

Effect of Intraocular Silicone Oil on Ocular Tissue

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ABSTRACT

The aim of this study was to find out to which extent the instilled silicone oil affects the changes of lens, cornea, and the ocular pressure with regard to its time kept in the operated eye with a lens. The study was carried out on the sample of 40 patients, divided in three groups. The first group of patients with the silicone oil kept in the eye during 3 months, the second one during 3–6 months, and the third one during 6–9 months. Statistically important changes were observed in the progression of the lens opacification with the patients, progressively with the time of keeping the silicone oil in the eye. The followed cornea opacifications and increased ocular pressure were not statistically significantly linked with the length of keeping the silicone oil in the eye, so that it can be concluded that the silicone oil is the best substitute for the vitreous body but it should be removed from the eye, most frequently, in the period of 3–6 months from the date of its instillation, and after 3 weeks at the earliest.

Key words: vitrectomy, silicone oil, lens, cornea, intraocular pressure

Introduction

The vitreoretinal surgery belongs to the range of the newest and most up-to-date methods of surgical treatment of numerous eye diseases that were, until recently, considered as incurable, and which, in most cases, ended with a loss of eyesight.¹ Silicone oil has been proved as one of the best substitutes for vitreous body. It should be clean, without gases, heavy metals and ions, and of 5.000 cs viscosity, and 1.4 refractory index^{2,3}. Yet, numerous authors quote its bad effects too on the ocular tissue, especially on the lens, cornea and eye pressure. That is why the aim of this study was to show how the time of keeping the silicone oil in the eye affects the said structures.

Silicone oil is an active *instrument* for the reposition of the mobile retina, and it makes internal tamponade, stabilization and fixing of retina after vitrectomy^{1,4,5}. Because of possible complications, as described in the literature, the silicone oil should be removed from the operated eye with a precondition that retina is stable and well fixed⁶. It is difficult to fix the right time for its removal since there are no certain parameters that might indicate when the proliferation process has ended. Nevertheless, as per the quoted studies, it is re-

moved – most frequently – within 3 months from the date it was instilled^{2,8,9}.

Patients and Methods

All treated patients were operated at the Ophthalmology Clinic of the Medical School in Zagreb, in the period from January 1, 1996 to May 1, 1999.

The subject of this study was a group of 40 operated patients, primarily with a lens, who had the silicone oil implanted in the eye during the vitreoretinal surgery, and removed from the eye after a certain period. Possible changes of the eye tissue, especially of the retina, lens, and the eye pressure, have been followed with the patients after removal of the silicone oil from the eye in comparison with the eye status prior to its implantation.

The Fisher's exact test was used as a statistical method of data processing. Considering the number of treated patients, the significance level p was determined as $p=0.05$. In the case of the Fisher's exact test that, if the p value is under 0.05 it is a statistically significant phenomenon, otherwise it is not.

Results

All treated patients were divided in 3 groups according to the time the silicone oil was kept in the operated eye. The first group was with silicone oil during 3 months, and shorter; the second group 3–6 months, and the third one 6–9 months, see Figure 1. It is clear that the silicone oil in this study was removed from the eye, most frequently, within 3–6 months, and its effect on the lens opacification is shown in Figure 2.

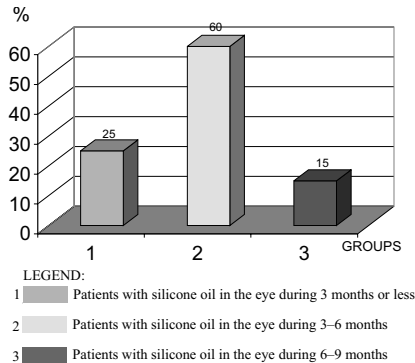


Fig. 1. Distribution of patients as per the time of keeping the silicone oil in the eye expressed in months.

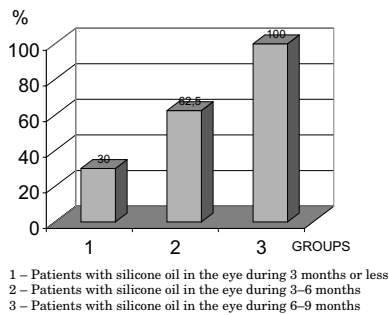


Fig. 2. Illustration of the lens opacification progression in the eyes with instilled silicone oil with regard to the time of its being kept in the eye.

It was found out that a significant lens opacification progression was due to the longer period of keeping the silicone oil in the eye. Within the first group, there was 30% lens opacification, in the second one – 62.5%, and in the third one – 100%. This phenomenon is statistically significant, since the result of Fisher's exact test $p=0.03$ is lower than anticipated $p=0.05$ ($p=0.03$, $p<0.05$). During the study, the effect of the time the silicone oil was kept in the eye on the cornea was also studied, as shown in Figure 3. In the first group, there were 30% of patients with a benign cornea edema, in the second one – 16.7%, and in the third group there was no patient with cornea pathological changes. Consequently, it can be concluded that there was no significant cornea damages, and benign changes found in the first and second group of patients can be attributed to the recent cornea

surgical manipulations and destabilization. Statistical analysis with the above mentioned test did not show any significant relationship between the time the silicone oil was kept in the eye and the cornea changes ($p=0.29$, $p>0.05$).

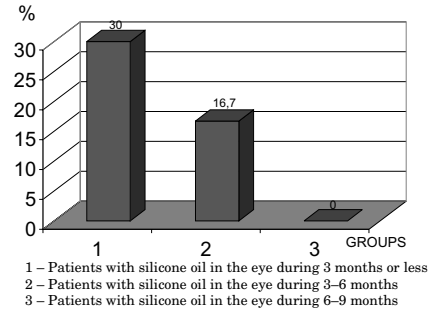


Fig. 3. Illustration of the cornea changes in the eyes with instilled silicone oil with regard to the time of its being kept in the eye.

The study results of how the time of keeping the silicone oil in the eye affects the ocular pressure are shown in Figure 4. In the first group of patients with silicone oil in the eye during 3 months or less, there was 50% of patients with increased ocular pressure but less than 30 mmHg, and in the second and third group, the pressure falls down to 16.7% of patients with somewhat increased ocular pressure but also less than 30 mmHg, which might be due to the soft emulsification of silicone oil and the consequential obstruction of the trabecular system. No statistically significant dependence was found between the time of keeping the silicone oil in the eye and the increased ocular pressure ($p=0.3$, $p>0.05$).

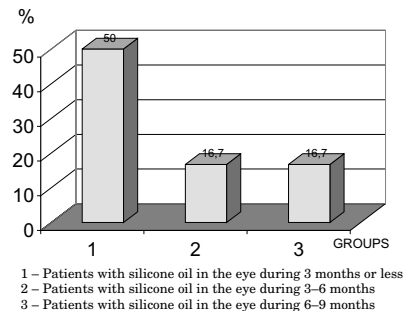


Fig. 4. Illustration of the ocular pressure increase in the eyes with instilled silicone oil with regard to the time of its being kept in the eye.

Discussion

The fact that the silicone oil, as the best substitute for the vitreous body by now, can have certain negative effects on the eye, was a challenge to carry out this study. While observing the changes on the eye lens in the group of patients who kept the silicone oil in the eye during a period of 3 months, the lens opacification pro-

gression was found in 30% of patients, and as this period extends, in the second group of patients with the silicone oil in the eye during 3–6 months, there are 62.5% of patients with the lens opacification progression. Finally, in the third group with silicone oil in the eye during 6–9 months, the lens opacification progression was found in 100% of patients, which corresponds to the data obtained from the available literature.

A statistical analysis of data by use of Fisher's exact test, a level of statistical significance $p=0.03$ was obtained, in relation to $p=0.05$ as set up by the study. Since the result obtained is lower than the set up variable, it means that the time of keeping the silicone oil in the eye of the patient has a statistically significant effect on the lens opacification progression ($p=0.03$, $p<0.05$). As stated in certain German studies, a silicone oil tamponade compulsorily leads to the lens opacification after 6–12 months, i.e. it has a cataractous effects requiring additional surgical treatment^{10,11}. Observing the cornea condition with silicon oil in its vitreous part, it can be seen that in the first group of patients who kept the silicon oil in the eye up to 3 months, there were 30% of patients with cornea changes but of quite benign nature in the form of a benign edema and peripheral opacification.

In the second group of patients with silicone oil kept in the eye during 3–6 months, this problem is reduced to 16.7% while in the third group of patients with silicone oil in the eye kept during 6–9 months there were no visible cornea changes under the bio-microscope. It can be concluded that the changes found in the first group were partially due to a fresh surgical trauma, and the absence of such changes in the third group is partially a result of an earlier removal of silicone oil from the eye with minor complications, and of a relevant surgical method and the use of purified silicone oil as well.

Through statistical data analysis by using Fisher's exact test, a statistical significance level of $p=0.29$ was obtained in relation to the set up $p=0.05$. This result does not indicate the statistical significance of the interdependence between the time of keeping silicone oil in the eye and the cornea changes, since the result obtained of $p=0.29$ is higher than the set up $p=0.05$.

Histological analyses carried out in certain West-European countries have proved that there is a certain loss of the cornea endothelial cells, even up to 58%, and cor-

neal opacification up to 40% which indicates the necessity of removing the silicone oil from the eye, as soon as the retina stability first, and then the stability of other parts of the eye allow it but not earlier than three weeks after the instillation of silicone oil¹². A protracted silicone oil tamponade can result in an increased number of vacuoles in the retina, and in other parts of the eye as well, e.g. in the trabeculum, the cornea endothelium, which can affect the ocular pressure as well.

In this study, in the first group of patients with silicon oil kept in the eye up to 3 months, there were 50% eyes with somewhat increased ocular pressure but not exceeding 30 mmHg, and in the second and third group of patients this number was reduced to 16.7%. According to the West-European studies with vitrectomy patients and instilled silicone oil in the eye, there were 18.5% of patients with increased ocular pressure, which is mostly caused by the trabecular system obstruction due to the emulsification of the silicone oil itself¹³. Statistical data analysis by means of Fisher's exact test applied in the statistical data processing, the level of statistical significance of $p=0.3$ was obtained in relation to the set up $p=0.05$. This result of $p=0.3$ does not indicate the statistical significance of interdependence between the time silicone oil is kept in the eye and the increased ocular pressure with these patients ($p=0.3$, $p>0.05$). According to the similar studies performed with pediatric population in Israel this number of glaucoma was about 25%¹⁴.

Conclusion

It results from this study that the silicone oil is, actually, the best substitute for the vitreous body because of its stabilization role, and the role of preventing proliferation, and because of internal eye tamponade but it has also a noticeable effect on the lens opacification progression, and somewhat smaller effect on the cornea condition and ocular pressure, and that, in the cases where the stability of retina and other eye structures allow it, it should be removed from the eye, most frequently, in the period from 3 to 6 months from the date of its instillation but not earlier than 3 weeks after surgery.

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UČINAK SILIKONSKOG ULJA INSTILIRANOG U OKO NA OČNO TKIVO

SAŽETAK

Cilj istraživanja je bio pokazati u kojoj mjeri instilirano silikonsko ulje u oku utječe na promjene leće, rožnice te na očni tlak obzirom na vrijeme njegova zadržavanja u operiranom fakičnom oku. Istraživanje je provedeno na uzorku od 40 pacijenata podijeljenih u tri grupe. Prva sa silikonskim uljem u oku tri mjeseca i kraće, druga tri do šest mjeseci i treća šest do devet mjeseci. Uočene su statistički značajne promjene u progresiji zamućenja leća u ovih pacijenata progresivno s vremenom zadržavanja silikonskog ulja u oku. Praćena zamućenja rožnice i povećanje očnog tlaka nisu bila statistički značajno povezana s duljinom zadržavanja silikonskog ulja u oku, te se iz iznesenog zaključuje da je silikonsko ulje najbolji nadomjestak za staklasto tijelo, ali ga se treba odstraniti iz oka najčešće u periodu od tri do šest mjeseci od njegove instilacije, a najranije nakon tri tjedna.