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Incidence of Stromal Rejection in Deep Anterior Lamellar Keratoplasty in North Eye Center/Erbil

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Abstract

Background and objectives: Deep anterior lamellar keratoplasty has emerged as a preferred surgical option for corneal diseases, with its primary advantage being the preservation of endothelial cell density, thus reducing the risk of endothelial graft rejection. This study aimed to assess the incidence of stromal rejection in Deep anterior lamellar keratoplasty among patients in Erbil city, Kurdistan Region of Iraq.

Methods: This retrospective cross-sectional study analyzed the incidence of stromal rejection in 477 patients who underwent deep anterior lamellar keratoplasty at the North Eye Center, Erbil, Kurdistan Region of Iraq, from March 2016 to January 2023. Of these, 28 patients developed stromal rejection. Medical records were reviewed to identify risk factors associated with stromal rejection, with diagnoses confirmed via slit lamp examination and visual acuity measurements. Data were analyzed using SPSS version 28, with significance set at $p \leq 0.05$. Ethical approval was obtained, and patient confidentiality was maintained.

Results: The incidence of stromal rejection in deep anterior lamellar keratoplasty was 5.87% among the patients. The study revealed a statistically significant association between rejection and clinical assessment, with loose sutures being a significant risk factor ($p = 0.001$). Specifically, 50% of the patients who experienced stromal rejection had loose sutures. Additionally, stromal neovascularization contributed to 25% of the rejection cases ($p = 0.001$). Treatment primarily involved antibiotics and steroids, with lubricants having no significant impact on rejection rates. Male predominance was observed among patients (72.1% male, 27.9% female), with no significant gender association with rejection ($p = 0.341$).

Conclusion: The findings underscore the efficacy of Deep anterior lamellar keratoplasty in treating corneal disorders while highlighting the importance of vigilant postoperative care, particularly in monitoring suture integrity to prevent rejection.

Keywords: Incidence, Keratoplasty, Keratoconus, Risk factors, Stromal rejection

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Introduction

For many corneal diseases, deep anterior lamellar keratoplasty (DALK) is the first option for surgery; the only complete contraindication is bullous keratopathy, this procedure includes the removal of the damaged anterior layers of the corneal stroma of the eye cornea, DALK protects the host's healthy Descemet membrane (DM) and endothelium.[1] The primary benefit of DALK is the preservation of endothelial cell density and the patient's own endothelium, which removes the possibility of endothelial graft rejection.[2] Since keratoconus is the most common cause of keratoplasty in some areas, in one retrospective study done in south of Iraq on 1000 confirmed cases in two centers of lasik in Najaf and Basrah the prevalence of Keratoconus was about 4.9%, more cases were below 30 years old and regarding gender females were more predominant.[1] Because individuals with keratoconus benefit mostly from maintaining their own endothelium, it is likely the most common indications for DALK are stromal scars and opacities, stromal dystrophies (Avellino, granular, and lattice), and additional corneal ectasia (post-laser in situ keratomileusis keratectasia and pellucid marginal degeneration) are now included in the list of indications for DALK.[2] Although the long term complication resulted from DALK is less when compared with other procedures like penetrating keratoplasty (PKP) with regard to refractive error and corneal astigmatism, but still there is risk of stromal rejection in DALK especially with grafts larger than 9mm. [3,4] The primary factors that led surgeons to choose DALK over PKP were reduced complications, intraoperative safety, and the need to protect the endothelium. [5] Since Keratoconus cases are present in Iraq and one of the methods of treatment is DALK which is performed by many ophthalmologists, no study about this topic has been done previously in Kurdistan Region of Iraq (KRI) this was the reason behind doing this research, the aim of this study is to find the incidence of stromal rejection in deep anterior lamellar keratoplasty in Erbil city of KRI. The objectives were to assess the incidence of stromal rejection in deep anterior lamellar keratoplasty, identify the risk factors of stromal rejection in deep anterior lamellar keratoplasty and also to find the complications associated with stromal rejection in deep anterior lamellar keratoplasty.

Patients and methods

The current study was a retrospective cross-sectional analysis in which 477 patients underwent deep anterior lamellar keratoplasty, and 28 of these patients developed stromal rejection. Researchers examined the records of cases with keratoconus incidence in the department of ophthalmology at North Eye Center, Erbil, Kurdistan Region of Iraq. The study was conducted from the beginning of March 2016 until the middle of January 2023. The researchers aimed to estimate and determine the incidence of stromal rejection in deep anterior lamellar keratoplasty and identify associated risk factors. The medical records of the 28 patients without systemic medical problems that may affect graft rejection who experienced stromal rejection in Deep Anterior Lamellar Keratoplasty were thoroughly reviewed. A total of 477 patients who visited the same center in Erbil and had DALK were included in the study. All subjects underwent pre- and postoperative visual acuity examinations, with further evaluations performed based on a convenient sampling method. The study involved analyzing old files and medical records to obtain necessary data. The diagnosis of rejection was determined by using a slit lamp to assess the presence of stromal haze that affected vision, along with measurements of uncorrected visual acuity and pinhole visual

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acuity. Appropriate treatments were analyzed during each visit. Data were collected without storing or publishing personal identities, and both the incidence of stromal rejection and the risk factors were obtained to provide efficient and accurate statistics. The data were recorded on a specially designed questionnaire, entered into Microsoft Excel (Excel 2016), and then analyzed using the Statistical Package for Social Sciences (SPSS) version 28. The results were compared across different variables, with a statistical significance level set at ≤ 0.05. The results were presented as rates, ratios, frequencies, and percentages in tables and figures, and were analyzed using t-tests and Chi-square tests. The study included all cases admitted to the center who developed stromal rejection at North Eye Center. Patients older than 15 years, regardless of gender, were included. Cases that did not undergo deep anterior lamellar keratoplasty and participants in the pediatric age group were excluded. This study was submitted to the Ethics and Scientific Committees of the Kurdistan Higher Council of Medical Specialties for scientific and ethical approval. The study was explained to each patient, and verbal consent was obtained. Confidentiality and anonymity of data were ensured throughout the study.

Results

A total of 477 cases of different corneal pathologies most commonly keratoconus enrolled in our study, the oldest cases was 78 years old and youngest presented in 15 years in which created a population of 43.86 years in average, most (72.1%) of patients were male and (27.9%) of them were female, all (100%) of participants were from Erbil, according to clinical assessment loose suture removed procedure was done to (10.5%) of cases and loose suture presence in (2.9%) of them (1.5%) of patients experienced stromal new vascularization, (1.3%) of them had epithelial defect, calcium deposition occurred to only (0.4%) of cases, majority (82.2%) of subjects treated with antibiotics and steroids, (17.8%) of them treated with antibiotics, steroids and lubricants, rejection occurred to only (5.9%) and finally (1%) put on eye glasses. Table (1), Figure (1 and 2).

Table (1): General background, clinical assessment and treatment plan of patients.

Variables	Categories	Frequency	Percent
Gender	Male	344	72.1
	Female	133	27.9
Residence	Erbil	477	100
Clinical assessment	Doing well	386	80.9
	Loose suture removed	50	10.5
	Corneal edema	3	0.6
	Epithelial defect	6	1.3
	Dry eye	4	0.8
	Loose suture	14	2.9
	Stromal new vascularization	7	1.5
	Lipid deposition	5	1
	Calcium deposition	2	0.4
Treatment plans	Antibiotics and steroids	392	82.2
	Antibiotics, steroids and lubricants	85	17.8
Rejection	Yes	28	5.9
	No	449	94.1
Eye glasses	No	472	99
	Yes	5	1
Contact lens	No	477	100
Total		477	100%

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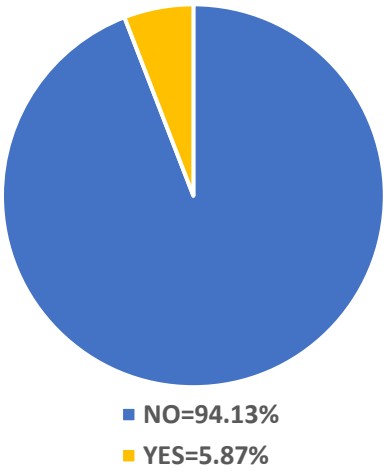

Figure (1): Stromal rejection in Deep Anterior Lamellar Keratoplasty.

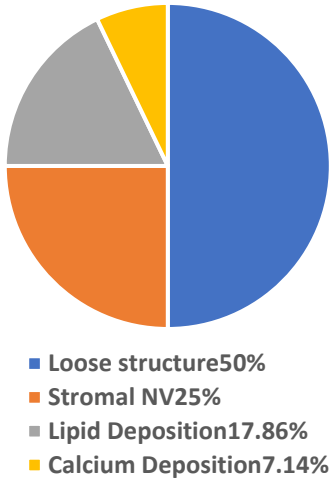

Figure (2): Risk factors for rejection.

Results of Table (2) show that there was no significant statistical association between rejection and gender, treatment plans and eye glasses and p-value was > 0.05. There was a significant statistical association between rejection and clinical assessment, for patients whose loose suture removed; rejection did not occur, likewise for corneal edema, epithelial defect group and those who did well while patients with loose suture, stromal new vascularization, lipid deposition and calcium deposition developed rejection. Chi square test was done and p-value was 0.001.

Table (2): Association between rejection and risk factors

Variable	Categories	Rejection		p-value
		Yes	No	
Gender	Male	18 (64.3%)	326 (72.6%)	0.341
	Female	10 (35.7%)	123 (27.4%)	
Treatment plans	Antibiotics and steroids	25 (89.3%)	367 (81.7%)	0.446
	Antibiotics, steroids and lubricants	3 (10.7%)	82 (18.3%)	
Eye glasses	No	27 (96.4%)	445 (99.1%)	0.262
	Yes	1 (3.6%)	4 (0.9%)	
Clinical assessment	Doing well	0 (0%)	386 (86%)	0.001
	Loose suture removed	0 (0%)	50 (11.1%)	
	Corneal edema	0 (0%)	3 (0.7%)	
	Epithelial defect	0 (0%)	6 (1.3%)	
	Dry eye	0 (0%)	4 (0.9%)	
	Loose suture	[1]4 (50%)	0 (0%)	
	Stromal new vascularization	7 (25%)	0 (0%)	
	Lipid deposition	5 (17.9%)	0 (0%)	
	Calcium deposition	2 (7.1%)	0 (0%)	
Total		28 (100%)	449 (100%)	

Discussion

In general, DALK is more preferable surgical procedure over penetrating keratoplasty (PKP) for treating corneal disorders, in PK endothelial failure and immune graft rejection continue to be long-term problems that cause late graft failure. A workable substitute that allows for the preservation of the host's endothelial cells to reduce the possibility of rejection and failure is DALK,

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it had a better 10-year graft survival rate, less post operative complications.[6, 7] Other studies showed that in eyes with advanced keratoconus, both corneal transplantation procedures resulted in a notable improvement in the refractive and visual parameters. Compared to PK, DALK produced improved visual acuity and refraction with less problems linked to sutures.[8] More than three quarters of study sample were male and there were no statistically significant association with DALK rejection this was inconsistent with a study done by Hopkinson between years 1999 and 2012 in which patients with keratoconus (KC), gender matching was substantially linked to lower graft failure and rejection rates but in high-risk situations, the effect of gender matching was less noticeable, Antibiotics and steroid were used in nearly all cases in this study with small numbers of them also lubricants were add to this treatment, adding this lubricants were not statistically associated with rejection rate of DALK, in a study done by Kasamatsu between 1997 and 2021 out of 411 DALK cases, 24 developed immunologic reaction 24.4% of them were due to reduction of topical steroid use, another study showed that although systemic immunosuppression have limited evidence to support its use for treating and avoiding rejection events, topical immunosuppressants and steroids are the most widely used as an effective options.[9-11] In this study loose suture was associated with about 50% of rejection cases, this is true as in this situation the sutures become slack or loosened over time as a result of various causes which may be natural or due to healing process, this was in line with a study done by Feizi on 633 DALKs in whom 69% of them developed suture related complication, 32.7% of them related to loose sutures.[12] The significant association between loose sutures and the incidence of stromal rejection in this study is consistent with existing literature that emphasizes the importance of suture management in preventing complications. Loose sutures can induce localized inflammation, which may lead to neovascularization and subsequent stromal rejection. A study by Watson et al. emphasized the role of meticulous suture management and the early removal of loose sutures in reducing the risk of rejection in DALK patients. This underscores the necessity of close postoperative monitoring and timely intervention to mitigate potential risks.[13] Cornea neovascularization (NV) was another risk factor for corneal rejection after DALK procedure which contributed to 25% of rejection cases in this study, this was in line with a study done by Pellegrini on 616 DALK cases between 2012 and 2020, showed that the incidence of stromal NV after one year was 8.7% and 13.2% after 5 years, also significant predictors of corneal NV include older age, ocular allergy, and early topical steroid cessation.[14] Neovascularization can facilitate the entry of immune cells into the corneal stroma, increasing the risk of immune-mediated rejection. Previous research by Pelligrene et al. supported this finding, indicating that stromal neovascularization significantly raises the likelihood of rejection in DALK and PKP procedures alike. Preventative measures, such as the use of anti-VEGF (vascular endothelial growth factor) agents preoperatively or postoperatively, have been proposed to reduce the incidence of neovascularization, thereby decreasing the risk of rejection.[14] DALK has gained recognition as a preferred alternative to penetrating keratoplasty (PKP), particularly in conditions like keratoconus and stromal opacities where the endothelium remains unaffected. The reduced risk of endothelial rejection in DALK is one of its major advantages, but stromal rejection remains a significant concern. The incidence of stromal rejection in our study was 5.87%, which aligns with other studies that report a varied

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range depending on patient population, surgical technique, and postoperative care protocols. For instance, a study by Giannaccare. (2018) observed a stromal rejection rate of approximately 5,3% in patients undergoing DALK, highlighting that while the procedure is generally safe, rejection can still occur under specific circumstances.[4] Finally, while our study did not find a significant difference in rejection rates between patients treated with antibiotics and steroids alone and those who also received lubricants, the role of adjunctive therapies remains a topic of debate. Corticosteroids as mentioned by Fogla are essential in preventing and managing acute rejection in corneal transplants, with systemic and topical immunosuppressants also being explored for enhanced outcomes. Early recognition and targeted treatment are key to reversing rejection and ensuring long-term graft survival. Further research is warranted to explore these potential benefits, particularly in high-risk patients. [15]

Conclusion

The findings underscore the efficacy of DALK in treating corneal disorders while highlighting the importance of vigilant postoperative care, particularly in monitoring suture integrity to prevent rejection. This study contributes to the understanding of DALK outcomes and risk factors in the Erbil population, providing valuable insights for clinical practice and future research endeavors.

Conflicts of interest

Declared none.

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