

## Assessment of corneal endothelial status post phacoemulsification with 1% ultrasound power in hard cataracts

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### Abstract

**Purpose:** This study was conducted to discover that whether Co-axial micro incision cataract surgery using 1% ultrasound is superior to phacoemulsification using higher powers in terms of corneal endothelial safety over a period of one year.

**Materials and Methods:** This comparative randomized study was conducted from 11-01-2014 to 03-31-2016. Patients with hard cataracts [5.0-6.9 of lens opacities classification system-III] were randomized into four groups and underwent cataract surgery using ultrasound powers of 1%, 5%, 10% and 20% respectively. Post-operatively they were assessed in terms of- corneal endothelial cell loss, co-efficient of variation of cell size, percentage of hexagonal cells and corneal thickness. The other parameters that were investigated were - frequency of significant posterior capsular opacification, best corrected visual acuity and Intraocular pressure variations.

**Results:** This study found that application of 1% ultrasound power is superior to 5%, 10% or 20% power in phacoemulsification cataract surgery in terms of quantitative endothelial cell analysis (endothelial cell density, percentage of loss of endothelial cells, coefficient of variation, central corneal thickness and percentage of hexagonal cells) over one year follow up post-operatively. On comparison all parameters were found to be statistically significant when compared to the application of 20% power.

**Conclusion:** Negative effects of ultrasound power (used in phacoemulsification) on corneal endothelial health have been well documented in the literature. We found that minimizing this power to 1% is effective in maintaining corneal endothelial viability without compromising the surgical experience and post-operative visual outcome.

**Keywords:** 1% Ultrasound power, Coefficient of variation, Endothelial cell density, Percentage hexagonal cells, Phacoemulsification.

### Introduction

Cataract surgery forms the major workload of eye units worldwide and is a major health care expense. Advancement in the technology of cataract surgery has transformed it from being a simple rehabilitative surgery into a precision refractive surgery. The aim of today's cataract surgery is not only to somehow remove the cataract and put intra ocular lens but to achieve best possible visual acuity with minimal complications together with fast recovery and rehabilitation.<sup>1</sup>

Since the time Kelman introduced his technique of phacoemulsification in 1967, there have been constant advancement ranging from development of Laser emulsifier,<sup>2</sup> SONAAR machines, introduction of cold phaco with modulations of ultrasound in the form of pulse, micropulse and bursts.<sup>1-4</sup>

Although safety and surgical outcomes have dramatically improved owing to the recent advances; phacoemulsification induced corneal decompensation due to endothelial cell loss remains an imperative complication.<sup>2,4</sup>

A loss of 3.2% - 23.2% of endothelial cells have been shown in various studies since 1967. Also other recent studies show that the percentage of postoperative endothelial cell loss in coaxial microincision cataract surgery ranged from 7.2% to 26.8%.<sup>5-9</sup>

The degree of trauma by the ultrasonic oscillations used in phacoemulsification scale with exposure, intensity, and duration leading to plasma membrane disruption and free radical (hydroxyl ion) generation. There is a statistically significant endothelial cell loss related to increased cumulative dissipated energy, aspiration time and volume of balanced solution used.<sup>9-16</sup>

If we could assess a minimal ultrasound technique in a scientific setting we might achieve the desired goal of negligible endothelial assault without resorting to major modifications of instrumentation and machine.

In view of the above findings we conducted a randomized controlled trial at our institution in the year 2010 to study the effect of minimizing ultrasound power used in phacoemulsification on corneal endothelial cell loss. In this study various complications and visual outcomes following standard coaxial microincision cataract surgery using 1% and 40% ultrasound were compared over a period of one year. This study revealed that the endothelial cell loss was significantly higher in patients who underwent phacoemulsification using 40% ultrasound than those with 1% ultrasound. Many studies have followed up corneal endothelial status post cataract surgery up to a period of one year. A brief review of related literature reveals certain illuminating points.<sup>17-19</sup>

In 1979 Waltman SR, Cozean CH Jr studied the effect of phacoemulsification on corneal endothelium and observed that phacoemulsification caused 29% more endothelial cell loss than intracapsular cataract extraction. Lesiewska Junk H, Kaluzny J et al in 2002 revealed that the mean rate of corneal endothelial cell loss two years after surgery was significantly higher and it does not depend on preoperative density. In another study conducted in China in the year 2006, Ke Yao et al compared clinical outcome between conventional phacoemulsification and phacoemulsification using millennium custom control software and at 3 months post-surgery, endothelial cell loss ratio showed statistical difference ( $p = 0.032$ ) between the two groups.<sup>20-22</sup>

In 2007, Leonardo Mastropasqua et al compared 1.8-2.2-mm coaxial MICS with torsional ultrasound. Morphologic analysis by in vivo confocal microscopy showed a significant decrease in endothelial cell count at the centre of the cornea in both groups, but no statistically significant difference between the groups. Effat A et al in the year 2007 compared two phacoemulsification techniques, namely phaco prechop and divide and conquer and hypothesized that the mean endothelial cell count 3 months postoperative in pre chop group was significantly higher than that in divide and conquer.<sup>23</sup>

Viraj Vasavada et al conducted a study in India in the year 2009 to evaluate the intraoperative performance and postoperative outcomes after microcoaxial phacoemulsification and calculated that the endothelial cell density decreased by a mean of 5.8% and the mean coefficient of variation by 3.3.<sup>24</sup>

Though endothelial cell density has been a subject of extensive research, as far as our search goes there has not been any previous attempt to correlate it with the phaco power used during the procedure. In our study we attempted to discover that whether Coaxial microincision cataract surgery using 1% ultrasound is superior to Coaxial microincision cataract surgery using 5%, 10% and 20% ultrasound, in terms of corneal endothelial safety over a period of one year in patients of grade 5.0-6.9 senile cataract.

## **Materials and Methods**

We initiated our study with the aim to compare the corneal endothelial status of patients with hard cataracts [5.0-6.9 of Lens Opacities Classification System-III (LOCS-III)] having undergone Coaxial micro incision cataract surgery using ultrasound powers of 1%, 5%, 10% and 20% keeping the vacuum settings constant at 300mmHg and micropulse at 50 pulse per second in terms of- corneal endothelial cell loss, co-efficient of variation of cell size, percentage of hexagonal cells and corneal thickness.

The four groups were compared over a period of one year in terms of- frequency of significant posterior capsular opacification, visual acuity, Best corrected visual acuity and changes in refractive status and intraocular pressure.

This comparative randomized study was conducted from 11-01-2014 to 03-31-2016 after approval from institutional review committee. All patients aged over 40 years and with a visually significant senile cataract of grade 5.0-6.9 (LOCS III grading) were included in the study. Patients with pre-operative endothelial cell density count less than 1500cells/mm<sup>2</sup>, suffering from any posterior or organic pathology which may compromise the visual recovery eg. corneal dystrophies or scars, with raised intraocular pressure (> 21 mmHg) or with a history of any previous intraocular surgery were excluded from the patient groups.

A total of 160 patients were included and were divided into four groups with forty patients in each group using 1%, 5%, 10% and 20% ultrasound power respectively. Of the 160 patients who participated in the study 155 completed the study and 5 patients were lost to follow up. Of these 5 patients, 1 patient expired at 6 months; 3 patients were lost to

follow up at 1 year and 1 patient developed complications at 1 week follow up, thus was excluded from the study.

Previously diagnosed patients of cataract reporting to eye Out Patient department were worked up for the procedures with due protocol (history taking, comprehensive preoperative eye examination including specular microscopy, fundus examination, biometry, visual acuity, slit lamp examination, grading of cataract). A written consent explaining nature of each test and the subsequent surgical procedure to be undertaken was duly obtained from all patients participating in the study.

One eye of each patient that fulfilled the inclusion and exclusion criteria was allocated to the study group. Patients were randomly distributed into 4 groups by an independent observer using envelope technique.

All surgeries were performed by one surgeon. Uniform pre- regime of dilatation of pupil was done with tropicamide + phenylephrine hydrochloride eye drops every 15min for 45min before surgery. Plain tropicamide was used in hypertensive patients. All surgeries were performed under topical anaesthesia/ peribulbar block with 2% lidocaine + adrenaline + 0.5% bupivacaine with hyaluronidase. Ultrasound power was set according to the group to which the case has been randomized. Surgeries were performed using the Phaco Machine (Alcon) one unit; Model no. Infinity Vision System (S.no 1301255401x). 1.8mm incision was used for entry and nucleus was dissembled by direct phaco chop technique. The vacuum settings were kept constant at 300mmHg while the micropulse was kept at 50 pulse per second.

Standard post-operative care was provided to all patients including but not restricted to systemic antibacterials (Ciprofloxacin 500 mg BD for 5 days), topical steroid and anti-bacterial combinations (Prednisolone acetate + Moxifloxacin 0.5%) tapered over four to six weeks.

Postoperative evaluation including visual acuity, specular microscopy, slit lamp examination and intraocular pressure measurement was done on day 1, at 1 week and on 1<sup>st</sup>, 3<sup>rd</sup>, 6<sup>th</sup>, 9<sup>th</sup> and 12<sup>th</sup> month after the surgery by a third blinded observer. Noncontact specular microscopy (EM - 3000; TOMEY: VERSION 2A/OJ) was used to calculate the endothelial cell density, coefficient of variation of cell size, percentage of hexagonal cells and corneal thickness before surgery and post operatively on each visit. Endothelial cell loss was calculated as a percentage of preoperative cell density. ETDRS chart was used for visual acuity assessment while Intraocular pressure was measured using a Goldmann applanation tonometer.

Post operatively any cases requiring Nd-Yag laser capsulotomy for significant posterior capsular opacification were noted along with any other cause for diminution of vision.

Statistical analysis was performed by the SPSS program for Windows, version 17.0. Continuous variables are presented as mean  $\pm$  SD, and categorical variables are presented as absolute numbers and percentage. Data was checked for normality using the Shapiro-Wilk test. Normally distributed continuous variables were compared using

ANOVA. In addition Tukey multiple comparison test, Tamhane’s T2 test and Spearman’s Correlation was applied.

**Results**

Of the total 160 patients included in the study 87 were males and 73 females. The mean age of patients included in groups using 1%, 5%, 10% and 20% ultrasound power were 62.98 years, 63.15 years, 62.55 years and 63.35 years, respectively. The average cataract density in the four groups was noted 5.92, 6.00, 5.91 and 6.02 respectively (LOCS-III).

On postoperative Day 1 the % fall of visual acuity from baseline in 1% group was significantly lower than that in 5%, 10% and 20% groups. The Best Corrected Visual Acuity (BCVA) at 1 year follow up in the four groups was comparable at 0.11, 0.15, 0.14 and 0.18 in groups I, II, III, IV respectively. There was no statistically significant difference observed when 1% group was compared with the other 3 groups.

The pre-operative baseline Endothelial Cell Density (ECD) in groups 1% (2585.78), 5% (2649.48), 10% (2628.65) and 20% (2718.15) was comparable. When examined post-operatively from day one to one year the ECD was found to be consistently high in the 1% power group as compared to others. [Table 1]

Reduction in ECD from baseline was observed at each postoperative visit in all the four groups. At the end of 1 year the mean ECD in 1% group was 2310.46 which was higher when compared to 5% (2136.70), 10% (1919.53) and 20% (1804.39) groups and the difference was statistically significant (p<0.001). Simultaneously the endothelial cell loss at the end of 1 year in each group was 1% (283.82), 5% (512.78), 10% (694.35) and 20% (876.75) respectively which was also statistically significantly lower in 1% group when compared to other groups. [Table 2]

The Central Corneal Thickness (CCT) approached the baseline in 1%, 5% and 10% groups around 1 month postoperatively whereas in the 20% group it approached the baseline around 9 months.

The baseline value of Coefficient of Variation (CV) as well as percentage of endothelial hexagonal cells in all the groups was comparable when examined by a specular microscope. At 1year follow-up both these parameters were lower in the 1% group as opposed to the other three groups but the difference was statistically significant only when the 1% group was compared to the 20% group (p=0.008). [Table 3 and Table 4 respectively.]

Only 1 patient from the 20% group developed complication of posterior capsular rent and thus was excluded from the study.

The other parameters which were evaluated during the study included intraocular pressure, keratometric values and incidence of posterior capsular opacification post-operatively.

There was no statistically significant difference observed in the IOP measurements when 1% was compared with 5%, 10% and 20% groups at day1 (p=0.498), 1week (p=0.230), 1 month (p=0.352), 3 months (p=0.2), 6 months (p=0.645), 9 months (p=0.374) and 1 year (0.727).

Neither was there any statistically significant difference in postoperative keratometric values amongst the four groups (p=0.523).

During the 1 year follow up none of the patients from the 1% group had developed PCO whereas in 5%, 10% and 20% groups 1, 2 and 1 patients were affected by it respectively. This finding was not statistically significant.

Following the results this study shows an advantage of using 1% ultrasound power in phacoemulsification cataract surgery over 5%, 10% and 20% in terms of quantitative endothelial cell analysis (endothelial cell density, percentage of loss of endothelial cells, coefficient of variation, central corneal thickness and percentage of hexagonal cells) over one year follow up post-operatively. All the parameters were statistically significant when compared to the application of 20% power.

Better preservation of corneal endothelial cell function and improved vitality could be directly attributed to use of reduced lower ultrasound power for phacommechanics.

**Table 1: Comparison of ECD amongst study groups**

ECD	Group 1%	Group 5%	Group 10%	Group 20%	P value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Baseline	2585.78 ± 284.75	2649.48 ± 215.32	2628.65 ± 279.39	2718.15 ± 227.58	0.133
Day 1	2394.95 ± 356.19	2448.85 ± 363.93	2350.55 ± 402.02	2245.85 ± 289.53	0.133
1 week	2451.15 ± 301.96	2437.15 ± 370.27	2306.45 ± 326.01	2148.40 ± 298.89	<0.001
1 Month	2385.82 ± 327.05	2319.55 ± 336.27	2129.0 ± 293.39	1986.18 ± 258.88	<0.001
3 Month	2317.88 ± 314.96	2212.98 ± 307.95	2028.48 ± 287.58	1843.56 ± 177.79	<0.001
6 Month	2319.80 ± 321.70	2171.68 ± 280.48	1959.15 ± 280.86	1847.49 ± 186.66	<0.001
9 Month	2261.92 ± 455.18	2152.48 ± 279.88	1934.90 ± 285.05	1823.15 ± 173.94	<0.001
1 year	2310.46 ± 318.89	2136.70 ± 279.03	1919.53 ± 291.54	1804.39 ± 168.70	<0.001

**Table 2: Comparison of Endothelial loss amongst study groups**

Endothelial Cell Loss	N	Mean ± SD	Min – Max	P value
Group 1%	40	283.82 ± 141.96	89 – 878	<0.001
Group 5%	40	512.78 ± 182.35	129 – 1063	
Group 10%	40	694.35 ± 166.81	256 – 1118	
Group 20%	40	876.75 ± 258.81	46 – 1626	

**Table 3: Comparison of coefficient of variation amongst study groups**

CV	Group 1%	Group 5%	Group 10%	Group 20%	P value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Baseline	37.03 ± 3.66	36.05 ± 3.13	36.53 ± 3.54	36.80 ± 3.00	0.596
Day 1	47.13 ± 10.71	46.78 ± 9.66	46.53 ± 9.29	53.93 ± 10.21	0.002
1 week	39.33 ± 3.66	39.03 ± 4.97	39.58 ± 3.97	41.85 ± 3.55	0.010
1 Month	37.88 ± 5.64	36.88 ± 2.33	38.48 ± 3.42	39.26 ± 1.85	0.031
3 Month	36.13 ± 2.05	35.85 ± 2.35	37.10 ± 2.15	37.62 ± 2.14	0.001
6 Month	35.33 ± 1.49	35.30 ± 1.62	36.05 ± 1.86	36.56 ± 2.45	0.007
9 Month	34.28 ± 1.76	35.23 ± 3.38	35.33 ± 1.88	35.92 ± 2.10	0.016
1 year	34.31 ± 2.05	34.65 ± 1.85	34.84 ± 1.95	35.76 ± 2.06	0.012

**Table 4: Comparison of percentage hexagonal cells amongst study groups**

6A	Group 1%	Group 5%	Group 10%	Group 20%	P value
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Baseline	50.78 ± 7.70	49.63 ± 4.51	48.00 ± 9.26	51.20 ± 10.69	0.322
Day 1	42.20 ± 11.88	40.58 ± 7.93	39.13 ± 11.22	41.30 ± 13.33	0.661
1 week	43.63 ± 7.55	44.50 ± 4.92	40.53 ± 12.74	38.41 ± 9.45	0.012
1 Month	42.18 ± 8.39	43.15 ± 5.95	39.13 ± 11.13	35.49 ± 8.25	<0.001
3 Month	40.85 ± 9.49	41.68 ± 5.89	38.00 ± 11.19	34.03 ± 8.44	0.001
6 Month	39.58 ± 9.43	41.03 ± 5.64	37.21 ± 11.26	32.69 ± 8.22	<0.001
9 Month	38.95 ± 9.61	39.78 ± 6.17	36.38 ± 11.37	32.64 ± 7.47	<0.001
1 year	38.15 ± 9.19	38.95 ± 6.15	35.79 ± 11.49	29.79 ± 8.62	<0.001

**Discussion**

The objectives before commencing this study had been to achieve the maximum corneal functionality after a phacoemulsification surgery. We are well aware that use of ultrasonic power in phaco causes the temperature to rise inside the ocular tissue to very high grades though momentarily.

Though phacoemulsification reduces the intra-ocular instrumentation as compared to sclera incision cataract surgeries or extracapsular cataract extraction surgeries, it causes damage to the corneal endothelial vitality by use of ultrasound power which is ultimately derived by piezoelectric mechanisms. In this context Rupert RA Bourne et al investigated whether modern phacoemulsification surgery results in more damage to corneal endothelium than extracapsular cataract extraction. The results showed that there was no such change in the coefficient of variation at 1 year postoperatively.<sup>18</sup>

Our aim was to take the ultrasound power that is applied in a surgery to the minimum possible value without compromising with the surgical efficiency and basic outcome. The reason to choose hard cataracts for this study was to make sure the former constant stood the test. Though we have included cataracts over grade 5.9 in our study, Jerome Richard et al in their clinical study included cataracts graded up to nuclear opalescence 4.9 only.<sup>25</sup>

Another effect of ultrasound power on the eye has been documented as acute postoperative rise in IOP due to factors like inflammation of the trabecular meshwork secondary to dissipated ultrasound energy. This rise in IOP though is transient and IOP returns to normal within 24-48 hrs. Our study also documented that there were no adverse events as far as ocular tension was concerned.

In a study similar to this one, Anna Reuschel et al carried out comparison of visual acuity and power settings between torsional and longitudinal phacoemulsification and noted that the mean preoperative VA of 0.41 log MAR in the torsional group and 0.38 log MAR in the longitudinal group, improved to 0.07 log MAR postoperatively in both groups. Likewise Celso Takashi Nakano et al documented that visual acuity was better in the group which used aqualase technique instead of usual.<sup>26</sup>

Similar trends were seen in this study with improvement of BCVA at the end of one year to 0.11 though we varied the power settings instead of technique used.

Sobotka AC, Ventura et al conducted a study in 2001 to evaluate corneal thickness and discovered that the significant postoperative corneal swelling which developed on day 1 of surgery was restored to normal values by one year postoperatively.<sup>27</sup>

In another study conducted by David R Lucena et al, CCT was significantly increased (p<0.05) at 1, 8, 15 and 30 days postoperatively, returning to baseline at 60 days. Rita Mencucci et al in their trial found that corneal thickness increased by 10.2 µm in the overall sample and approached baseline values by 3 months with an increase of 3.4 µm.

Alessandro Franchini et al compared standard coaxial phacoemulsification with microincision cataract surgery while Rita Mencucci et al compared corneal endothelial changes after phacoemulsification performed with a standard technique versus a bimanual microincision cataract surgery (MICS). Both the studies found that there was no significant difference between the two groups in terms of coefficient of variation in cell size. On the other hand the study conducted by Viraj Vasavada et al a decrease in mean coefficient of variation of endothelial cells by 3.3.<sup>24,28</sup>

A previous attempt to study the effects of ultrasound power on endothelial cells was made by Atland OD and Dalecki D in 2004 by exposing human umbilical vein endothelial cells (HUVEC) and bovine aortic endothelial cells (BAEC) to ultrasound. They concluded that very low intensity U/s power increased nitric oxide production, which by scavenging the free radicals proved to be protective to the endothelium as compared to the traumatic effect of higher intensities.<sup>16</sup>

Ophthalmic studies conducted by Alessandro Franchini et al and Baradaran Rafi et al concluded that the effect of ultrasound power was much more potent as compared to vacuum, infusion rate or intraocular pressure on endothelial cell loss after phacoemulsification.<sup>11,28</sup>

Further studies conducted by Viraj Vasavada et al and Murano Nao, Ishizaki M et al confirmed ultrasound oscillations in the anterior chamber cause corneal endothelial damage by generation of free radicals and lower incidence of corneal endothelial injury<sup>35</sup> was observed when 14% ultrasound power was used. These findings are congruent with our study though the previous studies have had a U/s power range between 14% to 67%. In this study 1% power was used and the maximum range extended to 20%.<sup>2,24,26</sup>

## Conclusion

In conclusion we may state that researches found in the literature have all pointed to the negative effect of ultrasound power employed in phacoemulsification towards endothelial health, but it hasn't been attempted to minimize this power so as to reduce the nefarious effect. After one year follow-up this study conclusively found that 1% ultrasound power was much superior to 20% power (which in itself is a very low grade) in maintaining the corneal endothelial viability and at the same time providing a surgical experience which did not compromise on the visual outcome.

**Conflict of Interest:** None.

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