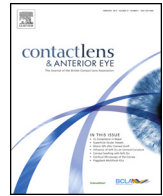




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Tear break-up time for tear film evaluation: Are moistening solutions interchangeable?



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ABSTRACT

Purpose: It was the main purpose of this study to investigate the influence of the moistening solution on TBUT measurements in an asymptomatic population.

Methods: An online survey was employed to determine the compliance of Spanish eye care practitioners with the recommended normalized procedure to administer TBUT. For the purpose of examining the clinical relevance of discrepancies from the recommended procedure, a randomized, double-masked, bilateral study was designed in which a micropipette was used to moisten fluorescein strips with a controlled volume of six different solutions, commonly available in the contact lens office, and TBUT was measured in 58 non-dry eye (OSDI < 15) subjects (age from 19 to 32 years).

Results: Results from the online survey revealed that 64% of Spanish practitioners frequently use (or have used) different solutions to moisten fluorescein strips during TBUT assessment. Statistically significant differences in TBUT values were found between the various solutions as a whole ($\chi^2 = 198.384$, $p < 0.001$), as well as between all solutions when explored pair-wise (all $p < 0.001$), except for the two saline solutions.

Conclusions: The present findings support the relevance of selecting the appropriate solution when conducting TBUT for the evaluation of the tear film. Deviations from the recommended procedure may result in misdiagnosis of dry eye and unnecessary patient referral.

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1. Introduction

Tear break-up time (TBUT) remains one of the most commonly employed tests to assess tear film stability and for dry eye diagnosis [1,2]. First introduced by Norn in 1969, TBUT was defined as the time “interval between the last complete blink and the presentation of the first appearance of a dry spot or disruption in the tear film” [2,3]. While many variations exist, the usual technique requires the instillation of sodium fluorescein into the tear film, whereupon the ocular surface is observed with a slit-lamp and a combination of excitatory cobalt blue light and a Wratten #12 yellow observation filter [4]. TBUT values may be influenced by the amount, concentration, pH, presence of preservatives and type of fluorescein, among other factors [5,6].

Several attempts at controlling the volume of instilled fluorescein have been explored. Indeed, pipetting 1 μ l of 2% fluorescein solution was found to result in an improved repeatability of TBUT measurements [7], although there remains debate regarding the

increased risk of microbial contamination associated with unpreserved fluorescein solutions and the need for contact of the pipette with the ocular surface [8]. Similarly, the Dry Eye Test (DET; Amcon Laboratories, Inc., USA) was developed to deliver the same small volume of fluorescein solution by application of slightly modified impregnated strips to the superior temporal bulbar conjunctiva [1]. More recently, a Modified Fluorescein Strip (MFS) test was described in which the top 1 mm of a standard fluorescein strip is folded to ensure optimal volume of instilled solution and improve repeatability [9].

It may also be noted that the method of instilling fluorescein solution may affect the cutoff values and the predictive value of the test in the diagnosis of dry eye. Thus, while a cutoff of ≤ 10 s is generally accepted with standard fluorescein impregnated strips [2,10], a ≤ 5 s cutoff was proposed when microquantities of fluorescein are instilled [11]. Similarly, whereas sensitivity and specificity values of 72% and 62%, respectively, are associated with a 10 s cutoff point [10], other authors describe a sensitivity of 94%, as compared with OSDI scores, when the MFS test was employed with a cutoff value of 5 s [9].

The standards published by The Diagnostic Methodology Subcommittee of the International Dry Eye WorkShop recommend TBUT to be performed with fluorescein impregnated strips

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Which of the following solutions do you use (or have used) to moisten fluorescein strips when conducting TBUT? (More than one answer is possible)

Saline solution Multi-purpose solution Wetting solution Artificial tears Other

Do you use any means to control the volume of fluorescein you instill on the ocular surface during TBUT?

Yes No

Fig. 1. Web-based survey sent to 100 Spanish registered optometrists to assess habits while conducting TBUT.

moistened with a single drop of 0.9% non-preserved saline [12]. However, it is not exceptional for practitioners to employ alternative solutions to moisten fluorescein strips, such as artificial tears [13], or to instil diagnostic drops containing a mix of fluorescein and oxybuprocaine (*Fluotest*®, Alcon, Spain) [14]. It may be speculated that other solutions commonly available in the contact lens fitting room, such as multipurpose solutions, may be used by practitioners instead of non-preserved saline for the purpose of moistening fluorescein strips during tear film assessment.

It was the first aim of the present study to assess, through an online survey, the compliance of Spanish eye care practitioners with the recommended normalized procedure to administer TBUT. Once the survey responses were analysed and it was determined that practitioners employ a variety of solutions for TBUT measurements, a study was designed to determine the influence of the moistening solution on TBUT measurements. For this purpose, TBUT was measured on a sample of non-symptomatic subjects (OSDI score < 15) by moistening conventional fluorescein strips with a constant, controlled volume of six different solutions, commonly available in any contact lens office.

2. Survey design and results

A simple, user-friendly, anonymous online survey was developed, which could be completed in less than 1 min (see Fig. 1). The survey form consisted of 2 questions in which practitioners were first instructed to report on the type of solution they used to moisten fluorescein strips by selecting one or several of the 5 different main solution categories they were provided with, and then they were asked a simple dichotomous question devised to determine whether they employed any means to control the volume of fluorescein instilled in the tear film of their patients. A link to the survey site was sent by email to one hundred registered optometrists randomly selected from the distribution list of the Faculty of Optics and Optometry of Terrassa (Spain).

A total of 47 registered optometrists answered the web-based survey. Of all respondents, 64% admitted using, or having used, one or several different solutions, apart from saline solution, to moisten fluorescein strips during tear film assessment (multi-purpose solution, 26%; artificial tears, 23%; wetting solution, 16%; others, 8%). In addition, 77% of the respondents reported not employing any means to control the volume of fluorescein they instilled to the ocular surface during TBUT.

3. Methods

3.1. Participants

Fifty eight students of optometry (45 female) were enrolled on the second part of study. Mean \pm SD age of participants was 21.74 ± 2.64 years (range from 19 to 32 years). All subjects had good ocular health and were free of symptoms of dry eye, as evaluated with the Ocular Surface Disease Index questionnaire (OSDI score < 15 [15]). Exclusion criteria were history of ocular or corneal surgery or injury, current use of any ocular medication, ointment or artificial tear substitutes and current or recent contact lens wear. In addition, pregnancy, diabetes and any other systemic condition or use of medication known to influence tear film stability also resulted in exclusion from the study.

All participants provided written informed consent after the nature of the study was explained to them. The study was conducted in accordance with the Declaration of Helsinki tenets of 1975 (as revised in Tokyo in 2004) and received the approval of an Institutional Review Board (Universitat Politècnica de Catalunya).

3.2. Moistening solutions

Six different solutions were employed for the purpose of moistening conventional 1 mg fluorescein sodium sterile strips (*Fluorets*®, Chauvin Pharmaceuticals Ltd., Surrey, UK). Solutions were selected from those commonly encountered in any optometric practice and represent a sample of the types of solutions listed in the survey, including several with added viscosity agents. A summary of the characteristics of the solutions employed in the study may be found in Table 1.

3.3. Procedure

A randomized, double-masked, bilateral study was implemented to determine TBUT values with each solution. All sessions took place at the same time of the day and consecutive sessions were 1–3 days apart, with a minimum wash-out period of 24 h between sessions. The same experienced examiner conducted all clinical procedures, and solutions were tested in a random order, under controlled and constant room temperature ($20^\circ\text{C} \pm 2^\circ\text{C}$) and humidity ($40\% \pm 10\%$) conditions. TBUT was captured via video recording and an independent observer, masked to the type of solution under evaluation, later determined the time interval between the last complete blink and the first appearance of a dry spot.

For each solution, a micropipette was used to ensure that only $2 \mu\text{l}$ of solution was applied to the fluorescein strip in order to deliver a controlled, constant volume to the ocular surface. The strip was then lightly applied for 1 s to the superior-temporal bulbar conjunctiva, by raising the upper eyelid while subjects were instructed to look inferior-nasally. Video capture was repeated 3 times, with subjects blinking normally for about 20 s between each recording. Both eyes were used for the study and, in each session, the same type of solution was employed in both eyes. Fluorescein was first instilled in one eye, selected at random, and following video capture, the same procedure was repeated in the contralateral eye.

TBUT was observed with a Topcon SL-D7 slit-lamp (Topcon España S.A., Barcelona, Spain) with a cobalt blue light filter and a Wratten #12 yellow filter (Kodak, Rochester, NY, US) positioned in front of the observation system. Slit-lamp magnification was set at $10\times$ and a circular beam of 10 mm in diameter was employed to illuminate the ocular surface. A slit-lamp mounted video camera was used to capture TBUT and a frame by frame examination of recordings was later performed by the independent observer. The median of the three measurements was recorded as the TBUT value for that particular subject and solution. In addition, the difference

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