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TEAR OSMOLARITY DURING THE FIRST POSTOPERATIVE MONTH AFTER CATARACT SURGERY

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The purpose of this study was to evaluate tear osmolarity changes in a healthy ocular surface in an eye that had been operated on within the first month after cataract surgery. This aim was achieved by forming two groups from the included patients. Patients with one eye exposed to cataract surgery formed the study group, while the eyes of the same patients with no cataract surgery were set as the control group. Both the operated and non-operated eye of each patient were scanned before surgery, the following morning, one week and one month after surgery. Tear osmolarity did not differ between the groups before the operation. On the first day after the surgery, tear osmolarity significantly decreased, below the detection range of the TearLab device (< 275 mOsm/l). The osmolarity level in the control group did not change. One week after surgery, osmolarity in the study group increased to 312.64 mOsm/l, which was significantly different from that of the control group. One month after surgery, tear osmolarity in the study group had returned to the pre-operative level. Tear osmolarity is thus clearly affected by cataract surgery. The average values were seen to change quite significantly during the first postoperative month.

Keywords: *ocular surface, phacoemulsification.*

INTRODUCTION

In total, 4.3 million cataract surgeries took place among the European Union Member States in 2014, making it the most common procedure performed by ophthalmic surgeons. In the United States, 9000 cataract specialists performed 3.6 million surgeries in 2015. It is estimated that more than 23 million procedures were performed worldwide in 2016 (Packard, 2008). Despite such a large number of cataract surgeries, the scope of knowledge regarding ocular surface changes during the first postoperative month is relatively low (Elksnis, 2019). One of the characteristics of ocular surface homeostasis is tear osmolarity (Lemp, 2011). The correlation of this factor with dry eye symptoms after cataract surgery has been widely studied in the late postoperative period, starting from one month after the surgery (Gonzalez-Mesa, 2016). The results obtained do not indicate significant changes from before to after surgery in the long-term, or when comparing an operated eye with a non-operated one (Potvin, 2015). As mentioned above, this study focuses on tear osmolarity changes seen during the first postoperative month, in order to understand and obtain more information about ocular surface healing after cataract surgery. The purpose of the study was to evaluate changes in tear osmolarity in the healthy ocular surface of an operated eye the morning after, one week after, and one month after cataract surgery, and to compare the results with those for the non-operated eye.

MATERIALS AND METHODS

The study was carried out at the Department of Ophthalmology, Pauls Stradiņš Clinical University Hospital, in Rīga, Latvia, from 1 May until 21 December 2017.

The study necessitated selecting patients with a healthy ocular surface. For this reason, patients presenting any conditions that might affect the homeostasis and tear osmolarity measurements, i.e., patients with diabetes, pseudoexfoliation syndrome, pterygium, glaucoma, and/or daily eye drop and/or contact lens use, were excluded. To ensure the exclusion of patients suffering from dry eye disease, a modified dry eye symptom questionnaire was administered the day before the surgery. If a patient indicated any complaints or symptoms, the person was not included in the study.

After selecting patients meeting all the criteria mentioned above, two study groups were formed. The patient eyes that were exposed to cataract surgery formed the study group, while the eyes of the same patients that did not have the relevant surgery formed the control group. Tear osmolarity measurements were performed by applying a TearLab Osmolarity System (TearLab Corporation, San Diego, CA, USA). Both eyes (operated and non-operated) were scanned before the surgery, as well as before any application of local medication.

All cataract surgeries were performed by a single surgeon, with the administration of sub-tenon anaesthesia. The procedure included two clear corneal incisions: continuous curvilinear capsulorhexis and extracapsular phacoemulsification with intraocular lens implantation in the capsular bag. A standard postoperative medication, according to the praxis of the clinic, consisted of topical anti-inflammatory dexamethasone and antibiotic eye drops of polymyxin B and neomycin, which was prescribed after surgery and gradually reduced over a period of four weeks.

Further tear osmolarity measurements were obtained the morning after, one week after, and one month after the cataract surgery. All measurements were taken two hours after the last eye drop was applied, to avoid any potential effects on the tear osmolarity measurements.

All the evaluation and statistical analyses of the data obtained during the study were performed using IBM Statistical Package for the Social Sciences (SPSS), Statistics 24 (IBM Corporation, Armonk, NY, USA).

Informed consent was obtained from all the participants included in this study. All procedures performed in this study adhered to the ethical standards of the institutional and national research committees, as well as with the 1964 Helsinki declaration and its later amendments, or comparable ethical standards. Ethical approval was issued by the Ethical Committee of Rīga Stradiņš University.

RESULTS

In total, 90 patients (180 eyes) were included in this study. The average age of the patients was 72.66 ± 4.82 SD years. The age of the patients ranged from 63 to 86 years; most of the patients were 68 years old (Fig. 1). The patient age box chart (Fig. 2) indicates that the median age was 72 years, the first quartile was 69 years, and the third quartile was 75 years.

The study included 29 (32.2%) male patients with an average age of 71.41 ± 4.35 SD years, and 61 female patients with an average age of 73.25 ± 4.95 SD years. No statistically significant difference in age between the male and female patients was found (p = 0.11).

The mean tear osmolarity before surgery in the study group was 296.87 mOsm/l, while in the control group it was 297.27 mOsm/l; no statistically significant difference was observed (p = 0.84, Mann–Whitney test) (Fig. 3).

One day after the cataract surgery, the tear osmolarity for all operated eyes significantly decreased, and was below the detection range of the TearLab device. The osmolarity became hypo-osmolar. According to TearLab's guidelines, the device used is capable of registering measurements from 275 to 400 mOsm/l, and all measurements below 275 mOsm/l are considered hypo-osmolar (Corporation TearLab, 2012). It was not possible to determine an exact value for the hypo-osmolar measurements, and for statistical analyses 275 mOsm/L was considered the average osmolarity measurement on the first day after the cataract surgery. The mean osmolarity among the control group eyes on the first day after the surgery was 298.43 mOsm/l. A significant difference was observed (p < 0.001, Mann–Whitney test) between the two groups. One week after the surgery, a considerable increase in tear osmolarity in the eyes of the study group occurred, which reached 312.64 mOsm/l. Tear osmolarity for the control group was 299.78 mOsm/l,

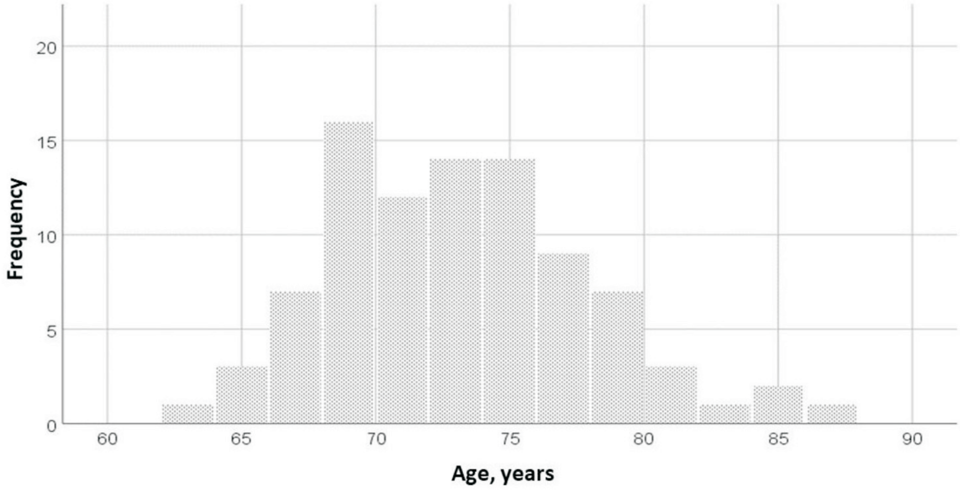

Fig. 1. Patient age histogram.

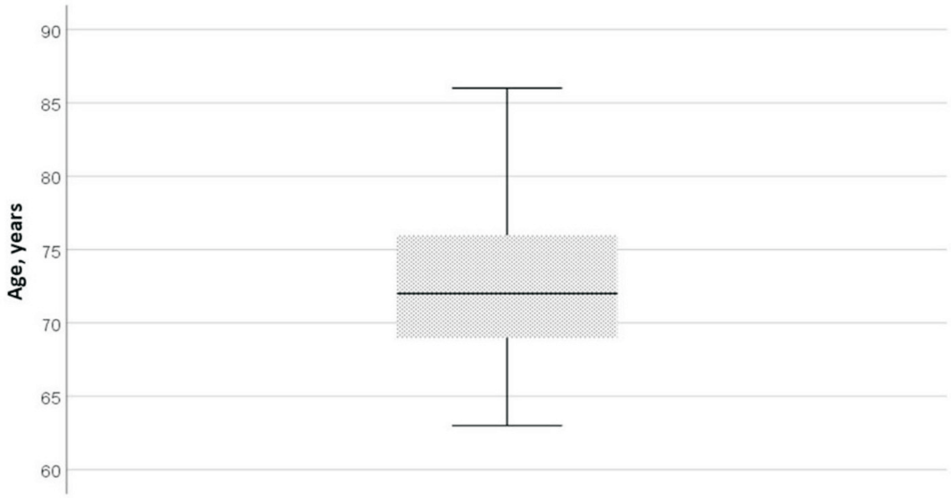

Fig. 2. Patient age box chart.

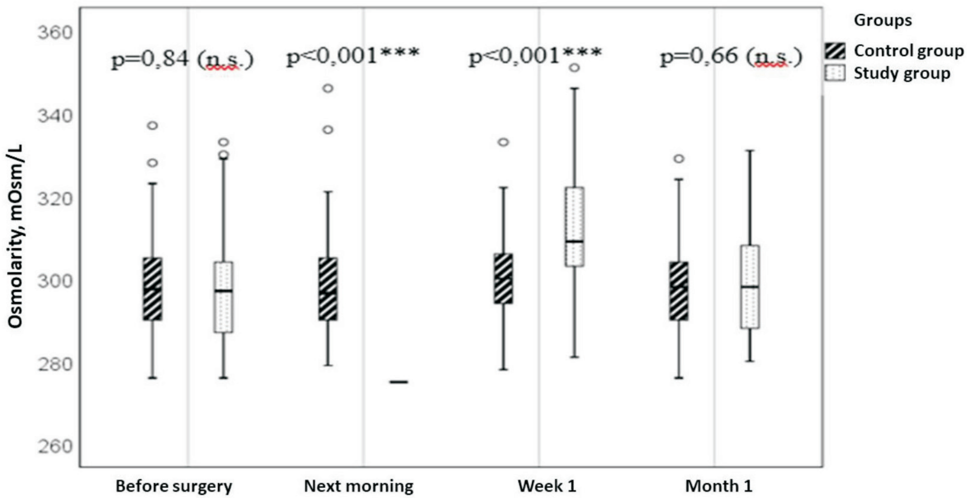

Fig. 3. Comparison of tear osmolarity between study and control groups before the surgery, the next morning, and at week 1 and month 1 after the surgery.

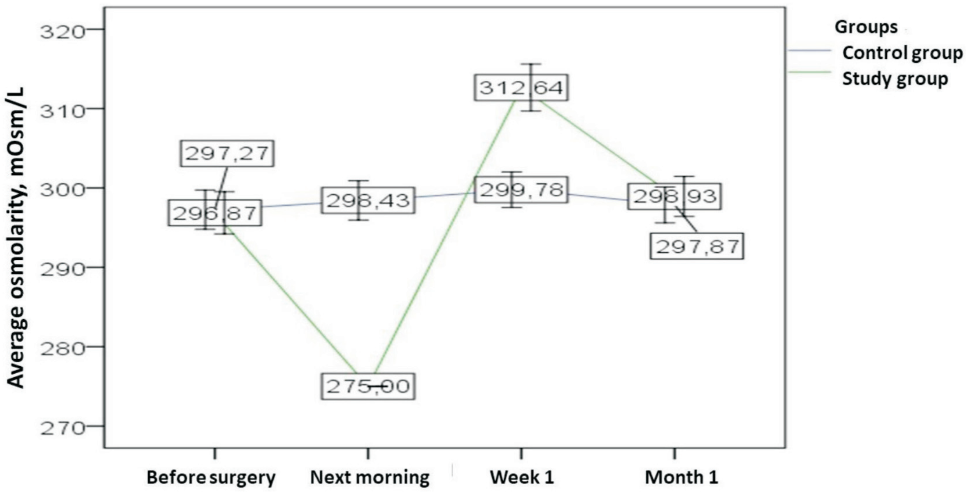

Fig. 4. The mean tear osmolarity changes in the study and control groups during the first postoperative month.

which significantly differed from that of the study group ($p < 0.001$, Mann–Whitney test). One month after the cataract surgery, the tear osmolarity of the study group (298.93 mOsm/l) had returned to the pre-operative level. The corresponding measurement for the control group was 297.87 mOsm/l ($p = 0.66$ Mann–Whitney test).

According to the repeated variance–covariance analysis, the average tear osmolarity level in the operated eyes changed significantly during the first postoperative month ($p < 0.001$), while no such changes were noticed in the non-operated eyes ($p = 0.86$) (Fig. 4).

In addition, a statistically significant correlation was observed between the patient age and the difference in measured osmolarity from before surgery to one month later. Linear regression analysis showed that the difference in tear osmolarity increased by 0.30 mOsm/l ($p = 0.03$) each year (Fig. 5).

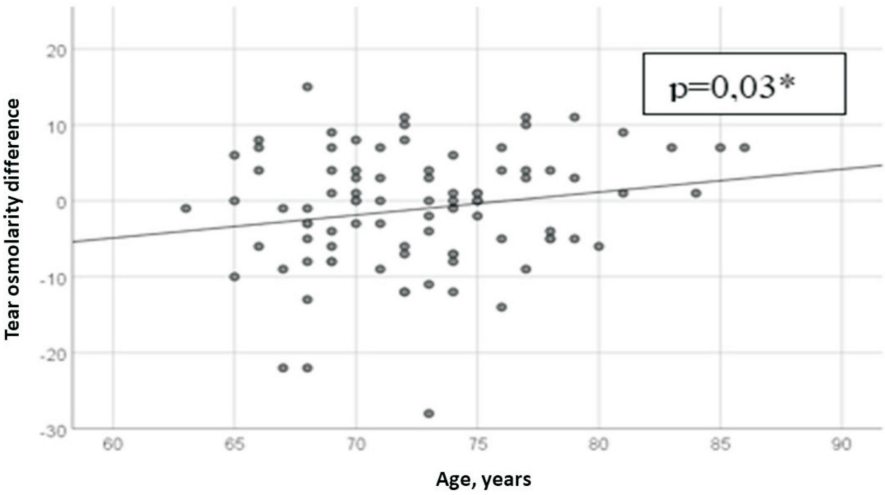

Fig. 5. Correlation between the patient age and the differences in tear osmolarity results before and after the surgery.

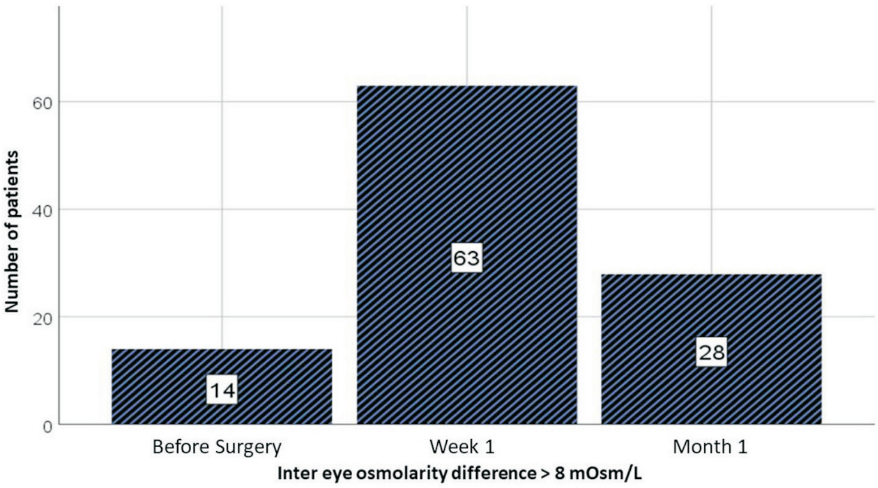

Fig. 6. Number of patients diagnosed with ocular surface homeostasis loss according to inter-eye osmolarity difference.

The inter-eye difference, which is a key value of the ocular surface, was analysed in depth; values up to 8 mOsm/l between the operated and non-operated eye were considered as physiological, according to the TearLab guidelines (Corporation TearLab, 2012). Fourteen (15.56%) patients showed an inter-eye difference greater than 8 mOsm/l before the cataract surgery. One week after the surgery, 63 (70%) patients were diagnosed with a loss of ocular surface homeostasis. One month after the surgery, this diagnosis was given to 28 (31.11%) patients (Fig. 6). The inter-eye difference on the first day after the surgery was not analysed, because values for this measurement were not obtained in the study group.

DISCUSSION

Tear osmolarity has already been broadly studied (Potvin, 2015). Tear osmolarity is not only an important factor in characterising the ocular surface's health and helping ophthalmologists to improve their knowledge about postoperative healing, but it also impacts the calculation of the intraocular lens (Epitropoulos, 2015). Various literature sources suggest that an undiagnosed or untreated dry eye disease with hyperosmolarity can lead to inaccurate intraocular lens calculations, and consequential implantation, which results in postoperative refractive error and dissatisfied patients (Epitropoulos, 2015). To avoid the effects of tear film instability on lens calculation, more attention is being paid to the ocular surface and tear osmolarity by cataract and refractive surgeons, who acknowledge them as effective diagnostic tools during pre-operative screening for high-risk patients (Epitropoulos, 2015; Willcox, 2017). Tear film thickness varies from 6 μm to 20 μm, and in physiological terms, the refractive power does not differ by more than 0.1 diopters between two separate blinks. Meanwhile, in the case of hyperosmolarity, the refractive power of the tear film can change by as much as 1.0 diopters (Cochener-Lamard, 2019). These results encourage the consideration of new prospective study directions involving tear osmolarity and lens calculation, not only for intraocular lens, but also for eyeglasses. According to secondary sources, the most frequently used type of intraocular lens is monofocal, which, in most cases, demands near-distance correction with eyeglasses after surgery (De Silva, 2016). In practice, the recovery period after surgery varies up to around one month (Porela-Tiihonen, 2016), which corresponds to the tear osmolarity stabilisation time employed in the present study. Some literature sources suggest that, for most patients, it may be possible to prescribe glasses from two weeks after an uneventful phacoemulsification cataract surgery (Caglar, 2017). However, surgeons have to consider that the recovering homeostasis of an ocular surface with hyperosmolarity of the tear film can lead to inaccurate refraction results.

In 2016, the *American Journal of Ophthalmology* published a study conducted by Spanish experts (Gonzalez-Mesa, 2016). It explicitly claimed that hyperosmolarity correlates with the severity of the dry eye condition. The observation periods were one month and three months after cataract surgery, and no significant changes were observed in the osmolarity measurements taken for the operated eye (Gonzalez-Mesa, 2016). This was the reason for the study taking a more detailed look at the tear osmolarity values during the first postoperative month. Taking into account the present study's results and comparing them with information provided by sources in the literature, it can be concluded that one month after cataract surgery is the required time period for tear osmolarity stabilisation, after which it levels off to pre-operative measurements.

As already mentioned, tear osmolarity (and hyperosmolarity in particular) is significantly correlated with the severity of the dry eye disease symptoms (Sullivan, 2010). Some studies claim that tear osmolarity is the only reliable indicator of the severity of dry eye disease (Sullivan, 2010). Based on the existing data described in the literature, which indicate correlation between hyperosmolarity and symptom severity (Potvin, 2015; Sullivan, 2010), dry eye symptoms after surgery were not evaluated with any specific questionnaires in the present study.

To make this study unique and include patients with intact ocular surface homeostasis, any conditions affecting tear osmolarity were grounds for exclusion. For example, clinical conditions such as pterygium and pseudoexfoliation syndrome are reported to increase tear osmolarity, thus changing the activity of the mucin-producing goblet cells and affecting the production of the tear film's inner layer (Astrom, 2007; Julio, 2012; Oncel, 2012; Gipson, 2016). Tear osmolarity is increased not only by ocular conditions, but also by systemic diseases such as diabetes mellitus (Fuerst, 2014). A topic that is already being widely discussed concerns contact lens-wearers; many studies prove that contact lenses can act as a friendly foreign body to the ocular surface, increasing tear osmolarity (Muselier-Mathieu, 2014). Finally, all the patients undergoing check-ups before the surgery and using any kinds of eye drops were not included, given that regular local therapy with eye drops changes the osmolarity (Labbe, 2012; Lee, 2013; Lee, 2014).

The last mentioned inference above illuminates one of this study's weak points, that is, that not only does cataract surgery have an effect on tear osmolarity, but also locally used eye drops after operation. This is important given that such medication was prescribed, and gradually decreased over a period of four weeks after surgery, which is equal to the time period over which the measurements of tear osmolarity returned to pre-operative levels. It is dangerous and against postoperative guidelines to leave a patient without local anti-inflammatory and antibiotic eye drops; however, in further studies, the control group could be composed of non-operated eyes, for which local therapy is prescribed following the same regimen as that for operated eyes. This could give more precise data on effects of cataract surgery on tear osmolarity changes. Considering the information above, this study cannot declare cataract surgery as the only factor that affects the ocular surface's homeostasis in the first postoperative month.

Upon analysing the study results in greater detail, a slight, yet not significant, difference can be observed in the mean tear osmolarity between the groups before the operation. Of course, the average values in both groups are under 300 mOsm/l, which, according to TearLab's guidelines, indicate healthy, intact ocular surface tear osmolarity (Corporation TearLab, 2012). However, on the first day after cataract surgery, the average osmolarity significantly decreased in the operated eyes, indicating a difference between the groups. The osmolarity became hypo-osmolar, and reached a level below the range that the TearLab device is capable of recording. In other words, tear osmolarity decreased below 275 mOsm/l (the lower end of the device's range). Surprisingly, on the first day after the surgery, all of the operated eyes became hypo-osmolar. The tear osmolarity reduction could be explained by the presence of intense irritation after the surgery, which triggers lacrimal gland hyperfunction and excessive lacrimation (Sutu, 2016). This leads to the dilution of tears in the first few days after surgery. In addition, the effects of frequent use of dilutional postoperative eye drops cannot be forgotten (Li, 2007; Willcox, 2017). On the first day after the surgery, no significant changes in tear osmolarity were observed in the eyes of the control group. The results remained within the range of normal osmolarity, and the comparison with results obtained for eyes having undergone surgery showed that statistically significant changes had occurred.

At one week after the surgery, a significant increase in tear osmolarity was demonstrated in the study group, exceeding the upper border of that of a healthy ocular surface. In contrast, no changes were found in the control group. A statistically significant difference was observed between the groups. The increase in tear osmolarity one week after the surgery can be explained by the increase in inflammatory factors, which are at their peak during the first few days after surgery (Sutu, 2016). It should be remembered that even a small incision, i.e. minimally invasive cataract surgery, is traumatic to human tissue. Structural changes undergone by Goblet cells in conjunctiva can lead to dry eye disease (Oh, 2012).

One month after the surgery, as expected, the average values in the study group decreased to pre-operative levels, and synchronised with the results of the non-operated eyes. The analysis of the osmolarity data suggests that one month is a sufficient period of time for tear osmolarity to stabilise, and for the ocular surface to heal. Due to the postoperative check-up limitations, the exact healing time cannot be determined. In spite of that, in a month, the osmolarity returned to pre-operative levels, complying with the results described in other studies (Gonzalez-Mesa, 2016).

When performing an analysis of each group separately, significant changes in tear osmolarity can be observed during the first postoperative month in the study group ($p < 0.001$). Meanwhile, no significant changes were recorded in the control group ($p = 0.86$).

Another aspect worth mentioning is the inter-eye osmolarity difference, which, according to TearLab's osmolarity system guidelines, is typically around 8 mOsm/l. Any broadening of this difference indicates instability in the tear film, and is a hallmark of dry eye disease (Corporation TearLab, 2012). Of all the patients included, 14 (15.56%) demonstrated an inter-eye difference higher than 8 mOsm/l before the operation. Naturally, within a week, the number increased to 63 patients (70%). In contrast, one month after the surgery, 28 (31.11%) patients were diagnosed with inter-eye differences greater than 8 mOsm/l. These results are considered an interesting topic for further research: is a period of one month enough for the ocular surface to recover?

Statistical analyses of the pre-operative results and those taken one month after the cataract surgery ($p = 0.03$) suggest that with every year of life (i.e., as the subject gets older), the difference in tear osmolarity increases by 0.30 mOsm/l. This newly discovered fact provides ideas for future studies on the stabilisation ability of tear osmolarity among different age groups.

CONCLUSION

To summarise the results of the present study, there is no denying that tear osmolarity is affected during the first month after cataract surgery. The average values change quite significantly during the first postoperative month, which is also the approximate period of time required for a healthy ocular surface's tear osmolarity to recover and reassume pre-operative levels. No changes were observed in non-operated eyes. The data acquired will help practitioners to elucidate the recovery process of the ocular surface after cataract surgery. Further studies should be performed for complete understanding of the effect of cataract surgery on tear osmolarity and the ocular surface.

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ASARU OSMOLARITĀTES IZMAIŅAS MĒNEŠA LAIKĀ PĒC KATARAKTAS OPERĀCIJAS

Pētījuma mērķis bija noskaidrot, kā mainās asaru plēvītes osmolaritāte pēc kataraktas operācijas pacientiem ar veselu acs virsmu. Mērķa sasniegšanai tika izveidota pētījuma grupa, kas ietvēra pacientus, kuriem tika veikta plānveida kataraktas operācija. Kontroles grupā kā nemainīgs raksturlielums tika iekļauta to pašu pacientu acs, kurai netika veikta operācija. Asaru plēvītes osmolaritāte tika noteikta ar *TearLab Osmolarity System* iekārtu (*TearLab Corporation, San Diego, CA, USA*) pirms kataraktas operācijas, nākamajā rītā, vienu nedēļu un vienu mēnesi pēc operācijas. Pirms operācijas asaru osmolaritātes vidējie mērījumi grupu starpā statistiski ticami neatšķīrās. Pēc operācijas tika novērotas statistiski ticamas izmaiņas asaru osmolaritātes mērījumos pētījuma grupā ($p < 0{,}001$), savukārt osmolaritātes izmaiņas dinamikā neoperētajā acī netika novērotas ($p = 0{,}86$). Veicot mērījumus, tika novērotas izteiktas osmolaritātes izmaiņas pēcoperācijas rītā, asarām kļūstot hipoosmolārām (< 275 mOsm/l). Nedēļu pēc operācijas tika novērota tendence šim rādītājam palielināties, asarām kļūstot hiperosmolārām (312,64 mOsm/l). Mēnesi pēc operācijas acs asaru plēvītes osmolaritātes mērījumi atgriezās pirmsoperācijas līmenī un vairs statistiski ticami neatšķīrās grupu starpā. Iegūtie dati ļauj detalizētāk izprast izmaiņas acs virsmas homeostāzē agrīnajā kataraktas pēcoperācijas periodā. Rezultāti liecina, ka asaru osmolaritāte mainās pēc operācijas un atšķiras no neoperētās acs stāvokļa. Asaru osmolaritāte mēneša laikā atgriežas pirmsoperācijas uzrādīto rezultātu līmenī.