

Clareon Intraocular Lens: Results of Cataract Surgery. Exilaser Cuenca Ophthalmological Center, Ecuador June 2020 – July 2021

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ABSTRACT

Objective: To analyze visual acuity, refractive cylinder, refractive sphere and complications in cataract surgery by phacoemulsification with Clareon intraocular lens. **Methodology:** A descriptive-observational, longitudinal study based on the review of medical records of the Exilaser Ophthalmology Clinic of 114 patients who underwent cataract surgery by phacoemulsification with a Clareon intraocular lens was carried out. Descriptive statistical techniques such as frequencies, measured percentages were used on those cases of central tendency and comparative analysis with T Student.

Results: The most frequent pre-surgical visual acuity on the Snellen scale was 20/CD with 27.2%, the most frequent corrected pre-surgical visual acuity was 20/CD with 14.0%, the most frequent pre-surgical refractive cylinder value was 0 with 50.9%, the most frequent pre-surgical refractive sphere value was 0 with 28.9%. Post-surgical visual acuity was 20/30 with 20.2%, Corrected Post-surgical Visual Acuity was 20/20 with 53.5%, the most frequent post-surgical refractive sphere value was 0 with 40.4%, the most frequent Post-surgical Refractive Cylinder value was 0 with 14.0%. 99.1% did not present trans-surgical complications and 91.2% did not present post-surgical complications.

Conclusions: Cataract surgery by phacoemulsification with CLAREON intraocular lens improves Visual Acuity and the Refractive Sphere, with statistically significant results, with minimal intra-surgical and post-surgical complications.

Abbreviations: Visual acuity (VA), Visual acuity without correction (AVSC), Visual acuity with correction (AVCC), Refractive sphere (ER), Refractive cylinder (CR), Intraocular lens (IOL), Dioptres (D).

Keywords: cataract; intraocular lens implantation; visual acuity; surgical complications

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RESUMEN

Objetivo: Analizar de la Agudeza visual, cilindro refractivo, esfera refractiva y complicaciones en la cirugía de catarata por facoemulsificación con lente intraocular Clareon. **Metodología:** se realizó un estudio descriptivo - observacional, de corte longitudinal basado en la revisión de historias clínicas de la Clínica Oftalmológica Exilaser de 114 pacientes sometidos a cirugía de catarata por facoemulsificación con lente intraocular Clareon, se utilizaron técnicas estadísticas descriptivas como frecuencias, porcentajes medidas de tendencia central y análisis comparativo con T de student. **Resultados:** la agudeza visual prequirúrgica más frecuente en escala de Snellen fue 20/CD con el 27,2%, la agudeza visual prequirúrgica corregida más frecuente fue 20/CD con el 14,0%, el valor de cilindro refractivo prequirúrgico más frecuente fue 0 con el 50,9%, el valor de esfera refractiva prequirúrgica más frecuente fue 0 con el 28,9%, la agudeza visual postquirúrgica fue 20/30 con el 20,2%, la Agudeza Visual Postquirúrgica Corregida fue 20/20 con el 53,5%, el valor de esfera refractiva postquirúrgica más frecuente fue 0 con el 40,4%, el valor de Cilindro Refractivo Postquirúrgico más frecuente fue 0 con el 14,0%, en el 99,1% no presentaron complicaciones transquirúrgicas, en el 91,2% no presentaron complicaciones postquirúrgicas. **Conclusiones:** la cirugía de catarata por facoemulsificación con lente intraocular CLAREON, mejora la Agudeza Visual y la Esfera Refractiva, con resultados estadísticamente significativos, con mínimas complicaciones transquirúrgicas y postquirúrgicas. **Abreviaturas:** Agudeza visual (AV), Agudeza visual sin corrección (AVSC), Agudeza visual con corrección (AVCC), Esfera refractiva (ER), Cilindro refractivo (CR), Lente intraocular (LIO), Dioptrías (D)

Palabras clave: catarata; implantación de lente intraocular; agudeza visual; complicaciones quirúrgicas

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INTRODUCTION

According to WHO data in 2019 there are around 65.2 million people with visual impairment due to cataract. In Ecuador, with the data obtained by the National Institute of Statistics and Census (INEC), the prevalence of visual impairment is 1.3% due to life expectancy has been increasing, the prevalence of cataract is expected to increase. How García, R. and collaborators in their study carried out in Cuba in 2017, reported that the prevalence of cataracts predominated in patients between the ages of 70-79 years, being women the most affected. In the studies carried out by Garg, P et al, the importance of cholesterol and antioxidant levels as causes of cataracts in advanced ages is pointed out. (1-6)

Despite being a disease that can drastically affect a person's quality of life due to decreased vision, this is a reversible pathology through surgical treatment: the extraction of the affected crystalline lens being replaced with an intraocular artificial lens (MESS). The implementation of new surgical methods has been revolutionary, as in the case of phacoemulsification, where the lens is extracted through a small incision, becoming the technique of choice to treat cataracts. (7, 8)

Various authors worldwide such as He L, Cui Y. and collaborators; Ibanez I; Toyama et al.; Lujan P et al; Among others, they obtained positive results with the use of phacoemulsification surgery, improving short-term vision, taking into account different variables such as visual acuity (VA), refractive sphere (RE), refractive cylinder (CR), personal and ophthalmological history, among others. The study mentions that postoperative corneal edema, a history of glaucoma, very old age or a very long surgery are independent risk factors for having a visual complication; it is worth mentioning that these complications are rare. (9-13)

It is clear that IOLs and phacoemulsification surgery have changed the lives of millions of patients since their invention, so we consider it important to study the results of different IOLs to compare how much they improve visual acuity, their possible complications, their interaction with the comorbidities, among other variables.

The focus of this study, the Clareon intraocular lens, is a monofocal IOL that is made of a new acrylic hydrophobic material, based on the characteristics of the AcrySof platform (previous model from the same commercial house). Stephen Lane et al in a study compared the Clareon IOL with AcrySof, enVista, TECNIS and Vivinex iSert IOLs. Tested in 35 °C deionized water for axial displacement,

optical tilt, and decentering with the effect of compression, Clareon and AcrySof showed significantly less ($P < 0.001$) axial displacement at 10 mm compression compared to all other models. Clareon's mean optical run out was found to be 0.04 ± 0.02 mm, which is less than the maximum of 0.6 mm specified by the International Organization for Standardization (ISO; 23). Optical tilt was also below the ISO-specified maximum value of 5° optical tilt, with a mean value of $0.5 \pm 0.2^\circ$. (14-16)

Gerd Auffarth compared results of in vitro evaluations of the Clareon IOL and the TECNIS, EnVista and Vivinex lenses, subjected to an accelerated aging process to induce glare formation, Clareon had a mean number of 4.09 bright microvacuoles/mm², a number that characterizes it as Grade 0 on the Miyata flash scale. This concludes that it has a low probability of flashing over time. (14, 15)

To assess how the biomaterial interacts with the eye, comparative studies were performed between Clareon and AcrySof IOLs, with a viscosurgical ophthalmic device (VOD) and silicone oil was evaluated. The silicone oil adhesion study revealed comparable results between both lenses, the percentage coverages obtained are much lower than in silicone IOLs and hydrophobic material, likewise the authors of the investigation indicate that with these results there would be no problems with these lenses if the patient needs retinal surgery in the future. (14, 15)

The one referred to by the manufacturer Alcon as “AutonoMe” is the mechanism responsible for the delivery of the Clareon IOL. It is an automated, disposable, preloaded and easy-to-use system. It consists of a piston which moves downward to deliver the IOL, the same one that is driven by a cartridge. The IOL is delivered folded and directly into the lens capsule. The IOL is delivered folded and directly into the lens capsule. The entire mechanism can be operated with one hand for ease of use. It is possible to insert the lens with incisions between 2.2 -3.2 mm and provides full visibility of the IOL during the procedure. The use of the injectors reduces damage to the IOL during insertion and decreases bacterial contamination (14-16).

The present study analyzes preoperative and post operative variables of patients undergoing phacoemulsification surgery with the Clareon IOL, and also analyzes the results taking into account the age, comorbidities or ophthalmologic history of the patients in search of possible variations in the visual acuity results.

MATERIALS AND METHODS

Methodology

A descriptive-observational, lengthwise study was performed at the “Centro Oftalmológico Exilaser”, in the city of Cuenca, province of Azuay, Ecuador. We worked with the universe of clinical records, constituted by 114 patients with senile cataract who underwent phacoemulsification surgery with Clareon intraocular lens implantation, between June 2020 and July 2021. The surgeries were performed by 2 ophthalmologists trained in the phacoemulsification technique with minimal variability in the surgeon factor.

Inclusion criteria: Patients undergoing surgery by phacoemulsification with Clareon intraocular lens, with complete data in the clinical history before surgery and medical control one month later.

Exclusion criteria: Medical records with incomplete data, patients with simultaneous cataract and retina or cataract and glaucoma surgeries.

Statistical analysis: The following variables were studied: age, personal pathologic history, surgical history, ophthalmologic history, trans-surgical complications and post-surgical complications. The following variables AVSC, AVCC, Cylinder and refractive sphere were analyzed preoperatively and analyzed again one month after surgery. Descriptive statistics of frequency and percentage were obtained for all variables. For the analysis of the pre-surgical and post-surgical results, Student's t-test was performed for paired samples; and for the analysis of the variables age, personal history and ophthalmologic surgical history together with the pre and post-surgical results, Student's t-test was used for independent samples, verified with Levene's test for equal variances and with a 95% confidence interval. It is clarified that the authors of the research have no conflicts of interest and the research is self-financed.

RESULTS

Table 1. Summary of qualitative variables

Variable		Frequency	Percentage
Age	< 70 years	53	46,5%
	>70 years	59	53,5%
Pathological personal history	None	64	56,14%
	Diabetes mellitus type 2	25	21,9%
	Arterial hypertension	25	21,9%
Ophthalmological surgical history	None	96	84,2%
	Cataract surgery	3	2,6%
	Vitreotomy	4	3,6%
	Myopia surgery	3	2,6%
	Trabeculectomy	1	0,9%
	Pterygium surgery	6	5,3%
	Corneal suture	1	0,9%
Transoperative complications	None	113	99,1%
	Posterior capsule rupture	1	0,9%
Post-surgical complications	Retinal detachment	1	0,9%
	Corneal edema	7	6,1%
	Corneal edema	7	6,1
	Uveitis	2	1,8%

The distribution of patients is close to 50% in both age groups, with a slight majority of patients older than 70 years. More than half of the patients had no comorbidities, type 2 diabetes mellitus and arterial hypertension were both 21.9% of frequency. More than 80% of the patients had no ophthalmologic surgical history. There was only one trans-surgical complication (posterior capsule rupture). Postoperative complications had a low frequency, the most relevant was corneal edema with 6.1%.

Pre-Surgical Parameters

Table 2. Pre-surgical visual acuity

Visual acuity range	Visual Acuity is measured without correction Pre-surgical		VACC Pre-surgical	
	Frequency	Percentage	Frequency	Percentage
20/20 - 20/60	16	14,0 %	56	49,2 %
20/70 - 20/200	34	29,8 %	24	21,0 %
20/300 - 20/400	21	18,5 %	8	7,0 %
20/CD, 20/MM, 20/PL	43	37,6 %	26	22,8 %
Total	114	100%	114	100%

The normality statistics of the AVSC were: Mean= 20/324 with DS= 20/213, Median= 20/400 Mode= 20/CD. The normality statistics of the BCVA were Mean=20/202 and DS= 20/223 Median= 20/70 Mode= 20/CD.

Table 3. Pre-surgical refractive cylinder

RC Pre-surgical	Frequency	Percentage
Less to -3,00	1	0,9 %
-2,05 to -3,00	4	3,6 %
-1,05 to -2,00	16	14,0 %
0,00 to -1,00	93	81,6%

The normality statistics were: Mean -0.59 D and SD: 0.76, Median: 0.00 Mode: 0.00.

Table 4. Pre-surgical refractive sphere

RE presurgical	Frequency	Percentage
Less to -2,00	32	28,1 %
-1,05 to -2,00	13	11,4 %
+1,00 to -1,00	52	45,6 %
+1,05 to +2,00	11	9,6 %
Higher to +2,00	6	5,3 %

The normality statistics were: Mean: -1.075 D and SD: 2.397, Median: -0.25 Mode: 0.00.

Post Surgical Parameters

Table 5. Postoperative visual acuity

VA RANGE	VASC postsurgical		VACC postsurgical	
	Frequency	Percentage	Frequency	Percentage
20/20 - 20/60	81	71,1 %	104	91,1 %
20/70 - 20/200	27	23,7 %	4	3,5 %
20/300 - 20/400	0	0 %	0	0 %
20/CD, 20/MM, 20/PL	6	5,2 %	6	5,2 %
Total	114	100%	114	100%

The VASC normality statistics were: Average: 20/83 SD: 20/137, Median: 20/40, Mode: 20/30. The VACC normality statistics were: Average: 20/59 SD: 20/138, Median: 20/20, Mode: 20/20.

Table 6. Post-surgical refractive cylinder.

RC Pre-surgical	Frequency	Percentage
Less to -3,00	1	0,9 %
-2,05 to -3,00	1	0,9 %
-1,05 to -2,00	27	23, 6 %
0,00 to -1,00	85	74,6 %

The normality statistics were Mean: -1.43 D with SD: 6.98, Median: -0.75, Mode: -0.50.

Table 7. Post-surgical refractive sphere.

RE presurgical	Frequency	Percentage
Less to -2,00	2	1,8 %
-1,05 to -2,00	9	7,8 %
+1,00 to -1,00	93	81,6 %
+1,05 to +2,00	8	7,0 %
Higher to +2,00	2	1,8 %

The normality statistics were: Average: +0.08 D with SD: 1.02, Median: 0.0, Mode: 0.0.

Table 8. Correlations of paired samples of preoperative and postoperative results, T Student 95% confidence interval.

Variables	N	Correlation	Sig.
VASC presurgical & VASC postsurgical	114	,285	,002
Pre-surgical AVCC & post-surgical AVCC	114	,313	,001
Pre-surgical ER & post-surgical ER	114	,239	,010
Pre-surgical CR & Post-surgical CR	114	-,054	,569

Variables	Average	N	Standard Deviation	Average Error
Pre-surgical AVSC	20/324,1	114	213,261	19,974
Post-surgical AVSC	20/83,7	114	137,904	12,916
preoperative CCVA	20/202,3	114	223,68219	20,94976
Postoperative CCVA	20/59,8	114	138,95617	13,01444
Pre-surgical ER	-1,1	114	2,39721	0,22452
Post-surgical ER	0,1	114	1,02141	0,09566
Pre-surgical RC	-0,5	114	0,76434	0,07159
Post-surgical RC	-1,4	114	6,98067	0,65380

The T-Student test shows that both the BCVA and BCVA showed improvement after surgery, a statistically significant result. The mode for postoperative BCVA and BCVA were 20/30 and 20/20, respectively.

No difference was found between the pre-surgical CR and post-surgical CR.

There is a difference in ER Pre-surgical and ER Post-surgical, with results much closer to a refraction of 0 after surgery.

Table 9. Correlations of Independent samples results according to age, T Student confidence interval 95%.

	Sig. (valor p.)	Average difference	Typ. error of the difference	95% confidence interval for the difference	
				Lower	Upper
Pre-surgical VASC	,001	20/127,3	20/38,0	52,0	202,6
Preoperative CCVA	,048	20/82,7	20/41,4	,6	164,8
Post-surgical VASC	,113	20/37,8	20/23,7	-9,1	84,9
Postoperative CCVA	,279	20/28,6	20/26,3	-23,5	80,7

	Age	N	Average difference	Standard deviation.	Average typ. error
Pre-surgical AVSC	<70 years	52	20/392,1	216,0	29,9
	>70 years	61	20/264,7	188,0	24,0
Preoperative CCVA	<70 years	52	20/247,6	244,5	33,9
	>70 years	61	20/164,8	195,6	25,0
Post-surgical AVSC	<70 years	52	20/98,3	168,9	23,4
	>70 years	60	20/60,5	67,6	8,7
Postoperative CCVA	<70 years	52	20/75,1	171,2	23,7
	>70 years	61	20/46,4	105,1	13,4

Patients under 70 years showed lower visual acuity in pre-surgical variables. But there is no significant difference between the two groups after surgery.

Table 10. Correlations of Independent samples according to Personal history, T Student confidence interval 95%.

	Sig. (valor p.)	Average difference	Typ. error of the difference	95% confidence interval for the difference	
				Lower	Superior
Pre-surgical AVSC	,071	20/-71,3	20/39,1	-149,0	6,2
AVCC prequirúrgica	,739	20/14,0	20/42,0	-69,2	97,2
Preoperative CCVA	,948	20/-1,5	20/23,9	-49,0	45,8
AVCC posquirúrgica	,779	20/-7,4	20/26,3	-59,6	44,8

	Personal medical history	N	Average	standard Deviation	Typ. error average
Pre-surgical AVSC	YES	58	20/288,6	212,4	27,8
	NO	55	20/360,0	203,8	27,4

Preoperative CCVA	YES	58	20/209,7	244,5	32,1
	NO	55	20/195,7	198,3	26,7
Post-surgical AVSC	YES	58	20/77,3	123,7	16,2
	NO	54	20/78,9	129,7	17,6
Postoperative CCVA	YES	58	20/56,0	124,9	16,4
	NO	55	20/63,4	154,5	20,8

No significant difference was found between patients with and without a personal history in their pre- and postoperative VA results.

Table 11. Correlations of Independent samples according to ophthalmological surgical history, T Student 95% confidence interval.

	Sig. (valor p.)	Average Difference	Typ. error of the difference	95% confidence interval for the difference	
				Lower	Upper
Pre-surgical AVSC	,469	20/40,3	20/55,4	-69,5	150,2
Preoperative CCVA	,513	20/38,4	20/58,6	-77,7	154,6
Post-surgical AVSC	,000	20/130,5	20/30,9	69,2	191,8
Postoperative CCVA	,000	20/134,0	20/34,6	65,4	202,6

	Ophthalmic surgical history	N	Average	Standard deviation	typ. error average
Pre-surgical AVSC	YES	17	20/357,6	200,2	48,5
	NO	96	20/317,2	212,5	21,6
Preoperative CCVA	YES	17	20/235,5	223,1	54,1
	NO	96	20/197,1	222,8	22,7
Post-surgical AVSC	YES	17	20/188,8	267,6	64,9
	NO	95	20/58,2	63,0	6,4
Postoperative CCVA	YES	17	20/173,5	275,9	66,9
	NO	96	20/39,4	86,0	8,7

There is no difference in the preoperative VA variables between patients with a history of ophthalmologic surgery and those who do not. But after surgery, patients who had a history of ophthalmologic surgery presented lower visual acuity with values of AVCC and AVSC close to 20/200.

DISCUSSION

The age range most frequently subjected to phacoemulsification surgery with Clareon IOLs was the highest at 70 years, representing more than half of the universe. Almost the entire universe is older than

50 years, which is why it is considered a diagnosis of senile cataract. The Isabel Ibáñez study at the Ircovisión Clinic in Murcia, which evaluates the visual acuity results of phacoemulsification cataract surgery with another intraocular lens (Tecnis Symphony), finds that the most frequent age range is from 42 years to 78 years (10). Talavero P. reports in his research an average age of between 60 and 63 years (11).

Regarding the personal pathological history, more than half of the patients did not present a pathological history, while the rest presented arterial hypertension and diabetes mellitus at the same frequency. Similarly, in the study carried out by Luján Paredes et al. reports that the most frequent pathological history is arterial hypertension with more than a third of the cases (12). This frequent appearance of chronic degenerative diseases is once again explained by the advanced age in which the senile cataract occurs.

Regarding ophthalmological surgical history, it was observed that almost the entire universe did not present a history. This is in contrast to the research carried out by Luján Paredes S et al. where they found that 37.5% had previous surgery (12).

The results of the present investigation show that there is an improvement in VA, highlighting that both pre-surgical BCVA and pre-surgical BCVA had a higher frequency of 20/CD, and after phacoemulsification surgery with the Clareon IOL the most common post-surgical BCVA passed to be 20/30 and the post-surgical BCVA 20/20, that is, a very notable improvement in visual acuity, statistically verified when applying the T-Student test, with $p < 0.05$. This agrees with the study carried out by Ibáñez I., which evaluates the VA results of phacoemulsification cataract surgery with another IOL (Tecnis Symphony), the study shows that uncorrected distance visual acuity was 0.1 Log MAR, and the BCVA of about 0.07 Log MAR concluding that they improve both the quality of life and patient satisfaction (10). In the same way, it is similar to the results obtained by Luján P. et al. who evaluated the VA variation after phacoemulsification surgery with other types of intraocular lens, presenting a variation from pre-surgical to post-surgical visual acuity of 0.29 to 0.43 (1 equals a VA of 20/20), which would be expressed as an increase in its VA (12).

On the other hand, the study showed a statistically significant difference between pre-surgical and post-surgical RE, decreasing the mean diopters recorded in patients after surgery. No statistically significant

difference was found for preoperative and postoperative CR. When comparing with the study by Asena B, who analyzes the results of 2 intraocular lenses (AcrySof PanOptix and AT LISA tri 839MP), we find similarity with their results, since it shows that preoperatively, refraction was similar in both groups, after the operation. , mean CR values were similar between the 2 diffractive IOL groups, however, there were statistically significant differences between groups in ER (15). In the same way, we found similarity in the results of the refractive sphere and discrepancy with the results of the refractive cylinder with the study by Isabel I, which mentions that the refractive values after IOL implantation are notably improved with respect to the preoperative values. the mean value of the ER improved to -0.38 D and for the CR a mean of -1.06 D (17).

These results can be explained by the surgical technique used, which is phacoemulsification, in which a small incision is made in the sclerocorneal limbus of between 2.2 and 3.2 mm to introduce the intraocular lens, for which, according to the bibliography, an effect common is to cause mild astigmatism due to irregularities caused in the cornea that alter the refractive cylinder, therefore the results do not show improvement in the pre-surgical and post-surgical refractive cylinder, while the refractive sphere is significantly improved by the characteristics of the IOL, which prior to its placement it is chosen according to the refractive characteristics, which in the Clareon IOL range from +6.0 +30.0 D in 0.5 D increments with the possibility of adapting to the needs of any patient.

Regarding the comparative tests according to age, it was found that patients under 70 years of age showed significantly lower preoperative BCVA and preoperative BCVA than patients over 70 years of age ($p=0.001$), an approximate mean of 20/400. compared to a mean of 20/250, later when evaluating the post-surgical results these results did not show a significant difference between the age groups, presenting approximate means of 20/70 and 20/40 respectively.

The Student's T test for independent samples according to personal pathological history does not show a significant difference in pre-surgical or post-surgical VA, showing means in the pre-surgical parameters of BCVA 20/350 and BCVA 20/200; and means in the post-surgical parameters of AVSC of 20/70 and AVCC 20/60 ($p>0.05$).

The Student's T test for independent samples shows that there is no significant difference for the presurgical VA variables according to ophthalmological surgical history (approximate means of 20/350

for BCVA and 20/200 for BCVA in both groups), while there is a difference Significant for post-surgical VA, on the one hand, patients with a history presented mean BCVA and BCVA of 20/200; and the patients with no history presented means of BCVA and BCVA of 20/60 and 20/40 respectively ($p < 0.05$).

Regarding trans-surgical complications, almost all the patients did not present them, the only complication presented was rupture of the posterior capsule in one patient. When compared with the study by Toyama T. et al. carried out at the Tokyo Metropolitan Geriatric Hospital, where 2 groups of patients (over 90 years and over 80 years) who underwent intraocular lens phacoemulsification surgery of various sizes were analyzed. models it was found that in group 1, anterior capsular rupture occurred in 2.9%, posterior capsule rupture in 0.72% and Zinn zonular dialysis in 1.4%. In group 2, anterior capsular tear occurred in 2%, Zinn zonular dialysis in 0.66%, and a very large wound in 0.66%, confirming that there are low rates of trans-surgical complications (13).

The Clareon IOL has the AutoNoMe system, the mechanism responsible for delivering the IOL, which reduces traumatic processes and facilitates one-hand placement for the surgeon, thereby reducing the risk of trans-surgical complications.

Regarding post-surgical complications, almost all the patients did not present complications and in the patients who did present them, they were mostly mild complications such as corneal edema and uveitis that subside with medical treatment, although in one case retinal detachment was reported due to having suffered eye trauma prior to surgery. Comparing with the study by Isabel I. that analyzes the results of the Tecnis Symphony intraocular lens, it was observed that two patients had to undergo a capsulotomy due to opacification of the posterior capsule secondary to surgery. On the other hand, the study by Toyama T. et al, who found that in group 1, there was an IOP elevation in 2.2%, corneal epithelial damage in 2.2% and cystoid macular edema in 0.72 %, in group 2, IOP elevation occurred in 4.6% and corneal epithelial damage in 0.66%, these complications required complementary medical treatment in most cases. (13)

In comparison with our study, similar frequencies of post-surgical complications were observed, although of less medical severity in the case of the Clareon IOL. Corneal edema and uveitis are common complications due to tissue manipulation typical of surgery; in the case of the phacoemulsification

technique, it is due to the incision made for lens placement, although the use of increasingly smaller cuts and the delivery of the Folded 6mm IOLs have decreased the frequency of complications as evidenced in studies (17).

If we analyze the most relevant post-surgical complications caused by the IOL described in the bibliography, intraocular lens decentrations and dislocations, uveitis-glaucoma-hyphema syndrome, opacifications, IOL flashes and refractive problems stand out; these complications appear due to errors committed in surgery and intraocular lens defects, some may appear months to years after surgery. As it is a modern surgical technique and an intraocular lens with new technology, complications have been reduced. According to the studies carried out by the manufacturer (Alcon), this is explained by the hydrophobic acrylic material of the Clareon IOL, which is resistant to the appearance of flashes (grade 0 on the Miyata scale), due to its optical decentration of 0.04, which is less than maximum specified by the International Organization for Standardization and optical inclination of 0.5 which is below that specified by ISO standards, for which reason it is considered a long-term resistant lens and no complications of this type were found in our study (18,17).

CONCLUSIONS

More than half of the patients did not present additional comorbidities, more than three quarters suffered from senile cataract as the only ophthalmological pathology and had not had previous ophthalmological surgeries.

Phacoemulsification cataract surgery with Clareon intraocular lens shows statistically significant improvement in post-surgical VA and post-surgical corrected VA, observing that most patients have 20/20 visual acuity.

Regarding refraction, ER is statistically lower after surgery. There is no statistically significant difference between pre-surgical and post-surgical CR.

Patients under 70 years of age have lower pre-surgical VA and pre-surgical AVC than those over 70 years of age. After surgery this difference is no longer statistically significant.

The comparison of patients with a pathological history does not show a statistically significant difference in the pre-surgical or post-surgical measurements.

The comparison of patients with an ophthalmological surgical history does not show a statistically significant difference in the pre-surgical measurements, but after surgery the patients without a surgical history show better visual acuity.

There is evidence of minimal frequency of trans-surgical complications. The frequency of post-surgical complications is very low, highlighting that most of the complications presented are mild and do not require secondary medical interventions.

Phacoemulsification surgery with Clareon IOL is beneficial by improving visual acuity, reducing the refractive sphere, with minimal intra-surgical and post-surgical complications.

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Annexes

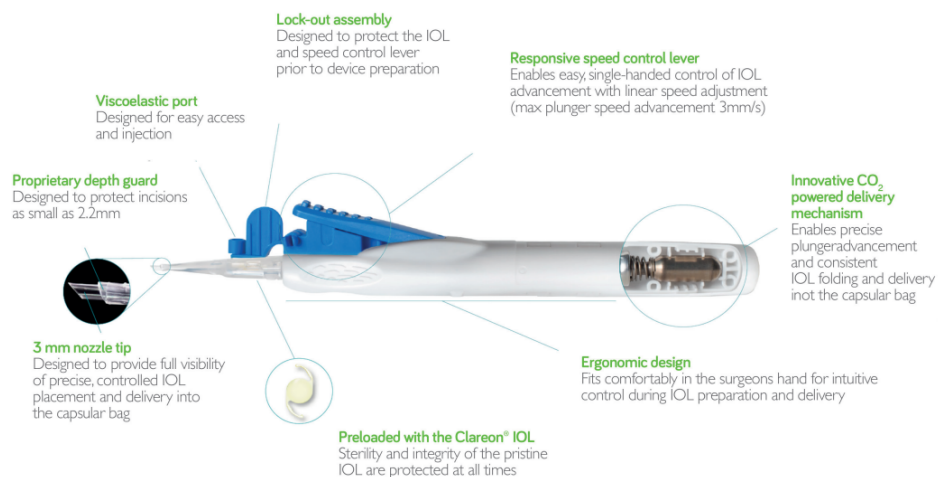
Figure 1. Clareon IOL specifications.

<i>Lens Specifications</i>	<i>Clareon®</i>
Optic type	Asymmetric biconvex optic
Asphericity	-0.2 µm (anterior surface)
Optic material	Hydrophobic acrylic
Optic diameter	6.0 mm diameter
Overall length	13.0 mm
IOL powers (equivalent diopters)	+6.0 to +30.0 D (in 0.5 D increments)
Haptic angulation	0° planar
Haptic configuration	STABLEFORCE™ modified IOL haptics
Photoprotection	UV and blue light filtration
Refractive index	1.55
Suggested A-constant (SKR-T)	119.1 (PCI-Optical)

PCI, partial coherence interferometer.

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Figure 2. Characteristics of the AutonoMe mechanism.



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