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JOSEPH TAUBER, M.D.

Medical and Surgical Eye Care ♦ Corneal Transplantation
Corneal Disease and Surgery ♦ Laser Vision Correction

March 29, 2017

As Medical Director for Saving Sight, I am frequently asked about the effectiveness and indications for the use of "serum tears," a term that is used to describe autologous serum used as a topical ophthalmic lubricant. The use of this type of lubricant eyedrop has been reported for over four decades spanning countries around the globe. Favorable results have been reported in many of the most severe dry eye patient groups, including patients with Sjogren's Syndrome, Graft versus Host disease, diabetic keratopathy and others. Because autologous serum tears are not prepared commercially, large randomized clinical trials have never been conducted, because of the cost involved and the lack of a governmental or industry sponsor. Despite this, numerous publications on this topic are available, including controlled small series, open label trials and case reports. Reviews of both methodology and effectiveness have been published from several US sites, England, Sweden, Japan and other nations.

As a corneal specialist in private practice, I have personally prescribed autologous serum tears to dozens of patients, many of whom continue to use these lubricants over many years. I have found particular effectiveness in very dry patients with Sjogren's Syndrome, Rheumatoid arthritis and Diabetes.

As new publications appear every few months, it is difficult to maintain a complete bibliography, but representative articles are attached.

I am available to answer additional questions as they arise.

Sincerely,

Joseph Tauber, MD

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BIBLIOGRAPHY

Randomized double-blind clinical trial of autologous serum versus artificial tears in dry eye syndrome.

Urzua CA1, Vasquez DH, Huidobro A, Hernandez H, Alfaro J. Curr Eye Res. 2012 Aug;37(8):684-8

Abstract

PURPOSE:

To determine symptoms improvement in dry eye patients with short-term autologous serum (AS) eyedrops treatment using the standardized Ocular Surface Disease Index (OSDI) survey.

MATERIALS AND METHODS:

A double-blind randomized crossover clinical trial was conducted, comparing short-term (2 weeks) topical treatment with AS eyedrops diluted at 20% versus conventional artificial tears treatment in adult severe dry eye syndrome (DES) patients. The main outcome measure was assessment of symptoms with OSDI survey. Secondary outcomes were corneal and conjunctival fluorescein staining score of OXFORD and tear break up time (TBUT).

RESULTS:

Twelve severe DES patients were included. Autologous serum treatment showed a statistically significant ($p = 0.002$) higher OSDI decrease (50%) versus conventional treatment (22%). There were no significant changes in objectives parameters (OXFORD and TBUT).

CONCLUSIONS:

Severe DES patients treated with AS achieve better symptoms improvement compared to artificial tears in a short-term treatment.

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The efficacy of autologous serum eye drops for severe dry eye syndrome: a randomized double-blind crossover study.

Celebi AR1, Ulusoy C, Mirza GE. Graefes Arch Clin Exp Ophthalmol. 2014 Apr;252(4):619-26

Abstract

BACKGROUND:

To evaluate the efficacy of autologous serum (AS) eye drops for the symptomatic relief of severe dry eye syndrome (DES), as compared to conventional preservative-free artificial tears (PFAT).

METHODS:

This prospective double-blind randomized crossover study used the Ocular Surface Disease Index (OSDI), tear film break-up time (TBUT), Schirmer's Test, and OXFORD Scale at baseline and after each of two 1-month treatment periods to measure the effect of 20 % diluted AS eye drops vs. PFAT in 20 consecutive severe DES patients that were refractory to conventional treatment.

RESULTS:

The study included 20 (18 female and two male) severe DES patients (40 eyes). Significantly higher TBUT ($P < 0.001$, Wilcoxon signed-rank test) and a greater decrease in OSDI score (55.18 % decrease in the AS treatment group vs. 19.50 % decrease in the PFAT treatment group) ($P < 0.001$, Student's paired samples t-test) were observed in the AS treatment group after 1 month of treatment. There wasn't a significant difference in Schirmer's test and OXFORD conjunctival and corneal vital dying grading scores between the two treatment groups after 1 month of treatment ($P > 0.05$ [Mann-Whitney U test]).

CONCLUSIONS:

AS eye drops were more effective than conventional eye drops for improving tear film stability and subjective comfort in patients with severe DES.

Blood-derived topical therapy for ocular surface diseases.
Soni NG1, Jeng BH1. Br J Ophthalmol. 2016 Jan;100(1):22-7

Abstract
Human serum-derived and plasma-derived therapies have become increasingly popular in the treatment of ocular surface disorders, with mounting clinical and scientific evidence suggesting good safety and efficacy profiles. These therapies may be considered for various ocular surface conditions, such as dry eye syndrome and persistent epithelial defect, when conservative management does not suffice. The costly and inconvenient process of obtaining the blood-derived products is the barrier to their more widespread use. Some blood-derived therapies, such as umbilical cord serum-derived and platelet-derived plasma preparations, may be more viable options since these therapies can be made readily available to patients. In this review, the existing literature on the safety and efficacy of blood-derived products, such as autologous serum tears, in the treatment of ocular surface diseases is discussed. Issues relevant to the production of autologous serum tears are also described.

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Transfus Apher Sci. 2016 Feb;54(1):164-7. doi: 10.1016/j.transci.2016.01.022. Epub 2016 Jan 20.

Quality standards, safety and efficacy of blood-derived serum eye drops: A review.

van der Meer PF[1], Seghatchian J[2], Marks DC[3].

Author information

1 Sanquin Blood Supply, Department of Product and Process Development, Amsterdam, The Netherlands.
2 International Consultancy in Blood Components Quality/Safety Improvements, Audit/Inspection and DDR Strategies, London, UK. Electronic address: jseghatchian@btopenworld.com.
3 The Australian Red Cross Blood Service, Sydney, Australia.

Abstract

Serum eye drops (SEDs) are being used increasingly to treat dry eye syndrome and persistent corneal epithelial defects, and are usually prescribed when conventional treatments fail. SEDs are commonly sourced from the patient's own blood via an autologous collection. Although SEDs are clearly beneficial, they are not available for those patients that cannot donate sufficient blood, and some centres are moving to allogeneic SEDs. Many studies have reported that both allogeneic and autologous SEDs are effective. However, few large randomised controlled trials have been conducted to date, and clinical evidence is therefore limited to smaller studies. Alternatives to serum are also being explored, such as platelet lysate and products made from platelet rich plasma, as they are a rich source of growth factors. This article reviews how some centres are approaching allogeneic collections for SEDs, and alternatives to serum that are currently being explored.

Br J Ophthalmol. 2016 Jun 6. pii: bjophthalmol-2015-307666.

Treatment of severe chronic ocular graft-versus-host disease using 100% autologous serum eye drops from a sealed manufacturing system: a retrospective cohort study.

Tahmaz V[1], Gehlsen U[1], Sauerbier L[1], Holtick U[2], Engel L[3], Radojska S[4], Petrescu-Jipa VM[4], Scheid C[5], Hallek M[6], Gathof B[7], Cursiefen C[3], Steven P[1].

Author information

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7 Competence Center for Ocular GvHD, Medical Faculty, University of Cologne, Cologne, Germany Institute of Transfusion Medicine, Medical Faculty, University of Cologne, Cologne, Germany.

Abstract

BACKGROUND/AIMS:

To analyse patients with chronic ocular graft-versus-host disease (GvHD) under treatment with 100% autologous serum eye drops from a sealed manufacturing system.

METHODS:

17 patients with chronic ocular GvHD received 100% autologous serum eye drops from single use vials manufactured in a sealed system. Retrospective analysis included visual acuity, corneal staining, frequency of artificial tears, ocular symptoms by means of a questionnaire and information on subjective side effects and cost compensation.

RESULTS:

Data of prior to autologous serum eye drops therapy and at a 6-month follow-up were obtained. They demonstrated a significant increase in visual acuity (logMAR oculus dexter/right eye (OD) 0.5±0.32 to 0.4±0.3; oculus sinister/left eye (OS) 0.6±0.35 to 0.3±0.35; p=0.177/0.003) and significant improvement in corneal staining (Oxford grading scheme: OD from 3±1.03 to 2±1.43, OS from 4±1.0 to 2±1.09, p=0.004/0.001) and ocular symptoms (ocular surface disease index: 88±20.59 to 63±22.77; p=0.02). Frequency of artificial tears was reduced and no side effects were reported. Patient satisfaction was 100%, and cost compensation by health insurance reached 80%.

CONCLUSIONS:

100% autologous serum eye drops using a sealed manufacturing system were efficient in improving the ocular surface, patient symptoms and visual acuity without side effects. It seems to be safe to use 100% autologous serum despite earlier suspicions regarding immune complex accumulations and exacerbation of ocular surface inflammation. The potential effects of serum levels of systemic immunosuppressives through readministration onto the ocular surface need to be elucidated.

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Transfus Apher Sci. 2015 Aug;53(1):92-4. doi: 10.1016/j.transci.2015.05.015. Epub 2015 Jun 9.

Serum eye drop preparation in Australia: Current manufacturing practice.

Marks DC[1], Fisher J[2], Mondy P[2], Segatchian J[3], Dennington PM[2].

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2 The Australian Red Cross Blood Service, Sydney, Australia.

3 International Consultancy in Blood Components Quality/Safety Improvement, Audit/Inspection & DDR Strategy, London, UK.

Abstract

Serum eye drops are used to treat diseases such as dry eye syndrome (keratoconjunctivitis sicca), a disease of the surface of the eye that results in an unstable tear film. Patients are referred to the Australian Red Cross Blood Service by ophthalmologists for autologous serum eye drops when other therapies such as artificial tears or topical immunosuppressive agents have failed. In order to manufacture autologous serum eye drops, whole blood is collected from the patients using standard blood collection procedures. The blood is then allowed to clot to produce serum and processed into 20% serum eye drops, which are then returned to the patient for their own use. The eye drops are packaged into a long length of tubing, which is then heat-sealed to produce single-use segments. The demand for serum eye drops in Australia is increasing every year, with a 30% increase in the past 12 months.

The efficacy of autologous serum eye drops for severe dry eye syndrome: a randomized double-blind crossover study.

Celebi AR[1], Ulusoy C, Mirza GE.

Author information

1 Department of Ophthalmology, Republic of Turkey, Ministry of Health, Nigde State Hospital, Feridun Zeren Street, 51000, Nigde, Turkey, arcenkcelebi@gmail.com.

Abstract

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AS eye drops were more effective than conventional eye drops for improving tear film stability and subjective comfort in patients with severe DES.

Br J Ophthalmol. 2016 Jun 6. pii: bjophthalmol-2015-307666.

Treatment of severe chronic ocular graft-versus-host disease using 100% autologous serum eye drops from a sealed manufacturing system: a retrospective cohort study.

Tahmaz V[1], Gehlsen U[1], Sauerbier L[1], Holtick U[2], Engel L[3], Radojska S[4], Petrescu-Jipa VM[4], Scheid C[5], Hallek M[6], Gathof B[7], Cursiefen C[3], Steven P[1].

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7 Competence Center for Ocular GvHD, Medical Faculty, University of Cologne, Cologne, Germany Institute of Transfusion Medicine, Medical Faculty, University of Cologne, Cologne, Germany.

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Int Med Case Rep J. 2016 Mar 2;9:47-54. doi: 10.2147/IMCRJ.S97297. eCollection 2016.

The use of autologous serum for the treatment of ocular surface disease at a Swedish tertiary referral center.

von Hofsten J[1], Egardt M[2], Zetterberg M[3].

Author information

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3 Department of Ophthalmology, Sahlgrenska University Hospital, Mölndal, Sweden; Department of Clinical Neuroscience and Rehabilitation, University of Gothenburg, Gothenburg, Sweden; Department of Ophthalmology, Institute of Neuroscience and Physiology, The Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden.

Abstract

PURPOSE:

The study aims to describe an intact cohort with mixed ocular surface disease (OSD) treated with autologous serum (AS) eye drops in a tertiary eye center.

PATIENTS AND METHODS:

All cases (n=32 eyes, 24 patients) treated with AS for OSD at the Department of Ophthalmology, Sahlgrenska University Hospital, Mölndal, between 2002 and 2013 were included and medical records were reviewed retrospectively.

RESULTS:

Mean duration of treatment with 20% AS was 28.3±56.1 (median: 12, range: 3-217) days. The most common indication for AS treatment was a persistent epithelial defect (PED), which was seen in 16 eyes of 14 patients. Mean duration of PED prior to treatment was 19.3±18.9 (median: 10, range: 5-68) days. Complete or partial epithelial healing occurred in nine eyes (56.2%). The remaining seven eyes (44%) did not respond to treatment or data were missing. The second group consisted of nine eyes of five patients with superficial punctate keratitis (SPK) secondary to dry eye syndrome. Complete or partial healing of the epithelium occurred in five eyes (56%), and the remaining four eyes (44%) were lost to follow-up. A third group included five eyes with AS as an adjuvant treatment after corneal perforation, whereas a fourth group consisted of one patient with dry eye after laser-assisted in situ keratomileusis (LASIK).

CONCLUSION:

In this cohort, patients with PED or SPK responded well to treatment with AS. Standardized preparation protocols, defined optimal serum concentrations for various indications, and large randomized clinical trials are needed to fully comprehend the role of AS in the treatment of OSD.

Comparison of Autologous Serum Versus Preservative Free Artificial Tear in Patients with Dry Eyes Due to Systemic Isotretinoin Therapy.

Curr Eye Res. 2017 Jan 31:1-5. doi: 10.1080/02713683.2016.1255758

Yılmaz U[1], Küçük E[1], Koç Ç[2], Gökler E[3].

Abstract

PURPOSE:

To investigate dry eye development in the patients receiving systemic retinoic acid therapy and to compare effectiveness of Autologous Serum (AS) and preservative free artificial tear (PFAT) in the patients with dry eye disease.

METHOD:

This prospective, crossover, double blind study was conducted on patients who have dry eyes due to systemic isotretinoin treatment for different indications. Patients detected as having dry eye during systemic isotretinoin treatment were included to our study. At baseline, 1 and 2 month of study, detailed ocular examination, best corrected visual acuity measurement, intraocular pressure measurement, and Tear Break-up Time (TBUT) and Schirmer Test (ST) without topical anesthesia were performed. We compared the efficacy of AS and PFAT. To accomplish crossover after the first month, treatment given to each patient was switched to the other treatment. Statistical analysis was measured using SPSS version 20.0. p values of < 0.05 were considered as statistically significant.

RESULT:

At the end of the first month, there was a significant improvement for the TBUT test in both AS and PFAT groups compared to baseline (respectively $p < 0.001$, $p < 0.001$). TBUT was found to be significantly higher in the AS group compared to the PFAT group at the end of the first month ($p < 0.001$). At the end of the second month, TBUT was found to be significantly higher in the AS group compared to the PFAT group at the posttreatment time ($p < 0.001$). There was a significant OSDI score decreasing in both groups compared to that reported previously at the end of the first and second months (respectively $p < 0.001$, $p < 0.001$). OSDI score decreasing was more significant in the AS group compared to the PFAT group at both time points (respectively $p < 0.001$, $p < 0.001$).

CONCLUSION:

AS may be an effective alternative to PFAT in the treatment of dry eye developed during isotretinoin use.

Safety and efficacy of autologous serum eye drop for treatment of dry eyes in graft-versus-host disease.

Cutan Ocul Toxicol. 2016 Jul 22:1-5. [Epub ahead of print]

Azari AA[1], Karadag R[1,2], Kanavi MR[3], Nehls S[4], Barney N[4], Kim K[5], Longo W[4], Hematti P[4], Juckett M[4].

Abstract

PURPOSE:

To evaluate the treatment of autologous serum eye drops (ASED) on dry eyes in patients with graft-versus-host disease (GVHD).

METHODS:

A retrospective chart review of 35 patients with a history of ocular GVHD following hematopoietic stem cell transplantation that used ASED to alleviate dry eye symptoms was performed. Patients were categorized into three different groups. If patients had available ophthalmic data before and after starting treatment was group 1 (n = 14), had available ophthalmic data after starting treatment in group 2 (n = 10) and had available ophthalmic data before treatment or did not have any data after starting treatment in group 3 (n = 11). Data were collected on patient's age, gender, primary diagnosis, visual acuity and fluorescein corneal staining were collected on individual eyes in order to evaluate the efficacy of the ASED on alleviating dry eye-related signs and symptoms.

RESULTS:

No adverse ocular effect from the ASED was found in our series (except one fungal keratitis). All patients reported either improvement (55%) or stability (45%) in their ocular symptoms upon the use of ASED. In patients with available data before and after starting treatment, the corneal staining score improved by a median of 1 ($p = 0.003$) and the LogMAR visual acuity had a non-significant improvement.

CONCLUSION:

In our study, ASED used by patients with ocular GVHD were both safe and effective. ASED should be considered in patients with GVHD who suffer from dry eyes.

Apoptosis of conjunctival epithelial cells before and after the application of autologous serum eye drops in severe dry eye disease.

Rybickova I[1,2], Vesela V[1], Fales I[3], Skalicka P[2], Jirsova K[1].
Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2016 Jun;160(2):271-5. doi: 10.5507/bp.2016.001. Epub 2016 Feb 29.

Abstract

AIMS: To assess the impact of autologous serum eye drops on the level of ocular surface apoptosis in patients with bilateral severe dry eye disease.

METHODS:

This prospective study was conducted on 10 patients with severe dry eye due to graft versus host disease (group 1) and 6 patients with severe dry eye due to primary Sjögren's syndrome (group 2). Impression cytology specimens from the bulbar conjunctiva were obtained before and after a three-month treatment with 20% autologous serum eye drops applied a maximum of 12 times a day together with regular therapy with artificial tears. The percentage of apoptotic epithelial cells was evaluated immunochemically using anti-active caspase 3 antibody.

RESULTS:

In group 1, the mean percentage of apoptotic cells was 3.6% before the treatment. The three-month treatment led to a significant decrease to a mean percentage of 1.8% (P = 0.028). The mean percentage of apoptotic conjunctival cells decreased from 5.4% before the treatment to 3.8% in group 2; however, these results did not reach the level of significance.

CONCLUSION:

Three-month autologous serum treatment led to the improvement of ocular surface apoptosis, especially in the group of patients with severe dry eye due to graft versus host disease. This result supports the very positive effect of autologous serum on the ocular surface in patients suffering from severe dry eye.

KEYWORDS:

apoptosis; autologous serum; caspase 3; conjunctival epithelium; dry eye disease

Expert opinion in the management of aqueous Deficient Dry Eye Disease (DED).

Sy A[1,2], O'Brien KS[3], Liu MP[4], Cuddapah PA[5], Acharya NR[6,7], Lietman TM[8,9], Rose-Nussbaumer J[10,11].
BMC Ophthalmol. 2015 Oct 13;15:133. doi: 10.1186/s12886-015-0122-z.

BACKGROUND:
Dry eye disease (DED) affects millions of people worldwide. There are a variety of new treatments beyond traditional therapies such as preservative free artificial tears. Here, we conduct a survey to identify the most common treatments used among specialists and assess their interest in newer therapies.

METHODS:
An international survey was distributed to dry eye researchers and expert practitioners via an internet survey. The survey data collected were analyzed with descriptive statistics.

RESULTS:
One hundred and fifteen respondents completed the survey; of these, 66 % were cornea specialists. The most commonly prescribed topical treatments included cyclosporine A (CSA) 0.05 % (71/104, 68 %), fluorometholone (FML) 0.1 % (59/99, 60 %), loteprednol etabonate 0.5 % (50/99, 51 %), and autologous serum eye drops (ASD; 48/97, 49 %). The most commonly prescribed non-topical medications included essential fatty acid supplements (72/104, 69 %), low-dose doxycycline (oral; 61/100, 61 %), and flaxseed supplements (32/96, 33 %) as well as punctal plugs (76/102, 75 %). Respondents reported treatment with topical corticosteroids for 2 to 8 weeks (46/86, 53 %), followed by less than 2 weeks (24/86, 28 %) and with topical CSA between 2 to 8 weeks (45/85, 53 %) followed by 2 to 6 months (24/85, 28 %). The top three signs and symptoms reported to indicate treatment response were, in order, fluorescein staining of the cornea, reduction in foreign body sensation, and reduction in burning sensation.

CONCLUSION:
This survey offers insight into current expert opinion in the treatment of DED. The results of this survey are hypothesis generating and will aid in the design of future clinical studies.

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Autologous serum eye drops for the treatment of ocular surface disease.

Azari AA[1], Rapuano CJ.
Eye Contact Lens. 2015 May;41(3):133-40.

OBJECTIVE:
To examine the evidence for the role of autologous serum eye drops (ASD) in disease of the ocular surface.

METHODS:
A search of the literature published through May 2014 using PubMed, the ISI Web of Knowledge database, and the Cochrane Library was performed. Qualified articles were selected after review of titles, abstracts, and references.

RESULTS:
There was a significant improvement in either symptoms or some of the clinical examination findings, including tear breakup time, corneal staining, Schirmer values, and impression cytology in eyes with persistent corneal epithelial defect, graft-versus-host disease, Sjögren- and non-Sjögren-related dry eye disease, limbal stem-cell deficiency, recurrent corneal erosion, superior limbic keratoconjunctivitis, and postrefractive surgery. However, most of the studies were nonrandomized in nature.

CONCLUSIONS:
Despite the paucity of strong supporting evidence from randomized double-masked clinical studies, there seems to be a trend toward superiority of ASD in alleviating some of the clinical signs and symptoms associated with corneal pathology in a variety of conditions that affect the ocular surface compared with conventional lubricating drops/ointments.

John Smith, MD

123 Main Street, Anytown, NY 00000

September 17, 2020

Re: _____ DOB _____

To Whom It Concerns:

The above named has been under my care for several years for treatment of:

	Severe dry eye disease		Graft vs. Host disease
	Recurrent corneal erosions		Sjogren's Syndrome
	Recurrent corneal ulceration		Diabetic keratopathy
	Recurrent / nonhealing corneal defect		Chronic keratitis

and continues to suffer with severe symptoms of discomfort and blur despite standard therapy, including:

	Non-preserved lubricant drops and gels		Topical Xiidra
	Nighttime ointment		Punctal occlusion
	Topical Restasis		Bandage soft contact lens wear

At this point, the best remaining treatment option is frequent application of an artificial lubricant eyedrop prepared from the patient's own serum. This treatment, called **autologous serum tear therapy**, has been used for years and has shown documented improvement in a range of severe cases, including controlled trials (references attached). These drops are prepared and formulated by an Eye Bank.

This letter is written to inform you that these specially formulated tears / lubricants are critical to controlling this severe eye condition, and they must be considered medically necessary. They should be treated as any other covered medication expense. Whether classified as a transfusion-type administration or as a medication, this treatment is medically necessary. I hope you will reimburse our patient for these expenses promptly.

Thank you for your help with this patient.

Sincerely,

John Smith, M.D.