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Evaluation of pre-operative and post-operative endothelial cell counts in single-site versus twin-site phacoemulsification trabeculectomy: A Prospective, randomized study

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Abstract
Introduction: Phacotrabeculectomy is a combined procedure in which both cataract extraction and glaucoma filtering surgery are performed in the same operative session. The one-site approach consists of both cataract extraction and trabeculectomy occurring through a single scleral incision. The two-site approach begins with cataract surgery, typically through a clear cornea incision, followed by a completely separate trabeculectomy performed superiorly upon completing the cataract procedure. This study looks at IOP changes, vision, loss of endothelial cells and BCVA between single-site and twin-site phacoemulsification -trabeculectomy surgeries, Methods: This prospective, randomized study was conducted between September 2014 to August 2015 with sample size of 80 subjects at National institute of Ophthalmology, Pune.
Results: The endothelial cell loss was significantly more in single site surgery when compared to twin site surgery, in both at 1 month and 3 months follow-up time points (P-value<0.001, unpaired t test). BCVA improved by 50.82% in Single Site and 62.97 % in Twin Site when compared to Pre-op Visual Acuity at 3 months post-op time point. Distribution of subjects improved to the desired direction on BCVA in both single site and twin site procedures at both 1 month and 3-month follow-up time points.
Conclusion: Phacotrabeculectomy surgery should be considered in patients with required low target IOP, complex medical regimens and advanced glaucoma. In terms of corneal safety twin site surgery has an edge over single site surgery at a follow up period of 3 months.

Keywords: trabeculectomy, glaucoma, twin site, IOP, endothelial cell loss

Introduction
The techniques of combined phacoemulsification-trabeculectomy are under continual development as new suture-less incisions, filtration procedures, and antimetabolite uses are studied. The results of numerous studies show that the combined procedure is an effective method of treatment of glaucoma and cataract [1]. Phacotrabeculectomy is a combined procedure in which both cataract extraction and glaucoma filtering surgery are performed in the same operative session. The one-site approach consists of both cataract extraction and trabeculectomy occurring through a single scleral incision. The two-site approach begins with cataract surgery, typically through a clear cornea incision, followed by a completely separate trabeculectomy performed superiorly upon completing the cataract procedure. Since, there are a few studies on loss of endothelial cells between single-site and twin-site phacoemulsification -trabeculectomy surgeries, we undertook this study, in which we have also evaluated the post-operative Best corrected visual acuity (BCVA) and Intra Ocular Pressure (IOP) at 1 month and 3 months follow-up periods, in addition.

Material and Methods
This prospective, randomized study was conducted between September 2014 to August 2015 with sample size of 80 subjects at National institute of Ophthalmology, Pune. Surgeries were performed by a single surgeon. Subsequent to the diagnosis of glaucoma and cataract the patient was counseled about the various treatment modalities available to him along with its benefits and complications. A formal consent was sought from the patient before the procedure was carried out under all aseptic precautions. The patient was then followed up at regular intervals for 6 months. The parameters collected were Specular Microscopy, best corrected visual acuity (BCVA) and Intra Ocular Pressure.

Inclusion criteria included patients from either gender, aged 55 to 85 years and Presence of visually significant cataract in patients with a. POAG which was not controlled by maximum drug therapy or patients with advanced disc damage; b. When there was appreciable visual field loss and optic disc damage with moderate IOP control (Mean Deviation ≥ 12); or c. Advanced field loss (Mean Deviation ≥ 18) where even transient IOP elevations might cause further optic nerve damage. Patients with endothelial pathology, preoperative inflammatory ocular disease, pseudo-exfoliation, angle closure disease / shallow anterior chamber, complicated cataract, more than grade III nuclear sclerosis, non – dilating pupil, previous intraocular surgery / trauma to same eye, and those who did not understand implication of protocol, and refused consent were excluded.

Pre-operative examination consisted of BCVA, IOP measurement by Goldmann Applanation Tonometer, Slit-lamp examination, Dilated Fundus examination, and specular microscopy through non-contact Specular Microscope (Topcon). At follow-up visits i.e., at (Day 30 {1 Month} & Day 90 {3 Months}), Visual acuity, detailed slit-lamp examination for any post-op surgical complications, specular Microscopy for endothelial cell counts, and dilated Fundus examination.

All readings were taken by single observer to obtain consistent results. For analysis, only ECC taken by non-contact Specular Microscope (Topcon) were taken into consideration. Specular Count was graded as Significant pr not on the basis of P values.

Procedure: Pre-operative preparations included written informed consent, Xylocaine sensitivity, and advised nil by mouth 2 hours before surgery. Dilatation of pupil was done with tropicamide (0.8%) and phenylephrine hydrochloride (0.5%) eye drops every 15 minutes for 4 times, 1 hour before surgery. Local Anesthesia with Plain Xylocaine 2% (peribulbar block) was done. Steps of Single site phacotrabeculectomy with mitomycin C (MMC) were, eye was painted and draped, eyelid was retracted with eye speculum, superior rectus bridal suture was taken, fornix based conjunctival flap was made, bleeders, if any were cauterized with electric cautery, triangular 4×4mm partial thickness scleral incision with limbal base was done with 15 number blade mounted on Bard- Parker handle. A weck-cel sponge with MMC (0.2mg/ml) was positioned on scleral flap for 2 min. After MMC application, area was thoroughly washed with 30 ml balanced salt solution. A limbal based triangular flap of two third of scleral thickness was dissected. Sclerocorneal tunnel was made by crescent. A keratome (2.8 mm) was used to enter the anterior chamber through sclerocorneal tunnel. Anterior chamber was formed with visco-elastic substance & continuous curvilinear capsulorrhexis was performed using a bent 26 no. needle. Phacoemulsification was performed using AMO Compact phacoemulsification machine. Stop and chop technique was used. The power setting was decided as per the grade of cataract. Cortical matter was removed by bimanual irrigation and aspiration. A foldable lens was implanted in the bag. Side ports were sealed by hydration. The sclerostomy of 1.5 mm with Kelly‘s punch was made followed by peripheral iridectomy. Then scleral flap was reposited and one fixed or releasable apical suture was taken with 10-0 nylon suture. Conjunctival flap closed with two water tight 8-0 vicryl sutures. Injection Moxifloxacin 0.5 mg in 0.1 cc given intra-camerally. Subconjuctival injection of Gentamycin & Dexamethasone was given inferonasally. Atropine ointment was applied & eye padded.

Steps of twin site phacotrabeculectomy with mitomycin C (MMC) were similar initial steps of single site procedure till a sclerocorneal tunnel by crescent. After that a separate superotemporal self-sealing clear corneal incision was taken (2.8 mm in size). Anterior chamber was formed with visco-elastic substance & continuous curvilinear capsulorrhexis was performed using a bent 26 no. needle. Phacoemulsification was done using AMO Compact phacoemulsification machine. Stop and chop technique was used. The power setting was decided as per the grade of cataract. Cortical matter was removed by bimanual irrigation and aspiration. A foldable lens was implanted in the bag. Wound was sealed by hydration. Now a keratome (2.8 mm) was used to enter the anterior chamber via previously dissected sclerocorneal tunnel. The sclerostomy of 1.5 mm with Kelly‘s punch was made followed by peripheral iridectomy. Then scleral flap was reposited and one fixed or releasable apical 10-0 nylon suture was taken. Conjuctival flap closed with two water-tight 8-0 vicryl sutures. Injection Moxifloxacin 0.5 mg in 0.1 cc given intra-camerally. Subconjuctival injection of Gentamycin & Dexamethasone was given inferonasally. Atropine ointment was applied & eye padded. Post-operative follow up was on Day 30 (1 Month) and Day 90 (3 Months) respectively. Day 30 (1 month) and Day 90 (3 months) and follow up visit patients were assessed under following parameters: Thorough slit lamp examination for bleb morphology was performed at every visit & post-op. Operative bleb manipulation like argon laser suturolysis, releasable suture release and regular digital massage was performed accordingly. Best corrected visual acuity was recorded at each visit with Snellen’s visual acuity chart. IOP was recorded with Goldmann Applanation Tonometer. Endothelial Cell Counts were done with Non-Contact Specular Microscope (Topcon) were assessed on Day 30 and day 90 follow-ups.

Statistical analysis: The data are presented using percentage s and for quantitative variables with mean and SD and range. The pre-op and post-op comparisons are done using Paired t test, after confirming the underlying normality assumption of difference of variables measured. A p value of less than 0.05 was set for statistical significance. Data was analyzed in SPSS (Statistical package for social sciences) version 19.0. The study protocol approved by local ethical committee (National Institute of Ophthalmology) adhered to the tenets of the Declaration of Helsinki.

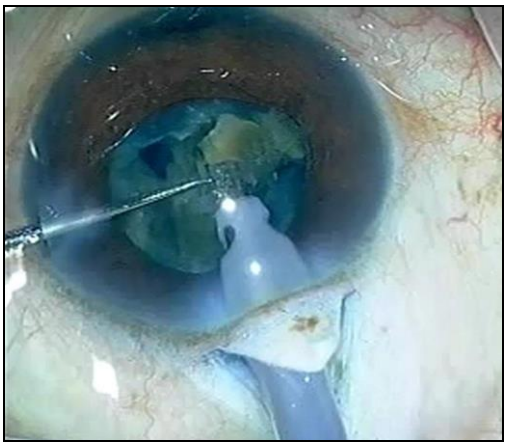

Fig 1: Single Site surgery

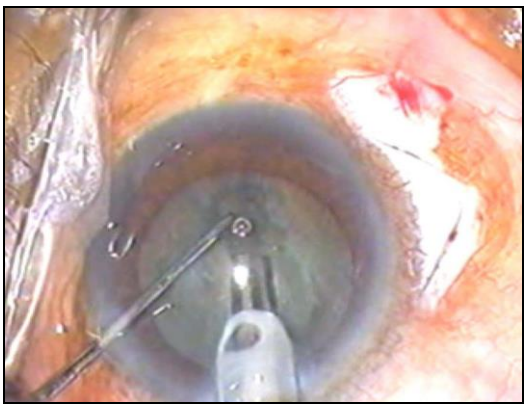

Fig 2: Twin-site phacotrabeculectomy

Results

In this study 109 eyes of 80 patients were included out of which 59 eyes were operated by single site phacotrabeculectomy with MMC & 50 eyes were operated by twin site phacotrabeculectomy with MMC. Table 1 shows the distribution of study subjects based on descriptive characteristics and other parameters among two study groups, single site and twin site. The average Log MAR visual acuity (Pre-op) and (1-month post-op follow-ups) differs significantly between study groups (P-value<0.001, unpaired t test). The endothelial cell loss was significantly more in single site surgery when compared to twin site surgery, in both at 1 month and 3 months follow-up time points (P-value<0.001, unpaired t test). BCVA improved by 50.82% in Single Site and 62.97 % in Twin Site when compared to Pre-op Visual Acuity at 3 months post-op time point (Table 2). Distribution of subjects improved to the desired direction on BCVA in both single site and twin site procedures at both 1 month and 3-month follow-up time points (Table 3).

Table 1: Distribution of study subjects based on descriptive characteristics and other parameters among single-site or twin-site groups.

(N=109)

Variable		Single site		Twin site		P value
Categorical		**n**	**%**	**n**	**%**	
Age-group in years	55-64	14	23.7	7	14	
	65-74	27	45.8	29	58	
	75-84	18	30.5	14	28	
Gender	Male	32	54.23	39	78	0.015
	Female	27	45.77	11	22	
Laterality	Right eye	31	52.54	25	50	0.849
	Left eye	28	47.46	25	50	
Quantitative		Mean	SD	Mean	SD	
Age in years		70.07	7.59	70.74	6.16	0.611
Pre-op vision (Log Mar)		0.62	0.21	0.85	0.39	<0.001
Pre-op IOP mmHg		24.85	3	24.86	2.58	0.274
Pre-op ECC/mm^2		2230.61	243.91	2155.94	323.50	0.183

Table 2: Inter group Comparison of pre-operative and post-operative Vision, IOP, Endothelial Cell Counts and relative changes between two study groups at different time points.

Variable	Follow-up	Single Site Group (n=59)	Twin Site Group (n=50)	P-value
Vision (Log MAR)	Pre-op	0.62 ± 0.21	0.85 ± 0.39	<0.001
	Post Op 1 month	0.50±0.18	0.60 ± 0.28	0.038
	Post op 3 Month	0.31±0.14	0.31 ± 0.17	0.769
IOP (mmHg)	Pre-op	24.85 ± 3.00	24.26 ± 2.58	0.274
	Post Op 1 month	13.15 ± 1.76	13.24 ± 2.47	0.835
	Post op 3 Month	11.73 ± 1.19	11.90 ± 1.05	0.427
ECC/mm^2	Pre-op	2230.61 ± 243.91	2155.94 ± 323.50	0.183
	Post Op 1 month	2079.46 ± 235.99	2056.88 ± 316.73	0.706
	Post op 3 Month	1980.75 ± 232.99	1978.94 ± 302.93	0.967
Endothelial cell loss	at 1 month	151.15 ± 58.17	99.06 ± 54.93	< 0. 001
	at 3 months	249.86 ± 62.44	177.0 ± 114.99	< 0.001
Relative % change with respect to preop value in vision	at 1 month	19.67	29.72	
	at 3 months	50.82	62.97	
Relative % change with respect to preop value in IOP	at 1 month	47.07	45.42	
	at 3 months	52.80	50.95	
Relative % change with respect to preop value in Endothelial cell loss	at 1 month	6.78	4.59	
	at 3 months	11.2	8.21	

Table 3: Distribution of patients according to best corrected visual acuity (BCVA) single site and Twin site Phacotrabeculectomy.

	Group	BCVA				Total
		≥ 6/9	6/12 - 6/18	6/24 - 6/36	≤ 6/60	
Pre-operative	Single site	0	25	26	8	59
	Twin site	0	13	17	20	50
At 1 month	Single site	2	46	9	2	59
	Twin site	1	29	12	8	50
At 3 months	Single site	21	35	1	1	58
	Twin site	19	29	0	2	50

Discussion: Since the first phacoemulsification procedure performed by Kelman[2] in 1967, corneal endothelial cell loss (ECL) remains a serious concern in cataract surgery.[3] Damage to the corneal endothelium is influenced by various pre- and intra-operative factors.[3] In phacoemulsification, the amount of ECL determines final postoperative corneal transparency and to some extent visual acuity. Thus, attempts to protect the corneal endothelium and to minimize their damage can play an important role in improving quality of life in patients with cataracts [4-5]. Risk of endothelial cell damage increases with a high nucleus grade, advanced age, long phacoemulsification time (Phaco time), high ultrasound energy, small pupil diameter, large infusion volume, type of intraocular lens (IOL), and short axial length [2-8]. Hence, a surgeon who is more familiar with temporal entry for phacoemulsification, will be causing less endothelial cell damage in twin site surgery, the steps of trabeculectomy essentially being the same for both single site and twin site surgeries.

A study by Nassiri *et al*, which is a historical cohort study compared corneal endothelial cell loss in single site and twin site phacotrabeculectomy. In both groups, the longer the follow-up time was, the higher the corneal endothelial cell loss and the corneal endothelial cell area expansion were. One-site surgery seems to cause less corneal endothelial cell damage than the 2-site operation during the median follow-up time of 1 year, while in our study the, mean corneal endothelial cell density (±SD) in single site group, at a follow up period of 3 months was 1980.75±232.99/mm^2, while that in twin site group was 1978.94±302.93/mm^2, with no statistically significant difference between the two [9].

The study by Soro Martinez *et al*., which was an observational retrospective study, compares phacoemulsification trabeculectomy + intraocular lens implantation with trabeculectomy alone. Here, 80 eyes of 62 patients were divided into one control group and three experimental groups, in which trabeculectomy or phacotrabeculectomy and IOL implantation were performed. Mean corneal endothelial cellular density (±SD) was 2,619 ±319/mm^2 in the control group, 2,447 ±425/mm^2 in the trabeculectomy group, 1,968 ±342/mm^2 in the one-step phacotrabeculectomy group, and 1,551 ±323/mm^2 in the two-step phacotrabeculectomy group. This study states that corneal endothelial cell loss is more in combined surgery and that two-step procedure causes more endothelial cell loss than single step surgery. In our study, mean corneal endothelial cellular density (±SD) was 2,230.61±243.91/mm^2 in single site and 2155.94±323.50/mm^2 in twin site phacotrabeculectomy, while the post-operative mean corneal endothelial cellular density at 3 months was 1980.75±232.99/mm^{2}in single site and 1982.94± 303.49/mm^2 in twin site phacotrabeculectomy. The endothelial cell loss (at a follow up period of 3 months) is 249.86±62.44/mm^2 in single site and 177.00±114.99/mm^2 in twin site surgery. Hence, there is a significantally lower loss of corneal endothelial cells in twin site phacotrabeculectomy as compared to single site. In the present study, the visual acuity after a follow up period of 3 months improved both in single site and twin site to values being 50.82% in single site and 62.97% in twin site surgeries and IOP was reduced to an average of 11.81±1.13 at a follow up period of 3 months [10].

A prospective randomized controlled trial in 2008 by Buys YM *et al*., noted no statistically significant difference in post-operative IOP between two types of surgeries. Corneal endothelial cell counts were significantly lower in the twin-site group at 3 and 12 months [11]. Another study suggested that patients with glaucoma may have lower corneal endothelial cell density compared to those without glaucoma of the same age group. The proposed mechanisms are direct damage from IOP, congenital alteration of the corneal endothelium in patients with glaucoma, glaucoma medication toxicity, or a combination of these [12].

A single-site surgery is likely faster to perform than a twin-site procedure, but more recent studies have begun to show that not only does a twin-site procedure produce better post-operative IOP control, but also produce less need for adjunct anti glaucoma medications. A twin-site procedure also has safety advantages over a single-site technique as there is less risk of anti-metabolites entering the anterior chamber, and less manipulation of the conjunctiva and sclerostomy. Moreover, most of the surgeons are familiar with temporal entry for routine phacoemulsifications, hence they invariably cause lesser damage to the endothelium in case of twin site surgeries. Phacotrabeculectomy surgery should be considered in patients with required low target IOP, complex medical regimens and advanced glaucoma. In terms of corneal safety twin site surgery has an edge over single site surgery at a follow up period of 3 months. The results of twin site and single site phacotrabeculectomy in terms of IOP and visual outcome is comparable at a follow up period of 3 months.

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