A comparative study of dry eye followingmanual small incision cataract surgery and phacoemulsification surgery.

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Abstract:

Cataract is the leading cause of blindness in the world. At the same time cataract surgery is the most successful and rewarding surgery in the field of ophthalmology. However, after cataract surgery many patients complain of foreign body sensation, irritation, redness, blurring of vision which are considered as unwanted effects of the surgery. These effects are worse in the elderly population and those with ocular surface disorder. Thus, in spite of a perfect cataract surgery and a good Snellen visual acuity the patients may remain dissatisfied. This study has been undertaken to critically evaluate the unwanted side effect of dry eye production following manual SICS and phacoemulsification surgical procedures and ascertain the superiority of one against the other. Tear Meniscus Height (TMH), Schirmer's 1 Test (S_1T), Tear Break-up Time (TBUT) and Ocular Surface Disease Index (OSDI) questionnaire were used to record the type of dry eye. The dry eye related data were collected pre-operatively and postoperatively at 1week, 1 month and 3 months. In this study, it was found that MSICS is as effective as phacoemulsification with no difference between both these techniques as regarding effects on tear film stability and tear secretion.

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I. Introduction

Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.¹ Dry eye has become one of the most important factors influencing quality of life (QOL) in elderly patients. Incidence of dry eye in the United State has been estimated to be around 2.7% per year. Incidence of dry eye in India amongst eye out patient department patients has been estimated to be around 0.46% with a male: female ratio of 1:1.22.

A smooth ocular surface & lacrimal film are essential for the formation of clear image, as they constitute the first refractive medium. Minor variations in ocular surface or changes in tear film have direct repercussions on quality of vision. Cataract surgery is known to alter tear film & ocular surface both qualitatively and quantitatively.²

The causes of dry eyes are abnormalities of the tear film itself, like aqueous tear deficiency, mucin deficiency, lipid abnormalities and lid surfacing abnormalities, or epitheliopathies. Dry eye is thought to be a disturbance of the Lacrimal Functional Unit (LFU), an integrated system which comprises of the lacrimal glands, the ocular surface lids, and the sensory and the motor nerves that connect them.³

A disease in or a damage to any component of the Lacrimal Functional Unit (LFU) can destabilize the tear film and this can lead to ocular surface disease that expresses itself as dry eye. Any irregularity of the otherwise smooth and uninterrupted ocular surface leads to dry eye by causing instability of the tear film and thereby, break-up of the tear film quickly before the next blink. One or more of these causative factors can be involved in the pathogenesis of dry eye in patient post-cataract surgery.⁴ These effects of dry eye are worse in the elderly population and those with ocular surface disorder.⁵

Each year, cataract surgery permits millions of people to improve and recover their vision. This eye surgery has been conducted since ancient times, but has undergone significantly advanced developments over the past fifty years in the form of manual small incision cataract surgery & phacoemulsification in order to become common and effective procedure.⁶

Phacoemulsification is by far the most widely used procedure in the developed world, many ophthalmologists use non-phaco small incision surgery in developing countries, which is just as effective when done correctly.⁷

However dry eye conditions remain a common accompaniment of these otherwise uneventful surgeries. Studies have highlighted a temporary or even permanent derangement of tear function & ocular surface following both Manual SICS & phacoemulsification procedures.^{8,9,10,11}Comparative studies for these procedures, evaluating tear function & ocular surface integrity using acceptable functional indices are lacking. This study has been undertaken to critically evaluate the unwanted side effect of dry eye production following manual small incision cataract surgery & phacoemulsificationsurgery and ascertain the superiority of one against the other.

II. **Aims And Objects**

1. To find out Dry Eye following Manual Small Incision Cataract Surgery and Phacoemulsification Surgery. 2. To compare Dry Eye following Manual Small Incision Cataract Surgery and Phacoemulsification Surgery.

III. **Material And Methods**

Study design: Cohort study.

Study setting: The study was conducted in the Department of Ophthalmology, RIMS, Imphal, Manipur. **Study duration:** The study was carried out from September 2016 to August 2018.

Study population: Study population consisted of post operated cataract patient both manual small incision cataract surgery (MSICS) and Phacoemulsification admitted in department of Ophthalmology, RIMS, Imphal. **Sample size:** Taking Mean \pm SD of Schirmer's test as 6.60 \pm 1.754 for SCIS and 6.949 \pm 1.663 for Phacoemulsification, sample size is calculated by the formula

 $N = (s1)^2 + (s2)^2 / e^2$

Where s- standard deviation,

e - L/2 (L=margin of error, 0.5) Therefore, N = $\frac{(1.754)^2 + (1.633)^2}{2}$

0.25

= 4 x 5.742 0.25

= 91.872

Hence the calculated sample size was 92 for each operation.

Study Variables: Age, sex, religion, education, address, duration of surgery.

Inclusion Criteria:

1. Age > 50 years.

Post operated cataract patients having unilateral or bilateral age related nuclear and cortical cataracts 2. which ranged from grade 1 to hyper-mature cataracts admitted in RIMS, Imphal.

3. Patients who are willing to participate in the study.

Exclusion Criteria:

1. Cataract caused by an aetiology other than age, e.g., trauma, uveitis, drug induced.

- 2. Pre-existing ocular diseases glaucoma, disorders of lids, conjunctiva, cornea, and sclera.
- 3. Chemical burn, radiation.
- 4. Use of contact lens.
- 5. Patients on chronic ocular medications.
- 6. Patients who have undergone corneal refractive surgery.
- 7. Patients who had ocular allergies, pterygium, or blepharitis.
- 8. Previous history of dry eye disease.

Methodology: All post operated cataract patients admitted with clinical diagnosis of "Senile Cataract" under Ophthalmology Department in RIMS Hospital, Manipur, were taken as participants for this study.

After taking the proposed Informed Consent, data was collected in this order:

1. The patients' symptoms were thoroughly evaluated and recorded and the symptoms which were relevant to the dry eyes will be analyzed.

2. The marginal tear strip height was recorded by using a slit lamp.

3. The Schirmer's test-I was done and the readings of all the patients had been noted and analyzed to assess the basal and the reflex secretions of the tears by placing the Schirmer's strip, which is made up of the whatman no. 41 filter paper with its dimensions, 5mm x 35mm.

4. The tear film break-up time assessment was done to assess the stability of the precorneal tear film that is the mucin component of the tear film.

All the above tests were done on each patient and the data was graded, based on the guidelines of the 2007 Report of The International Dry Eye Workshop (DEWS). The grading was done as has been shown in [Table 1]

	0			
Dry eye severity	1	2	3	4 (Must have signs and
level				symptoms)
Discomfort, severity	Mild and/or episodic;	Moderate episodic or	Severe frequent or	Severe and/or disabling
& frequency	occurs under	chronic, stress or no	constant without stress	and constant Tear film
	environmental stress	stress		breakup time (s)
Tear film break-up	Variable	≤10	≤5	Immediate
time (s)				
Schirmer score	Variable	≤10	≤5	≤2
(mm/5 min)				

Table.1 Grading of 2007 - the International Dry Eye Workshop (DEWS).

Fig 1. Ocular Surface Disease Index

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 during the last week?	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

Have problems with your eyes limited you in performing any of the following <u>during the last week</u> ?	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
 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 1 to 5

(A)

				_
Subtotal	score fo	r answers	6 to	9 (

Have your eyes felt uncomfortable in any of the following situations during the last week?	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



Statistical analysis:

Data was calculated using SPSS version 21 software for Windows. Descriptive statistics was used to find out the mean, percentages and proportions. Chi square test and t-test will also be used for categorical variables. Ethic's Issue: The study was carried out only after obtaining approval from the Institutional Ethics Committee (IEC), Regional Institute of Medical Sciences, Imphal. Confidentiality and privacy were maintained. Conflict of interest: None

IV. **Results And Observation**

In our study, 100 patients out of 200 underwent manual small incision cataract surgery (MSICS) and another 100 underwent Phacoemulsification. All the patients were operated by the same surgeon. The Mean ages and SD of SICS and Phacoemulsification groups were 67.23 ± 9.09 and 65.85 ± 9.9 years respectively (p value of 0.3). The range of the age in SICS is 50-88 years and 50-90 years in Phacoemulsification respectively. Maximum number of patients are in the age of 60-80 years for both SICS and Phacoemulsification.

Table 2. Age and Gender distribution among the studied patients						
	p-value					
Age	Mean \pm SD	67.23 ± 9.09	65.85 ± 9.9	0.3 (NS)		
		(50-88)	(50-90)			
Gender	Male Female	30	39	0.18 (NS)		
		70	61			

	a 1	1			
Table 2. Age and	Gender	distribution	among	the studied	patients

Table 2shows age and gender distribution of the study group. Female dominates in both SICS and Phacoemulsification. Maximum number of patients are in 60-80 years age group.



Fig 2 shows gender wise distribution of patient in manual small incision cataract surgery. There was more of female patient with ratio of male: female 30:70.



Fig 3. Phacoemulsification – Gender wise distribution (N=100)

Fig 3 shows gender wise distribution of patient in Phacoemulsification. There was more of female patient with ratio of male: female 39:61.



Fig 4 shows age wise distribution of patients in manual small incision cataract surgery. The maximum number of patients were in the age group 70-80 years in female and 60- 70 years in male. The range of age for SICS was 50-88 years.



Fig 5. Phacoemulsification – Age wise distribution (N=100)

Fig 5shows age wise distribution of patients in Phacoemulsification. Majority of patients were in 70-80 years in female and 50-60 years in male. The range of age was 50-90 years.



Fig 6 shows surgical time distribution of the patients in SICS and Phacoemulsification. As the surgery was done by the same surgeon and maximum number of the patient are within 20-30 minutes for both of the surgery

When we analysed the patients according to those who had undergone manual small incision cataract surgery and those who had undergone phacoemulsification, preoperatively the mean and standard deviation of tear meniscus height, Schirmer's test, tear film breakup time, ocular surface disease index (OSDI) were respectively 0.32 ± 0.064 , 13.54 ± 1.226 , 13.66 ± 1.027 and 12.54 ± 1.431 in patients who underwent SICS and 0.32 ± 0.065 , 13.54 ± 1.200 , 13.939 ± 1.008 and 12.410 ± 1.198 in patients who underwent Phacoemulsification.

Postoperatively, the mean and standard deviation for ocular surface disease index (OSDI) at 1 week was found out to be 30.26 ± 3.433 in SICS patients, 20.08 ± 1.873 at 1 month, 18.61 ± 1.455 at 3 months. In Phaco patients OSDI at 1 week was 31.02 ± 73 at 1 month was 19.45 ± 1.559 and at 3 months was 18.333 ± 1.714 . Likewise the mean and standard deviation of tear film breakup time in SICS patients, which came out to be 6.91 ± 1.583 at 1 week, 7.82 ± 1.604 at 1 month and 9.97 ± 1.585 at 3 months. In Phaco patients, it was 7.45 ± 2.016 at 1 week, 7.97 ± 1.85 at 1 month, and 10.09 ± 1.504 at 3 months.

The mean and standard deviation of tear meniscus height at 1 week was 0.247 ± 0.059 in SICS patients, at 1month was 0.251 ± 0.06 , at 3 months 0.260 ± 0.046 . Whereas in Phaco patients, tear meniscus height was found out to be 0.279 ± 0.065 at 1 week, 0.281 ± 0.065 at 1 month, 0.286 ± 0.057 at 3 months. Like-wise the mean and standard deviation of Schirmer's test at 1 week was 6.72 ± 1.923 in SICS patients, at 1 month was 7.96 ± 1.901 and at 3 months was 10.2 ± 1.595 . Whereas in Phaco patients, Schirmer's test was found out to be 7.54 ± 2.19 at 1 week, 8.14 ± 1.943 at 1 month, 10.42 ± 1.634 at 3 months. The preoperative and postoperative findings are shown in table 3 to 6.

Table 3: Preo	perative values	of different drv	eve indices for	patients undergoin	g cataract surgery (n=200)

	Tear Meniscus Height (TMH) Mean ± SD	Schirmer's Test (ST) Mean ± SD	Tear Break Up Time (TBUT) Mean ± SD	Ocular Surface Disease Index (OSDI)
				Mean ± SD
SICS	0.32±0.064	13.54±1.226	13.66±1.027	12.54±1.431
Phacoemulsification	0.32±0.065	13.54±1.200	13.939±1.008	12.410±1.198
p-value	0.64	0.56	0.045	0.48

Table 4: values of different dry eye indices for patients undergoing cataract surgery after 1 week of
surgery (n=200)

	Tear Meniscus Height (TMH) Mean ± SD	Schirmer's Test (ST) Mean ± SD	Tear Break Up Time (TBUT) Mean ± SD	Ocular Surface Disease Index (OSDI) Mean ± SD
SICS	0.247±0.059	6.72±1.92	6.91±1.583	30.26±3.43
Phacoemulsification	0.279±0.065	7.54±2.19	7.45±2.016	31.02±3.30
p-value	0.001*	0.005*	0.037	0.112

Table 5: Values of different dry eye indices for patients undergoing cataract surgery after 1 month of surgery (n=200)

	Tear Meniscus Height	Schirmer's Test	Tear Break Up Time	Ocular Surface
	(TMH) Mean ± SD	(ST) Mean ± SD	(TBUT) Mean ± SD	Disease Index (OSDI)
				Mean ± SD
SICS	0.251±0.06	7.96±1.901	7.82±1.604	20.08±1.873
Phacoemulsification	0.281±0.065	8.14±1.943	7.97±1.85	19.45±1.559
p-value	0.001*	0.509	0.541	0.01*

Table 6: Values of different dry eye indices for patients undergoing cataract surgery after 3 months of surgery(n=200)

	Tear Meniscus Height (TMH) Mean ± SD	Schirmer's Test (ST) Mean ± SD	Tear Break Up Time (TBUT) Mean ± SD	Ocular Surface Disease Index (OSDI) Mean ± SD
SICS	0.260±0.046	10.2±1.595	9.97±1.585	18.61±1.455
Phacoemulsification	0.286±0.057	10.42±1.634	10.09±1.504	18.333±1.714
p-value	0.001*	0.337	0.584	0.221

Table 7: Grading of dry eye after 1 week post-operative time according to DEWS classificationMSICSPhaco

Grade	S1T	TBUT	OSDI	S1T	TBUT	OSDI
Ι	10	5	18	27	19	21
II	56	79	63	50	61	57
III	34	16	21	23	20	22
IV	0	0	0	0	0	0

Table 7 shows dry eye grading after 1 week post-operative time. Maximum number of the patients have grade II dry eye both in SICS and Phacoemulsification.

Table 8: Grading of dry eye after 1-month postoperative time according to DEWS classificationMSICSPhaco

Grade	S1T	TBUT	OSDI	S1T	TBUT	OSDI
Ι	25	12	30	27	22	37
II	69	80	62	69	63	57
III	6	8	8	4	5	6
IV	0	0	0	0	0	0

Table 8 shows dry eye grading after 1 month of postoperative time. Maximum number of the patients have grade II dry eye both in SICS and Phacoemulsification.

Table 9: Grading of d	ry eye after 3 months postoperative time according to DEWS classification
MSICS	Phaco

Grade	S1T	TBUT	OSDI	S1T	TBUT	OSDI
I	70	65	78	62	61	73
II	30	35	22	38	39	27
III	0	0	0	0	0	0
IV	0	0	0	0	0	0

Table 9 shows dry eye grading after 3 months of post-operative time. Maximum number of the patients have grade I dry eye both in SICS and Phacoemulsification.

V. Discussion

Any irregularity of the otherwise smooth and uninterrupted ocular surface leads to dry eye by causing instability of the tear film and thereby, break-up of the tear film quickly before the next blink. One or more of these causative factors can be involved in the pathogenesis of dry eye in patient post-cataract surgery.⁴

The study consisted of 200 patients (100 SICS and 100 Phacoemulsification). The Mean ages & SD of SICS & Phacoemulsification groups were 67.23 ± 9.09 and 65.85 ± 9.9 years respectively (p value of 0.3). The range of the age in SICS is 50-88 years and 50-90 years in Phacoemulsification respectively. Maximum number of patients are in the age of 60-80 years for both SICS and Phacoemulsification. The study done by Cetinkaya S et al ¹²found that the mean age was 68.46 ± 8.14 (SD) (range 56– 83) years which was comparable with the present study. Another study conducted by Jiang D et al¹³ found that the mean age of the patient who underwent cataract surgery was 65.4 ± 12.4 which is in accordance with the present study.

On day 7 postoperatively, the mean and SD scores of OSDI questionnaire (preoperatively vs. postoperatively, 12.54 ± 1.431 vs. 30.26 ± 3.43 , respectively) in SICS and $(12.410\pm1.198$ vs $31.02\pm3.30)$ in

Phacoemulsification with p values of 0.117 and 0.017 respectively which was significant in Phacoemulsification. TBUT (preoperatively vs. postoperatively, 13.66±1.027 vs. 6.91±1.583 seconds) in SICS and (13.939±1.008 vs 7.45±2.016) in Phacoemulsification with a p-value of 0.157 and 38 0.332 which was not significant in either group. Tear Meniscus Height (TMH) (preoperatively vs. postoperatively, 0.32±0.064 vs 0.247±0.059) in SICS p-value of 0.97 and (0.32±0.065 vs 0.279±0.065) in Phacoemulsification with a p-value of 0.59 which was not significant. Schirmer's I Test (preoperatively vs. postoperatively, 13.54±1.226 vs. (6.72 ± 1.92) in SICS (p-value <0.05) and ($(13.54\pm1.200 \text{ vs } 7.54\pm2.19)$ in Phacoemulsification with a p-value of <0.05 was significant showed a trend toward dry eye syndrome. Kasetsuwan N et al¹⁴ concluded that the severity of dry eye peaked seven days post phacoemulsification and as measured by OSDI questionnaire and three clinical tests. Within thirty days and 3 months post-surgery, both the symptoms and signs showed rapid and gradual improvements respectively. Rizvi Y et al¹⁵ on their study comparative assessment of tear function and ocular surface following cataract surgery employing manual SICS and phacoemulsification techniques found that Schirmer's I test (S1T), tear break-up time (TBUT) and tear meniscus height (TMH) after 7 days post-operative were all reduced showing a trend toward dry eye syndrome. Chao PM et al¹⁰ validated this view in their study on 49 patients without dry eye, none of whom developed dry eye disease following phacoemulsification surgery. They reported temporary reduction in physiological tear levels, seen one weekpost-surgery gradually returning to normal baseline levels by third month. As regarding symptoms of dry eye, the present study has shown that there was significant increase in symptoms of dry eye 1 week after postoperative in phacoemulsification (p-value < 0.05) and returning for baseline preoperative prevalence after 3 months. This was applied for all symptoms including heavy eyelid, secretions, foreign body sensation, eye redness, stinging and feeling of dryness. Similar study was found by Saif MY et al.¹⁶

Proposed mechanisms for decrease in tear production after clear cornea phacoemulsification included, the corneal incisions caused certain corneal irregularities that might produce tear film disruptions and decrease in corneal sensation secondary to severing of the corneal nerves that disrupted the feedback loop of the cornea and lacrimal gland.¹⁷

Tear film stability was significantly compromised in present study as supported by low FTBUT values. This finding could not be attributed to clear cornea phacoemulsification alone. The low FTBUT values were likely to be the result of the use of topical eye drops with preservatives, exposure to light of microscope, frequent irrigation of cornea as they could cause toxicity to the cornea and conjunctiva. These preservatives acted like detergents that caused break down of the tear lipid layer resulting in low FTBUT. Pisella PJ¹⁸ et al compared the ocular symptoms (foreign body sensation, tearing, burning sensation, and itching) of patients on preservative-free glaucoma medications showed a significant decrease in symptoms with the use of preservative-free medication and a reversal of symptoms after the medication with preservative was removed.

On day 30 (1 months) postoperatively, the mean and SD scores of OSDI questionnaire (preoperatively vs. postoperatively, 12.54 ± 1.431 vs. 20.08 ± 1.873 , respectively) in SICS (p-value of 0.82) and $(12.410\pm1.198$ vs 19.45±1.559) in Phacoemulsification (p-value of 0.27) which was not significant. TBUT (preoperatively vs. postoperatively, 13.66 ± 1.027 vs. 7.82 ± 1.604 seconds) in SICS and $(13.939\pm1.008$ vs $7.97\pm1.85)$ in Phacoemulsification with a p-value of 0.04 and 0.28 in which SICS was statistically significant in MSICS. Schirmer's I test (preoperatively vs. postoperatively, 13.54 ± 1.226 vs 7.96 ± 1.901) in SICS and $(13.54\pm1.200$ vs 8.14 ± 1.943) in Phacoemulsification with a p-value <0.05 for both SICS and Phacoemulsification were significant. Cho YK et al¹⁹found similar finding in their study. Tear meniscus 40 height (TMH) (preoperatively vs. postoperatively, 0.32 ± 0.064 vs 0.251 ± 0.06) in SICS p-value of 0.75 and $(0.32\pm0.065$ vs 0.281 ± 0.065) in Phacoemulsification with a p-value of 0.59 which was not significant. In our study, the TBUT gradually improved at 1 month after phacoemulsification which could be due to the decreased frequency of topical medications at around this time and returned to near normal levels at 3 months (medication stopped) after surgery.

On day 90 (3 months) postoperatively, the mean and SD scores of OSDI questionnaire (preoperatively vs. postoperatively, 12.54 ± 1.431 vs. 18.61 ± 1.455 , respectively) in SICS (p-value of 0.52) and $(12.410\pm1.198$ vs. 18.333 ± 1.714) in Phacoemulsification (p-value of 0.35) which was not significant. TBUT (preoperatively vs. postoperatively, 13.66 ± 1.027 vs. 9.97 ± 1.585 seconds) in SICS and $(13.939\pm1.008$ vs. 10.09 ± 1.504) in Phacoemulsification with a p-value of 0.05 and 0.02 in which both SICS and Phacoemulsification were statistically significant. Schirmer's I Test (preoperatively vs. postoperatively, 13.54 ± 1.226 vs. 10.2 ± 1.595) in SICS and $(13.54\pm1.200$ vs. 10.42 ± 1.634) in Phacoemulsification with a p-value <0.05 for both SICS and Phacoemulsification were significant. Tear meniscus height (TMH) (preoperatively vs. postoperatively, 0.32 ± 0.064 vs. 0.260 ± 0.046) in SICS p-value of 0.83 and $(0.32\pm0.065$ vs. 0.286 ± 0.057) in Phacoemulsification with a p-value of 0.55 which was not significant.

VI. Conclusion

There are many factors that might affect the ocular surface environment after cataract surgery. Topical anaesthesia and eye drops containing preservatives like benzalkonium chloride are well known to have effects on the corneal epithelium. Exposure to light from the operating microscope might also be associated with postoperative dry eye. Most corneal surgical procedures disrupt the normal organization of the corneal innervation, and thus results in pathologic changes of the cornea and attendant discomfort. Most surgical procedures that cause denervation of the cornea result in impaired epithelial wound healing, increased epithelial permeability, decreased epithelial metabolic activity and loss of cytoskeletal structures associated with cellular adhesion.²⁰

The present study has shown that MSICS is as effective as Phacoemulsification with no difference between both these techniques as regarding effect on tear film stability and tear secretion. Phacoemulsification and SICS reduced the tear secretion in the studied patients so, it is necessary to use artificial tear preparations for managing corneal damage and dry eye symptoms.

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