

Role of Amniotic Membrane Graft in the Management of Corneal Ulcer in a Tertiary Care Hospital in Peshawar

Palwasha Ali*, Samina Karim

Department of Ophthalmology, Hayatabad Medical Complex, Peshawar, Pakistan

*Corresponding author's email address: palwashakkhan@gmail.com

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Abstract: Corneal ulcers are a significant cause of visual morbidity and, if inadequately treated, may lead to corneal scarring or perforation. Amniotic membrane grafting has emerged as an effective therapeutic option due to its anti-inflammatory, anti-fibrotic, and epithelial healing properties. However, local data regarding its efficacy remains limited. **Objective:** To determine the efficacy of amniotic membrane grafting in the management of corneal ulcers at a tertiary care hospital in Peshawar. **Methods:** This descriptive study was conducted at a tertiary care hospital in Peshawar and included 139 patients aged 18–60 years of either gender presenting with corneal ulcers. A corneal ulcer was defined as involvement of more than 50% of the corneal depth, dry eye, and confirmed bacterial growth. Patients with glaucoma, chronic dacryocystitis, or corneal ulcers associated with entropion were excluded. All patients underwent amniotic membrane grafting, and treatment efficacy was assessed at eight weeks post-procedure. Data were analyzed using SPSS version 26, and outcomes were reported as frequencies and percentages. **Results:** A total of 139 patients were enrolled, with a mean age of 46.91 ± 13.54 years and a mean body mass index of 24.45 ± 1.89 kg/m². There were 74 (53.2%) male and 65 (46.8%) female patients. Successful treatment outcomes were achieved in 121 patients, yielding an overall efficacy rate of 87.1%. **Conclusion:** Amniotic membrane grafting demonstrated high efficacy in the management of corneal ulcers, with a success rate of 87.1%. This technique appears to be a safe and effective therapeutic option for treating corneal ulcers and may help reduce disease-related morbidity when applied appropriately.

Keywords: Corneal Ulcer, Amniotic Membrane Graft, Surgical Transplantation, Efficacy

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Introduction

Corneal ulceration is considered a major cause of visual impairment alongside blindness globally that results due to diverse aetiology, including infectious keratitis, trauma, and immune-mediated damage. Despite improvements in antimicrobial therapy and supportive care, a significant number of ulcers remain refractory to conventional management, leading to epithelial defects and perforations. Amniotic membrane grafting (AMG) has emerged as a valuable surgical adjunct for the treatment of complex corneal ulcers due to its unique biological properties that promote wound healing and reduce scar formation. Human amniotic membrane comprises a rich complement of growth factors and matrix constituents that form a microenvironment for ocular surface regeneration when applied as a graft to the damaged cornea (1-4).

The study demonstrated that AMG can considerably shorten healing time for persistent epithelial impairment and non-healing ulcers, providing improved comfort and visual outcomes compared with standard medical methods alone. The study highlighted that AMG acts not just as a mechanical obstacle but also as a biological scaffold, assisting cellular migration and adhesion, while encouraging tissue repair and minimizing vascularization and fibroblast-mediated scarring (5-8). AMG is reported to be safe and effective in such situations, with evidence of favourable outcomes, such as complete epithelialisation and reduced need for therapeutic keratoplasty. Studies focusing on infectious keratitis-related corneal ulcers in which AMG achieved baseline healing and contributed to stable visual outcomes, strengthening its role as a significant tool in surgical management. Contemporary research has demonstrated complex immunomodulatory effects of the AMG, including facilitation of regulatory cytokine signalling and suppression of neutrophil-driven tissue destruction, thereby promoting a favourable healing environment (9, 10). Reports showed that AMG is not only feasible but also highly successful in treating persistent epithelial defects and difficult ocular surface disorders, with comparable success rates. Current data strongly support

AMG as a useful and promising intervention in the management of refractory and severe corneal ulcers, with the potential to reduce morbidity and improve the quality of life for affected patients worldwide (11-13).

Corneal ulcers are characterised by epithelial breakdown, enzymatic degradation, and impaired regeneration, leading to progressive tissue loss and increased risk of perforation. Amniotic membrane provides a natural basement membrane-like scaffold that promotes epithelial cell migration and adhesion, thereby accelerating surface healing while concurrently suppressing excessive inflammation. By stabilising the corneal surface and reducing the risk of complications, AMG offers a biologically sound and clinically effective strategy for improving both anatomical and functional outcomes in cases of corneal ulceration.

Methodology

This descriptive study was conducted in the department of ophthalmology at Hayatabad Medical Complex, Peshawar, after obtaining ethical approval from the hospital. The study was conducted from 07-04-2024 to 07-10-2024. One hundred thirty-nine patients were selected. The sample size was calculated using the World Health Organization sample size calculator, with parameters set to 95% confidence interval, 5% margin of error, and an anticipated efficacy rate of 90% based on a previous study (14). A non-probability consecutive sampling technique was used.

Eligible patients were aged between 18 and 60 years of either gender presenting with a corneal ulcer defined as an ulcer seen with > 50% corneal deoth on slit lamp examination, Schmer's test without anesthesia showing tear production with values <10 mm at 5 minutes, confirming dry eye, and positive bacterial growth with growth $\geq 10^3$ CFU/mL on culture. Patients with a history of glaucoma, chronic dacryocystitis, and ulcers with entropion were excluded.

Informed consent was taken from each patient. Basic demographics, including age, gender, body mass index, profession, duration of ulcer,



socioeconomic status, educational level, and residential status, were recorded. Patients fulfilling the inclusion criteria from the Department of Ophthalmology at HMC Peshawar were included in the study after obtaining ethical committee approval. Informed consent was taken from patients after explaining the purpose and benefits of the study. Basic demographics, including age, gender, BMI, profession, duration of ulcer, socioeconomic status, educational level, and residential status, were recorded at inclusion.

The human amniotic membrane was prepared using the standard protocol. The placenta was obtained from the Department of Obstetrics and Gynaecology shortly after elective caesarean deliveries from mothers who had been screened for HIV, hepatitis B, and syphilis in the first trimester in the antenatal clinic. The placenta was cleaned with a balanced salt solution containing 50 µg/ml ceftriaxone, 50 µg/ml streptomycin, 100 µg/ml amikacin, and 2.5 µg/ml amphotericin B. The amniotic membrane was separated from the chorion by blunt dissection through the potential spaces between the two tissues. This tissue was transported to the eye operating theatre in a sterile tray and used on the same day.

Amniotic membrane transplantation was performed under aseptic conditions. Uncooperative patients were given peribulbar anaesthesia, and topical anaesthesia (0.5% proparacaine) was used for young cooperative patients. The necrotic tissue at the base of the ulcer was debrided and sent for culture and sensitivity testing. The rolled-up edge of the ulcer or the loosely adherent epithelium adjacent to the ulcer was also removed. The amniotic membrane was trimmed to fit the ulcer and placed with its epithelial side up. Then the amniotic membrane was secured with 10-0 nylon suture with the suture knots buried. A double-layer amniotic membrane transplantation was done for ulcers of depth more than three-fourths of the cornea with descemetocoele. For a double-layered AMT, one layer of amniotic membrane was overlaid on another layer, both with the epithelial side up. After trimming to fit the ulcer's shape, both layers were secured in place with 10-0 nylon continuous suture. At the end of the surgery, Gatifloxacin ointment was applied, and the eye was patched for 6 hours, after which antimicrobial agents were resumed. Patients were examined, and efficacy was recorded at the eighth week. Efficacy was defined as complete epithelialization, >50% reduction in infiltrate size, no progression in depth, culture negativity, formation of an anterior chamber in perforations, and symptom relief after the procedure. All data were recorded on the specially designed proforma.

Data was analyzed using SPSS 26. Frequencies and percentages were presented for gender, socioeconomic status, educational level, residential status, profession, and efficacy. The mean and SD were calculated for quantitative variables, including age, BMI, and ulcer duration. Efficacy was stratified for age, gender, BMI, duration of ulcer, socioeconomic status, educational level, profession, and residential status. Post-stratification chi-square test or Fisher's exact test was applied; $p \leq 0.05$ was considered significant.

Results

The study included 139 patients. Their mean age was 46.91 years (SD = 13.54). The mean duration of the corneal ulcer was 2.48 months (SD = 1.15). Mean Body Mass Index (BMI) was 24.45 (SD = 1.89).

Regarding the demographics, 74 patients (53.2%) were male, and 65 (46.8%) were female. Regarding the educational status, 51 patients (36.7%) had no formal education. Regarding employment, 60 patients (43.2%) were employed. The remaining demographic details are presented in Table 1. Figure 1 shows the age distribution of the patients; the majority were older than 45 years (94, 67.6%).

Treatment efficacy was defined as complete epithelialisation, a significant reduction in infiltrate size, halted progression, and symptom relief. Efficacy was achieved in 121 cases (87.1%) (Table 2). Table 3 presents the stratification of efficacy with various parameters.

Table 1: Demographics

Demographics		n	%
Gender	Male	74	53.2%
	Female	65	46.8%
Education status	Uneducated	51	36.7%
	Primary	30	21.6%
	Secondary	37	26.6%
Profession	Employed	60	43.2%
	Unemployed	79	56.8%
	Residential status	Urban	62
Rural		77	55.4%
Socioeconomic status	Low	53	38.1%
	Middle	59	42.4%
	High	27	19.4%

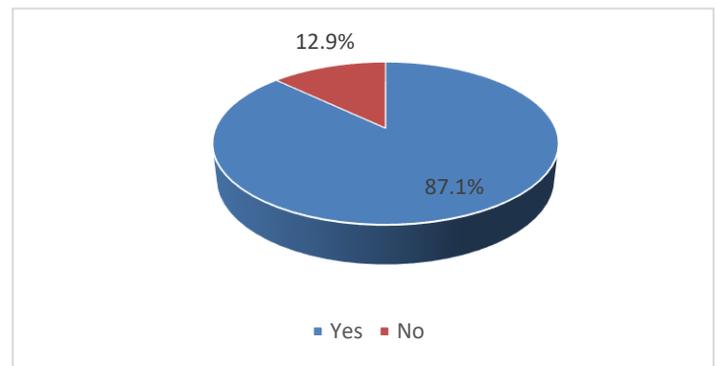


Fig 1: Efficacy of amniotic membrane graft

Table 2: Stratification of efficacy with various parameters

Parameters	Efficacy					p value
	Yes		No			
	n	%	n	%		
Age distribution (Years)	18 to 30	26	21.5%	2	11.1%	0.53
	31 to 45	14	11.6%	3	16.7%	
	> 45	81	66.9%	13	72.2%	
BMI (Kg/m2)	18 to 25	64	52.9%	12	66.7%	0.27
	> 25	57	47.1%	6	33.3%	
Duration of ulcer (Months)	1 to 2	65	53.7%	9	50.0%	0.76
	> 2	56	46.3%	9	50.0%	
Gender	Male	61	50.4%	13	72.2%	0.08
	Female	60	49.6%	5	27.8%	
Education status	Uneducated	42	34.7%	9	50.0%	0.51
	Primary	28	23.1%	2	11.1%	

	Secondary	32	26.4%	5	27.8%	
	Higher	19	15.7%	2	11.1%	
Profession	Employed	53	43.8%	7	38.9%	0.69
	Unemployed	68	56.2%	11	61.1%	
Residential status	Urban	56	46.3%	6	33.3%	0.30
	Rural	65	53.7%	12	66.7%	
Socioeconomic status	Low	52	43.0%	1	5.6%	0.003
	Middle	45	37.2%	14	77.8%	
	High	24	19.8%	3	16.7%	

Discussion

Amniotic membrane transplantation (AMT) has been widely documented as a valued surgical procedure for managing refractory corneal ulcers, with a well-established body of evidence supporting its mechanisms and clinical application. The collective findings from the studies underscore its role in facilitating epithelialization, modulating inflammation, and providing tectonic support. These studies, conducted across diverse geographic and resource settings, consistently report that AMT promotes healing in ulcers that have proven unresponsive to conventional medical therapy (14, 15). The therapeutic efficacy is largely associated with the membrane's biological properties, which act as a scaffold for epithelial migration, reduce protease activity, and dampen the local immune response, thereby creating a conducive microenvironment for ocular surface recovery (1, 16).

The demographic and clinical profiles of patients undergoing AMT, as reported in the literature, indicate that it is typically used for severe non-healing conditions. The mean age of patients in studies often falls within the fifth to seventh decades of life, suggesting a predisposition toward older adults who may have comorbidities that affect wound healing (17-19).

Technical aspects of AMT, including membrane preparation and surgical methodology, significantly influence outcomes. The literature highlights a range of practices, from the use of fresh, short-term-stored membranes in settings with limited cryopreservation facilities to sophisticated cryopreservation protocols using agents such as dimethylsulphoxide (20). Surgically, the choice between inlay, overlay, or combined sandwich techniques is decided by ulcer depth and the presence of perforation, with multilayer approaches being advocated for more severe structural compromise (21). Success rates for anatomical restoration and epithelial healing in studies are high, with benefits in pain relief and inflammation reduction noted from the early postoperative period (22).

The present study included 139 patients who were offered a detailed demographic and outcome analysis that aligns with the literature. The mean age of the cohort was 46.91 ± 13.54 years, which is consistent with the adult population typically requiring such intervention, although slightly younger than the averages reported in some other studies, reflecting regional epidemiological patterns or differences in inclusion criteria (18). The gender distribution of 74 males (53.2%) and 65 females (46.8%) further confirms the balanced demographic as noted by Chauhan et al. (18).

A key contribution of this study is the precise quantification of ulcer chronicity, reporting a mean duration of 2.48 ± 1.15 months before AMT. The study observed 87.1% treatment efficacy rate, which validates the high success rates cited in the literature (14, 1, 19). This outcome was achieved with a clearly defined composite endpoint of epithelialisation, infiltrate reduction, arrested progression, and symptom relief. The efficacy demonstrated in the current study validates AMT as a highly effective intervention for corneal ulcers. The patients who failed to achieve efficacy need consideration. Potential reasons could be very large or centrally located perforations, underlying uncontrolled autoimmune activity, or severe dry eye disease, which can compromise graft integration and healing (15).

Conclusion

In conclusion, the present study validates the high efficacy of amniotic membrane transplantation for the management of corneal ulcers. This study observed 87.1% success rate in patients with corneal ulcers. Future research should aim for prospective controlled designs with standardized protocols, detailed etiological stratification, and longer follow-up to assess the durability of visual rehabilitation and further refine patient selection criteria for amniotic membrane transplantation.

Declarations

Data Availability statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department concerned. (IRB).

Consent for publication

Approved

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Conflict of interest

The authors declared no conflicts of interest.

Author Contribution

PA (Trainee Medical Officer)

Contributed to study design, data collection, and initial manuscript drafting

Assisted in data acquisition, literature review, and manuscript editing
Performed statistical analysis and contributed to the interpretation of results

SK (Associate Professor)

Contributed to patient recruitment, data entry, and results compilation

Assisted in referencing, proofreading, and final revisions of the manuscript

Guided study execution and critically reviewed the manuscript

All authors reviewed the results and approved the final version of the manuscript. They are also accountable for the integrity of the study.

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