasing population and the increasing life expectancy, the number of older people will double from 606 million in 2000 to 1.2 billion in 2025. It is estimated that 75% of older people will be living in low and middle income countries by 2025 (**Evans, 2008).**

In the last couple of decades, the choice of cataract surgery has shifted to mainly sutureless small incision cataract surgery (SICS) or phacoemulsification (PE). Phacoemulsification is the preferred choice in the western developed countries or in urban settings. SICS is significantly faster, less expensive and less technology dependent than phacoemulsification. The visual acuity and the complication rates are similar to phacoemulsification **(Ruit et al., 2007).**

Endothelial cell loss and corneal decompensation after cataract surgery is well-documented. All surgical procedures that involve entry into the anterior chamber damage a proportion of endothelial cells. After endothelial cell loss, the adjacent cells enlarge and slide over to maintain endothelial cell continuity, which is observed as a change in the endothelial cell density and morphology (**Ganekal and Nagarajappa, 2014).**

Endothelial cell density and morphometry are essential for adequate follow-up of corneal grafts and diseases. Fast, easy-to-use and reliable instruments to measure the endothelial cell layer are required in clinical routine. In specular microscopy an image of the corneal endothelium is obtained after refraction of light at the anterior corneal surface. Endothelial cell density can be estimated by counting the number of cells within a certain area. While contact specular microscopy instruments provide excellent images, these have the disadvantage of directly touching the cornea. Noncontact specular microscopes are appreciated by clinicians and patients for their convenient handling **(Gasser et al., 2015).**

The aim of this study was to compare the effect on corneal endothelial cells between phacoemulsification and sutureless manual small incision cataract surgery as regard changes in cell density and polymegathism.

PATIENTS AND METHODS

Study patients included 80 consecutive patients who were age-matched and had similar lenticular changes based on lens opacities classification system III. All patients had a minimum follow-up period of 6 months. The duration of study was from January 2014 to June 2016. The consecutive patients were divided into two equal groups: Group (A) underwent phacoemulsification, and Group (B) underwent MSICS. Written informed consent was obtained from all subjects prior to participation. Patients were free to withdraw from the study at any time and were assured that the study would not compromise the quality of their eye care.

Patients with senile cataract and a normal endothelium were included. Patients with dense brown cataract, complicated cataract to local or general disease, complicated cataract to trauma, corneal endothelial dystrophies or diseases, glaucoma, prior eye surgeries, systemic disease as diabetes mellitus or hypertension, intraoperative posterior capsular rupture with vitreous loss were excluded from the study.

Phacoemulsification: The procedure started with the main incision which was superior three step clear corneal incision at 11 o`clock using a 2.4 mm keratome. Two side stab incision (0.9 mm) was done perpendicular to the main incision using MVR NO. 20. The anterior chamber was filled with sodium hyaluronate (Healon® Abbott Laboratories Inc. Abbott Park, Illinois, USA). Continuous curvilinear capsulorrhexis (CCC) of 5–5.5 mm was performed with a bent 25 gauge insulin needle or a capsulorhexis forceps. Hydrodissection was done using the same viscoelastic canula in all cases. Rotation of the nucleus. Coating of the corneal endothelium was done using HPMC viscoelastic substance. The phacoemulsification machine used was the Infiniti OZil IP (Alcon Laboratories, Inc., Fort Worth, TX, USA) machine with a Kelman-style curved 45° phacoemulsification tip. Phacoemulsification was performed using a stop and chop technique. Residual cortex was removed with bimanual irrigation / aspiration (I/A) system. The capsular bag was inflated and the anterior chamber was deepened with HPMC. Implantation of the foldable intra-ocular lens. Residual viscoelastic substance was removed with bimanual irrigation / aspiration (I/A) system. Hydration of the incisions using balanced salt solution. Subconjunctivally, Gentamycin 20 000u and Dexamethasone 2.5 mg were injected.

Manual small incision cataract surgery: A superior rectus bridle suture was inserted. Fornix-based conjunctival flap was dissected. Gentle cautery over the sclera. The linear scleral incision was made using Bard-Parker knife with No. 11 blade. The incision was constructed in frown shaped way with a length of 6.5-7 mm and the apex of the incision is 1.5 mm to 2 mm behind the superior limbus centered to 12 o'clock. The depth of the incision should be ½ thickness of the sclera. 3 mm crescent knife was used to construct the scleral tunnel till about 1 mm of clear cornea. The anterior camber was entered with a 3.2 mm keratome. 1 mm side port stab into clear cornea at the 10 o'clock was made. The viscoelastic substance was injected into the anterior chamber. The capsule was opened with continuous curvilinear capsulorrhexis, using a 25 gauge insulin needle. Hydrodissection caused subluxation of the nucleus into the anterior chamber. Ample visco-elastic substances was injected on top and underneath the nucleus. The internal opening of the tunnel was widened with the keratome making sure that the internal opening reaches laterally out to the limbus at each end. Nucleus delivery was done using irrigating Vectis. The vectis was advanced so its tip was just under the lower pole of the nucleus with continuous irrigation to push the posterior capsule away from the loop. The loop was pressed downwards on the posterior lip of the incision to open up the tunnel. Once the nucleus had been removed, the epinucleus and the cortex were removed by irrigation combined with aspiration using a Smicoe cannula. The rigid PMMA intraocular lens with 6.5 mm optical diameter was implanted into the capsular bag. The residual viscoelastic substances in the anterior chamber was removed. Paracentesis was hydrated with increasing the intra ocular pressure so that the internal flap of the wound was sealed, the wound was tested for any leak using cellulose sponge, and the incision was left sutureless. The conjunctiva was closed by gentle diathermy. Subconjunctivally, Gentamycin 20 000u and Dexamethasone 2.5mg were injected.

Statistical analysis: Statistical analysis was performed using Stata 11 for categorical variables, $\chi 2$ or Fischer's exact test were used and for continuous variables, Independent sample t test was used. Normality of continuous variable was checked using Shapiro-Wilk test. Logistic regression was used for univariate and multivariate analysis to look for risk factors for poor outcomes. Multi-collinearity between variables were assessed looking at the variance inflation factor, and fitness of the model was assessed using the Hosmer Lemeshow test for goodness of fit.

RESULTS

The study included 80 patients who were randomized to surgery, 40 patients had phacoemulsification and 40 patients had MSICS. The mean age of *Group 1* was 61.70±5.12 years, and of *Group 2* was 61.85±4.17 years. There were 70 % females and 30% males. There was no statistically significant difference in demographic variables.

There was no statistically significant difference in endothelial cell density between the phacoemulsification group and the SICS group preoperatively and at 1 month and 6 month postoperatively (Table 1).

Table (1): Comparison of endothelial cell density between the two groups (Mean ± SD).

Groups / Endothelial cell density	Group (A) No= 40	Group (B) No= 40	P-value
Pre	2429.75 ± 370.31	2443.53 ± 318.13	0.859
Post 1	2062.58 ± 324.07	2068.23 ± 270.54	0.933
Post 6	1992.38 ± 323.31	2016.48 ± 262.82	0.715

There was no statistically significant difference in endothelial loss between both groups after 1 month and 6 months postoperative (Table 2).

Table (2): Comparison of endothelial cell density percentage change between the two groups (Mean ± SD).

Groups / Endothelial cell density percentage change	Group (A) No= 40	Group (B) No= 40	P-value
ECL % change at 1 month	14.99 ± 1.54	15.36 ± 1.25	0.246
ECL % change at 6 month	17.74 ± 1.38	17.47 ± 1.12	0.347

There was no statistically significant difference between both groups after 1 month and 6 months postoperativly as regard the coefficient of variation in cell size (table 3).

Table (3): Comparison of coefficient of variation between the two groups (Mean ± SD).

Groups / Coefficient of variation	Group (A) No= 40	Group (B) No= 40	P-value
Pre	24.43 ± 4.29	23.93 ± 4.57	0.615
Post 1	27.43 ± 4.31	26.75 ± 4.45	0.493
Post 6	29.20 ± 4.46	28.25 ± 4.46	0.344

DISCUSSION

Despite the advances with modern technology in the treatment of cataract, the greatest challenge in our field continues to be large and increasing backlog of cataract blindness in developing countries. Nowadays cataract surgeries are classified as refractive surgery with increasing expectation from patient. Manual SICS costs much less than phacoemulsification. Significant loss of endothelial cell in any cataract surgery can lead to corneal decompensation and loss of corneal clarity, therefore it was necessary to know which surgical technique will be safer in view of endothelial cell loss and visual acuity **(Jagani et al., 2015).**

Advances in technology and improvements in technique have made cataract surgery safe and effective at restoring vision to millions of patients worldwide. Phacoemulsification with intra-capsular intraocular lens (IOL) implantation has been universally adopted in developed countries and manual small incision cataract surgery has been adopted in developing countries **(Zi et al., 2015).**

Endothelial alteration is considered an important parameter of surgical trauma and essential for estimating the safety of the surgical technique. After cataract surgery, endothelial cell density decreases at a greater rate than in healthy, unoperated corneas. There is a wide variation in endothelial cell loss between the various studies even when the mode of surgery is same (e.g., SICS). This is due to various factors including, different inclusion and exclusion criteria, different grades of cataract, different methods of nucleus delivery in SICS, different types of irrigating solution and viscoelastics. The reported endothelial loss varies between 4% and 25%, and the period of increased postoperative endothelial cell loss remains unknown. Endothelial cell loss begins soon after surgery, continues for at least 10 years postoperatively and may throughout the patient's life (**Ganekal and Nagarajappa, 2014).**

In the early postoperative period, while hexagonality increases, endothelial cell density begins to decrease. And endothelial pump functions in the damaged regions generally improve within a period of 14 days. The coefficient of variation showed an objective parameter to evaluate the variability between cell areas. The normal value must be under 30% **(Hayashi et al., 2011).**

The underlying mechanism which causes polymegathism and pleomorphism is possibly related to changes in endothelial cytoskeletal F-actin. Cytoskeletal F-actin plays an important role in maintaining the cell shape. Stress such as contact lens wear may affect the cysoskeletal F-actin and then cause the corneal endothelial cell shape change **(Azar et al., 2001).**

Endothelial cell loss begins soon after surgery, continues for at least 10 years postoperatively and may throughout the patient's life **(Mencucci et al., 2006).**

A significant positive correlation was found between the endothelial cell loss and nuclear sclerosis grade, and between the endothelial cell loss and phacoemulsification power and time, and that the high cumulative dissipated energy and large volume of BSS used during phacoemulsification was associated with a high endothelial cell loss **(Atas et al., 2014).**

In our study, the mean age was 61.70 ± 5.12 years in the phacoemulsification group and 61.85 ± 4.17 years in the SICS group, and the male to female ratio was 30%: 70% in both groups. The percentage of the endothelial cell loss (ECL) in phacoemulsification after 1 month postoperativly was 15.17 ± 1.70, and at 6 months postoperative was 18.15 ± 2.66. The percentage of the endothelial cell loss (ECL) in MSICS after 1 month postoperative was 15.36 ± 1.25, and after 6 months postoperative was 17.47 ± 1.12.

Gogate and associates (2010) stated that the mean endothelial cell loss after 1 week postoperative in phacoemulsification group was 13.2 % and after 6 weeks postoperatively it was 15.5 %, on the other hand the mean endothelial cell loss in the sutureless MSIC group after 1 week postoperative was 11.1% and after 6 weeks was 15.3%. There was no statistically significant difference in endothelial cell loss between the phacoemulsification group and the SICS group**.**

Ganekal and Nagarajappa (2014) stated that phacoemulsification was performed by the chop technique and MSICS was performed by the visco-expression technique. The mean endothelial cell loss in phacoemulsification group was 3.27%, and the mean endothelial cell loss in SICS group was 13.49% after 6 weeks postoperatively. Their results are different from ours in phacoemulsification group as the endothelial cell loss is very low in comparison with our results. This may be due to different techniques used in the 2 studies. Their results are similar to our results in MSICS group although the technique of surgery is different in the 2 studies. So, irrigating vectis technique and viscoexpression technique causes similar endothelial cell loss after MSICS.

Jagani and associates (2015), revealed that the percentage of endothelial cell loss in phacoemulsification group (A) were 12.33 % after 1 week, 15.93 % after 6 weeks, and 16.89 % after 3 months. The percentage of endothelial cell loss in MSICS group (B) were 10.63 % after 1 week, 15.12 % after 6 weeks, and 16.24 % after 3 months. There was no statistically significant difference in endothelial cell loss after 1 week, 6 weeks, and 3 months.

As manual SICS is economical and less dependent on technology than phacoemulsification. It may be the appropriate surgical procedure for treatment of cataract in the developing world. Proper case selection, diligent surgery, and adequate postoperative care are essential to maintain a clear cornea.

One of the limitations of this study was that only one technique of phacoemulsification and one technique of MSICS were compared; other techniques may give different results.

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مقارنة دراسية مجهرية للخلايا المبطنة للقرنية بين ازالة المياه البيضاء باستحلاب العدسه وبين جرح شقي صغير بلا غرز

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المقدمة: يحتاج المرضى ذوي الدخل المنخفض إلي إجراء عملية إزالة المياه البيضاء مجانا في المستشفيات العامة. يمكن إزالة المياه البيضاء بإستحلاب العدسة أو إزالة المياه البيضاء بشق صغير بلا غرز. تعتبر إزالة المياه البيضاء بشق صغير بلا غرز أكثر فاعلية من حيث التكلفة.

الهدف من الدراسة: هذه الدراسة أسست لمقارنة تأثير عملية إزالة المياه البيضاء بشق صغير بلا غرز أو إزالة المياة البيضاء بإستحلاب العدسه على الخلايا المبطنة للقرنية من حيث عدد الخلايا، والإختلاف في حجم الخلايا.

المرضى و طرق البحث: تم إجراء هذه الدراسة على 80 عين لمرضى مصابين بالمياه البيضاء. تم تقسيم المرضى إلى مجموعتين؛ كل مجموعة 40 عين. المجموعة الأولى أجريت لها عملية إزالة المياه البيضاء بإستحلاب العدسه و المجموعة الثانية أجريت لها عملية إزالة المياه البيضاء بشق صغير بلا غرز. تم تصوير الخلايا المبطنة للقرنية بالمجهر قبل إجراء العملية و بعد العملية بشهر وبعد 6 شهور.

النتائج: أظهرت النتائج النهائية للدراسة أنه لا يوجد فروق ذات دلالة إحصائية بين عملية إزالة المياه البيضاء بإستحلاب العدسه أو إزالة المياه البيضاء بشق صغير بلا غرز من حيث التأثير على الخلايا المبطنة للقرنية. و على ذلك فإن عملية إزالة المياه البيضاء بشق صغير بلا غرز تعتبر عملية امنة و فعالة. و تعتبر أكثر اقتصادية من عملية إزالة المياة البيضاء بإستحلاب العدسه.