COMPARISON OF VISUAL OUTCOMES OF DEEP ANTERIOR LAMELLAR KERATOPLASTY AND PENETRATING KERATOPLASTY

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ABSTRACT

BACKGROUND
Deep Anterior Lamellar Keratoplasty (DALK) has been used as an alternative to PK in the last few years in cases with intact endothelium. This surgical technique conserves the patient’s own endothelial cells. The present study was conducted with an aim to compare the visual outcome and various complications of Deep Anterior Lamellar Keratoplasty (DALK) and Penetrating Keratoplasty (PK).

MATERIALS AND METHODS
A non-randomised controlled trial of 80 cases in which either Deep Anterior Lamellar Keratoplasty (DALK) or Penetrating keratoplasty (PK) done from January 2013 to January 2016, was conducted at SMS Medical College & Hospital, Jaipur. The main outcomes measured were visual outcome, graft survival and complications.

RESULTS
There were not much differences between PK and DALK groups in terms of age and gender. Preoperative visual acuity in both the groups was less than 3/60. There was no significant difference between PK and DALK groups in terms of the postoperative BCVA at 1 year. BCVA was 6/24 or better in 44.73% cases in DALK group and in 40% cases in PK group. Postoperative complications were significantly more frequent after PK.

CONCLUSION
Visual returns of Deep Anterior lamellar Keratoplasty are comparable to that of Penetrating keratoplasty (PK) with less complications. Although the learning curve is a bit steep but being an extraocular procedure with preservation of host endothelium, it is a major advantage over Penetrating keratoplasty (PK).

KEYWORDS
Deep Anterior Lamellar Keratoplasty (DALK), Penetrating Keratoplasty (PK).


BACKGROUND
Penetrating keratoplasty (PK) has been used as a standard technique in the treatment of corneal stromal pathologies and yields acceptable optical and visual results, as presented in previous studies. However, graft failure problems may occur in about 18-34% of cases. Approximately, half of graft failures are the result of endothelial rejection. Deep anterior lamellar keratoplasty (DALK) has been used as an alternative to PK in the last few years in cases with intact endothelium, such as stromal scar, stromal dystrophies, and keratoconus. This surgical technique conserves the patient’s own endothelial cells. Minimal endothelial cell damage results in longer graft survival postoperatively. The lower reported intraoperative and postoperative complication rates with lamellar keratoplasty is another reason to prefer DALK.

However, intraoperative complication rates may be slightly higher in the early stages of the DALK procedure. Furthermore, the procedure has a long learning curve, is laborious and has a longer surgery duration.

The basic principle of lamellar keratoplasty is to replace only that part of cornea that is diseased and leave the recipient’s normal anatomic layers intact. The idea is to do the least amount of resection with greatest amount of benefit thus leaving the healthy endothelium and Descemet's membrane as an immunological barrier to the rejection.

Current techniques of Deep Anterior Lamellar Keratoplasty (DALK) are of Two Types
1. Deep stromal dissection achieved manually, microkeratome assisted or using femtosecond laser. A variable amount of stroma is left behind, therefore the interface between donor and recipient is intrastromal. Stroma to stroma interface may impede visual acuity by optical interference.
2. Big Bubble technique- Refers to injection of air deep into the stroma generating a big air bubble between stroma & the Descemet's membrane, thus causing a large detachment of Descemet's Membrane without using a surgical instrument. This provides safe, speedy & consistent exposure of the smooth & shining surface of
Descemet's membrane. On the donor side, Descemet's membrane is peeled off by the non-toothed forceps resulting in another uniform & smooth surface. The apposition of donor button to the bare Descemet's membrane provide an interface of high quality. The procedure is standardised because the interface achieved is exactly the same in every case.

The present study was conducted with an aim to compare the visual outcome and various complications of Deep Anterior Lamellar Keratoplasty (DALK) and Penetrating keratoplasty (PK).

MATERIALS AND METHODS
Design & Sampling
Design
Non-randomised controlled trial.

Study Period
January 2013 to January 2016.

Sampling
Patients who were following the inclusion criteria according to our study during the study period at SMS Medical College & Hospital, Jaipur were included in the study.

Sampling Procedure and Justification of sampling size
In the study period, 80 cases were according to the inclusion criteria and were operated during the study period; so we have 80 cases in the study. Consecutive patients were alternately selected to receive one of the two surgical methods. So, 40 cases were of Deep Anterior Lamellar Keratoplasty (DALK) by Big Bubble technique and their results were compared with 40 cases of penetrating Keratoplasty. All the cases were done by the same surgeon.

Ethical Issues
The study followed the tenets of the Declaration of Helsinki and had local Ethical Committee approval. An informed consent was obtained from all participants.

Inclusion Criteria
Keratoconus, Keratoglobus, Pelucid marginal degeneration, keratectasia following refractive surgery, Stromal opacities/scars sparing Descemet's membrane and Corneal dystrophies involving anterior/deep stroma.

Exclusion Criteria
Corneal conditions with diseased endothelium, pre-existing rupture in Descemet's membrane, Deep scars involving Descemet's membrane, any pre-existing posterior segment pathology and any significant ocular surface abnormality (severe dry eye, Limbal Stem Cell Deficiency)

A non-randomised controlled trial of 80 cases in which either Deep Anterior Lamellar Keratoplasty (DALK) or Penetrating keratoplasty (PK) done between January 2013 to January 2016; was conducted at SMS Medical College & Hospital, Jaipur. The main outcome measured were visual outcome, graft survival and complications.

As per records patients underwent an ophthalmic examination weekly in 1st month, biweekly in 2nd month and then monthly till 12 months postoperatively. Ocular examinations included evaluation of Snellen best spectacle corrected visual acuity (BCVA), biomicroscopy of the anterior segment, intraocular pressure (IOP) measurement with Goldmann applanation tonometer or Tonopen, and fundus examination.

Minimum postoperative follow-up was 12 months. Drop outs from follow-up were excluded. Main outcome measured was BCVA at 1 year. Secondary outcome measured were immune rejection, graft clarity, IOP, intraoperative and postoperative complications.

Procedure followed for PK
Full thickness donor graft was sutured by 16 interrupted 10-0 nylon monofilament sutures to the host.

Procedure followed for DALK
A detailed history and clinical examination of the eye was done. Routine preoperative investigations were ordered. Deep Anterior Lamellar Keratoplasty (DALK) by Big Bubble technique was carried out-

- Intravenous mannitol (1-1.5 mg/kg body weight) was given preoperatively.
- Peribulbar anaesthesia was given in cooperative patients. In uncooperative patients and children general anaesthesia was given.
- By using Suction Trephine 420 Micron groove was made in the host cornea.
- A partial thickness removal of anterior stroma was done by using crescent knife.
- After making a small incision in the stroma, a blunt tipped probe was introduced in deep stroma. DALK cannula with inferior opening was used to achieve injection of air in the deep stroma resulting in formation of big bubble (Figure 1) between stroma and the Descemet’s membrane.
- Trifacet probe was introduced into the deep stromal layers and a sharp blade was used to dissect the remaining stromal layer in two cruciate incisions.
- Removal of stroma (Figure 2) was achieved using directional scissors.
- Peeling of endothelium from the donor cornea was done after taking the appropriate-sized endothelial punch.
- Suturing of donor cornea over the Bare Descemet’s membrane of the host (Figure -3) was done by 16 interrupted 10-0 nylon monofilament sutures.
- Drop of antibiotic-steroid with cycloplegic instilled and eye was patched for 24 hrs.
- Topical steroid-antibiotic combination was used in tapering doses till 3-6 months, following which it was used as and when condition demanded.
- Cycloplegics were withdrawn after 2 weeks. Topical lubricants were continued in all cases till last followup.

2 cases had ruptured Descemet’s membrane during different stages of surgery and had to be converted to Penetrating keratoplasty (PK) and excluded from study.

Statistical Analysis
Statistical analysis was performed using primer software. Comparison among groups was performed using Chi-square test and independent samples test. P values <0.05 were considered to be significant.
RESULTS

- There were not much differences between PK and DALK groups in terms of age and gender. (Table 1).
- Preoperative visual acuity in both the groups was less than 3/60. (Table 2).
- There was no significant difference between PK and DALK groups in terms of the postoperative BCVA at 1 yr.

Postoperative complications were significantly more frequent after PK. (Table 4). IOP elevations occurred in 25 cases with PK and 2 cases with DALK and were controlled with brimonidine or its fixed combination with timolol. A fixed dilated pupil occurred in 1 eye due to prolonged use of Homatropine after the operation in PK. Endothelial rejection episodes occurred in 5 eyes in PK. They were treated with intravenous pulsed methylprednisolone 500 mg for three days followed by oral route. Grafts cleared after the treatment. No rejection episode was observed in 38 DALK-operated eyes. Postoperative double anterior chamber occurred in 1 eye with microperforation in DALK group. It was successfully managed with air injection into the anterior chamber.

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Parameter</th>
<th>PK (n=40)</th>
<th>DALK (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>AGE (years) (mean)</td>
<td>48.2 yrs</td>
<td>45.6 yrs</td>
</tr>
<tr>
<td>2.</td>
<td>Sex (Male/Female)</td>
<td>22/18</td>
<td>20/18</td>
</tr>
<tr>
<td>3.</td>
<td>Eyes (Right/Left)</td>
<td>28/12</td>
<td>24/14</td>
</tr>
</tbody>
</table>

Table 1. Comparison of Demographic Features of PK & DALK Group

PK – Penetrating Keratoplasty
DALK – Deep Anterior Lamellar Keratoplasty.

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Preoperative Visual Acuity</th>
<th>PK (n=40)</th>
<th>DALK (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>PL+ PR Accurate</td>
<td>25(62.5%)</td>
<td>23(60.5%)</td>
</tr>
<tr>
<td>2.</td>
<td>1/60 to 3/60</td>
<td>15(37.5%)</td>
<td>15(39.47%)</td>
</tr>
</tbody>
</table>

Table 2. Comparison of Preoperative Visual Acuity in PK & DALK Group

P value -0.957 (non-significant)

PK – Penetrating Keratoplasty
DALK – Deep Anterior Lamellar Keratoplasty

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Postoperative (BCVA) at 1 yr.</th>
<th>PK (Cases) (n=40)</th>
<th>DALK (Cases) (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>1/60 to 3/60</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>2.</td>
<td>4/60 to 6/60</td>
<td>10</td>
<td>6</td>
</tr>
<tr>
<td>3.</td>
<td>6/60 to 6/36</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>4.</td>
<td>6/24 or better</td>
<td>16</td>
<td>17</td>
</tr>
</tbody>
</table>

Table 3. Comparison of Postoperative BCVA in PK & DALK Group

P value 1.00 (non-significant)

PK – Penetrating Keratoplasty
DALK – Deep Anterior Lamellar Keratoplasty

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Complications</th>
<th>PK</th>
<th>DALK</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>IOP elevation</td>
<td>25</td>
<td>2</td>
</tr>
<tr>
<td>2.</td>
<td>Rejection Episode</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>3.</td>
<td>Suture loosening</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>4.</td>
<td>Dilated pupil</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>5.</td>
<td>Double anterior chamber</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4. Postoperative Complications

P value -0.03 (less than 0.05 - Significant)
PK – Penetrating Keratoplasty
DALK – Deep Anterior Lamellar Keratoplasty

DISCUSSION

In this study, BCVA at 12 months was similar in PK group and DALK group. This similarity may be because 16 interrupted sutures are placed in both PK & DALK. Our results are comparable to other studies as Akdemir et al. reported mean BCVA at 1 yr. 0.15 logMAR for DALK and 0.21 for PK without a statistical significance. Donoso et al. reported 0.17 for both surgeries. Smadja et al. reported a logMAR BCVA of 0.09 for DALK at 12 months.

In our DALK surgeries, intraoperative DM perforation occurred in 5.2% cases and converted to PK. DM perforation rate has been reported between 4.0%-39.2% and large DM tears needing conversion to PK between 2.3%-27.3% in the literature. Our rates are consistent with these reports.

Formation of type 2 bubble during air injection is associated with high perforation rate.
In our study, postoperative complications are reported more frequently after PK compared to DALK and it is comparable to 31.8% vs. 4.5% in another study.16 This may be because DALK is essentially an extracocular procedure and there are less chances of complications in DALK as compared to PK.

IOP elevation occurred in 62.5% of PK and 5.26% of DALK eyes in our study. This finding is consistent with previous report of 46.2% vs. 1.3%.13 It is likely to be a consequence of the use of steroid drops for shorter period and lower intensity after DALK.

Endothelial rejection episodes were observed in 12.5% of our PK cases. Cohen et al17 reported this rate as 13.3% for PK and Donoso et al11 as 8%. Zhang et al13 reported 7.7% allograft rejection. This may be because most common cause of rejection is endothelium and endothelium is not transplanted in DALK while full thickness transplantation is carried out in PK. Although stromal rejection episode has been reported in 1.7% to 11.3% within 4 yrs., no rejection episode was observed in our DALK cases.14,18 The median predicted survival was reported as 49.0 yrs. in DALK and 17.3 yrs. in PK.19 Reported annual endothelial cell loss rates of 14.1% in PK and 5.8% in DALK are much higher than physiologic loss of 0.6% per year.20,21 It suggests that the removal of stroma and exposure of DM may lead to endothelial cell loss due to indirect trauma.

The limitations of this study include small sample size and relatively short follow-up.

CONCLUSION

The big bubble technique allows safe and consistent exposure of Descemet’s membrane. There are minimal chances of endothelial cell damage, a distinctive advantage over penetrating keratoplasty. The procedure is essentially extracocular and minimises the risk of endophthalmitis. Minimum use of postoperative steroids reduces steroid-induced complications.

Thus, visual returns of Deep Anterior Lamellar Keratoplasty are comparable to that of Penetrating keratoplasty (PK) with less complications. Although the learning curve is a bit steep but being an extracocular procedure with preservation of host endothelium, it is a major advantage over Penetrating keratoplasty (PK).

REFERENCES