BioShare: A Field-Deployable Ocular Bandage for Combat Eye Trauma

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MHSRS FOCUS AREA: EXPEDITIONARY MEDICINE

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15
eyes treated, no adverse events

5 min
single-step field application

3–5 days
to full bioresorption

65778
applicable CPT code

BACKGROUND

Corneal epithelial defects from blast, laser, chemical, and penetrating injury are a leading cause of preventable vision loss in deployed personnel. Ocular injuries account for approximately 13% of combat casualties despite the eye representing less than 0.1% of total body surface area [1,2].

Standard of care for persistent epithelial defects — cryopreserved amniotic membrane — depends on continuous frozen storage and a rigid conformer ring that is poorly tolerated and requires clinician removal. Neither is compatible with Role 1 or Role 2 care in austere environments, where evacuation to ophthalmologic capability may be delayed by 8 hours or longer. Delayed or improvised management increases the risk of scarring, infection, and permanent visual impairment.

THE CAPABILITY GAP

No shelf-stable, single-application amniotic membrane therapy exists that a non-ophthalmologist can place in the field and that requires no follow-on removal procedure.

This leaves a gap at exactly the point of care where ocular trauma is most likely to be first managed: forward of definitive ophthalmologic support, by a medic or general medical officer with no slit-lamp access. Existing amniotic membrane products were designed for a fixed clinical setting, not for evacuation timelines measured in hours to days.

Without a field-deployable option, casualties either go untreated until evacuation to a higher role of care, or are managed with improvised measures that do not match the standard of care — both increasing the risk of scarring and permanent visual impairment.

REFERENCES

1. Combat ocular injury incidence — Weichel ED, Colyer MH, et al. Ophthalmology.

2. Anatomy and physiology of the cornea. Delmonte DW, Curr Opin Ophthalmol. 2011;22(4):291-297.

MILITARY RELEVANCE

Logistics
Room-temperature storage removes the cold-chain requirement that confines amniotic membrane therapy to fixed medical facilities.

Scope of practice
5-minute single-step application designed for placement by a combat medic or general medical officer without slit-lamp exam or ophthalmology consult.

No retrieval
Full bioresorption in 3–5 days eliminates the removal visit, reducing evacuation burden and follow-on provider contact.

Return to duty
Faster epithelial closure is intended to shorten time-to-RTD and reduce ocular injuries progressing to permanent visual impairment.

Dual use
Directly transferable to civilian emergency, rural, and disaster-response settings.

DEVICE & METHODS

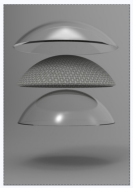


Fig. 1 — BioShare Device

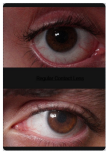
Device. Bilayer bioresorbable collagen ocular bandage encapsulating a [dehydrated / cryopreserved] human amniotic membrane graft between two collagen shields. Placed directly on the ocular surface without sutures, adhesive, conformer ring, or overlying bandage lens.

Composition. Bovine Collagen crosslinked. Membrane processed per GMP methods. Shelf life 36 mo. at -51°C to 71°C (MIL-STD-810H).

Study design. Case series 3223, single-arm safety study, n = 15 eyes. One patient with Parkinson's disease presented with an epithelial defect refractory to prior therapy.

5-min single-step application | Room-temperature storage | Self-resorbing in 3–5 days

RESULTS



Device placed on 15 eyes; no adverse events reported. One patient demonstrated visual acuity of 20/400 at baseline and 20/400 after 72 hours of wear — stable acuity with no deterioration of vision. CPT Code 65778 (placement of amniotic membrane on the ocular surface; without sutures) applies to reimbursement for this procedure.

Fig. 2 — BioShare Lens vs. regular contact lens

CONCLUSIONS

- Bandage placed on 15 eyes with no adverse events, without a conformer ring, suture, or removal procedure.
- Room-temperature stability and single-step application address the two logistics constraints preventing use forward of Role 3.
- These preliminary data support advancement to a prospective multi-site study and FDA 510(k) submission.

NEXT STEPS

- FDA Pre-Submission completed 7/1/26; 510(k) submission targeted Q2 2027.
- Prospective 3-site study, n = 100, initiating 12/2026.
- Seeking DoD validation partners — USAMMDA, USAISR, Vision Center of Excellence, MTEC.

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