EVALUATION OF EFFICACY AND SAFETY OF ZARACCOM RIGID INTRAOCULAR LENSES IN CATARACT TREATMENT:

A National, Prospective Clinical Device Study

ANALYSIS REPORT

Protocol Date	**:**	10 Sept 2007
Final Study Report Date	**:**	23 Oct 2007
Interim Analysis Report Version	**:**	v1
Number of Centers	**:**	1
Clinical Device	**:**	Zaraccom R 160A hydrophobic, rigid, monobloc, posterior chamber intraocular lens
Coordinating Investigator	**:**	Op. Dr. Hayrettin Kılıç Ministry of Health, Balıkesir State Hospital Ophthalmology Clinics Balıkesir Tel: 0266 243 45 45
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Study Dates	**:**	June 2005 – January 2006

The present study has its origins in Declaration of Helsinki and has been conducted in compliance with the EN ISO 14155, Good Clinical Practice, and ethical considerations designated by the relevant Legal Regulations concerning Clinical Trials in Turkey.

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1 SYNOPSIS

Study title	Evaluation of efficacy and safety of Zaraccom Rigid intraocular lenses in cataract treatment: A national, prospective clinical device study.
Analysis report date	25 Oct 2007
Interim analysis report version	v1
Indication	Cataract
Clinical device	Zaraccom R 160A hydrophobic, rigid UV-absorber, sterile, monobloc, posterior chamber intraocular lens
Study design	A national, single center, prospective clinical device study.
Objectives	Primary objective: • To evaluate the efficacy of Zaraccom Rigid lenses in cataract treatment. Secondary objective: • To evaluate the safety of Zaraccom Rigid lenses in cataract treatment.
Number of centers	1
Analyzed sample size	41
Patient selection criteria	Inclusion criteria: Patients fulfilling all the below criteria were included in the study: • Age ≥18 years, • Female or male, • Diagnosed with cataract, • Planned surgery, • Patients who were informed about the study and whose written informed consent for participation were obtained from themselves or their legal representatives. Exclusion criteria: Patients fulfilling at least one of the below criteria were not included in the study: • Patients with a chronic disease that could constitute a handicap for the surgery,

	• Patients who are allergic to the medication that would possibly be administered during, before or after the operation.
Study procedures	Patients who could possibly be included in the study were determined by the physicians in the study center and were informed about the study. The following procedures were implemented on the patients in the first evaluation after their informed consents were obtained. Data were recorded on the pre-operative report form. • Assessment of patients' eligibility for the study. • Ophthalmologic history and examination, • Operation history, • Concomitant diseases. Clinical status of the patients who were placed intraocular lens into posterior chamber during the cataract surgery were reported by post-operative status report form in the post-operative 6th month: • Ophthalmologic examination, • Medication used since the previous visit, • Developed pathologies and complications • Evaluation of the adverse events
Evaluation criteria	<u>Primary Evaluation Criterion:</u> • Ratio of the patients having post-operative Best Corrected Visual Acuity (BCVA) of 0.5 (6/12; 20/40) or more. <u>Secondary Evaluation Criterion:</u> • Number, severity, relation with the study device and outcome of the complications, pathologies and adverse events that develop within the study period.
Statistical Analysis	<u>Statistical analysis plan:</u> All study data were summarized using descriptive statistics (e.g. mean, median, standard deviation, ratio). Age group analyses and the comparison of the data from pre-operative and post-operative examinations were done by the appropriate parametric or non-parametric tests according to the type and distribution of the data. Level of statistical significance was set at $p<0.05$.
Results	Totally, 41 patients (females 65.9%, males 34.1%) were analyzed and the mean age was 59.7±9.5. <u>Efficacy Results:</u> Visual acuity did not display any significant difference between the age groups at the pre-operative ($p=0.209$) and the post-operative examinations ($p=0.463$). Compared

	to pre-operative values, visual acuity was significantly improved at post-operative 6th month ($p<0.001$). Pre-operative and post-operative intraocular pressure (IOP) was not significantly different ($p=0.090$). Safety Results: Totally 5 adverse events were observed. In terms of severity, all were mild events. The most prevalent diagnosis was corneal stromal oedema (40.0%). Topical corticosteroids were the mostly preferred treatment to overcome adverse events (80.0%). All patients experiencing adverse events have completely recovered. No significant adverse event was observed.
Conclusions	Pre-operative VA of the operative eye ($p=0.209$) was not different between the age groups. Likewise, age did not result in significant difference in VA rates measured at post-operative 6th month ($p=0.463$). VA rates were significantly improved after operation ($p<0.001$). The improvement of VA postoperatively in almost all of the patients shows that Zaraccom Rigid Intraocular Lens has a considerable efficacy in the treatment of cataract, regardless of the age groups. Additionally, the lack of a significant change ($p=0.090$) in IOP after operation is advantageous in respect of reducing pain and the risk of post-operative complications. The results of the present study show that Zaraccom Rigid Intraocular Lens is effective in improving visual acuity after cataract surgery and the encountered adverse events are minor in terms of severity, relation to the device and outcomes.

2 SIGNATURE PAGE

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3 INTRODUCTION

3.1 Background

Cataract is clouding of the lens of the eye, which impedes the passage of light. Cataract develops up on the degeneracy, due to increasing age and accumulation of some other factors, in the chemical structure of the crystalline lens in eyes. Occasionally, children may be born with the condition, or cataract may develop after an injury, inflammation or disease. Cataract is a common problem in all populations and the leading cause of blindness in the world today (1). The WHO programme “Prevention of Blindness and Visual Impairment” has revealed that age related cataract is responsible for 47.8% of world blindness and cataract is even a more significant cause of low vision in both developed and developing countries (2). It is also the leading cause of vision loss in the United States and responsible for about 60% of all health care costs related to vision (3,4). By the year 2020, 30.1 million Americans older than 40 years were estimated to have cataract (5).

Cataract can develop independently or concomitant to other problems, regardless of gender or economic status. Despite the recent developments in treatment strategies, yet the current knowledge is not enough to prevent, delay or reverse the process (6). In the world, surgical intervention is the only method applied in the treatment of cataract. Cataract surgery now accounts for more than half the ophthalmic procedures in some regions, and in several countries it is the most common elective surgery (7,8). The objective of the surgical intervention is to improve the patients’ quality of life by improving visual acuity and visual functioning.

Recent improvements in cataract surgery are mostly related to the techniques used in the surgery and the properties of the intraocular lenses. Facoemulsification method, which includes the placement of intraocular lens (IOL) in the posterior chamber of the eye, is currently the most commonly preferred one (9). The efforts spent on the development of different lens structures aim to provide maximum biocompatibility (10). Some optical criteria such as good solubility, lack of spherical aberrations and minimized intraocular reflection effect and mechanical criteria like smooth surface, low weight, minimized anterior-posterior diameter and use of non-biodegradable materials that are inert to external factors such as UV, should be considered while designing IOLs to achieve good biocompatibility (11). All the biocompatibility tests that the designed IOL material should be passed through are included in the Intraocular Lens Guidance Document (12).

Preventable complications of phacoemulsification include incision-related, radial and posterior capsule tear, dislocation of nucleus due to operational procedures; postoperative:

endoophthalmitis; postoperative: posterior capsule opacification, and decentration of lenses (13,14). Opacification of the posterior capsule caused by postoperative proliferation of cells in the capsular bag remains to be the most frequent complication of cataract IOL surgery (15,16). Aiming to resolve these complications, various studies have been performed to examine the association between the IOL structure and the encountered problems. These studies have showed that selecting the correct IOL biomaterial is very important to obtain the optimum clinical outcome (17,18).

At the present, the materials primarily used in the structure of IOLs include silicone and acrylic/methacrylate polymers; while the lenses in acrylic group can be polymethacrylate (PMMA) or foldable (19). IOLs made of hydrophobic acrylic materials have been shown to have better capsular biocompatibility compared to other types (17). In terms of lens design, one-piece lenses with modified haptic design have resulted in better outcomes (20).

3.2 Zaraccom Rigid posterior and anterior chamber lenses

3.2.1 Mechanical Properties

Zaraccom Rigid intraocular lenses are manufactured as bonded UV-absorber, sterile, monobloc as posterior and anterior chamber lenses. These lenses have a biconvex optic with supporting haptics. Refractive index of the Zaraccom Rigid intraocular lenses are 1.51. A constant is 118.9. The lenses were designed and produced properly to absorb UV rays and resist YAG laser. The type of sterilization of Zaraccom Rigid intraocular lenses is by ethylene oxide. Refractive power of the lenses is 0 through +40 Dioptre for all models.

3.2.2 Raw Material

Zarracom Rigid Intraoculer Lenses are consisted of PMMA.

4 OBJECTIVES

4.1 Primary Objective

The primary objective of the present study was to evaluate the efficacy of Zaraccom Rigid lenses in cataract treatment.

4.2 Secondary Objective

The secondary objective was to evaluate the safety of Zaraccom Rigid lenses in cataract treatment.

5 STUDY PLAN

5.1 Study Design

This study was designed as a national, single center, prospective clinical device study.

5.2 Patient Selection

5.2.1. Inclusion criteria

Patients fulfilling all the below criteria were included in the study:

- Age ≥18 years,
- Female or male,
- Diagnosed with cataract,
- Planned surgery,
- Patients who were informed about the study and whose written informed consent for participation were obtained from themselves or their legal representatives.

5.2.2. Exclusion criteria

Patients fulfilling at least one of the below criteria were not included in the study:

- Patients with a chronic disease that could constitute a handicap for the surgery
- Patients who are allergic to the medication that would possibly be administered during, before or after the operation.

5.3 Control Group

There was no control group.

5.4 Planned and Analyzed Sample Size

By the time final analysis was performed, 41 patients were included in the study.

5.5 Study Centers

The study was carried out in Ministry of Health, Balıkesir State Hospital.

5.6 Study Procedures

Patients who could possibly be included in the study were determined by the physicians in the

study center and informed about the study. The following procedures were implemented on the patients in the first evaluation after their informed consents were obtained. Data were recorded on the pre-operative report form.

- Assessment of patients' eligibility for the study.
- Ophthalmologic history and examination,
- Operation history,
- Concomitant diseases.

Clinical status of the patients who were placed intraocular lens into posterior chamber during the cataract surgery were reported by post-operative status report form in the post-operative 6th month:

- Ophthalmologic examination,
- Medication used since the previous visit,
- Developed pathologies and complications
- Evaluation of the adverse events

5.7 Evaluation Criteria

5.7.1. Primary Evaluation Criterion

- Ratio of the patients having post-operative Best Corrected Visual Acuity (BCVA) of 0.5 (6/12; 20/40) or more, as had been specified in ISO 11979-7:2001(C).

5.7.2. Secondary Evaluation Criterion

- Number, severity, relation with the study device and outcome of the complications, pathologies and adverse events that develop within the study duration.

6. STATISTICAL METHODS

6.1. Statistical Analysis

All study data were summarized using descriptive statistics (e.g. mean, median, standard deviation, ratio). Age group analyses and the comparison of the data from pre-operative and post-operative examinations were done by the appropriate parametric or non-parametric tests according to the type and distribution of the data. Level of statistical significance was set at $p<0.05$.

7. STUDY ADMINISTRATIVE STRUCTURE AND RESPONSIBILITIES

7.1. Responsibilities of the Investigator

7.1.1. Protocol Compliance

It is the investigators' responsibility to conduct the study in compliance with the protocol. The investigators can utilize other healthcare staff for implementation of the study procedures.

7.1.2. Informed Consent

It is the investigators' responsibility to obtain patients' informed consents.

7.1.3. Case Report Forms

Patient data has been completely and accurately recorded on the case report forms (CRF) by the responsible investigators or the co-investigators in charge, using a black pencil.

It is the investigators' responsibility to provide an accurate and complete data collection.

In order to confirm the accuracy and completion of the data, the pages of CRFs have been signed by the investigator who did the recordings.

All corrections on the CRFs have been performed so that the erroneous original data would be decipherable. The investigator performing the correction dated and paraphed the correct data. If the reason of the correction was not clear, it should have been noted alongside.

7.1.4. Adverse Event Reporting

The investigators have followed-up the included patients in respect of the development of adverse events, evaluated the adverse events in terms of intensity, severity and relation with the study device, and recorded these evaluations on CRF.

In case of deaths related to the use of the study device and serious adverse events, the responsible investigator is obliged to inform the Ministry of Health and the Local Ethics Committee within 24 hours.

7.1.5. Monitorization

It is the investigators' responsibility to make the study documentation and source documents (hospital records, examination records, etc) available for the review of the monitor and to provide the monitor the necessary physical conditions and adequate time.

7.1.6. Study Device

The investigators or the co-investigators charged by the responsible investigators should

appropriately record and keep the study device.

7.1.7. Filing

It is the investigators' responsibility to appropriately keep the study records. All documents should be kept in a secure zone and safety regulations should be obeyed.

7.2. Responsibilities of the Sponsor

The present study has been conducted in the sponsorship of the Anatolia Medicine Technologies Co. It is the sponsor's responsibility to design the protocol, CRF, patient informed consent forms and other documentation, to print these in adequate numbers and distribute to the study center; to supply the study center with the devices that are to be used within the context of the study; to charge the monitor for the monitorization of the center before, during and after the study; to collect the data at the end of the study and to perform statistical analysis; to prepare interim and final study reports and to transmit to Ethics Committees.

The sponsor can pass some or all of its responsibilities to a Contract Research Organization. This situation does not eliminate any of the sponsor's responsibilities.

7.3. Monitorization of the Study

The monitor charged by the sponsor has frequently contacted the investigators before, periodically during and after the study. These contacts were as visiting or telephoning the center in the time intervals set by the sponsor. During these visits, the monitor reviewed the case report forms for confirmation of complete recording and compliance to the protocol. In these visits, the monitor also evaluated the issues such as adverse event reporting, appropriateness of patient information and informed consent acquisition procedures, the conditions where study devices are kept and presence of enough number of the device, investigator's file and other problems of the visited center.

7.4. Publication of the Study Results

Coordinating investigator, together with the other investigators, ensures that no data is published before all data are collected and analysis is completed.

The sponsor reserves all rights to review the obtained data prior to the presentation and publication of them. The reason for this is not to prevent or limit the publication or presentation, instead; it gives the sponsor the possibility to protect the acquired data and comment on the yet not represented information.

Before submission of an abstract or a manuscript of the study, the sponsor should provide the investigators with 14 days and 28 days, respectively, to comment on the abstract or the

manuscript. All parties should consider the comments that have rational scientific origins.

8. ETHICAL ISSUES

The study has been conducted in compliance with the Declaration of Helsinki, Good Clinical Practice and the ethical regulations set by the Legal Regulations for the Clinical Studies in Turkey.

8.1. Ethical Investigation

The study procedures were initiated after the approval of the coordinating center was obtained. Central Ethics Committee approval cannot be obtained, since there is no regulation of Ministry of Health concerning medical device studies.

8.2. Patient Information and Written Consent

All recruited patients were informed about the study and included after acquisition of their written informed consents for participation.

During a routine clinical application of the patients, the investigator or the staff he/she charged provided them with complete and satisfactory oral and written information regarding the structure, objectives, possible risks and benefits of the study. The patients were also notified that they could stop participation at any time. If the patients were willing to participate, the Informed Consent Forms were signed. Signed informed consent forms were obtained before any study procedure had been performed. The original copies of the informed consent forms were kept by the investigators whereas the other copy was given to the patients.

9. PROTOCOL DEVIATIONS

No protocol deviation was observed.

10.ADVERSE EVENTS, SERIOUS ADVERSE EVENTS AND DEATH

10.1. Definitions

10.1.1. Adverse Event

An Adverse Event (AE) is any untoward medical occurrence in a patient administered a device or a clinical investigation subject, which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including a clinically

significant abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a medical (investigational or marketed) device, whether or not considered related to the medical device.

10.1.2. Serious Adverse Event

A Serious Adverse Event (SAE) is any untoward medical occurrence that results in at least one of the below:

- Results in death,
- Is life-threatening,
- Requires inpatient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/ incapacity;
- Results in a congenital anomaly, neoplasm or birth defect.

Moreover, occurrences that do not result in death, that are not life-threatening or necessitate hospitalization but include a medical significance or require medical and surgical interventions to prevent the occurrence of the above mentioned outcomes are considered serious as well.

10.1.3. Unexpected Adverse Event

A medical occurrence that's nature, severity and incidence has not been formerly discussed in the current investigator's brochure, overall study plan or somewhere else is considered an unexpected adverse event if it is suspected to be reasonably related to the investigated device.

10.2. Adverse Event Reporting

All serious and unexpected adverse events should officially be reported.

In case of death or observation of serious adverse events that are related to study device, the Ministry of Health and local ethics committees should be informed both orally and written within 24 hours, by the investigator.

All serious and unexpected adverse events are also reported to ethics committees via the interim reports (minimum of 2 per year) and the final study report.

The adverse event form attached to the CRF should be also completed for all adverse events that develop during the follow-up period.

Study name, center and patient data, a clear definition of the adverse event, dates of onset/termination, severity, intensity, causality relationship with the device, outcome and treatment strategies should be reported both during the official reporting and completion of the

adverse event form.

10.3. Severity Assessment

Severity indicates the intensity of a medical occurrence, while seriousness refers to a medical occurrence that ends up with the outcomes mentioned in section 9.1.2 and is used to indicate reporting necessity. For this reason, a severe adverse event is not necessarily a serious event. For example, hours of nausea can be severe but clinically not serious. In terms of severity, adverse events are generally classified into 3 groups:

Mild: AE is perceivable but does not affect daily activity and does not necessitate medical treatment.

Moderate: AE decreases daily activity, necessitates medical treatment.

Severe: As limiting as to prevent working or performing daily activity, necessitates medical treatment. All SAEs are also considered severe.

10.4. Assessment of Relation to Study Device

The causality relationship between the AE and the device is assessed in 4 different levels according to the strength of the relationship: Probable relationship, possible relationship, doubtful relationship, and unrelated. Presence of outside factors, a logical time-line between the implantation of the device and the development of the event, and exclusion of other causes should be considered in the investigation of causality with the used device. According to this assessment causality relationship is defined as follows.

10.4.1. Probable Relation

An AE's relationship with the study device is considered "probable" under the following conditions:

1- If there is a logical time lapse and sequence between the implantation of the device and the development of AE,

2- If AE can not be logically explained by the known clinical condition of the patient, environmental and toxic factors or other treatments administered to the patient,

3- If AE follows a known and likely response pattern for the suspected drug,

10.4.2. Possible Relation

This category includes AEs that though are not very likely to be causally related to the study device, this possibility can not be excluded. The relationship of an AE and study device is

considered “possible” under the following conditions:

1- If there is a logical time lapse and sequence between the device implantation and the development of AE,

2- If AE can not be logically explained by the known clinical condition of the patient, environmental and toxic factors or other treatments administered to the patient,

3- If AE follows a known and likely response pattern for the suspected device.

10.4.3. Doubtful

In general this category includes AEs that follow the below listed conditions:

1- If there is no logical time lapse and sequence between the device implantation and the development of AE,

2- If AE can be logically explained by the known clinical condition of the patient, environmental and toxic factors or other treatments administered to the patient,

3- If AE does not follow a known and likely response pattern for the suspected device,

10.4.4. Unrelated

This category includes AEs that can be clearly and unquestionably linked to outside factors (i.e., disease, environment) and do not meet the criteria listed for “doubtful”, “possible” or “probable” relationship. Table 1 summarizes the assessment of relation to the study device.

Table 1. Assessment of the relation between the adverse event and study device.

AE characteristics	**Relation to device**			
	Probable	Possible	Doubtful	Unrelated
Certainly linked to external factors	-	-	-	+
Has logical time lapse between the device implantation	+	+	-	-
Can onset based on the clinical condition of the patient, environmental and toxic factors or other treatments administered to the patient	-	-	+	+
Follows a known and likely response pattern for the suspected device	+	+	-	-

11. RESULTS

11.1. Sociodemographic Characteristics

The analysis was performed on the data obtained from 41 patients (females 65.9%, males 34.1%) included. The mean age of the patients was 59.7±9.5. Distribution of the patients according to age groups is presented in Table 2.

Table 2. Distribution of the patients according to age groups.

Age Groups (years)	**Number (%)**
35-60	19 (46.3)
61-80	22 (53.7)
Total	41 (100.0)

The operative eye was the right eye in 19 (46.3%) and left eye in 22 (53.7%) of the patients.

11.2. Efficacy Results

11.2.1. Pre-Operative Results

Visual acuity (VA) measured before the operation is presented with respect to the age groups in Table 3. Pre-operative VA of the operated eye was not significantly different between the age groups (p=0.209, *Fisher Test).*

Table 3. Distribution of the patients according to pre-operative VA of the operative eye and age groups.

		Pre-operative VA of the operative eye		
		<0.5	**>0.5**	**Total**
35-60	**n**	17	2	19
	%	89.5	10.5	100.0
61-80	**n**	22	0	22
	%	100.0	0.0	100.0
Total	**n**	39	2	41
	%	95.1	4.9	100.0

VA of the fellow eye measured before the operation is presented with respect to the age groups in Table 4. VA of the fellow eye was not significantly different between the age groups (p=1.000, *Fisher Test).*

Table 4. Distribution of the patients according to pre-operative VA of the fellow eye and age groups.

		Pre-operative VA of the fellow eye		
Age		**<0.5**	**>0.5**	**Total**
35-60	**n**	14	5	19
	%	73.7	26.3	100.0
61-80	**n**	17	5	22
	%	77.3	22.7	100.0
Total	**n**	31	10	41
	%	75.6	24.4	100.0

11.2.2. Post-Operative Results

VA of the operative eye on the post-operative 6th month is presented with respect to the age groups in Table 5. Visual acuity did not display any significant difference between the age groups (p=0.463, *Fisher Test).*

Table 5. Distribution of the patients according to post-operative VA of the operative eye and age groups.

		Post-operative VA of the operative eye		
		<0.5	**>0.5**	**Total**
35-60	**n**	1	18	19
	%	5.3	94.7	100.0
61-80	**n**	0	22	22
	%	0.0	100.0	100.0
Total	**n**	1	40	41
	%	2.4	97.6	100.0

11.2.3. Pre- and Post-operative Comparisons

A comparison of pre-operative and post-operative VA of the operative eye is presented in Table 6. Compared to pre-operative values, visual acuity was significantly improved at post-operative 6th month (p<0.001, *McNemar Test*).

Table 6. Comparison of pre-operative and post-operative 6th month VA of the operative eye.

			Post-operative VA of the operative eye		
			<0.5	**>0.5**	**Total**
Pre-operative VA of the operative eye	**<0.5**	**n**	1	38	39
		%	2.6	97.4	100.0
	>0.5	**n**	0	2	2
		%	0.0	100.0	100.0
	Total	**n**	1	40	41
		%	2.4	97.6	100.0

The mean pre-operative intraocular pressure (IOP) was 15±2.8, while post-operative mean IOP was 15.5±2.6. The difference was statistically insignificant (p=0.090 Wilcoxon Test).

11.3. Safety Results

11.3.1. Adverse Events

Totally 5 adverse events were observed. In terms of severity, all were mild events. The most prevalent diagnosis was corneal stromal oedema (40.0%). Topical corticosteroids were the mostly preferred treatment to overcome adverse events (80.0%). All patients experiencing adverse events have completely recovered. Details of all observed adverse events are presented in Section 14.1.

11.3.2. Serious Adverse Events

No serious adverse event was observed.

11.3.3. Deaths

No death has been reported.

12. CONCLUSIONS

The results of this analysis performed on 41 patients showed that Zaraccom R 160A model Rigid Intraocular Lens is effective in terms of improving visual acuity after operation in patients with cataract.

The mean age of the included patients was 59.7±9.5, and distribution of the patients to 35-69 and 61-80 age groups was similar. Pre-operative VA of the operative eye (p=0.209) was not different between the age groups. Likewise, age did not result in significant difference in VA rates measured at post-operative 6th month (p=0.463). VA rate of the operative eye did not improve only in 1 patient in the 35-60 age group, whereas all patients in 61-80 age group had improved VA at the post-operative 6th month.

Following the operation, VA rates were significantly improved (p<0.001). The post-operative decrease in the number of patients having VA<0.5 is striking in both age groups. At the 6th month, only one patient displayed VA>0.5, which might be due to other concomitant conditions. The improvement of VA postoperatively in almost all of the patients shows that Zaraccom Rigid Intraocular Lens has a considerable efficacy in the treatment of cataract, regardless of the age groups. Additionally, the lack of a significant change (p=0.090) in IOP after operation is advantageous in respect of reducing pain and the risk of post-operative complications.

In terms of safety evaluations, Zaraccom Rigid Intraocular Lens implantation did not result in any serious adverse event and totally 5 patients encountered adverse events, which refers to the 12.2% of the whole study population. The mostly reported adverse event was corneal stromal oedema. Complete recovery was achieved in all of the patients facing adverse events.

The results of the present study show that Zaraccom Rigid Intraocular Lens is effective in improving visual acuity after cataract surgery and the encountered adverse events are minor in terms of severity, relation to the device and outcomes.

13. REFERENCES

1- Thylefors B, Negrel AD, Pararajasegaram R, Dadzie KY. Global data on blindness [review]. Bull World Health Organ. 1995;73:115-121.

2- Serge Resnikoff, Donatella Pascolini, Daniel Etya'ale, Ivo Kocur, Ramachandra Pararajasegaram, Gopal P. Pokharel, Silvio P. Mariotti. Global data on visual impairment in the year 2002. Bulletin of the World Health Organization 2004;82:844-851.

3- Rahmani B, Tielsch JM, Katz J, Gottsch J, Quigley H, Javitt J, Sommer A, for the Baltimore Eye Survey. The cause-specific prevanence of visual impairment in an urban

population. Ophthalmology. 1996;103:1721-1726

4- Ellwein LB, Urato CJ. Use of eye care and associated charges among the Medicare population: 1991-1998. Arch Ophthalmol. 2002;120:804-811

5- Congdon N, Vingerling JR, Klein BE, et al. Eye Diseases Prevalence Research Group. Prevalence of cataract and pseudophakia/aphakia among adults in the United States. Arch Ophthalmol 2004;122:487–94.

6- Ergin A. Göziçi Lens İmplantasyonu İle Gerçekleştirilen Senil Katarakt Cerrahisinde Görsel Sonuçlar Geriatri 2 1999 (2): 53-56.

7- Keeffe JE, Taylor HR. Cataract surgery in Australia 1985-1994. Australian and New Zealand Journal of Ophthalmology, 1996, 24: 313-317

8- Stunevi U, Lundstrom M, Thorburn W. A national cataract register. Acta Ophthalmologica Scandinavica, 1995, 73: 41-44.

9- Lang GK. Ophthalmology. A Short Textbook. Thieme Stuttgart. New York 2000.

10- Schauersberger J, Amon M, Kruger A, Abela C, Schild G, Kolodjaschna J. Comparison of the biocompatibility of 2 foldable intraocular lenses with sharp optic edges. J Cataract Refract Surg 2001; 27:1579–1585.

11- Holladay JT. Evaluating the intraocular lens optic. Survey of Ophthalmology. 1986;30(6):385-390.

12- Intraocular Lens Guidance Document U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health Intraocular and Corneal Implants Branch Division of Ophthalmic Devices Office of Device Evaluation.

13- Ram J, Apple DJ, Peng Q, Visessook N, Auffarth GU, Schoderbek RJ Jr, et al. Update on fixation of rigid and foldable posterior chamber intraocular lenses. Part II: Choosing the correct haptic fixation and intraocular lens design to help eradicate posterior capsule opacification. Ophthalmology 1999;106:891-900.

14- Ram J, Apple DJ, Peng Q, Visessook N, Auffarth GU, Schoderbek RJ Jr, et al. Update on fixation of rigid and foldable posterior chamber intraocular lenses. Part I: Elimination of fixation-induced decentration to achieve precise optical correction and visual rehabilitation. *Ophthalmology* 1999;106:883-90.

15- Apple DJ. Influence of intraocular lens material and design on postoperative intracapsular

cellular reactivity. *Trans Am Ophthalmol Soc* 2000;98:257-83.

16- Werner L, Apple DJ, Pandey SK. Postoperative proliferation of anterior and equatorial lens epithelial cells: A comparison between various foldable IOL designs. In: Buratto L, Osher R, Masket S, editors, *Cataract Surgery in Complicated Cases* . Thorofare, NJ, Slack Inc., 2000;pp399-417.

17- Abela-Formanek C, Amon M, Schauersberger J, Kruger A, Nepp J, Schild G. Results of hydrophilic acrylic, hydrophobic acrylic, and silicone intraocular lenses in uveitic eyes with cataract. J Cataract Refract Surg 2002; 28:1141–1152.

18- Abela-Formanek C, Amon M, Schauersberger J, Schild G, Kolodjaschna J, Barisani-Asenbauer T, Kruger A. Uveal and capsular biocompatibility of 2 foldable acrylic intraocular lenses in patients with uveitis or pseudoexfoliation syndrome. J Cataract Refract Surg 2002; 28:1160–1172.

19- Ayan T. Yeni Nesil Memorylens Göz İçi Lenslerinde Arka Kapsül Kesafet Gelişimi. Uzmanlık Tezi-2004.

20- Apple DJ, Solomon KD, Tetz MR, et al. Posterior capsule opacification. Surv Ophthalmol 1992; 37:73-116.

14. APPENDICES

14.1. Adverse Events

Operated eye	Age/ Sex	Lens model number	Power of IOL	Onset after implant (days)	Duration (days)	Severity of adverse event	Description of adverse event	Diagnosis of advers event	Treatment of adverse event	Outcome of adverse event	Comments	Does reporting physician believe adverse event is lens related?	Was adverse event serious.
Right	58/F	R160 A1	20.5	1	5	Mİld	Iritis mild central corneal oedema	Biomicroscopy	Topical corticosteroid	Complete recovery	Long operation time + multiple manuplation in anterior chamber	No	No
Left	59/F	R160 A1	25	6	5	Mİld	Inflammatuary deposits on IOL	Biomicroscopy	Topical corticosteroid	Complete recovery	Cause of multiple manuplation	No	.
Right	59/M	R160A	22	7	.	Mİld	Cystoid Macular Oedema	Clinical examination	NSAI 5x1 , Diamot 2x1/2	Complete recovery		No	No
Left	56/F	R160A	16	1	3	Mİld	Corneal Stromal Oedema (near incision place)	Biomicroscopy	Topical corticosteroid	Complete recovery	Bad tunnel incision	No	.
Left	56/M	R160A	17	5	7	Mİld	Corneal Stromal Oedema (near wound)	Biomicroscopy	Topical corticosteroid	Complete recovery	Endotel touching	No	No