

Comparative Evaluation of Therapeutic Outcomes of Amniotic Membrane Transplantation Versus Conventional Therapy in Non-Healing Corneal Ulcers

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Received: 27-04-2026 / Revised: 26-05-2026 / Accepted: 28-06-2026

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Conflict of interest: Nil

Abstract:

Background: Non-healing corneal ulcers are a significant cause of ocular morbidity and visual impairment. Conventional medical therapy may fail in some patients, resulting in prolonged inflammation, delayed epithelial healing, and increased risk of corneal perforation. Amniotic membrane transplantation (AMT) has emerged as a promising treatment because of its anti-inflammatory, anti-fibrotic, and epithelial regenerative properties.

Objective: To compare the therapeutic outcomes of amniotic membrane transplantation with conventional therapy in patients with non-healing corneal ulcers.

Methods: A comparative prospective study was conducted on patients diagnosed with non-healing corneal ulcers. Participants were divided into two groups: one group received amniotic membrane transplantation along with standard medical treatment, while the other received conventional medical therapy alone. Outcome measures included time to complete epithelial healing, reduction in ulcer size, improvement in visual acuity, pain relief, and incidence of complications. Patients were followed at regular intervals, and treatment outcomes were statistically analyzed.

Conclusion: Amniotic membrane transplantation is a safe and effective adjunctive treatment for non-healing corneal ulcers. Compared with conventional therapy alone, AMT promotes faster corneal healing, improves visual outcomes, and reduces complications, making it a valuable therapeutic option in the management of refractory corneal ulcers.

Keywords: Amniotic Membrane Transplantation (AMT), Non-Healing Corneal Ulcer, Corneal Ulcer, Conventional Therapy, Corneal Epithelial Healing, Ocular Surface Reconstruction, Visual Acuity, Ophthalmology, Corneal Regeneration, Therapeutic Outcomes.

DOI: 10.25258/ijcpr.18.6.297

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Introduction

The cornea is the transparent, avascular anterior part of the eye that plays a crucial role in the transmission and refraction of light. Maintenance of corneal transparency depends on the integrity of the corneal epithelium and the prompt healing of any epithelial defect. Corneal ulcers are a major cause of ocular morbidity and preventable blindness worldwide, particularly in developing countries. They commonly result from microbial infections, trauma, dry eye disease, neurotrophic keratopathy, autoimmune disorders, or chemical injuries. If left untreated or inadequately managed, corneal ulcers may progress to stromal melting, corneal perforation, scarring, and permanent visual impairment. A non-healing corneal ulcer is defined as a persistent epithelial defect with underlying stromal involvement that fails to heal despite appropriate medical therapy over a prolonged

period, usually two weeks or more. These ulcers present a significant therapeutic challenge because persistent inflammation, infection, impaired epithelial regeneration, and tear film abnormalities interfere with normal wound healing. Conventional treatment includes intensive topical antimicrobial agents, lubricants, cycloplegics, anti-collagenolytic agents, treatment of underlying systemic or ocular diseases, and supportive measures. Although these therapies are effective in many patients, some ulcers remain refractory, necessitating alternative treatment strategies. Amniotic membrane transplantation (AMT) has emerged as an effective biological dressing for the management of non-healing corneal ulcers. The human amniotic membrane, the innermost layer of the placenta, possesses unique biological properties, including anti-inflammatory, anti-fibrotic, anti-angiogenic,

antimicrobial, and epithelial regenerative effects. It promotes epithelial cell migration and adhesion, suppresses inflammation, reduces pain, and facilitates corneal wound healing while minimizing scar formation. These properties have made AMT an important adjunctive treatment in ocular surface reconstruction. Several clinical studies have demonstrated encouraging results with AMT in persistent epithelial defects and non-healing corneal ulcers. Patients treated with AMT often experience faster epithelial healing, reduced pain, improved visual acuity, and a lower risk of corneal perforation compared with conventional medical therapy alone. However, the degree of benefit may vary depending on the etiology, severity, and duration of the ulcer, highlighting the need for further comparative evaluation. The present study aims to compare the therapeutic outcomes of amniotic membrane transplantation with conventional therapy in patients with non-healing corneal ulcers. By evaluating parameters such as epithelial healing time, reduction in ulcer size, improvement in visual acuity, pain relief, and treatment-related complications, this study seeks to determine the effectiveness of AMT and its role in improving clinical outcomes in patients with refractory corneal ulcers.

Materials and Methods

This was a prospective, comparative, hospital-based study conducted in the Department of Ophthalmology at Radha Devi Jageshwari Memorial Medical College and Hospital Turki, Muzaffarpur. Study duration of one year. on patients diagnosed with non-healing corneal ulcers.

Study Population: A total of 92 patients with non-healing corneal ulcers attending the ophthalmology outpatient department and admitted to the hospital during the study period were included.

The study included 92 patients, who were equally divided into two groups:

- Group A (n = 46): Patients treated with amniotic membrane transplantation (AMT) along with standard medical therapy.
- Group B (n = 46): Patients treated with conventional medical therapy alone.

Inclusion Criteria

- Patients aged 18 years and above.
- Clinically diagnosed non-healing corneal ulcer persisting despite appropriate medical treatment for at least 2 weeks.
- Patients willing to participate and provide written informed consent.

Exclusion Criteria

- Corneal perforation requiring emergency surgical intervention.
- Active endophthalmitis.

- Ocular malignancy.
- Patients with severe systemic illness affecting wound healing.
- Patients unwilling to participate or lost to follow-up.

Treatment Protocol

Group A (AMT Group): Patients underwent amniotic membrane transplantation under aseptic conditions. The amniotic membrane was secured over the ulcer using interrupted 10-0 nylon sutures or fibrin glue, followed by standard postoperative medical therapy including topical antibiotics, lubricants, cycloplegics, and other medications as indicated.

Group B (Conventional Therapy Group): Patients received standard medical management consisting of appropriate topical antimicrobial agents, lubricating eye drops, cycloplegics, anti-inflammatory medication when indicated, and treatment of the underlying cause according to institutional protocol.

Outcome Measures

- Time to complete corneal epithelial healing.
- Reduction in ulcer size.
- Improvement in best-corrected visual acuity (BCVA).
- Relief of ocular pain.
- Corneal transparency and scar formation.
- Complications such as corneal perforation, recurrence, or need for additional surgical intervention.

Follow-up: Patients were evaluated on postoperative/day 1, 1 week, 2 weeks, 4 weeks, and 8 weeks. At each visit, slit-lamp examination, fluorescein staining, ulcer measurements, and visual acuity assessment were performed.

Statistical Analysis: Data were entered into Microsoft Excel and analyzed using SPSS software (version 26.0 or later). Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequencies and percentages. Comparisons between groups were performed using the independent Student's t-test for continuous variables and the Chi-square or Fisher's exact test for categorical variables. A p-value of <0.05 was considered statistically significant.

Ethical Considerations: The study was conducted after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants before enrollment, and the study adhered to the principles of the Declaration of Helsinki.

Results

A total of 92 patients with non-healing corneal ulcers were included in the study. Of these, 46 patients were managed with amniotic membrane transplantation (AMT) along with conventional medical therapy (Group A) and 46 patients received conventional medical therapy alone (Group B). All patients completed the scheduled follow-up. The baseline demographic and clinical characteristics were comparable between the two groups, with no statistically significant differences in age, sex distribution, ulcer size, duration of symptoms, or presenting visual acuity. Patients in the AMT group showed a significantly faster rate of corneal epithelial healing than those in the conventional therapy group. A greater proportion of patients in Group A achieved complete epithelial healing during the follow-up period. Reduction in ulcer size was also more pronounced in the AMT group.

Improvement in best-corrected visual acuity was greater in patients treated with AMT. Most patients in Group A demonstrated an improvement of one or more Snellen lines at the final follow-up, whereas

visual improvement in Group B was comparatively less. Pain scores decreased more rapidly following treatment with AMT. Patients receiving AMT reported earlier symptomatic relief, reduced conjunctival congestion, and better ocular comfort than those receiving conventional therapy alone.

Complications such as persistent epithelial defects, corneal thinning, and impending or actual corneal perforation occurred less frequently in the AMT group. A higher proportion of patients in the conventional therapy group required prolonged medical treatment or additional surgical intervention. Overall, the therapeutic success rate was higher in the AMT group than in the conventional therapy group. Statistical analysis demonstrated that the differences in epithelial healing time, improvement in visual acuity, and overall treatment success between the two groups were statistically significant ($p < 0.05$), indicating the superior efficacy of amniotic membrane transplantation as an adjunct to conventional therapy in the management of non-healing corneal ulcers.

Table 1: Distribution of Patients According to Age

Age Group (Years)	Group A (AMT) n=46	Group B (Conventional) n=46	Total (n=92)
18–30	8	7	15
31–40	12	11	23
41–50	13	14	27
51–60	9	10	19
>60	4	4	8

Table 2: Gender Distribution

Gender	Group A	Group B	Total
Male	28	30	58
Female	18	16	34

Table 3: Etiology of Non-Healing Corneal Ulcer

Etiology	Group A	Group B	Total
Bacterial	18	17	35
Fungal	15	16	31
Viral	6	5	11
Neurotrophic	4	5	9
Others	3	3	6

Table 4: Mean Time for Complete Epithelial Healing

Group	Mean $\pm$ SD (Days)	p-value
Group A (AMT)	18.4 $\pm$ 4.2	<0.001
Group B (Conventional)	29.6 $\pm$ 6.1	

Table 5: Complete Corneal Healing

Outcome	Group A	Group B	p-value
Complete Healing	42 (91.3%)	33 (71.7%)	0.016
Incomplete Healing	4 (8.7%)	13 (28.3%)	

Table 6: Improvement in Visual Acuity

Visual Outcome	Group A	Group B	p-value
Improved	38 (82.6%)	28 (60.9%)	0.021
Unchanged/Worse	8 (17.4%)	18 (39.1%)	

Table 7: Pain Relief at Final Follow-up

Pain Relief	Group A	Group B	p-value
Complete	40 (87.0%)	29 (63.0%)	0.009
Partial/None	6 (13.0%)	17 (37.0%)	

Table 8: Complications

Complication	Group A	Group B	p-value
Corneal Perforation	1 (2.2%)	5 (10.9%)	0.041
Persistent Epithelial Defect	3 (6.5%)	10 (21.7%)	
Additional Surgical Procedure	2 (4.3%)	8 (17.4%)	

Discussion

The present study compared the therapeutic outcomes of amniotic membrane transplantation (AMT) with conventional medical therapy in the management of non-healing corneal ulcers. A total of 92 patients were included, with 46 patients in each treatment group. The findings demonstrated that patients treated with AMT had better clinical outcomes than those receiving conventional therapy alone. Corneal ulcers that fail to heal despite appropriate medical treatment remain a significant challenge in ophthalmic practice because they are associated with prolonged inflammation, stromal degradation, secondary infection, and an increased risk of corneal perforation. Conventional therapy primarily controls infection and inflammation but may not adequately promote epithelial regeneration in refractory cases. In contrast, the amniotic membrane acts as a biological scaffold that facilitates epithelial cell migration, suppresses inflammation, reduces fibrosis, and promotes corneal wound healing.

In the present study, the AMT group showed a significantly shorter epithelial healing time than the conventional therapy group. This finding is consistent with previous studies, which have reported that AMT accelerates corneal epithelialization by providing a suitable substrate for epithelial cell growth and by releasing growth factors that enhance wound healing. Visual acuity improved more in patients treated with AMT than in those receiving conventional therapy alone. This improvement may be attributed to rapid epithelial healing, reduced stromal inflammation, decreased corneal scarring, and preservation of corneal transparency. Similar improvements in visual outcomes have been reported in earlier clinical studies evaluating AMT in persistent epithelial defects and non-healing corneal ulcers. Pain relief was also more pronounced in the AMT group. The anti-inflammatory and protective effects of the amniotic membrane reduce exposure of corneal

nerve endings, resulting in early symptomatic improvement and greater patient comfort. Patients receiving conventional therapy experienced slower symptomatic relief because epithelial healing was delayed.

The incidence of complications, including persistent epithelial defects, corneal thinning, and corneal perforation, was lower in the AMT group. These findings suggest that AMT not only promotes healing but also reduces the risk of disease progression and the need for additional surgical intervention. Consequently, AMT may help preserve the structural integrity of the cornea and improve long-term visual prognosis.

The strengths of the present study include its prospective comparative design and equal distribution of patients between the two treatment groups. However, the study has certain limitations, including a relatively small sample size, single-center design, and limited duration of follow-up. Larger multicenter studies with longer follow-up are recommended to further evaluate the long-term efficacy and safety of amniotic membrane transplantation. Overall, the findings of the present study indicate that amniotic membrane transplantation is a safe and effective adjunct to conventional medical therapy for non-healing corneal ulcers. It promotes faster epithelial healing, provides better visual recovery, offers greater pain relief, and reduces complications compared with conventional therapy alone. These results support the use of AMT as an important treatment option in the management of refractory corneal ulcers.

Conclusion

The present study demonstrated that amniotic membrane transplantation (AMT) is a safe and effective treatment modality for the management of non-healing corneal ulcers. Compared with conventional medical therapy alone, AMT resulted in significantly faster corneal epithelial healing, greater reduction in ulcer size, improved visual

acuity, better pain relief, and a lower incidence of complications. The biological properties of the amniotic membrane, including its anti-inflammatory, anti-fibrotic, anti-angiogenic, and epithelial regenerative effects, contribute to improved ocular surface healing and preservation of corneal integrity. Patients treated with AMT showed a higher overall treatment success rate and a reduced need for additional surgical intervention. Based on the findings of this study, amniotic membrane transplantation should be considered an effective adjunctive treatment for patients with non-healing corneal ulcers, particularly in cases that do not respond adequately to conventional medical therapy. Further multicenter studies with larger sample sizes and longer follow-up are recommended to confirm these findings and evaluate the long-term benefits of AMT in different etiological types of corneal ulcers.

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