



Novel Umbilical Cord and Amniotic Membrane Graft for Dry Eyes

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Disclosures: None

Purpose



Evaluate a novel umbilical cord and amniotic membrane allograft use for refractory dry eye disease

Methods

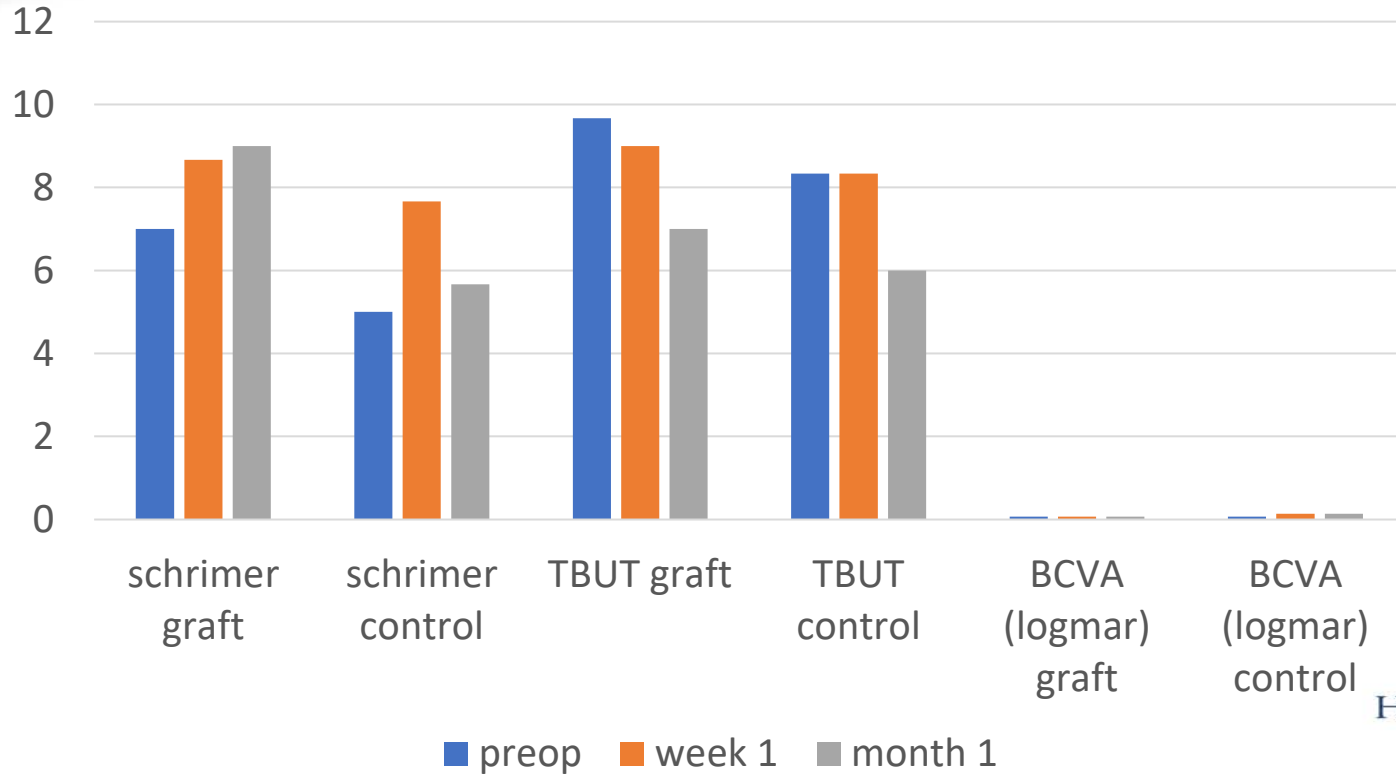
- Retrospective, pilot study
- 3 patients with refractory dry eye disease
- Cord tissue was placed into the superior fornix
- Data compared pre- and post-procedure to 1 month:
 - Best Corrected Visual Acuity (BCVA)
 - Fluorescein pattern (NEI scale)
 - Schirmer test
 - Dry Eyes WorkShop (DEWS) score (2007)
 - Ocular Surface Disease Index (OSDI)
 - Standard Patient Evaluation Evaluation of Eye Dryness (SPEED)
 - Visual Analog Scale (VAS) pain score

Results

- Tissue dissolved by 1 week visit
- No complications

Results

Treated vs Untreated Eye



DEWS

Table 5. Dry eye severity grading scheme

Dry Eye Severity Level	1	2	3	4*
Discomfort, severity & frequency	Mild and/or episodic; occurs under environmental stress	Moderate episodic or chronic, stress or no stress	Severe frequent or constant without stress	Severe and/or disabling and constant
Visual symptoms	None or episodic mild fatigue	Annoying and/or activity limiting episodic	Annoying, chronic and/or constant, limiting activity	Constant and/or possibly disabling
Conjunctival injection	None to mild	None to mild	+/-	+ / ++
Conjunctival staining	None to mild	Variable	Moderate to marked	Marked
Corneal staining (severity/location)	None to mild	Variable	Marked central	Severe punctate erosions
Corneal/tear signs	None to mild	Mild debris, ↓ meniscus	Filamentary keratitis, mucus clumping, ↑ tear debris	Filamentary keratitis, mucus clumping, ↑ tear debris, ulceration
Lid/meibomian glands	MGD variably present	MGD variably present	Frequent	Trichiasis, keratinization, symblepharon
TFBUT (sec)	Variable	≤ 10	≤ 5	Immediate
Schirmer score (mm/5 min)	Variable	≤ 10	≤ 5	≤ 2

*Must have signs AND symptoms. TFBUT: fluorescein tear breakup time. MGD: meibomian gland disease

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- No difference in either eye pre- and post-treatment

Ocular Surface Disease Index® (OSDI)²

Ask your patients the following 12 questions, and circle the number in the box that best represents each answer. Then, fill in boxes A, B, C, D, and E according to the instructions beside each.

Have you experienced any of the following <i>during the last week</i> ?	All of the time	Most of the time	Half of the time	Some of the time	None of the time
1. Eyes that are sensitive to light? . . .	4	3	2	1	0
2. Eyes that feel gritty?	4	3	2	1	0
3. Painful or sore eyes?	4	3	2	1	0
4. Blurred vision?	4	3	2	1	0
5. Poor vision?	4	3	2	1	0

Subtotal score for answers 1 to 5

Have problems with your eyes limited you in performing any of the following <i>during the last week</i> ?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
6. Reading?	4	3	2	1	0	N/A
7. Driving at night?	4	3	2	1	0	N/A
8. Working with a computer or bank machine (ATM)?	4	3	2	1	0	N/A
9. Watching TV?	4	3	2	1	0	N/A

Subtotal score for answers 6 to 9

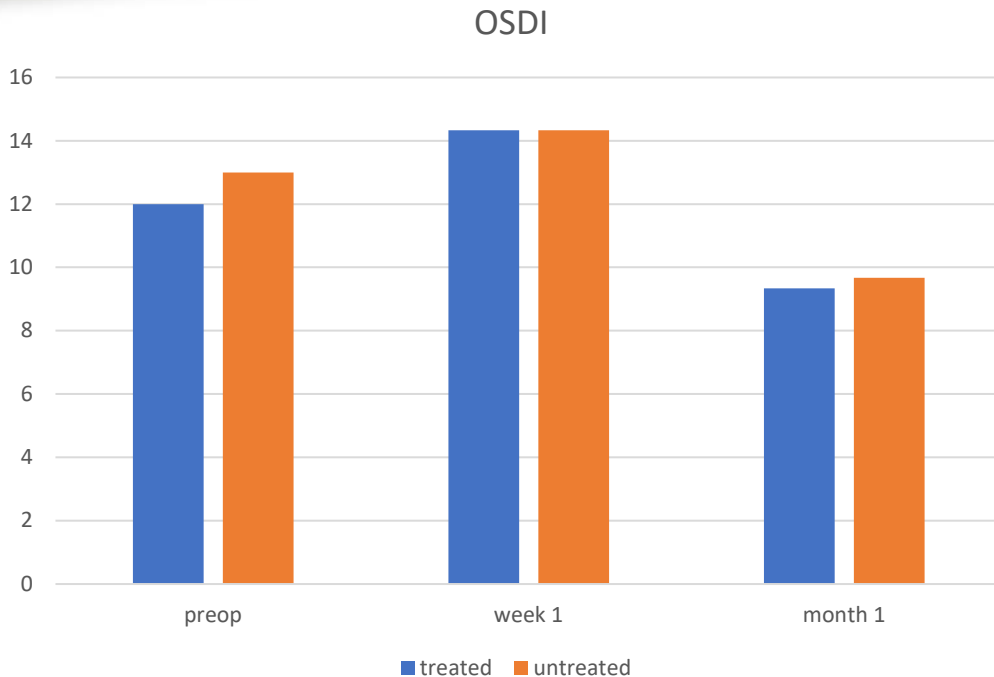
Have your eyes felt uncomfortable in any of the following situations <i>during the last week</i> ?	All of the time	Most of the time	Half of the time	Some of the time	None of the time	N/A
10. Windy conditions?	4	3	2	1	0	N/A
11. Places or areas with low humidity (very dry)?	4	3	2	1	0	N/A
12. Areas that are air conditioned?	4	3	2	1	0	N/A

Subtotal score for answers 10 to 12

Add subtotals A, B, and C to obtain D (D = sum of scores for all questions answered)

Total number of questions answered (do not include questions answered N/A)

Please turn over the questionnaire to calculate the patient's final OSDI® score.



SPEED™ QUESTIONNAIRE

Name: _____ Date: ___/___/___ Sex: M F (Circle) DOB: ___/___/___

For the Standardized Patient Evaluation of Eye Dryness (SPEED) Questionnaire, please answer the following questions by checking the box that best represents your answer. Select only one answer per question.

1. Report the type of SYMPTOMS you experience and when they occur:

Symptoms	At this visit		Within past 72 hours		Within past 3 months	
	Yes	No	Yes	No	Yes	No
Dryness, Grittiness or Scratchiness						
Soreness or Irritation						
Burning or Watering						
Eye Fatigue						

2. Report the FREQUENCY of your symptoms using the rating list below:

Symptoms	0	1	2	3
Dryness, Grittiness or Scratchiness				
Soreness or Irritation				
Burning or Watering				
Eye Fatigue				

0 = Never 1 = Sometimes 2 = Often 3 = Constant

3. Report the SEVERITY of your symptoms using the rating list below:

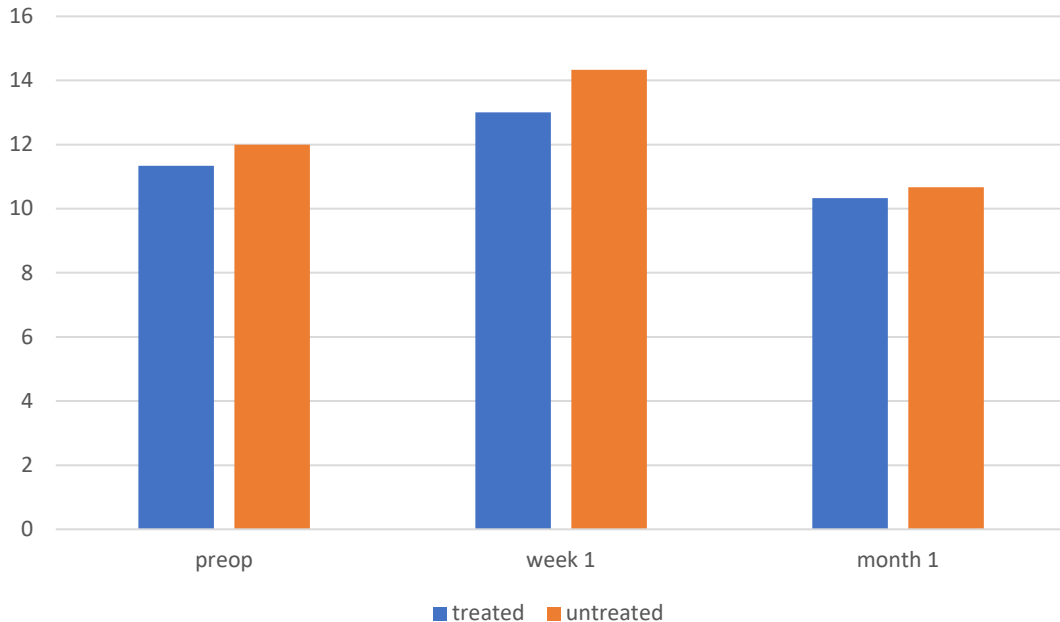
Symptoms	0	1	2	3	4
Dryness, Grittiness or Scratchiness					
Soreness or Irritation					
Burning or Watering					
Eye Fatigue					

0 = No Problems
 1 = Tolerable - not perfect, but not uncomfortable
 2 = Uncomfortable - irritating, but does not interfere with my day
 3 = Bothersome - irritating and interferes with my day
 4 = Intolerable - unable to perform my daily tasks

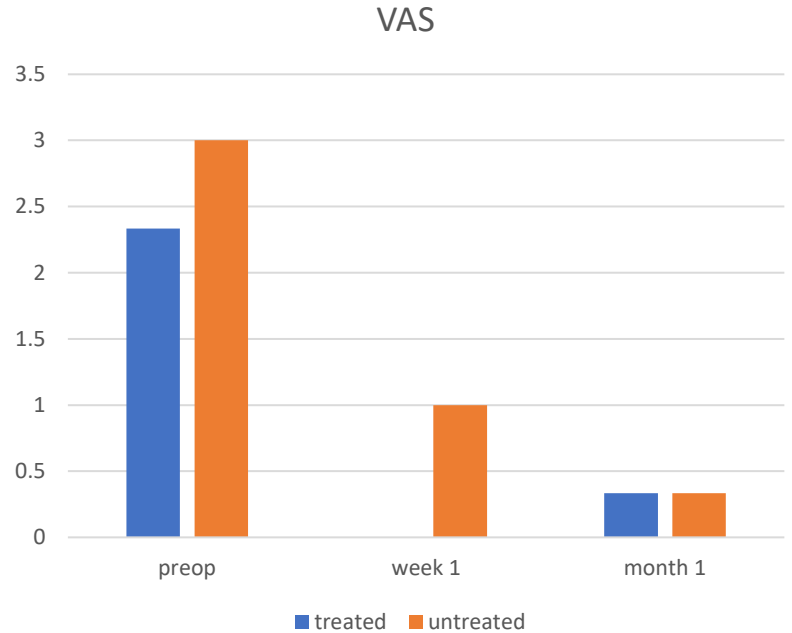
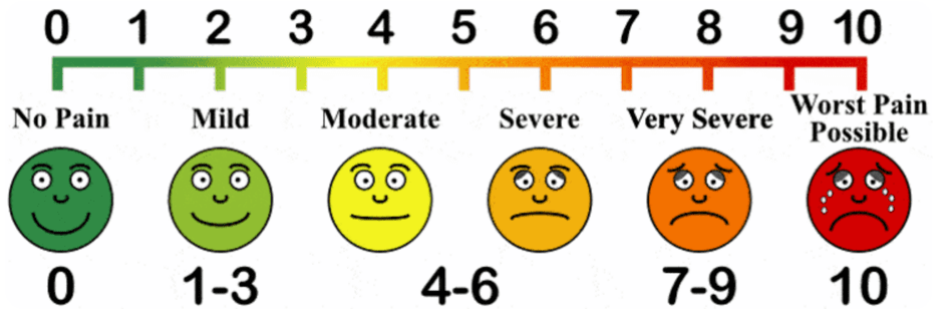
4. Do you use eye drops for lubrication? YES NO If yes, how often? _____

For office use only
 Total SPEED score (Frequency + Severity) = ___/28

SPEED

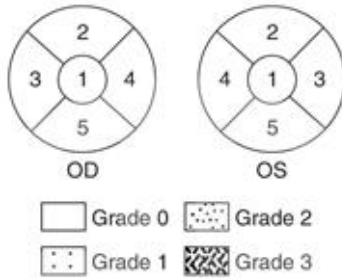


VAS

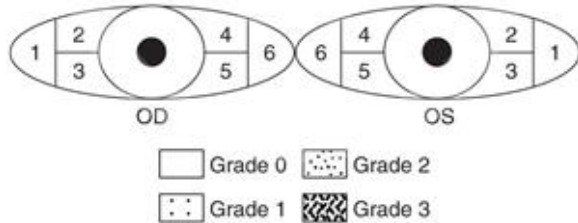


NEI

Score each of 5 areas of the cornea and total score:

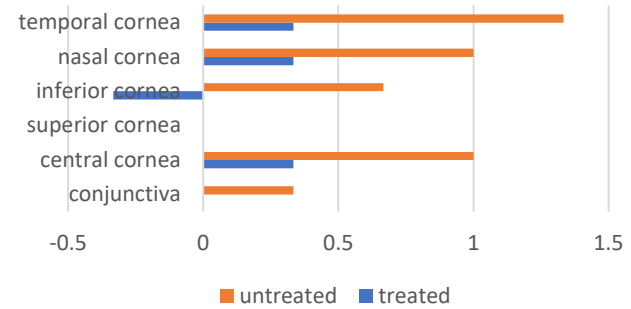


Score each of 6 areas of the conjunctiva and total score:

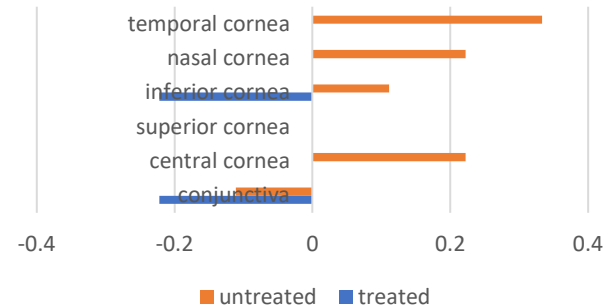


Add cornea and conjunctival scores for total score

Week 1 NEI Average



Month 1 NEI Average



Conclusion

- Technically easy procedure
- Minimal risk and discomfort
- Improved Schirmer, TBUT, NEI at month 1 compared to untreated eye
- OSDI, SPEED, and pain improved, but similar to untreated eye
- Limitations of study: small sample size, unmasked

References

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