Retrospective Analysis of Safety and Efficacy

Autologous Serum Tears for the Treatment of Ocular Surface Disease

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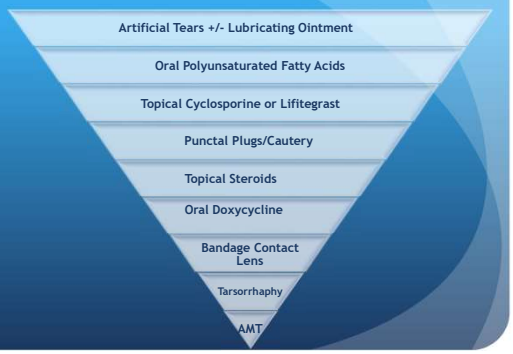
Background

- Ocular surface disease/Dry eye syndrome- complex, chronic, potentially debilitating disease affecting millions of Americans
- Quality-of-life studies suggest that impact of severe dry eye is comparable to moderate-severe angina[1]
- Many underlying causes of poor ocular surface with subset of patients (particularly with predisposing systemic conditions) remaining refractory to conventional therapies[2]

1. Weisenthal, et al. "External Disease and Cornea." Basic and Clinical Science Course. San Francisco: American Academy of Ophthalmology, 2016-2017. Print.
2. Young, et al. "The Use of Autologous Serum Tears in Persistent Corneal Epithelial Defects." Eye (2004). Vol 18, pp 609-614. Doi:10.1038/sj.eye.6700721.

Conventional Treatment Methods



Autologous Serum Tears for the Treatment of Ocular Surface Disease

Autologous Serum Tears (AST)

- Created from patients' own blood donation
  - Collected in lab, centrifuged to isolate serum, and bottled
- Contain numerous healing bioactive agents
  - Epidermal and nerve growth factors, fibronectin, albumin, vitamin A, and numerous anti-inflammatory antibodies found in natural tears [3]
- Early investigation in 1970s
  - Investigated as source of anti-proteases to arrest corneal ulceration[3]
- Trial of AST use in 15 patients 1984
  - Statistically significant improvement in symptoms and rose bengal staining[4]

3. Berman, MB, Barber, JC, et al. "Corneal Ulceration and the Serum Antiproteases." Investigative Ophthalmology. Volume 12. No 10. 1973: pp 759-770.
4. Fox RI, Chan R, Michelson J, et al. "Beneficial Effect of Artificial Tears Made with Autologous Serum in Patients with Keratoconjunctivitis Sicca." Arthritis Rheum 1984; 29: 577-83.

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Study Design

- Retrospective chart review of UT Southwestern Aston Clinic patients from 1/1/20111 to 8/1/2017 who were prescribed ASTs (all from UTSW, no dilution)
- 231 charts reviewed (156 included, 75 excluded)
  - Charts excluded for incomplete documentation, loss of follow up visits, prior treatment with ASTs before initial visit, or initiation of simultaneous additional therapy
- Charts reviewed for demographic information, adverse reactions, and the three main outcome measures of slit lamp exam findings, visual acuity, subjective patient reports at initiation and following use of ASTs

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Study Demographics

- 78% female, 22% male
- 80.77% Caucasian, 11.5% Hispanic, 3.8% African American, 1.9% Asian, and 1.9% South Asian
- 101/156 patients had underlying conditions predisposing to corneal surface disease
  - 52 (33%) - systemic conditions
  - 49 (31.4%) - localized conditions
  - 55 (35.6%) - no clear predisposing conditions

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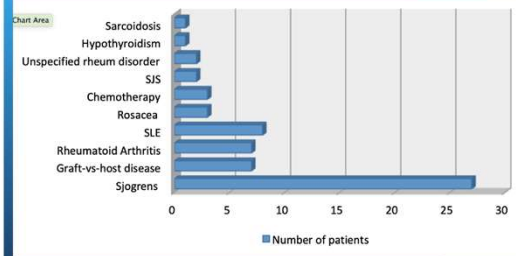
Underlying Systemic Conditions



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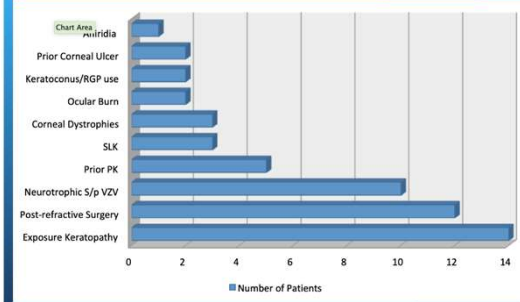
Underlying Ocular Conditions



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Prior Treatment

- Prior to AST initiation, all patients were using at least one conventional treatment modality (40 combinations)
  - 76.9% combination of treatments
  - 23.1% single treatment modality

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Prior Treatment

- 74.4% lubricating ATs or ointment
- 42.4% topical cyclosporine
- 20.5% topical steroid (loteprednol or PF 1%)
- 12.82% punctal occlusion
- 3 most common combinations
  - 26% Lubrication with tears and/or ointment alone
  - 15.4% Lubrication + restasis
  - 5.7% Lubrication + topical steroid

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Methods

- All patients received ASTs from UTSW with no dilution (100% serum)
- Majority use of QID, range from daily to 6xs/day
- Average follow up time after AST initiation 2.65 months
  - Range 0.25-9 months
  - 3 outlier points excluded (24 ,24, 22)

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Safety Outcomes

- No significant adverse events
  - 1 reported episode of urticaria that was later determined to be caused by another agent; ASTs successfully restarted
  - 4 patients discontinued due to increased mattering of lashes

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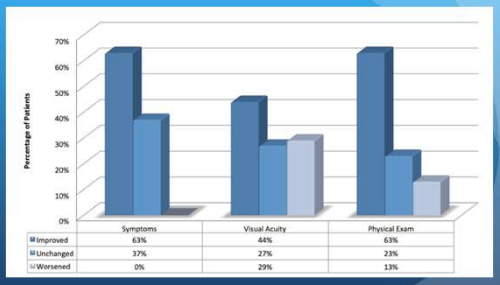
Main Efficacy Outcome Measures



	Symptoms	Visual Acuity	Physical Exam
Improved	63%	44%	63%
Unchanged	37%	27%	23%
Worsened	0%	29%	13%

- *VA improved in at least 1 eye while the fellow eye remained stable or improved

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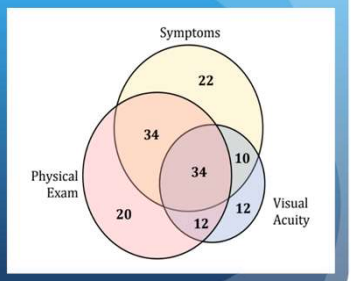
Aggregate Outcome Measures

- 91.7% of patients with improvement in at least 1/3 outcome measures
  - 21.8% improved 3/3
  - 32.3% improved 2/3
  - 34.6% improved 1/3



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Study Limitations

- Limited generalizability
  - Single center, majority Caucasian females
- Only patients who were compliant and had at least 1 follow up were included
  - Possible selection bias if patients self-discontinued if gtts not helpful
  - Patients continued to fill ASTs and "no-show" appts
- Lack of treatment standardization
  - Patients actually receiving maximum benefit?
- Varied and prior/concurrent treatments
  - Effective as a single agent?
  - Any synergistic or antagonistic treatment effects?

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Outcome Measure Limitations

- Visual acuity possibly limited by presence of cataract progression during study period
- Difficult to assess improvement in physical exam findings between different examiners
  - Inconsistent use of lissamine green, Shirmers, TBUT

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Conclusions

- 156 UT Southwestern Aston clinic patients from 2011-2017 demonstrated that ASTs made from undiluted serum are a safe and effective treatment modality as an adjunct to conventional therapies for the treatment of ocular surface disease.
  - 91.7% found to have improvement in at least 1 of 3 main outcome measures of symptoms, visual acuity, and slit lamp findings

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Further Work

- Relationship between patient characteristics and improvement
  - Identify ideal candidates for therapy
- Analysis of effectiveness with concurrent alternate therapies
  - Identify ideal treatment combinations
- Optimal treatment duration and frequency

Thank You!

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