Clinical Outcomes of Deep Anterior Lamellar Keratoplasty (DALK) in patients with Keratoconus: An Interventional study

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Abstract— *Keratoconus (KC) is a common ectasia of the cornea. Deep Anterior Lamellar Keratoplasty (DALK) is one of the modality to treat Keratoconus (KC). So this study was conducted to find out the clinical outcomes of DALK in patients with Keratoconus. For this study 33 eyes of patients with Keratoconus were operative and followed for 3, 6, 9, and 12 months to find out the clinical outcomes of DALK on various visual parameters. It was found that Best corrected Visual Acuity (BCVA) preoperative and postoperative at 3months, 6 months, 9 months and 12months were -1.106±0.160, -0.91±0.153, -0.725±0.107, -0.631±0.172 and -0.495±0.127 respectively, which is statistically significant (p value ≤0.001). Mean Refractive Spherical Equivalent (MRSE) preoperative and postoperative at 3, 6, 9 and 12months were -7.609±1.860, -6.109±1.287, -5.156±1.110, -4.390±0.858 and -3.812±0.790 respectively, which is also significantly improving. Epithelial Cell Density (ECD) preoperative and postoperative at 3, 6, 9 and 12 months were 2159.625±85.757, 2103.218±70.393, 2065.250±77.051, 2044.250±93.637 and1998.718±11.999 respectively. It is also statistically significant. Average Keratometry preoperative and postoperative at 3, 6, 9 and 12months were 59.000±1.722, 56.578±1.492, 55.734±1.156, 54.687±1.068 and 50.187±10.314 respectively, which is also significantly decreasing. Topographic Astigmatism preoperative and postoperative at 3, 6, 9 and 12 month's were3.968±1.046, 3.109±0.737, 2.765±0.729, 2.359±0.650 and 2.015±0.677 respectively. It is also statistically decreasing. Central Corneal Thickness (CCT) preoperative and postoperative at 3, 6, 9 and 12 months were 370.625±24.205, 502.500±9.993, 498.00±14.170, 496.562±15.576 and 492.843±14.438 respectively. CCT is also significantly improving. This concludes that outcomes of big bubble DALK in patients with KC was very effective and DALK should represent the technique of choice for surgical rehabilitation of patients with moderate to advanced KC intolerant to contact lenses.*

Keywords: Keratoconus (KC), Deep Anterior Lamellar Keratoplasty (DALK), Best corrected Visual Acuity (BCVA), Epithelial Cell Density (ECD), Central Corneal Thickness (CCT).

I. INTRODUCTION

Keratoconus (KC) is a common ectasia of the cornea.[1-2] Its reported incidence ranges between 50-230 per 100,000 and the estimated prevalence is 54.5:100,000. Clinically, the central or paracentral corneal stroma undergoes progressive thinning and loss of structural integrity that leads to bulging of the cornea, which gives the cornea its typical cone shape appearance in Keratoconus.

Keratoconus is a progressive asymmetrical, bilateral, non-inflammatory corneal ectasia which is characterized by corneal thinning and irregular astigmatism. It is aggravated by puberty, pregnancy, vernal kerato-conjunctivitis and lid rubbing.

The two main methods of corneal transplantation that can be used to treat keratoconus include Penetrating Keratoplasty (PK) and Deep Anterior Lamellar Keratoplasty (DALK).

Different DALK techniques have been described, based essentially on either manual dissection/ delamination of the corneal stroma or separation of the DM[3] from the stroma by means of intrastromal injection of fluid, viscoelastic, or air.[4] The ‘‘bigbubble’’technique applies a forceful injection of air into the deep stroma to obtain cleavage separation of the descemetic/predescemetic plane from the overlying stroma, with formation of a large air bubble between these 2 layers.[5]

The most recent and important development in the field of DALK is “The Big Bubble ”technique.[5,6] The big bubble technique introduced by Anwar and Teichmann[5] provides a planned , safe, quick and consistent exposure of DM by the injection of air deep into the stroma. The surface of the DM appears smooth after successful stromal resection.

Deep Anterior Lamellar Keratoplasty allows preservation of the host endothelium, abolishing the risk of endothelial immunologic rejection and potentially reducing the issue of late endothelial cell decay.[7] The surgical procedure is carried out "closed-sky" with decreased postoperative intraocular inflammation and risk of intraocular infection.[8]

This study was conducted to evaluate the clinical outcomes of Deep Anterior Lamellar Keratoplasty in Patients with Keratoconus reporting at SMS Hospital Jaipur

II. METHODOLOGY

This hospital based, intervention study was conducted in year 2017, at Upgraded Department of Ophthalmology, SMS Medical College, Jaipur (Rajasthan) India. Ethical clearance was obtained from Institutional Ethical committee. An informed, bilingual and written consent was obtained from all the patients.

The sample size required is 33 cases at 95% confidence and 80% power to verify the expected difference 1.66 D(± 1.52) in topographic astigmatism pre and post-operative in keratoconus.

So for this study, 33 eligible cases of Keratoconus going for Deep Anterior Lamellar Keratoplasty at Upgraded Department of Ophthalmology, SMS Medical College, Jaipur (Rajasthan) India were included in this study. For eligibility of cases, cases with corneal Thickness < 400 µm, Best corrected visual acuity (BCVA) < 6/36 and patient not fit for contact lens were included in this study. And patient with endothelial cell dysfunction, acute or healed hydrops, glaucoma & posterior segment pathology, sever dry eye and previous ocular surgery were excluded from study. Patient who had intra-operative complications were also excluded from study.

After taking demographic & baseline data and certain investigations, these cases were prepared for operation. After doing pre-operative procedures these cases were operated.

All patients will undergo a thorough examination including visual acuity, Intraocular pressure, Slit lamp and fundus examination on 1st postoperative day, 1st week, biweekly for first 2 months, 3rd month, 6th month, 9th month & 12th Month.

Best Corrected Visual Acuity was assessed by Snellen's Chart, Post operative refractive error by Automated Refractometer, Central corneal thickness by Corneal Topography (Pentacam) and Endothelial Cell Density by Specular Microscopy (Topcon Model). All the readings will be performed by a single observer to avoid bias, both pre and postoperatively.

III. RESULTS

Our study included 33 patients of keratoconus out of them one female patient could not followed up because of eye complication. A total of 32 patients with keratoconus were followed for 12 months, so these 32 cases were evaluated further. The mean age of subjects was 24.66±5.23 years. Majority of the subjects were in the age group of 15 – 30 years (75%) and two subjects were less than 15 years of age. Majority of patient were male (65.62%). (Table 1)

Table 1
Characteristics of Study Population

S. No.	Variable		Number	Percentage (%)
1	**Age in years**	≤ 15	2	6.3
		15 – 30	24	75
		≥ 30	6	18.8
2	**Sex**	Male	21	65.62
		Female	11	34.37
3	**Side of Eye**	Left Eye	15	46.88
		Right Eye	17	53.22

Effect of DALK Big-bubble technique in patients with Keratoconus on Best Corrected Visual Acuity (BCVA) and Mean Refractive Spherical Equivalent (MRSE) are shown in table 2 and figure 1. There was a significant decrease in BCVA values with the time ($p<0.001$) after DALK whereas significant increase in MRSE. (Table 2 and Figure 1)

Table 3
Preoperative and Postoperative BCVA and MRSE of DALK Big-bubble technique in patients with Keratoconus

Parameter	Pre operative	Post -operative Follow ups				P* Value
		3 months	6 months	9 months	12 months	
BCVA	1.1062±0.19	-0.91±0.153	-0.725±0.107	-0.631±0.172	-0.495±0.127	**<0.001**
MRSE	-7.609±1.86	-6.109±1.29	-5.156±1.110	-4.390±0.858	3.812±0.790	**<0.001**

BCVA= Best Corrected Visual Acuity, MRSE = Mean Refractive Spherical Equivalent
**** as per ANOVA***

Figure 1
Best corrected visual acuity (BCVA) before and after Deep Anterior Lamellar Keratoplasty (DALK) big-bubble technique

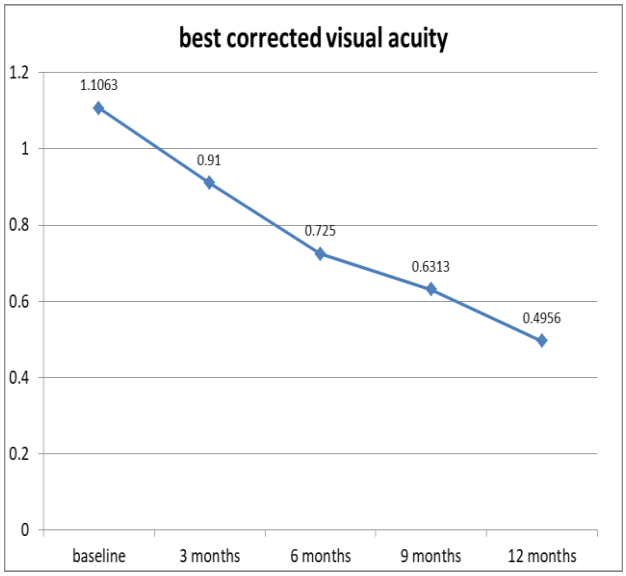
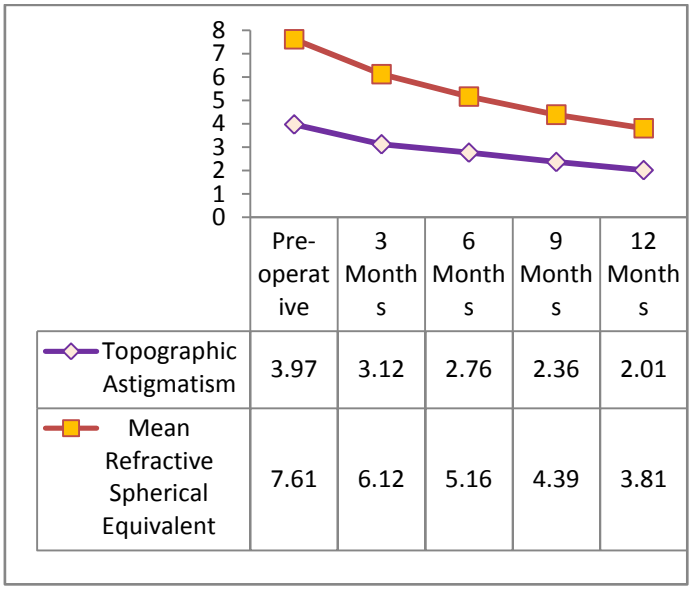


Figure 2
Topographic Astigmatism and Mean refractive spherical equivalent, before and after Deep Anterior Lamellar Keratoplasty (DALK) big-bubble technique.



	Pre-operative	3 Months	6 Months	9 Months	12 Months
Topographic Astigmatism	3.97	3.12	2.76	2.36	2.01
Mean Refractive Spherical Equivalent	7.61	6.12	5.16	4.39	3.81

Effect of DALK Big-bubble technique in patients with Keratoconus on Epithelial Cell Density (ECD) and Central Corneal Thickness (CCT) are shown in table 3. There was a significant decrease in ECD values with the time ($p<0.001$) after DALK whereas there is significant increase in CCT values with the time ($p<0.001$) after DALK. (Table 3)

Table 3
Preoperative and Postoperative Endothelial Cell Density and Central Corneal Thickness of DALK Big-bubble technique in patients with Keratoconus

Parameter	Pre operative	Post -operative Follow ups				P* Value
		3 months	6 months	9 months	12 months	
ECD	2159.625± 85.757	2103.218± 70.393	2065.250± 77.051	2044.250± 93.637	1998.718± 110.999	**<0.001**
CCT	370.625± 24.205	502.500± 9.993	498.00± 14.17	496.562± 15.576	492.843± 14.438	**<0.001**

ECD= Endothelial Cell Density, CCT = Central Corneal Thickness
**** as per ANOVA***

IV. DISCUSSION

In this present study patients with keratoconus were evaluated for the clinical outcomes of the DALK big-bubble technique. In our series, big-bubble formation was achieved in 84% of cases. This percentage is similar to the one (80% to 90%) originally reported by Anwar and Teichmann[5] in a large series of 181 cases of keratoconus.

In this study, there was a significant decrease in BCVA values with the time ($p<0.001$) after DALK whereas significant increase in MRSE. So there was improvement in both BCVA and MRSE after DALK in patients with keratoconus. Likewise there was a significant decrease in ECD values with the time ($p<0.001$) after DALK whereas significant increase in CCT. So there was improvement in both ECD and CCT after DALK in patients with keratoconus.

A prospective study done by Fontana L et al,[9] found an improvement in final BSCVA in whom big-bubble with exposure of the Descemet membrane was achieved.

Domenico Schiano-Lomoriello et al,[10] also reported an improvement in BCVA after 6 month follow up in both D-DALK and PD-DALK groups. Vito Romano et al,[103] also reported an improvement in UDVA and CDVA after DALK.

Another studies,[11-13] also found an improvement in the mean MRSE. MRSE mean preoperative, mean postoperative and P value were -11.36±2.45, -3.91±1.56 and ≤0.001 respectively. In present study MRSE mean preoperative, mean postoperative (12 month after) and P value are -7.609±1.860,-3.812±0.790 and ≤0.001 respectively, which is also suggestive of significant improvement in mean MRSE from base line after 12 month follow up.

Similar observations were made by Vito Romano et al,[8] who reported Preoperative MRSE −11.1 ± 5.6 diopters (D) and postoperative follow-up visit, MRSE to −2.6 ± 3.5 D.

Van Dooren et al,[14] found that ECD showed an 11% decrease during the first 6 months after DALK, and after wards the decrease was 1% - 2% per year. In present study we found reduction in ECD after DALK was 3.3% at 3 months, 5% at 6 months, 6.2% at 9 months and 7.5% at 12 months, this low rate of reduction in ECD may be due to small sample size in present study.

Fontana L et al,[9] reported that mean preoperative endothelial cell density was 2202.29 +/- 392.35 cells/mm and 2034 +/- 438.39 cells/mm two years after surgery. In present study endothelial cell density preoperative and post operative (12 month) 2159.625±85.757 and 1998.718±110.999, which is suggestive of significant improvement (p value ≤0.001).

V. CONCLUSION

It can be concluded from this study that big bubble DALK in patients with KC results in improvment of visual parameters like BCVA, MRSE, ECD and CCT. So it can be concluded that this big bubble DALK technique is effective in patients with keratoconus with good clinical outcomes.

CONFLICT OF INTEREST

None declared till now.

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