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PHD THESIS SUMMARY

„LAST GENERATION BIOMETRIC FORMULAS IN CATARACT SURGERY"

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Key Words: absolute prediction error, Barrett Universal II, biometric constants, biometric formulas, biometry, cataract, Haigis, Holladay I, Hoffer Q, lens, refractive prediction error, SRK/T;

General presentation of the thesis

Cataract is the number one cause of blindness in the world [1]. This is, however, a reversible cause. With the evolution of medical technology, cataract surgery not only cures this pathology, but also offers the possibility of obtaining good visual acuity without the patient needing external optical correction. In order to obtain optimal postoperative results, it is necessary to meet the following conditions simultaneously: adequate preoperative assessment, correct surgical technique with the avoidance of intra- and postoperative complications, implantation of a artificial lens that meets the desired optical and biological characteristics and a predictable and favorable postoperative evolution.

The first condition for obtaining a residual refraction as close as possible to the proposed refractive target is represented by the existence of devices whose technology allow the exact calculation of the power of the artificial lens to be implanted. At the base of this technology are the mathematical and physical formulas that allow obtaining ideal results.

Biometers used for patient assessment can be ultrasonic with applanation [2] or with immersion [2], optical coherence biometers, using partial coherence interferometry PCI [3] or low coherence interferometry OLCI [4], or swept-source using biometers SS -OCT [5]. The first optical coherence biometer used in studies evaluating refractive errors was the IOLMaster® biometer (Carl Zeiss Meditec, Berlin, Germany), which uses partial coherence interferometry to calculate axial length [3,4,6]. The Aladdin HW3.0 Biometer (Topcon, Tokyo, Japan) used in this study is a low-coherence optical interferometer that has been shown to be comparable to the IOLMaster® in terms of results and can be used for pre-operative evaluation and error refractive study [4].

Biometric calculation formulas used for determining the lens power needed to be implanted are constantly changing, and to evaluate their effectiveness, studies are needed to determine in which circumstances some formulas are more effective compared to others from previous generations, or from the same generation. From the point of view of the period of appearance and evolution, the most common biometric formulas are divided into:

- theoretical (Fyodorov [7], Colenbrander [8], Binkhorst [9]) and empirical (SRK I [10-12]) first generation formulas;
- theoretical (Binkhorst II [13]) and empirical (SRK II [14]) second generation formulas
- 3rd generation formulas (SRK/T [15], Hoffer Q [16], Holladay 1 [17]);
- 4th generation formulas (Holladay 2 [18], Haigis [19], Olsen [20-23], Barrett Universal II [24]);

- formulas based on artificial intelligence and formulas using the "ray-tracing" technique, which are not found in the classic classification of biometric formulas.

The 4th generation biometric formulas represent mathematical formulas that have recently started to be used in the calculation of the diopters for the intraocular lens implants used in cataract surgery. Although they are considered to be more effective [18-24], some surgeons avoid using them, preferring to use third-generation formulas, with which postoperative results are predictable and known, after long use in cataract surgery [16,17]. For this reason, the elaboration of as many studies as possible on an international level is encouraged, in order to support the hypothesis that the 4th generation formulas are compatible with any type of refractive error.

Currently there are agreements related to the use of these 4th generation biometric formulas [25-29], but errors are still encountered, with the impossibility of obtaining an ideal refractive target in some cases. Surgeons use different formulas, different lenses, and patients have different characteristics, thus there are many elements of variability that influence the postoperative result.

At a national level, no large-scale study has yet been carried out to help clarify the indication for the use of certain 4th generation formulas, as there are no Romanian authors who evaluated so far, the evolution of large groups of patients and compare several biometric formulas through several statistical methods. Hence the need to carry out a study focused on this topic, which will have a significant impact in the world of ophthalmology.

Until the technology improves and the databases used by AI-based formulas are enriched, the 3rd and 4th generation formulas currently remain the most predictable results for all refractive errors [26,28-33].

In the first section "Current state of knowledge", the doctoral thesis with the title "Last Generation Biometric Formulas in Cataract Surgery" proposes the systematization of theoretical information regarding embryology, anatomy and physiology of the lens, the principle of the schematic eye, generalities regarding refractive errors and their correction methods, the principles of cataract surgery and the types of intraocular implants used, the biometric evaluation of the patient requiring cataract surgery, the existing biometric formulas, as well as the mechanisms of possible intraocular implant calculation errors.

Personal research summary

Personal research objectives

The general objectives of the thesis are represented by the study and optimization of biometric analysis methods in everyday practice, with their adaptation to the new requirements of lens surgery, and the analysis of postoperative results, in order to identify the "ideal" calculation formulas in accordance with the refractive profile of each individual patient.

By carrying out this research, I want to identify and rank the effectiveness and predictability of the 4th generation biometric formulas, respectively Barrett Universal II and Haigis, for each refractive error separately, and optimize the protocol for choosing the right lens power, for obtaining ideal postoperative refractive results. The biometric formulas are evaluated for three implant types, that are commonly used in the clinic: two monofocal implants Acrysof® IQ SN60WF and Tecnis® ZCB00, and one multifocal implant Acrysof® IQ PanOptix TFNT0. These findings are intended to benefit the entire community of surgeons performing cataract surgery or refractive lens exchange.

After treating patients with artificial intraocular lens implantation, for which the diopter was established using the latest generation of calculation formulas, and using individual working parameters for each patient, it is desired:

- to reach and maintain the target refraction and obtain the desired visual acuity;
- to obtain maximum patient satisfaction regarding the quality of visual life;
- to develop of protocols for choosing the ideal calculation formula for each individual refractive error, based on the postoperative refractive results of our study.

The effectiveness of reaching the refractive target for each individual case was evaluated by analyzing the refractive prediction error, which is calculated as the difference between the obtained spherical equivalent and the target refraction. Statistical analysis of this error for each axial length group (<22 mm, 22-24.5 mm, >24.5 mm), was performed based on mean, standard deviation, range, and distribution into dioptric groups.

Another way to show the effectiveness of the formulas was to evaluate absolute prediction error, which is represented by the refractive prediction error regardless of sign.

In most cases, the refractive target was emmetropia. However, there were also cases in which it was opted for the implantation of a lens calculated to provide independence for reading vision, while maintaining a correction for distance vision, a situation found in most myopic patients. These cases did not influence the statistical analysis in a particular way,

because it was done in relation to the refractive prediction error and not conditioned by the achievement of emmetropia.

Personal research methodology

The study was carried out prospectively, non-randomized, interventional, on patients with various degrees of cataracts, who were operated on in the Clinical Emergency Hospital "Professor Doctor Agrippa Ionescu" in Bucharest, between January 1, 2018 and December 31, 2019. The patients signed the informed consent in accordance with the Declaration of Helsinki and the study was approved by the Ethics Committee of the hospital.

Among the patients operated in the clinic between January 1, 2018 and December 31, 2019, only patients who met the inclusion criteria were included in the study (1192 eyes from 1158 patients, of which 34 patients were operated on both eyes, 32 of them had multifocal implants and 2 monofocal implants, and 1124 patients operated on a single eye), For these patients it was opted for the implantation of one of the three types of lens more commonly used in the clinic (Acrysof® IQ SN60WF – 714 eyes, Tecnis® ZCB00 – 390 eyes, Acrysof® IQ PanOptix TFNT0 – 88 eyes) in order to create uniform groups that comply with the norms indicated for the study of refractive errors [34]. The three groups composed of eyes with each type of implant were in turn divided into three cohorts according to axial length:

1. Eye with Acrysof® IQ SN60WF monofocal implant (Alcon Laboratories, Inc.) (714 eyes) (Figure 10.4.1.)

- Group 1.1. with AL <22 mm (42 eyes)
- Group 1.2. with AL between 22 mm and 24.5 mm (354 eyes)
- Group 1.3. with AL >24.5 mm (318 eyes)

2. Eyes with monofocal implant Tecnis® ZCB00 (Johnson & Johnson Vision) (390 eyes) (Figure 10.4.2.)

- Group 2.1. with AL <22 mm (96 eyes)
- Group 2.2. with AL between 22 mm and 24.5 mm (234 eyes)
- Group 2.3. with AL >24.5 mm (60 eyes)

3. Eyes with Acrysof® IQ PanOptix TFNT0 multifocal implant (Alcon Laboratories, Inc.) (88 eyes) (Figure 10.4.3.)

- Group 3.1. with AL <22 mm (14 eyes)
- Group 3.2. with AL between 22 mm and 24.5 mm (68 eyes)
- Group 3.3. with AL >24.5 mm (6 eyes)

Data was collected for each patient and centralized in an Excel® database (version 15.0, Microsoft Corp.) for further statistical processing. Statistical analysis was performed using the SPSS program (version 24, IBM® SPSS® Statistics, IBM Corp.).

The evaluated formulas had the following constants, illustrated in Table I, which were optimized before the start of the study in collaboration with the manufacturers of each type of implant.

Retrospectively, the constants were reoptimized for four of the three formulas tested (Barrett Universal II, Hoffer Q, Holladay 1, SRK/T), using an online calculator available LCO V 5.1 [35] in which the postoperative refractive results were entered, generating new constants (Table I), for the SN60WF and ZCB00 monofocal implant cases. The differences between the refractive results obtained before and after this optimization are presented in a separate chapter.

Table I. Differences between the constants used initially in the study and the reoptimised constants using the on-line calculator [35].

Lens	Formula	Constant	Used	Reoptimized
SN60WF	Barrett Universal II	LF	1.884	1.962
	Haigis	a0	-0.769	-
		a1	0.234	-
		a2	0.217	-
	Hoffer Q	pACD	5.640	5.690
	Holladay 1	SF	1.840	1.910
	SRK/T	Constanta A	119.0	119.15
ZCB00	Barrett Universal II	LF	2.041	1.999
	Haigis	a0	1.302	-
		a1	0.210	-
		a2	0.251	-
	Hoffer Q	pACD	5.800	5.710
	Holladay 1	SF	2.020	1.950
	SRK/T	Constanta A	119.3	119.22
TFNT0	Barrett Universal II	LF	1.936	-
	Haigis	a0	1.390	-
		a1	0.400	-
		a2	0.100	-
	Hoffer Q	pACD	5.630	-
	Holladay 1	SF	1.830	-
	SRK/T	Constanta A	119.1	-

The statistical analysis consisted of a descriptive stage, carried out for all cohorts, and an inferential stage which was carried out for the cohorts that had a number of eyes greater than 30. The evaluation of the refractive results was carried out, after verifying the normality of the distribution of continuous variables by the Shapiro-Wilk test. Parametric tests were used for variables with Gaussian distribution, and non-parametric tests for variables with non-Gaussian distribution.

To compare the refractive prediction error for each biometric formula, we used the ANOVA test, and to test the correlations between variables, we used the Tukey test. Differences between the absolute prediction errors of the formulas were evaluated by the Friedman Test with post hoc analysis by the Wilcoxon signed-rank test with Bonferroni correction. Distribution of refractive prediction error into dioptric groups was compared by Cochran's Q test with post hoc analysis by McNemar test with Bonferroni correction. Statistical significance for all tests used, both parametric and nonparametric, was set for a P value of less than 0.05, and statistical significance for the Wilkoxon signed-rank test and the NcNemar test was set for a P value of less than 0.01, after applying the Bonferroni correction, which involves dividing the value of P by the number of evaluated formulas (P= 0.05/5= 0.01). Variables were expressed as mean, median, standard deviation, minimum and maximum, and proportions were expressed as percentages.

Personal research results

Tables II.1, III.1. and IV.1. shows the analysis of refractive prediction error and absolute prediction error for cohorts with each of the three axial length categories.

Tables II.2., III.2. and IV.2. reveal the distribution of the refractive prediction error into dioptric groups for the same cohorts.

In the groups of patients with an axial length below 22 mm, where the number of cases analyzed was over 30 (Group 1.1 and Group 2.1.), the statistical analysis followed a descriptive as well as an inferential stage, and results were obtained comparable with those of some studies published in the international specialized literature [26-29,36], but antithetical to other older studies [25,37,38], regarding the efficiency of the Hoffer Q formula in the case of eyes with small axial length. The Barrett Universal II formula performed superiorly for the majority of cases included in the study. The refractive prediction error fell within ±1.50 D for all formulas studied, but not in the range of ±1.00 D, where the results varied between 81.3% (for the Hoffer Q formula in the Tecnis® ZCB00 implant cohort) and 100% (for the rest of the formulas in the Acrysof® IQ SN60WF implant cohort). The number of eyes within ±0.50 D was even smaller, between 50% (for the Hoffer Q formula in the Tecnis® ZCB00 implant

cohort) and 85.7% (for the Barrett Universal II formula in the Acrysof® IQ SN60WF implant cohort), aspect that suggests the fact that, for hyperopic eyes, there is still great variability in refractive results, with the need to improve the efficiency of biometric formulas, a finding that was also made by other authors [26,29,39]. Tables II.1. and II.2. illustrate the results obtained in the cohorts with axial length below 22 mm.

In the groups of patients with an axial length between 22 and 24.5 mm, the statistical analysis followed a descriptive and an inferential stage for all cohorts, and similar results to the studies published in the international specialized literature were obtained, studies that are more numerous compared to those analyzing extreme axial lengths. The number of eyes within ±0.50 D was even higher compared to the cohorts with extreme axial lengths, with a minimum of 74.3% (for the Haigis formula in the Tecnis® ZCB00 implant cohort). Both the 4th generation formula Barrett Universal II and the 3rd generation formula Holladay 1 were significantly superior to the other formulas. Tables III.1. and III.2. illustrate the results obtained in cohorts with axial length between 22 and 24.5 mm.

In the case of patients with an axial length over 24.5 mm, where the number of cases analyzed was over 30 (Group 1.3. and Group 2.3.), the statistical analysis followed a descriptive as well as an inferential stage, and the obtained results were comparable as well to those of the studies published in the international specialized literature, namely the superiority of the Barrett Universal II formula [28,40-47] and the inferiority of the Hoffer Q formula which is recommended to be used in cases with short axial length, not long [25,37, 38,48,49]. Tables IV.1. and IV.2. illustrate the results obtained in cohorts with axial length over 24.5 mm.

The P values obtained from the statistical analysis of the refractive results for the five formulas, three categories of axial length and three types of lens are presented in tables V.1, V.2. and V.3.a/b/c.

Among the patients included in the study, the cases with monofocal implant were selected (Acrysof® IQ SN60WF – 714 eyes, Tecnis® ZCB00 – 390 eyes). Biometric variables and postoperative refractive results were entered retrospectively into an online calculator LCO V 5.1 [25], which generated new biometric constants for four of the five evaluated formulas: Barrett Universal II, Hoffer Q, Holladay 1 and SRK/T (Table I.) [50].

The refractive results obtained after this optimization were analyzed following the absolute prediction errors with the application of the Friedman test with post hoc analysis by Wilcoxon signed-rank test with Bonferroni correction (with statistical significance for $P<0.0125$). The P values of the applied tests can be found in Table VI.1. and Table VI.2.

It can be stated that the optimization according to the method available online [25] led to similar results to those obtained by using the constants optimized by the implant manufacturers, before the start of the study, but with the decrease of the differences between the formulas. For the Barrett Universal II formula, there were no significant changes in the refractive results, after adjusting the LF based on the optimization of the A constant [50].

The 3rd generation formula SRK/T did not stand out in any way for any cohort, performing well in most groups. This formula has been preferred and used by many surgeons with success. In the early 1980s, biometric formulas were theoretical or empirical (regression), and regression formulas such as the SRK formula [51] were preferred by surgeons. This formula is based on AL, K and the constant A and works optimally for medium axial lengths. Later, the SRK II formula was created [14] which adjusts the A constant according to the axial length. This formula later evolved into the SRK/T formula which is based on a combination of a linear regression method (empirical formula) and a schematic eye model (theoretical formula) [15]. From 1990 to the present, this has been a guiding formula and remains reliable. All formulas in the SRK group provide a good understanding of the influence of axial length, keratometry and A constant on the final diopter of the implant. Thus increasing AL causes the power to decrease, increasing K causes the power to decrease, and adjusting the A constant by increasing its value causes the lens power to increase.

The 4th generation formula Barrett Universal II showed the best results for all axial lengths, representing a useful tool for all surgeons, especially since it does not require adjustment. It considers 5 variables: AL, K, optical ACD, LT and WTW [24]. The constants used are the A constant and the LF which is dependent on the A constant. This formula can be used for a wide variety of implants without the results being influenced by factors such as the optical configuration, thickness and diopter of the implant. It is no longer necessary to apply corrections for extreme axial lengths, because it takes into account the changes in the principal planes that occur for different diopters of the implants [24]. Readjusting the LF by changing the A constant following the method presented in Chapter 16 did not produce significant changes in the absolute prediction error, which supports the claim that the Barrett Universal II formula is suitable for a wide range of axial lengths without requiring constant adjustment.

Table II.1. Statistical analysis of the refractive prediction error and the absolute prediction error for the groups with AL under 22 mm.

Group 1.1. (n:42 AL: <22 mm)					
	Barrett Universal II	Haigis	Hoffer Q	Holladay 1	SRK/T
MeanRPE(D)±SD	-0.014±0.307	-0.165±0.459	-0.317±0.321	-0.200±0.352	-0.042±0.342
Interval	1.01	1.54	1.06	1.13	1.01
MAE(D)±SD	0.240±0.180	0.331±0.350	0.391±0.215	0.334±0.216	0.282±0.182
MedAE	0.140	0.190	0.320	0.270	0.250
Group 2.1. (n:96 AL: <22 mm)					
MeanRPE(D)±SD	-0.137±0.590	0.017±0.611	-0.330±0.631	-0.145±0.582	0.059±0.603
Interval	2.10	2.20	2.17	2.30	2.48
MAE(D)±SD	0.473±0.369	0.472±0.378	0.576±0.410	0.476±0.356	0.449±0.399
MedAE	0.415	0.395	0.510	0.365	0.285
Group 3.1. (n:14 AL: <22 mm)					
MeanRPE(D)±SD	0.077±0.391	-0.184±0.526	-0.108±0.317	0.120±0.293	0.170±0.438
Interval	1.28	1.79	1.04	0.75	1.28
MAE(D)±SD	0.297±0.254	0.370±0.408	0.262±0.198	0.220±0.222	0.332±0.322
MedAE	0.190	0.280	0.200	0.100	0.240

MeanRPE(D)±SD: mean refractive prediction error ± standard deviation; MAE(D)±SD: mean absolute prediction error ± standard deviation; MedAE: median absolute prediction error;

Table II.2. Distribution of the refractive prediction error into dioptric groups for eyes with AL under 22 mm.

Group 1.1. (n:42 AL: <22 mm)				
Formula	±0.25D	±0.50D	±1.00D	±1.50D
Barrett Universal II	30 (71.4%)	36 (85.7%)	42 (100%)	42 (100%)
Haigis	30 (71.4%)	36 (85.7%)	36 (85.7%)	42 (100%)
Hoffer Q	6 (14.3%)	30 (71.4%)	42 (100%)	42 (100%)
Holladay 1	18 (42.9%)	30 (71.4%)	42 (100%)	42 (100%)
SRK/T	24 (57.1%)	36 (85.7%)	42 (100%)	42 (100%)
Group 2.1. (n:96 AL: <22 mm)				
Barrett Universal II	30 (31.3%)	66 (68.8%)	90 (93.8%)	96 (100%)
Haigis	36 (37.5%)	60 (62.5%)	84 (87.5%)	96 (100%)
Hoffer Q	24 (25%)	48 (50%)	78 (81.3%)	96 (100%)
Holladay 1	24 (25%)	60 (62.5%)	84 (87.5%)	96 (100%)
SRK/T	42 (43.8%)	60 (62.5%)	90 (93.8%)	96 (100%)
Group 3.1. (n:14 AL: <22 mm)				
Barrett Universal II	4	12	14	14
Haigis	6	8	12	14
Hoffer Q	4	12	14	14
Holladay 1	10	12	14	14
SRK/T	4	12	12	14

Table III.1. Statistical analysis of the refractive prediction error and the absolute prediction error for the groups with AL between 22 and 24.5 mm.

Group 1.2. (n:354 AL: 22-24.5 mm)					
	Barrett Universal II	Haigis	Hoffer Q	Holladay 1	SRK/T
MeanRPE(D)±SD	0.186±0.355	0.044±0.416	0.033±0.418	0.075±0.359	0.118±0.357
Interval	1.76	2.19	1.99	1.77	1.60
MAE(D)±SD	0.331±0.223	0.338±0.245	0.337±0.248	0.292±0.221	0.305±0.217
MedAE	0.280	0.270	0.310	0.270	0.260
Group 2.2. (n:234 AL: 22-24.5 mm)					
MeanRPE(D)±SD	-0.061±0.319	-0.219±0.405	-0.208±0.395	-0.163±0.349	-0.108±0.361
Interval	1.30	1.57	1.42	1.39	1.55
MAE(D)±SD	0.246±0.210	0.381±0.255	0.368±0.251	0.319±0.212	0.296±0.230
MedAE	0.180	0.290	0.340	0.280	0.250
Group 3.2. (n:68 AL: 22-24.5 mm)					
MeanRPE(D)±SD	0.151±0.315	0.056±0.365	0.079±0.405	0.140±0.345	0.110±0.110
Interval	1.28	1.33	1.58	1.22	1.35
MAE(D)±SD	0.292±0.187	0.300±0.213	0.327±0.249	0.302±0.215	0.322±0.189
MedAE	0.265	0.270	0.290	0.265	0.295

MeanRPE(D)±SD: mean refractive prediction error ± standard deviation; MAE(D)±SD: mean absolute prediction error ± standard deviation; MedAE: median absolute prediction error;

Table III.2. Distribution of the refractive prediction error into dioptric groups for eyes with AL between 22 and 24.5 mm.

Group 1.2. (n:354 AL:22-24.5 mm)				
Formula	±0.25D	±0.50D	±1.00D	±1.50D
Barrett Universal II	156 (44.1%)	270 (76.3%)	354 (100%)	354 (100%)
Haigis	168 (47.5%)	270 (76.3%)	354 (100%)	354 (100%)
Hoffer Q	150 (42.4%)	264 (74.6%)	348 (98.3%)	354 (100%)
Holladay 1	168 (47.5%)	300 (84.8%)	354 (100%)	354 (100%)
SRK/T	174 (49.2%)	288 (81.4%)	354 (100%)	354 (100%)
Group 2.2. (n:234 AL: 22-24.5 mm)				
Barrett Universal II	156 (66.7%)	198 (84.6%)	234 (100%)	234 (100%)
Haigis	96 (41%)	174 (74.3%)	228 (97.4%)	234 (100%)
Hoffer Q	60 (25.6%)	180 (76.9%)	234 (100%)	234 (100%)
Holladay 1	102 (43.6%)	192 (82.1%)	234 (100%)	234 (100%)
SRK/T	120 (51.3%)	186 (79.5%)	234 (100%)	234 (100%)
Group 3.2. (n:68 AL: 22-24.5 mm)				
Barrett Universal II	20 (29.4%)	68 (100%)	68 (100%)	68 (100%)
Haigis	22 (32.4%)	62 (91.2%)	68 (100%)	68 (100%)
Hoffer Q	20 (29.4%)	62 (91.2%)	68 (100%)	68 (100%)
Holladay 1	20 (29.4%)	68 (100%)	68 (100%)	68 (100%)
SRK/T	12 (17.6%)	64 (94.1%)	68 (100%)	68 (100%)

Table IV.1. Statistical analysis of the refractive prediction error and the absolute prediction error for the groups with AL over 24.5 mm.

Group 1.3. (n:318 AL: >24.5 mm)					
	Barrett Universal II	Haigis	Hoffer Q	Holladay 1	SRK/T
MeanRPE(D)±SD	0.038±0.335	-0.032±0.350	0.169±0.370	0.071±0.378	0.016±0.424
Interval	1.28	1.55	1.60	1.62	1.83
MAE(D)±SD	0.273±0.196	0.278±0.214	0.334±0.230	0.316±0.217	0.344±0.246
MedAE	0.250	0.250	0.300	0.300	0.290
Group 2.3. (n:60 AL: >24.5 mm)					
MeanRPE(D)±SD	0.019±0.203	-0.226±0.188	0.022±0.242	-0.049±0.133	0.066±0.157
Interval	0.73	0.72	0.87	0.47	0.49
MAE(D)±SD	0.131±0.153	0.272±0.106	0.162±0.177	0.113±0.082	0.148±0.079
MedAE	0.080	0.260	0.140	0.080	0.160
Group 3.3. (n:6 AL: >24.5mm)					
MeanRPE(D)±SD	-0.163±0.201	-0.250±0.062	-0.093±0.045	-0.176±0.028	-0.196±0.100
Interval	0.43	0.13	0.10	0.06	0.22
MAE(D)±SD	0.223±0.112	0.250±0.062	0.093±0.045	0.176±0.028	0.196±0.100
MedAE	0.240	0.220	0.100	0.190	0.170

MeanRPE(D)±SD: mean refractive prediction error ± standard deviation; MAE(D)±SD: mean absolute prediction error ± standard deviation; MedAE: median absolute prediction error;

Table IV.2. Distribution of the refractive prediction error into dioptric groups for eyes with AL over 24.5 mm.

Group 1.3. (n:318 AL:>24.5 mm)				
Formula	±0.25D	±0.50D	±1.00D	±1.50D
Barrett Universal II	162 (50.9%)	270 (84.9%)	318 (100%)	318 (100%)
Haigis	168 (52.8%)	270 (84.9%)	318 (100%)	318 (100%)
Hoffer Q	150 (47.1%)	252 (79.2%)	318 (100%)	318 (100%)
Holladay 1	144 (45.3%)	240 (75.5%)	318 (100%)	318 (100%)
SRK/T	144 (45.3%)	246 (77.4%)	318 (100%)	318 (100%)
Group 2.3. (n:60 AL: >24.5D)				
Barrett Universal II	54 (90%)	54 (90%)	60 (100%)	60 (100%)
Haigis	30 (50%)	60 (100%)	60 (100%)	60 (100%)
Hoffer Q	48 (80%)	54 (90%)	60 (100%)	60 (100%)
Holladay 1	60 (100%)	60 (100%)	60 (100%)	60 (100%)
SRK/T	54 (90%)	60 (100%)	60 (100%)	60 (100%)
Group 3.3. (n:6 AL: >24.5 mm)				
Barrett Universal II	0	6	6	6
Haigis	0	6	6	6
Hoffer Q	0	6	6	6
Holladay 1	0	6	6	6
SRK/T	0	6	6	6

Table V.1. Results obtained after applying the Friedman and Wilcoxon signed-rank test with Bonferroni correction for groups with over 30 cases.

	P value for Friedman test	P value for Wilcoxon signed-rank test with Bonferroni correction	
AL: < 22 mm			
Group 1.1.	0.096	-	-
Group 2.1.	0.116	-	-
AL: 22-24.5 mm			
Group 1.2.	<0.001	Holladay 1 – Hoffer Q	<0.001
		Holladay 1 – Haigis	0.001
Group 2.2.	<0.001	Barrett Universal II – Haigis	<0.001
		Barrett Universal II – Hoffer Q	<0.001
		Barrett Universal II – Holladay 1	<0.001
		Hoffer Q – Holladay 1	0.002
		Hoffer Q – SRK/T	0.008
		Haigis – Holladay 1	0.004
		Haigis – SRK/T	0.007
Group 3.2.	0.287	-	-
AL: > 24.5 mm			
Group 1.3.	0.001	Barrett Universal II – Hoffer Q	0.001
		Barrett Universal II – Holladay 1	0.009
		Barrett Universal II – SRK/T	0.001
		Haigis – Holladay 1	0.001
Group 2.3.	0.001	Barrett Universal II – Haigis	0.009
		Haigis – Holladay 1	< 0.001
		Haigis – SRK/T	0.001
Statistical significance: Friedman test with P <0.05; Wilcoxon signed-rank test with Bonferroni correction with P <0.01;			

Table V.2. Results obtained after applying ANOVA and Tukey tests for groups over 30 cases.

	P value for ANOVA test	P value for Tukey test	
AL: < 22 mm			
Group 1.1.	0.178	-	-
Group 2.1.	0.085	-	-
AL: 22-24.5 mm			
Group 1.2.	0.054	-	-
Group 2.2.	0.037	Barrett Universal II – Haigis	0.048
Group 3.2.	0.495	-	-
AL: > 24.5 mm			
Group 1.3.	0.002	Hoffer Q – Haigis	0.001
		Hoffer Q – SRK/T	0.024
Group 2.3.	<0.001	Haigis – Barrett Universal II	0.001
		Haigis – Hoffer Q	0.001
		Haigis – Holladay 1	0.03
		Haigis – SRK/T	<0.001
Statistical significance: ANOVA test with P <0.05; Tukey test with P <0.05;			

Table V.3.a. Results obtained after applying the tests Cochran Q and McNemar with Bonferroni correction for the groups with over 30 cases and AL <22 mm.

		P value for Cochran Q test	P value for McNemar test with Bonferroni correction	
AL: < 22 mm				
Grupul 1.1.	+/- 0.25 D	0.03	Barrett Universal II – Hoffer Q	0.008
			Haigis – Hoffer Q	0.008
	+/- 0.50 D	0.615	-	-
	+/- 1.00 D	0.092	-	-
Grupul 2.1.	+/- 0.25 D	0.225	-	-
	+/- 0.50 D	0.225	-	-
	+/- 1.00 D	0.048	Hoffer Q – SRK/T	0.031
Statistical significance: Cochran Q test with P <0.05; McNemar test with Bonferroni correction with P <0.01;				

Table V.3.b. Results obtained after applying the tests Cochran Q and McNemar with Bonferroni correction for the groups with over 30 cases and AL 22 – 24.5 mm.

		P value for Cochran Q test	P value for McNemar test with Bonferroni correction	
AL: 22-24.5 mm				
Group 1.2.	+/- 0.25 D	0.685	-	-
	+/- 0.50 D	0.061	-	-
	+/- 1.00 D	0.092	-	-
Group 2.2.	+/- 0.25 D	<0.001	Barrett Universal II – Haigis	<0.001
			Barrett Universal II – Hoffer Q	<0.001
			Barrett Universal II – Holladay 1	<0.001
			Hoffer Q – Haigis	0.009
			Hoffer Q – Holladay 1	<0.001
			Hoffer Q – SRK/T	<0.001
	+/- 0.50D	0.181	-	-
	+/- 1.00 D	0.092	-	-
Group 3.2	+/- 0.25 D	0.654	-	-
	+/- 0.50 D	0.110	-	-
	+/- 1.00 D	0.900	-	-
Statistical significance: Cochran Q test with P <0.05; McNemar test with Bonferroni correction with P <0.01;				

Table V.3.c. Results obtained after applying the tests Cochran Q and McNemar with Bonferroni correction for the groups with over 30 cases and AL >24.5 mm.

		P value for Cochran Q test	P value for McNemar test with Bonferroni correction	
AL: > 24.5 mm				
Group 1.1.	+/- 0.25 D	0.564	-	-
	+/- 0.50 D	0.065	-	-
	+/- 1.00 D	0.900	-	-
Group 2.1.	+/- 0.25 D	0.009	Haigis – Barrett Universal II	0.009
			Haigis – Holladay 1	0.002
			Haigis – SRK/T	0.008
	+/- 0.50 D	0.092	-	-
	+/- 1.00 D	0.900	-	-
Statistical significance: Cochran Q test with P <0.05; McNemar test with Bonferroni correction with P <0.01;				

Table VI.1. P values obtained through statistical analysis before reoptimisation.

AL: < 22 mm			
	P value for Friedman test	P value for Wilcoxon signed-rank test with Bonferroni correction	
Group 1.1.	0.048	Barrett Universal II – Hoffer Q	0.035
		Barrett Universal II – Holladay 1	0.070
Group 2.1.	0.045	Barrett Universal II – Hoffer Q	0.014
		Barrett Universal II – Holladay 1	0.027
AL: 22-24.5 mm			
Group 1.2.	<0.001	Holladay 1 – Hoffer Q	<0.001
Group 2.2.	<0.001	Barrett Universal II – Hoffer Q	<0.001
		Barrett Universal II – Holladay 1	<0.001
		Hoffer Q – Holladay 1	0.002
		Hoffer Q – SRK/T	0.008
AL: > 24.5 mm			
Group 1.3.	0.001	Barrett Universal II – Hoffer Q	0.001
		Barrett Universal II – Holladay 1	0.009
		Barrett Universal II – SRK/T	0.001
Group 2.3.	0.5	-	-
Statistical significance: Friedman test with P <0.05; Wilcoxon signed-rank test with Bonferroni correction with P <0.0125;			

Table VI.2. P values obtained through statistical analysis after reoptimisation.

AL: < 22 mm			
	P value for Friedman test	P value for Wilcoxon signed-rank test with Bonferroni correction	
Group 1.1.	0.271	-	-
Group 2.1.	0.163	-	-
AL: 22-24.5 mm			
Group 1.2.	<0.001	Barrett Universal II – Hoffer Q	0.007
		Holladay 1 – Hoffer Q	<0.001
		Hoffer Q – SRK/T	0.001
Group 2.2.	<0.001	Barrett Universal II – Hoffer Q	0.001
		Barrett Universal II – Holladay 1	0.003
AL: > 24.5 mm			
Group 1.3	0.187	-	-
Group 2.3.	0.001	Barrett Universal II – Hoffer Q	0.030
		Holladay 1 – Hoffer Q	0.039
Statistical significance: Friedman test with P <0.05; Wilcoxon signed-rank test with Bonferroni correction with P <0.0125;			

Personal research findings

The research carried out as part of the doctoral thesis "Latest Generation Biometric Formulas in Cataract Surgery" led to the following conclusions:

1. The statistical analysis was performed on a number of 1192 eyes from 1158 patients, operated for cataract or for refractive purposes, using the prediction of 5 biometric formulas incorporated in the software of the Aladdin HW3.0 optical coherence biometer (Topcon, Tokyo, Japan).
2. The study was prospective, non-randomized, interventional, the cases being followed for a period of 1 month. There were six study cohorts, depending on axial length (under 22 mm, between 22 and 24.5 mm, over 24.5 mm) and implant type (Acrysof® IQ SN60WF, Tecnis® ZCB00, Acrysof® IQ PanOptix TFNT0).
3. The main purpose of the study was to evaluate the refractive results obtained following the application of the five evaluated biometric formulas: the refractive prediction error, with the analysis of the mean, standard deviation and its range; absolute prediction error, with analysis of the mean and median; distribution of the refractive prediction error into dioptric groups. The reporting of the results was carried out in accordance with the internationally recommended norms for works studying the effectiveness of biometric formulas [330,331].
4. The statistical analysis was done for a wide range of axial lengths in order to establish the effectiveness of the formulas including for eyes with extreme diopters:
   - AL <22 mm
   - Acrysof® IQ SN60WF between 21.39 and 21.99 mm (mean 21.767±0.247 mm)
   - Tecnis® ZCB00 between 20.68 and 21.94 mm (mean 21.550±0.423 mm)
   - Acrysof® IQ PanOptix TFNT0 between 21.57 and 21.96 mm (mean 21.842±0.139 mm)
   - AL 22-24.5 mm
   - Acrysof® IQ SN60WF between 22.03 and 24.35 mm (mean 23.313±0.595 mm)
   - Tecnis® ZCB00 between 22.07 and 24.44 mm (mean 23.122±0.667 mm)
   - Acrysof® IQ PanOptix TFNT0 between 22.09 and 24.27 mm (mean 23.325±0.612 mm)
   - AL >24.5 mm
   - Acrysof® IQ SN60WF between 24.42 and 30.01 mm (mean 25.647±1.176 mm)
   - Tecnis® ZCB00 between 24.52 and 25.73 mm (mean 25.095±0.454 mm)
   - Acrysof® IQ PanOptix TFNT0 between 24.54 and 25.5 mm (mean 25.050±0.431 mm)

5. For cohorts with axial length <22 mm, contrary to expectations, the 3rd generation formula Hoffer Q, recommended for this category of eyes [48,49], had the worst results. The Barrett Universal II formula performed superiorly for the majority of cases included in the study.
6. For cohorts with axial length between 22 and 24.5 mm both the 4th generation Barrett Universal II formula and the 3rd generation Holladay 1 formula performed optimally.
7. For cohorts with axial length >24.5 mm, the superiority of the Barrett Universal II formula and the inferiority of the Hoffer Q formula was proven, a result similar to the findings in literature [25,28,37,38,40-46,48,49,52].
8. The 3rd generation formula SRK/T did not stand out in any way for any cohort, achieving good results in most groups, which reflects its safety, and why it has been used successfully for a long time and by many surgeons. The SRK/T formula is a guiding formula and remains unquestionable and reliable.
9. The 4th generation Barrett Universal II formula showed the best results for all axial lengths, and is a useful tool for all surgeons, especially since it does not require adjustment.
10. Readjusting the LF by changing the A constant according to the presented online method did not make significant changes in absolute prediction error, which supports the claim that the Barrett Universal II formula is suitable for a wide range of axial lengths without the need for adjustment of the constant.
11. The 4th generation Haigis formula did not perform as well as expected, highlighting the importance of optimizing all 3 constants, but optimization is difficult for clinics with a high flow of patients with all types of pathologies, where limited time is an obstacle.
12. In a separate chapter, some examples of special cases were presented, namely:
    - two cases with an axial length under 22 mm, one exemplifying the reduced efficiency of the Hoffer Q formula, contrary to expectations, and the second revealing the large difference between the refractive prediction errors of the tested formulas;
    - two cases with an axial length over 24.5 mm, the first showing the effectiveness of all the formulas for an eye with AL over 30 mm, and the second exemplifying an atypical case where the Hoffer Q formula behaved best, paradoxical to the observations in the specialized literature;

- a case that was not included in the statistical analysis because it did not meet the inclusion criteria, but which shows the significant importance of performing a correct biometric measurement.

These cases are of scientific importance, drawing attention to the variability of results that surgeons still encounter. Both the importance of perfecting the methods for obtaining optimal refractive results is revealed, as well as the possibility of the appearance of factors such as surgically induced astigmatism or biometry errors, which can influence the results.

13. In another separate chapter, the constants for 4 of the 5 formulas initially evaluated (Barrett Universal II, Hoffer Q, Holladay 1, SRK/T) were retrospectively optimized, through a method available online, and analyzed the absolute prediction errors. It was found that although the differences between the evaluated formulas decreased, revealed by the increase of P values in the Freidman test, the refractive results did not undergo statistically significant changes, drawing similar conclusions as before the reoptimization. The Barrett Universal II formula retained its superiority for the most studied groups.

Own contributions and originality of the scientific research

Regarding the personal contribution and the originality of the scientific research in this doctoral thesis, the following aspects are formulated:

1. According to the works accessed in the specialized literature, the present research represents the first work in Romania that describes in a standardized format [34,53], the refractive results obtained following the application of 5 biometric formulas, for a wide range of axial lengths, grouped into three categories.
2. The present paper not only analyzes the effectiveness of biometric formulas according to axial length, but presents results for 3 types of implant, with different optical properties, revealing the importance of carrying out personalized studies according to the characteristics of the implants.
3. Along with the advancement of medicine and technology has come improvement in the refractive results obtained from cataract surgery. Thus, the expectations of the patients also increased, which also determined the increase in the importance of choosing biometric formulas, which would provide these favorable results. The thesis is of particular importance in this aspect, especially by analyzing the results in the multifocal implant group.
4. The complexity of the scientific research in this thesis is given by the varied statistical analysis, implemented on a large number of operated cases, which were

divided into six different cohorts, depending on the type of implant (Acrysof® IQ SN60WF, Tecnis® ZCB00, Acrysof® IQ PanOptix TFNT0) and falling into a certain category of axial length (<22 mm, 22-24.5 mm, >24.5 mm), each of which has different particularities in terms of the optical properties of the implants, the variables of the evaluated eyes and the constants of the biometric formulas used.

5. The results obtained in this research were compared from a statistical point of view with the results of numerous studies published in the international specialized literature, following reports on the refractive prediction error with mean, standard deviation and interval, the absolute prediction error with mean and median, and the distribution of the refractive prediction error into dioptric groups. Following the analysis of these parameters, we obtained results comparable to various reports from international papers, where eyes with corresponding axial lengths were operated and the same biometric formulas were evaluated.

The original contributions of this doctoral thesis enrich the level of knowledge in the field of cataract surgery and crystalline refractive surgery, both in Romania and internationally, in the context of a technology in progress, and the desire of ophthalmic surgeons to obtain for their patients' refractive results as close to ideal as possible.

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