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Micronized Amniotic Membrane for Dry Eye Disease: A Case Series

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1. Abstract

Dry eye disease is common and affects millions of people through- out the world. Unfortunately, the management of this disease can be challenging due to persistent inflammation and damage to the ocular surface which can result in ocular discomfort, photophobia, and blurred vision. Herein, we report the outcome of three patients with moderate dry eye disease that was recalcitrant to conservative treatments including artificial tears, ophthalmic immunomodulator drops, and topical lubricants. All patients presented with superficial punctate keratopathy (1+ to 3+ SPK), moderate ocular pain (5-6 out of 10), and were subsequently treated with micronized amniotic membrane applied with a bandage contact lens for 3-4 days. After treatment, the patients reported no pain (0 of 10) and there was faint SPK. At 1 month, SPK had resolved and the patients' visual acuity was 20/20. This case series highlights the utilization of micronized amniotic membrane with a bandage contact lens to manage patients with moderate dry eye disease.

2. Introduction

Dry eye disease (DED) is a common disease with an estimated 16.4 million people affected in the United States, which represents 6.8% of the adult population [1, 2]. Unfortunately, this disease has a significant burden on patients with effects on vision quality, activities of daily living and work, and quality of life. Many patients report complaints of blurry vision, ocular discomfort, ocular fatigue, and light sensitivity that is often associated with eye redness and breakdown of the corneal epithelium. However, clinical presentations vary according to the severity and etiology of disease.

The management and treatment of DED can be challenging because of its multifactorial etiology [3]. Nonetheless, persistent inflammation and damage to the ocular surface is a common finding. Hence, the ultimate objective in the management of DED is to halt the progressive inflammation, restore the homeostasis of the ocular surface, and break the self-perpetuating cycle of deterioration [4]. To accomplish this goal, one common treatment modality used is placement of sutureless (self-retained) cryopreserved amniotic membrane (AM) for 3-5 days which has been shown to provide symptomatic relief in DED patients that was refractory to traditional treatment with a lasting benefit for a minimum of three months [5-9]. The benefit includes a significant decrease in symptom scores and corneal fluorescein staining from an overall average of 2.2 at baseline to 0.5 by 3 months [7, 10, 11]. However, the above AM application has generally been applied to moderate to severe dry eye with severe ocular surface damage and inflammation. Herein we report the novel use of micronized AM product derived from placenta and Umbilical Cord (AMUC) with a Bandage Contact Lens (BCL) in patients with moderate DED.

3. Clinical Cases

3.1. Case 1

A 54-year-old Caucasian female presented with complaints of blurry vision at distance and near, discomfort OS, burning OS, and foreign body sensation OS that was ongoing for over 5 years. The patient had a medical and ocular history of Lupus and Sjogren's Syndrome (diagnosed 2.5 years prior) and had been managing the symptoms of DED through use of 0.09% cyclosporine ophthalmic solution BID (Cequa; Sun Pharma, Mumbai, India), advanced artificial tears as needed throughout the day (Optase PF; Scope, New York, NY), and allergy itch relief eye drops QD (Pataday; Alcon, Geneva, Switzerland). The visual acuity was 20/30-2 OS. Examination revealed SPK 1++ that was diffuse throughout the inferior third of the left cornea (Figure 1), which exhibited a Tear Break-Up Time (TBUT) of 4 seconds OS and subjectively reported pain score of 5 out of 10. A thorough discussion of the treatment options

and their affiliated risks and benefits were carried out with the patient. Due to the recalcitrant nature of the moderate DED, AMUC particulate (Flo; BioTissue, Miami, FL) with bandage contact lens treatment was decided upon.The AMUC particulate, which comes as a lyophilized powder, was reconstituted in 2-4 drops of sterile water and mixed to yield a paste consistency on the inner surface of a BCL (Air Optix Night & Day; Alcon). After ensuring the BCL was hydrated and after application of topical anesthetic to the OS, the BCLwith AMUC was applied on the ocular surface, centered, and confirmed to have no bubbles under the lens using slit lamp examination. After 3 days of retaining the BCL with AMUC, the patient returned for follow-up and reported no ocular pain with clear and crisp vision. Examination revealed minimal to no SPK OS and the patient had a TBUT of 7 seconds and visual acuity of 20/20. This condition remained stable for at least 1 month (Figure 1B) while the patient continued conservative treatment including artificial tears as needed and cyclosporine ophthalmic solution BID.

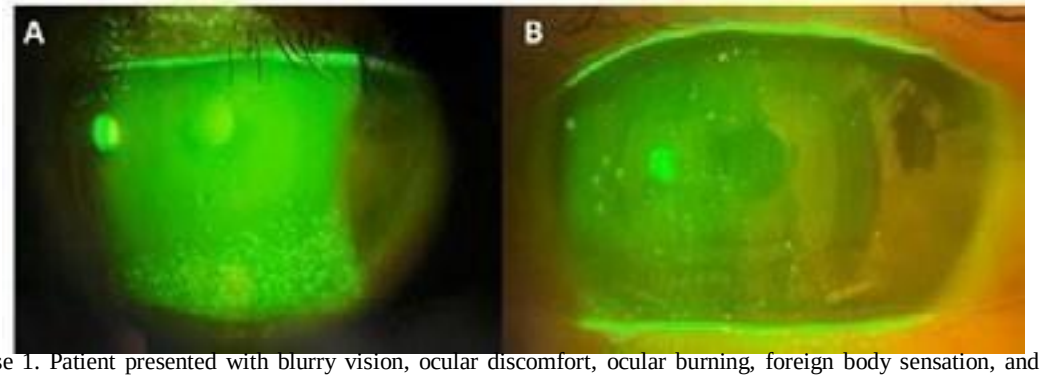

Figure 1: Case 1. Patient presented with blurry vision, ocular discomfort, ocular burning, foreign body sensation, and SPK 1++ that was diffuse through- out the inferior third of the cornea OS (A). After BCL with AMUC placement for 3 days, visual acuity improved from 20/30-2 to 20/20, TBUT improved from 4 to 7 seconds, and pain improved from 5 to 0. This was maintained for at least 1 month with no signs of SPK (B).

3.2. Case 2

A 57-year-old African American female presented with blurry vision and ocular pain and irritation OD. The patient had an ocular history of DED for 6 years that was recalcitrant to preservative free artificial tears, in-office eyelid exfoliation treatments (BlephEx; RySurg, Fort Worth, FL), ophthalmic ointment QHS, lubricant eye drops (Systane Complete; Alcon, Geneva, Switzerland), lid scrub treatments, extra strength allergy itch relief eyedrops (Pataday; Alcon, Geneva, Switzerland), and lifitegrast ophthalmic solution (Xiidra; Novartis, Basel, Switzerland). The symptoms had persist- ed and gotten worse over the previous 2-3 weeks despite recent use of warm compresses QD, preservative free artificial tears, and al- lergy itch relief eyedrops (Pataday; Alcon, Geneva, Switzerland). The patient reported her ocular pain to be moderate (6 out of 10). The visual acuity was 20/30+ OD and TBUT was 3 seconds OD. Examination revealed diffuse SPK 1+ in the superior and central cornea, SPK 2++ to 3+ in the inferior cornea (confluent), and 1+ hyperemia (Figure 2A). After discussion of various treatment options with the patient, it was ultimately decided to proceed with ap- plication of BCL with AMUC using the same application method as described for Case 1 and the patient was instructed to continue use of preservative free artificial tears. After 3 days, the patient returned and the BCL was removed. The patient reported no ocular pain with a visual acuity of 20/20 and TBUT of 6 seconds. Ex- amination revealed trace, faint punctate epithelial erosions (very mild, insignificant) in the inferior cornea (Figure 2B). The patient was advised to continue use of preservative free artificial tears BIDand return at 1 month. At 1 month, the patient reported she felt better than ever and reported no ocular pain or discomfort. Her vi- sual acuity was stable at 20/20 and TBUT improved to 7 seconds. Examination revealed similar faint insignificant punctate epithelial erosion in the inferior cornea (Figure 2C). At this point, the patient was instructed to continue the use of preservative free artificial tears BID to maintain the homeostasis of the ocular surface.

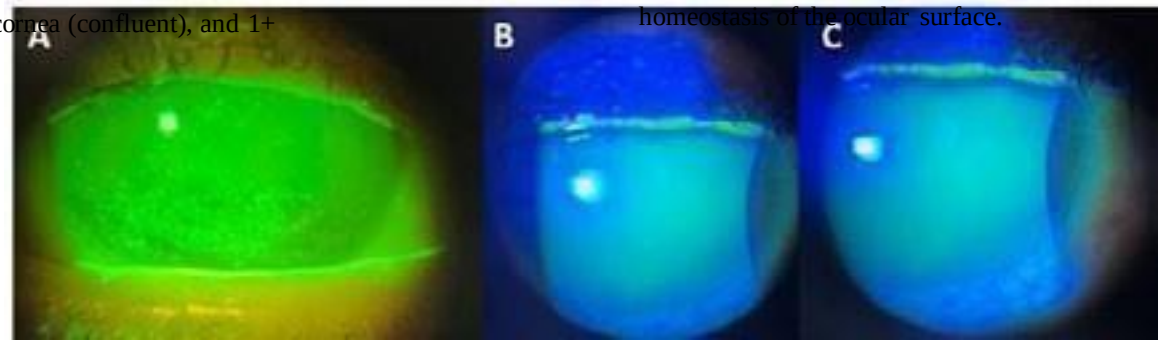

Figure 2: Case 2. Patient presented with blurry vision and ocular pain OD that had gotten worse over the last 2-3 weeks despite suffering from DED for 6 years. Patient had diffuse SPK 1+ in the superior and central cornea, SPK 2++ to 3+ in the inferior cornea (confluent), and 1+ hyperemia OD (A). After 3 days of BCL with AMUC treatment OD, corneal signs improved to just trace, faint punctate epithelial erosions (very mild, insignificant) in the inferior cornea(B). Pain improved from 6to0, visual acuity improved from 20/30+to 20/20, and TBUT improved from 3 to 6 seconds. The condition continued to remain stable at 1 month (C) and the TBUT improved to 7 seconds

3.3. Case 3

A 51-year-old Hispanic female presented with blurry vision and ocular pain and irritation OD, which started 5 years ago despite topical lubricant eye drops BID-TID OU (Systane Complete; Alcon, Geneva, Switzerland), preservative free artificial tears, topical ointment BID, lid scrubs and hot compress (Bruder mask) 15min QHS for 10 months with mild improvement, 0.05% cyclosporine ophthalmic solution (Restasis; Abbvie, Chicago, IL), topical steroid (PredForte) BID for 2 weeks and tapered to QD 2 weeks q3mo. The patient had been using topical gel gtts for the previous 2 years and did not want to use cyclosporine ophthalmic solution due to the price. Relevant medical history was Thyroid disease diagnosed 4 years prior.

The patient reported an ocular pain score of 5-6 out of 10 and vision fluctuations with increased haziness in the afternoon. Examination revealed diffuse SPK across the cornea, trace SPK in the superior cornea, SPK 1+ in the central cornea, SPK 3+ in the inferior (confluent) cornea, and trace hyperemia OD>OS. Visual acuity was 20/25-2 OU, TBUT was 5 seconds OD and 7 seconds OS, and the tear osmolarity was 320 mOsms/L OD and 315 mOsms/L OS. Due to the persistent signs and symptoms of DED, it was decided to proceed with application of BCL with AMUC in OU using the same method as described in Case 1 followed by preservative-free artificial tears QID. At 4 days, the BCL with AMUC was removed. The patient was asymptomatic and had a visual acuity of 20/20 OU and TBUT of 7 seconds OU. Examination revealed faint insignificant punctate epithelial erosion OS>OD and trace hyperemia OS only. The patient admitted that the BCL fell at some point over the previous 4 days, and she re-inserted it into the eye. Due to the near resolution of both DED signs and symptoms, the patient was instructed to maintain use of preservative free artificial tears QID. At 1 month, the patient reported overall symptomatic improvement with mild dryness symptoms (ocular pain score 1 out of 10 with mild foreign body sensation), which were successfully managed with preservative free artificial tears as needed OU. The patient was also using 0.05% cyclosporine ophthalmic solution, but only sporadically due to cost. Examination revealed trace SPK OU (Figure 3), TBUT of 6 seconds OD and 7 seconds OS, and tear osmolarity of 322 mOsms/L OD and 317 mOsms/L OS. The patient's visual acuity with correction was measured to be 20/25 OU and the patient reported the visual function to improve later in the day. The patient was instructed to maintain usage of the preservative free artificial tears QID and 0.05% cyclosporine ophthalmic solution BID OU for tear film replenishment.

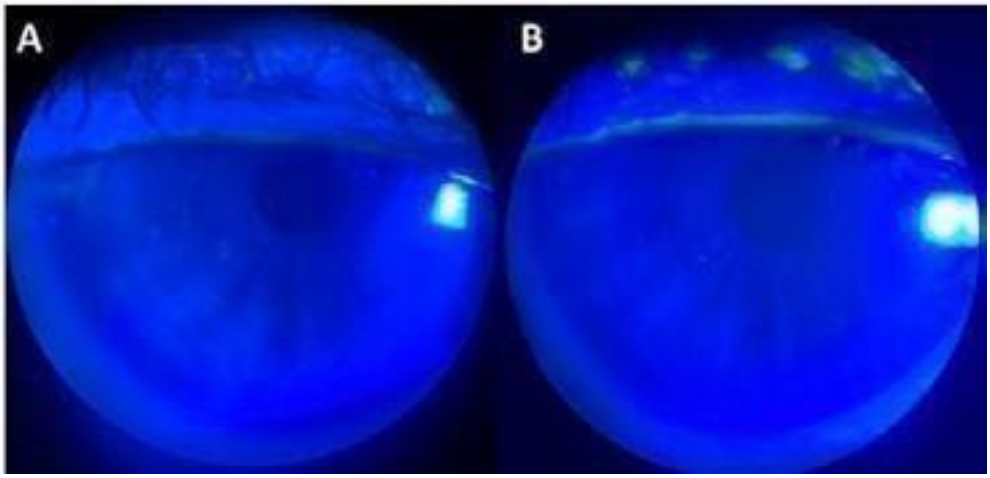

Figure 3: Case 3. Patient presented with blurry vision, ocular pain and irritation, and vision fluctuations with increased haziness in the afternoon which started 5 years ago. Corneas OU revealed diffuse SPK and confluent SPK 3+ in the inferior cornea. The patient received 4 days treatment of BCL with AMUC OU. At 1 month, the patient reported overall symptomatic improvement and examination revealed only trace SPK OU(A& B).

4. Discussion

DED is a difficult disease to manage due to the multiple different causes and substantial variability of signs and symptoms [12]. A number of treatments have been recommended for its use, however many treatment options are palliative or only address one particular element in this neuroanatomic integration [13]. Herein, our patients continued to have mild-to-moderate SPK and complaints of ocular pain for many years despite use of artificial tears, lubricant drops, and eyelid scrubs, of which all the treatments are aimed to address one particular aspect of this multifaceted disease process. In contrast, following topical application of AMUC in conjunction with a BCL for 3-4 days, all three cases showed notable improvement with resolution of ocular pain and corneal SPK and improvement of visual acuity that lasted for at least one month.

The benefits of AMUC are wide-ranging and include anti-inflammatory, anti-scarring, and anti-angiogenic properties that promote a regenerative healing environment [14, 15]. This multifaceted modality would not only promote cell death of pro-inflammatory cells and promote activation of anti-inflammatory M2 macrophage, but also promote corneal epithelial cell adhesion and growth [14, 15]. Previously, placement of self-retained cryopreserved AM has been shown effective in managing moderate to severe DED that is refractory to conventional maximal medical treatment [5-9], DED induced by glaucoma medication [16], DED induced by GVHD

[17, 18], DED induced by Sjogren syndrome [19, 20], and other auto-immune related DED [8]. The above clinical effectiveness may be explained by its ability to promote increased corneal nerve density [10]. Therefore, we speculate that the clinical benefit exerted by AMUC particulate and BCL might be similar. AMUC particulate product is comprised of both AM from the placenta and AM from the umbilical cord. While both AM from the placenta and umbilical cord contain similar composition, the AM from the umbilical cord has been shown to be more potent and contain more HC-HA/PTX3, a key relevant tissue characteristic responsible for the aforementioned AM's efficacy [14]. The additional benefits of AMUC particulate is that it is sterile and stable at room temperature while retaining the key biological components innate to the tissue [21]. Hence, this case series demonstrates that AMUC particulate with BCL may have great applicability in patients with moderate DED to provide an accelerated recovery with a lasting benefit for at least one month.

5. Conclusions

This case series highlights the utilization of AMUC with a BCL which may accelerate the recovery in patients with moderate DED.

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