2015 BMT Pharmacists Conference
Bandage Contact Lens Therapy for Severe Ocular GVHD

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Learning Objectives

- Describe signs, symptoms, and current management of ocular GVHD
- Recognize risks and benefits of bandage contact lens therapy
- List outcomes of the most recent clinical trial for bandage contact lens and ocular GVHD
- Identify new optical technologies to study the inflammation of the ocular GVHD

Disclosures

I have no conflicts of interest to disclose
Graft-versus-Host Disease (GVHD)

- GVHD is a major complication of allogenic tissue/hematopoietic stem cell transplantation
- 60% of GVHD patients have ocular involvement with significant compromise in quality of life due to ocular symptoms (such as severe photophobia, eye pain and decreased visual acuity)

Dry eye disease (DED) and GVHD

- DED is the most commonly found eye condition in GVHD
- DED is a diagnostic sign of chronic GVHD
- Limited success for DED treatment in GVHD patients

Ocular surface in GVHD

- Poor tear film
- Irregular corneal epithelium
- Conjunctiva inflammation
- Significantly impact the quality of life
- No reliable measure to accurately quantify symptoms
GVHD of the ocular surface

An abundant inflammatory cell infiltration at periductal areas of lacrimal gland chronic GVHD

Obstructed orifices of meibomian gland and Zeiss gland on eye lid margin with severely fibrotic tarsal conjunctiva

Ocular GVHD: debilitating problem

Our current understanding of GVHD

The Schirmer Test
Evaluating GVHD

Multicenter validation trial (Inamoto, 2012)
- NIH eye score
- Patient-reported global rating
- Lee eye subscale
- Ocular Surface Disease Index
- Schirmer test

Validation of Scales

Agreement in response between the measurement scales (kappa statistics)

<table>
<thead>
<tr>
<th></th>
<th>Global rating of eye symptoms</th>
<th>Global rating of Lee eye subscale</th>
<th>Ocular surface disease index</th>
</tr>
</thead>
<tbody>
<tr>
<td>Global rating of eye symptoms</td>
<td>0.19 (slight)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lee eye subscale</td>
<td>0.26 (fair)</td>
<td>0.42 (moderate)</td>
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<tr>
<td>Ocular surface disease index</td>
<td>0.14 (mild)</td>
<td>0.37 (mild)</td>
<td>0.47 (moderate)</td>
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<tr>
<td>Schirmer test</td>
<td>0.18 (slight)</td>
<td>0.10 (slight)</td>
<td>0.03 (slight)</td>
</tr>
</tbody>
</table>

Inamoto et al, 2011

Treatment of ocular GVHD

- Systemic treatment
- Multisystem involvement
- Local therapeutic approach
  - Topical lubrication (increase tears)
  - Punctual occlusion (decrease tear loss)
  - Topical immunosuppression
  - Protect damage that leads to vision loss
Mild ocular GVHD

- Few punctate epithelial erosions
- No significant decrease in vision
- Lubrication (tears or ointment) as needed

Local treatment: punctal occlusion

Dissolving plugs
- Collagen and other polymers
- Days - months

Silicone Plugs
- Reversible, could fall out, may cause irritation
- Cautery (permanent)

Topical therapeutics

- Topical Steroid (may cause cataract or glaucoma)
- Topical Immunosuppression
  - Cyclosporine A
  - (Restasis)
  - Investigational IL1-Ra (Kineret)
- Serum tears (not easily available, risk of contamination and infection)
Boston PROSE Lenses (conventional tx)

- Effective to relieve symptoms
- Expensive (Over $3000)
- Limited availability
- Extended initial fitting (approximately 2 weeks for individualized fitting of the lenses)

Therapeutic Soft Bandage Lenses

Clinical experience for treatment of GVHD patients

- Disposable soft contact lenses used for a diseased or injured cornea to protect or treat it. Commonly used after ocular surgery.
- Effective to immediately relieve symptoms in ocular GVHD
- Inexpensive (Less than $30/mo)
- Easily available
- Can be dispensed the same day
- Need daily antibiotic drops

A collaborative investigation

- UW Eye Institute
  - Shen and team (BCL treatment)
- Seattle Cancer Care Alliance
  - Professor Stephanie Lee (GVHD)
- UW Bioengineering
  - Professor Ricky Wang and team (OCT)
Clinical Trial Design

- Prospective Phase II clinical trial with IRB approval
- Patients (age 18-99) with chronic GVHD are selected
- Extended soft bandage contact lenses were applied to the GVHD-affected eyes with antibiotic coverage during the four week period.
- anterior segment OCT (AS-OCT) and patient survey are obtained. Patients are followed for three months.
- Clinical outcomes, such as visual acuity, corneal presentations (abrasion, punctate epithelial erosion and filament) are correlated with symptomatic survey findings as well as OCT findings.

Custom OCT for Anterior segment (Wang lab)

Detail findings on the ocular surface

Comparison of the results with and without contact lens
Enface view cutting through a plane approximately 100 microns from the apex

En-face view slicing through the depth (looking from outside into the eye)

Touring the cornea Out→in

3D visualization of the cornea
Tear Meniscus

Optical micro-angiography (OMAG)
Optical micro-angiography

Ocular GVHD: severe inflammation

Optical micro-angiography

Peng Li, Professor Wang’s Lab
Lymphatic and chemosis

BCL treatment outcomes

ocular surface disease index improves with treatment

Corneal surface result
Summary

- Soft BCL offers significant symptomatic relief in chronic GVHD patients
- Corneal surface improved with BCL therapy
- OCT can be an effective tool to understand ocular surface conditions
- Future benefit to general DED should be evaluated

Audience Response Question #1

Schirmer test, only “objective” scale in measuring tear production, correlates to patient-reported symptom changes accurately

a. True  
b. False

Audience Response Question #2

Treatments for ocular GVHD may include:

a. Lubrication eye drops  
b. Topical anti-inflammatory drops  
c. Punctal occlusion  
d. Bandage Contact lens  
e. All of the above
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