PREDICTIVE ACCURACY OF INTRAOCULAR LENSPOWER CALCULATION FORMULAE – SRK/T VS HAIGIS – A RANDOMISED CONTROL STUDY

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PREDICTIVE ACCURACY OF INTRAOCULAR LENSPOWER CALCULATION FORMULAE – SRK/T VS HAIGIS – A RANDOMISED CONTROL STUDY

DR. SWETHA RAVICHANDRAN

CHRISTIAN MEDICAL COLLEGE, VELLORE

BONAFIDE CERTIFICATE

This is to certify that this dissertation **Predictive accuracy of intraocular lens power calculation formulae – SRK/T vs Haigis – A randomized control study** done towards fulfillment of the requirements of the Tamil Nadu Dr MGR Medical University, Chennai for the MS Branch III (Ophthalmology) examination to be conducted in May 2020, is a bona fide work of Dr. Swetha Ravichandran, post graduate student in the Department of Ophthalmology, Christian Medical College, Vellore.

Dr. Andrew Braganza,
MS Ophthalmology,
Professor,
Department of Ophthalmology,
Christian Medical College,
Vellore - 632001.

Dr. Lekha Mary Abraham,
DO, DNB Ophthalmology,
Professor,
Department of Ophthalmology,
Christian Medical College,
Vellore - 632001.

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Dr. Sanita Korah, DO, MS, DNB

Professor, Head of the Department,

Department of Ophthalmology,

Christian Medical College,

Vellore – 632001

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Dr. Anna B. Pulimood

Principal,

Christian Medical College,

Vellore – 632001.

DECLARATION

This is to certify that this dissertation **Predictive accuracy of intraocular lens power calculation formulae – SRK/T vs Haigis – A randomized control study** done towards fulfillment of the requirements of the Tamil Nadu Dr MGR Medical University, Chennai for the MS Branch III (Ophthalmology) examination to be conducted in May 2020, is a bona fide work of Dr. Swetha Ravichandran, post graduate student in the Department of Ophthalmology, Christian Medical College, Vellore.

Dr. Swetha Ravichandran

Post Graduate Student,

Department of Ophthalmology,

Christian Medical College,

Vellore - 632001.

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Dr. Sanita Korah, DO, MS, DNB

Professor, Head of the Department,

Department of Ophthalmology,

Christian Medical College,

Vellore - 632001.

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Introduction

Introduction:

Cataract is the major cause of blindness worldwide. According to the World Health Organization, Cataract accounts for about 51 percent of blindness, that is about 20 million people in 2010. As the population grows and the life expectancy increases, the prevalence of cataract is also expected to increase

Cataract is cause by the degeneration and opacification of the lens fibres accompanied by aberrant lens fibres or deposits. These ultimately result in loss of transparency and loss of a clear image from being focused on the retina. Three processes are responsible for the formation of cataract – hydration of the fibres, denaturation of the proteins and sclerosis. Patients with cataract present with symptoms of gradual, painless, progressive decrease in vision, uniocular polyopia and eventually a white reflex in the visual axis. The symptoms depend upon the stages of cataract which usually progresses from immature to mature and hyper mature. Though predominantly cataract is an age-related disease, it can also occur due other causes such as trauma, metabolic diseases, dermatological diseases, physical factors or toxic agents.

No medical treatment has been proven to cure cataract. If opacification has begun, control of the general systemic condition such as diabetes which causes early lens changes, may halt the progress but the protein coagulation that has occurred remains irreversible. Therefore, the one and only treatment approved

for cataract is cataract surgery. Different methods of cataract extraction have evolved across centuries.

Initially, the lens along with the capsule was removed by rupturing the zonules, which has become obsolete now and was termed as intracapsular cataract extraction (ICCE). The procedure required a large incision and had high complication rates. The technique is indicated only when the lens is subluxated or zonular dialysis affecting more than 180 degrees. The extra capsular cataract extraction (ECCE) came into play where an opening in the anterior capsule of the lens enable delivery of the nucleus out and an intraocular lens implant is placed inside the bag left behind. Various techniques have evolved in perfecting this extracapsular lens extraction and eventually made a leap from manual small incision to phacoemulsification where the nucleus is emulsified, and the nucleus is removed by suction.

Removing the cataractous lens by either method renders the eye aphakic. The optical rehabilitation of the eye was earlier done by aphakic glasses which were nothing buy hyperopic glasses which just substituted for the lens extra-ocularly. However, the quality of the image and the cosmetic appearance was largely compromised.

The best optical rehabilitation following cataract extraction is by intraocular lenses. With current advent of modern technology, the target of treatment is to

achieve emmetropic correction. Various formulae have been deduced, derived and proven to aid in predicting the refractive outcome accurately yet refractive surprises occur post-surgery making target emmetropia elusive.

We currently use SRK/T formula on a regular basis for intraocular lens (IOL) implantation for cataract surgeries which is a third-generation formula. In this study we wish to compare the refractive outcomes of SRK/T with Haigis formula which is a fourth-generation formula. Haigis formula takes into account additional factors to predict the IOL power and has been considered superior in literature.

We propose to conduct a Randomized Control Trial on patients presenting in our department with Age related Immature Cataract to compare the predictive accuracy of SRK/T and Haigis intraocular lens power calculation formulae.

Aim of the study:

To compare the predictive accuracy of Refractive outcomes after cataract surgery using SRK/T and Haigis formulae

Objectives of the study:

Primary Objective:

To compare the refractive status after cataract surgery between SRK/T vs Haigis formula calculated preoperatively using IOL master.

Secondary Objectives:

1.To study the effect of axial length on the predictive accuracy of SRK/T and Haigis formula

2. To study the effect of anterior chamber depth on the predictive accuracy of Haigis formula

Review of Literature

Literature Review:

The first intraocular lens implantation was an historic milestone by Sir Harold Ridley at St. Thomas Hospital in London in 1949. It marked the beginning of a new era in the visual rehabilitation of patients after cataract surgery(1)

Biometry for Cataract surgery:

Biometry is the method of applying mathematics to biology(2). The term was originally used by Whewell(2) initially in the 1800s for calculating life expectancy. The refractive power of the eye primarily depends upon the cornea, the lens, ocular media, and the axial length of the eye. When planning for cataract surgery, in order to achieve the desired post-operative refraction, the required power of the intraocular lens (IOL) implant can be calculated if the corneal refractive power, media type, and axial length are known.

Fedorov and co-workers(3) first estimated the optical power of an IOL using vergence formulas in 1967. In the 1970s, after availability of accurate axial scans (A scan), studies were conducted to establish various theoretical vergence formulas. In the early 1980s, several IDEM (ideal emmetropia) lenses were also attempted by measuring the refractive error post implantation comparing to the target refractive error aimed at before surgery. On similar lines, Standard lenses were also attempted, after Gernet and Zorkendorfer(4) in 1982 showed that the average refractive power of natural lens is +23.70D. Although these were neither strictly mathematical nor ethically sound, they are mentioned in a

historical perspective. The theoretical formulae derived around the same time have been subjected to minor and major alterations in the variables since then in order to increase accuracy.

Hillman(5) in his study opines that cataract surgery technology and intraocular lens (IOL) technology have improved remarkably and become safe, the patients are expecting better postoperative refractive results, which are determined by the precise intraocular lens power calculation. The calculation is normally based on corneal power, axial length (AL) measurements and IOL calculation formulae. These three factors are considered to be the most critical factor for accurate IOL power calculation.

Hitzenberger(6) and his colleagues studied measurement of axial length in various eyes. Axial length (AL) is usually measured by applanation A-scan ultrasound, which is widely used technique. In A-scan biometry, the sound travels at a frequency of approximately 10 million Hz (10 MHz). This extremely high frequency allows for restricted penetration of the sound into tissues. The biometer measures axial lengths, the distance between the anterior corneal vertex and internal limiting membrane of the retina, along the optical axis with a resolution of 200 μm and precision of 150 μm . The method requires the use of topical local anaesthesia and contact of the cornea with a probe of A-scan, as ultrasound energy is emitted from the probe tip by pulsing electricity(7).

Olsen et al established that studies based on ultrasound biometry demonstrated 54% of all IOL power miscalculations result from wrong AL measurements(8).

Binkhorst(9), Boerrigter et al(10), Drexler(11), Olsen(12) et al studied that the error in axial length measurement of 100 μm results in postoperative refractive error of 0.25Dto 0.28D.

Drexler(11), Fercher(13) Haigis(14) and Hitzenberger(6)conducted various studies comparing laser doppler interferometry with ultrasound biometry and immersion biometry and established the following. The IOL Master is a non-contact partial coherence interferometry method for AL measurement, which has recently become commercially available It uses infrared diode laser (λ 780 nm) of high special coherence and short coherence length (160 μm). The optical scan uses an external Michelson interferometer to split the infrared beam into coaxial dual beams allowing the technique to be intensive to longitudinal eye movement. Both components of the beam illuminate the eye and are reflected at each interface where the change in refractive index occurs. If the optical path length is within the coherence length interference signal is detected by a photodetector. The IOL Master measures the ocular axial length between the corneal vertex and retinal pigment epithelium along the visual axis using red fixation beam, with a resolution of 12 μm and precision of 5 μm. Advantages of this technique is that there is no need for local anaesthesia and pupil dilation therefore method reduces the potential risk of corneal erosions or infection. The technique is observer-independent method for AL measurement.

Eleftheriadis(15) studied the refractive results of 100 consecutive cases of biometry done in IOL master. Goyal et al(16) compared the IOL master and A-

scan ultrasound in 2003. Haigis(17) and colleagues studied pseudo phakic correction factors in laser interferometry in 2001. These studies established that the measurement obtained by IOL Master has been reported more accurate and reproducible than that by ultrasound in a normal eye and in a pseudo phakic eye. Vogel et al(18) and Connors et al(19) studied the inter and intraobserver reliability if IOL master. With the advent of partial coherent interferometry, IOL master has proven its accuracy in IOL power calculation using different lens formulae as well. Ueda(20) and colleagues analysed the impact of various grades of nuclear cataracts and its effect on biometry in ultrasound vs IOL master which proved IOL master to be more accurate. Preussner (21) concluded that axial eye length with an error of approximately 0.2 D is no longer the dominating error if the measurements are performed by interferometry . But if the total error threshold is below the error of refraction, the accuracy of the IOL power calculation formula must be improved. This important part of IOL power calculation has been growing in recent years especially in eyes that have had refractive surgery.

Evolution of IOL power calculation formulae :

The first formula for the determination of intraocular lens power was published by Fedorov et al(6). In the early 1970s, first commercially available ultrasound instrumentation was adopted to clinical practice. This period gave birth to the first theoretical and empirical intraocular lens power calculation formulae. All original formulae by Fedorov , Binkhorst , Thijssen , Van der Heijde and Hoffer

are first generation theoretical formulae. They required axial length of the eye, the corneal power in dioptres, corneal radius and position of the intraocular lens along the optical axis of the pseudo phakic eye or anterior chamber depth (ACD). The main feature of first-generation theoretical formulae was that position of IOL in the eye is fixed for each lens type. This assumption was not unreasonable at that time, when cataract surgery was represented by intracapsular cataract extraction and anterior chamber intraocular lenses implantation; the anterior chamber IOL was assumed to have a defined position in relation to the anterior plane of the cornea. These theoretical formulae laid the basis for development and evolution to the current generation formulae.

Sanders, et al.(22) developed empirically determined regression formulae. First-generation regression formulas are linear functions based on retrospective analysis of postoperative refraction and biometric data and following intraocular lens implantation of a particular lens by a particular surgeon. The most relevant of these formulae is SRK formula. The required measurements are axial length and corneal power. One of the variables of the SRK formula is the A-constant which is a specific constant for each type of IOL and is determined empirically on the large sample of patients who underwent cataract surgery. A-constant is calculated for each lens type based on the refractive outcomes. This ensured that the A-constant lessened influence of variables like surgical technique, biometric instrumentation and measurement technique on IOL power calculation. For this reason, the SRK formula outperformed the first- generation theoretical formulae. The advantage of regression formula is that it is relatively simple to calculate.

Contributors to the second-generation theoretical formulae include Holladay, Prager, Chandler et al(23) and Colliac(24). Second-generation theoretical IOL power formulae differ from the first-generation formulae in that the position of the intraocular lens in the pseudo phakic eye. This position though not fixed changes as a function of two variables - axial length and corneal curvature of the eye. After Kelman (25) introduced the extracapsular cataract extraction by phacoemulsification, the second-generation of theoretical and regression formulae were developed. Phacoemulsification provided the opportunity to implant intraocular lenses within the capsular bag of crystalline lens. But the position of these posterior chamber intraocular lenses was difficult to predict, due to characteristics associated with individual lens capsule shrinkage, lens haptic design and placement of the intraocular lens within the crystalline lens capsule. This variability in the position of the implanted intraocular lens was the reason for the development of the second-generation intraocular lens power formulae.

The second-generation regression formulae by Thompson, Maumenee and Baker(26), Donzis, Kastl and Gordon(27), Olsen(12) ,Sanders, Retzlaff and Kraff(28) were designed to improved accuracy through the application of non-linear regression formulae. Most prominent amongst these is the SRK II regression formula which is a modification of the original SRK formula; it is an approximate linear function for eyes of average axial length, but exhibits nonlinearity in short and long eyes too.

Contributors to the third and fourth-generation formulas include Hoffer(4), Olsen(29), Retzlaff, Sanders and Kraff(30), Holladay(31) and Haigis(17). According to these studies, despite the advances in the precision of ocular biometry, differences in calibration, individual lens capsule shrinkage, IOL design as well as surgical variations limited the ability of any formula to predict the post-operative axial position of the intraocular lens. Hence, the modern generation formulae were developed. Most of them are modifications of original theoretical and regression formulae, through a combination of algebraic and statistical methods.

Olsen(8) in his study establishes that the greatest challenge for the calculation of intraocular lens power lies in the accurate prediction of pseudo phakic lens position and not in the intraocular lens power formulae themselves. The issue of the axial position of an intraocular lens in the pseudo phakic eye is still poorly understood and misrepresented topic in intraocular lens power calculation. Different researchers use in their formulae different variables like ‘A- constant’, ‘surgeon-factor’, ‘anterior chamber depth’ and ‘effective lens position’ to describe lens position in the pseudo phakic eye.

In this regard, the strength of the empirical approach (SRK and SRK-II regression formulae) is that it does not measure the position of the intraocular lens in the pseudo phakic eye, but this value is implicit in the calculation of the A-constant for each lens type. Olsen found that for any given formula as many as 20 – 40% of all undesirable Refractive outcomes following intraocular lens

implantation may be related to inaccurate prediction of the pseudo phakic lens position.

The IOL constants and the corresponding power of the IOL works based on a power prediction curve for a particular formula(32). Each formula has a fixed power prediction curve for each type of IOL. Greater the IOL constant, the greater the IOL power for the same set of axial length and keratometry readings. These formulae will give the same intraocular lens power for two eyes of same axial length and keratometry. However, in real it is not true as other variables also play an important part. The actual distance from the cornea to the lens which is the effective lens position and the geometry of the IOL (IOL design) are important such factors.

With standard constants used for intraocular lenses, surgeons can move from one formula to another for the same IOL implant. The shape of the power prediction curve is also constant for each formula irrespective of the IOL implant used. But variations in the keratometers, ultrasound machines, the capsulorrhexis and other surgical techniques can affect the IOL implant power to be implanted. They can all have an impact on the refractive outcome as independent variables.

The lens constant of a given IOL implant and formula can be “personalised” to make adjustments for the above mentioned variables(33). The third generation formulae assume the distance from the principle plane of the cornea to the thin lens equivalent IOL. It assumes that Short axial length eyes have shallow

anterior chamber and long axial length eyes have deeper anterior chamber. But most often short axial length eyes have a normal anterior chamber depth and anatomy in the pseudo phakic state. The lens volume prior to cataract extraction would have made the anterior chamber appear shallow in short axial length eyes. Therefore after cataract extraction the effective lens position would be almost the same as normal axial length eyes. But the formula would have calculated for a shallow anterior chamber depth. This can be attributed to limited predictive accuracy of refractive outcome in extremes of axial length in third generation formula such as SRK/T, Holladay and Hoffer Q formulae.

Holladay formula has been reported to be relatively accurate for normal to longer axial length eyes while Hoffer Q has been found to be better for shorter axial length eyes.

The SRK/T Formula:

The earliest IOL power calculation formulas, in the late 1970s and early 1980s, were either theoretical or regression formulas. One of the most successful regression formula was the SRK formula devised by Donald R. Sanders, John A. Retzlaff and Manus C. Kraff.

The SRK formula(30) uses P = A – BL – CK equation to calculate the IOL implantation power , where

- P is the implant power for emmetropia

- L is the axial length (mm)

- K is the average keratometry (D)

- A, B, and C are constants.

The values of B and C are 2.5 and 0.9, respectively, and the value of A varies with the IOL design and the manufacturer.

With this information, the formula can be written as P = A – 2.5L - 0.9K.

Over the years, surgeons discovered that the SRK formula is best used in eyes with average AL, between 22.00 and 24.50 mm. Subsequently they developed a formula, the SRK II for use in long and short eyes. In this formula, a correction factor was added to increase the lens power in short eyes and decrease it in long eyes: P = A1 – 0.9K -2.5L.

For eyes with AL of less than 20.00 mm, a numerical value of 3.00 is added to the A constant; a numerical value of 2.00 is added if the AL measures between 20.00 and 20.99, a numerical value of 1.00 if the measurement is between 21.00 and 21.99, and -0.50 if the AL is greater than 24.50 mm.

Newer formulae were developed to increase the predictive accuracy which includes anterior chamber depth (ACD) based on AL and corneal curvature. The SRK/T (T for theoretical) is a formula, representing a combination of linear regression method with a theoretical eye model.

Based on the nonlinear terms of the theoretical formulas, the SRK/T also incorporates empirical regression methodology for optimization, resulting in greater accuracy. The SRK/T and other third-generation formulas work best for near-schematic eye measurements.

The SRK/T formula optimized the prediction of postoperative ACD, retinal thickness AL correction and corneal refractive index. It can be calculated using the same A constants used with the original SRK formula or with ACD estimates. However, this calculation does not account for effective lens position.

The Haigis Formula:

The Haigis formula(33) is a newer formula which surmounts the limitations of the other third generation formulae. Instead of moving across the power prediction curve in a fixed formula specific manner, the Haigis formula uses three A constants, a0,a1 and a2. The three constants manage prediction across the position and shape of the power prediction curve.

The effective lens position (ELPO) or (d) is given as

$d = a0 + (a1 * ACD) + (a2 * AL)$

- ACD - the anterior chamber depth of the eye

- AL - the axial length of the eye which is the distance from the cornea vertex, to the vitreoretinal interface
- a0 - the constant that moves the power prediction curve up or down . It is similar to the A-constant, Surgeon Factor, or ACD does for the Holladay 1, Holladay 2, Hoffer Q and SRK/T formulae
- a1 - the constant tied to the measured anterior chamber depth
- a2 - the constant tied to the measured axial length

Thus the value of the effective lens position, d, is a function of multiple variables and not a single number as in the case of other third generation formulae.

The three a constants a0,a1,a2 are derived by multi-variate regression analysis. This is done from a large pool of surgeon and IOL specific outcomes in various axial length ranges and anterior chamber depth measurements. The resultant constants of a0,a1and a2 are close at hand to the actual results for a specific surgeon and IOL design. As a result the calculation in Haigis formula is individually adjusted for each surgeon and IOL combination.

Thus comparing, the third generation formulae effective lens position in various formulae are

- **SRK/T formula, d = A - constant**
- Hoffer Q formula, d = ACD
- Holladay 1 formula, d = Surgeon Factor

- Holladay 2 formula, d = ACD
- **Haigis formula, d = a0 + (a1 * ACD) + (a2 * AL)**

The fundamental to high predictive accuracy of the refractive status is based upon the correct effective lens position for a given patient and intraocular lens implant.

Therefore we look at actual observed outcomes and adjust "d" for measured axial lengths and anterior chamber depths. This can be done by multi-variable regression analysis.

For example, say there are two lenses of A-constant 118.4 used in SRK/T formula. Lens A is an acrylic single piece IOL with a positive shape factor and lens B is biconvex 3- piece PMMA IOL with 10 degree per millimeter of posterior haptic angulation.

The A constants for Lens A – a0: -1.441, a1: 0.064, a2: 0.261 and for Lens B – a0: 1.274, a1: 0.189, a2: 0.128.

Consider three patients, Patient 1: Axial length = 28.25mm, Anterior Chamber Depth = 3.45mm; Patient 2: Axial length = 23.45, Anterior Chamber Depth = 3.25mm; Patient 3: Axial length 21.25mm, Anterior Chamber Depth = 2.75mm.

The effective lens position ‘d’ can be calculated using d = a0 + (a1 * ACD) + (a2 * AL).

The table showing effective lens position ‘d’ for Haigis formula.

	Patient 1	Patient 2	Patient 3
Lens A	6.15	4.89	4.28
Lens B	5.54	4.89	4.51

In longer axial length eyes, the Haigis Formula will call for a higher power for Lens A than for Lens B. For axial emmetropes or normal axial length range, both constants will give the same IOL power. And for axial hyperopes or shorter axial length eyes, the Haigis Formula will call for a lower power for Lens A than for Lens B. This points out the fact that by regression analysis we can set in information regarding differences in geometry and design of the two IOLs within the three Haigis Formula lens constants.

Thus, the Haigis Formula has a new level of mathematical flexibility. As the a0, a1 and a2 Haigis constants for the more commonly used IOLs become established, the Haigis Formula is embedded with ultrasound machine such as the IOL master.

IOL Designs and Geometry:

Guell JL(34) studied the post-operative changes in various IOL types. Polymethyl methacrylate IOLs used to be the gold standard, but the inability of folding limits their use to selected countries and patients. Silicone IOLs were used more in the past because they are less suitable for microincisions. Foldable hydrophobic acrylic is the most popular material, which is also available in yellow (blue light absorbing) models and several IOL shapes. Although a very effective and safe material, water penetration producing glistenings and some dysphotopsia has been reported with some IOL types. Foldable hydrophilic material is widely employed in Europe, and especially for microincision cataract surgery lenses because of its plasticity, even if rare optics opacification and higher posterior capsular opacification rates have been reported in the past. Single-piece IOLs are the most employed in modern cataract surgery, but 3-piece IOLs are preferred for sulcus implantation and in infants. The aspheric design to correct or to control spherical aberration in implanted eyes is now the rule after the problems of centration we had before the capsulorrhexis era were solved.

Properties of a successful IOL(35) are biomaterial optical purity for long term transparency, refractive reliability, stable foldability, sharp edge technology for prevention of posterior capsular opacification and capsular bag performance. The long-term transparency can be affected due to lens opacification, posterior

capsular opacity, fibrosis and glistenings. Glistenings are fluid filled microvacuoles formed within the polymer matrix of the lens on exposure to the aqueous. Factors that influence the formation of posterior capsular opacification are IOL geometry, haptic angulation, the 360-degree square edge effect, IOL material and also high-quality surgery with capsular bag implantation. The choice of single piece vs three piece in prevention of PCO still points towards single piece. Haptic angulation increases the capsular bag tension, thereby increases the area of contact between the optic posterior surface and posterior capsule. The square edged concept is a physiological barrier by contact inhibition of cell migration from the equator of the capsular bag to the center of the posterior capsule. Hydrophobic acrylic lenses are now recommended due to its adhesive properties and lesser incidence of posterior capsule opacification.

Tecnis Intraocular lens:

An aspheric monofocal IOL may be ideal for most patients(36). The Tecnis IOL has a wave front-designed anterior-surface optic. This has a fixed amount of negative spherical aberration that compensates for the positive spherical aberration of the average human cornea. The Tecnis IOL is the only aspheric IOL developed based on wave front-aberration analyses of human corneas(36). Corneal topography measurements on patients with cataracts were averaged and used to design a model cornea reproducing the average spherical aberration in the aging eye.(37) A multicentric control trial demonstrated that

the Tecnis IOL design has significantly less spherical aberrations almost zero than a spherical acrylic IOL(38).

The Tecnis IOL has a rounded anterior edge designed to scatter light, to reduce internal reflections, a sloping side edge that minimizes the potential for edge glare, and a squared posterior edge that facilitates 360º capsular contact.

By targeting zero spherical aberration with the aspheric Tecnis IOL, it is possible to enhance contrast sensitivity and improve functional vision. A recent study conducted by Packer and colleagues showed that the Tecnis IOL provides up to 31% better contrast sensitivity under photopic conditions compared with a spherical IOL(39). The integration of wave front technology and lens-based surgery demonstrated by the Tecnis IOL represents a step toward improving functional vision and quality of life for cataract patients.

Hoya intraocular lens implant:

Hoya vivinex isert is a square edge IOL made of hydrophobic acrylic material with grade zero glistening and surface scattering. It is an ozone / ultraviolet rays treated IOL and hence has increased adherence of the IOL to the posterior capsule. The safety and efficacy of this surface modification was tested on animals and then a clinical trial was conducted. The clinical trial(40) demonstrated significant decrease in the incidence of posterior capsular opacification. The hoya lens is also an yellow lens – blue filtration which has proven to protect the retinal pigment epithelium and progression of macular

disease(41). When we remove the yellow crystalline lens the retina is exposed to increased blue light by a white IOL. This is toxic to the retina and causes progression of macular disease and disorders of the Retinal pigment epithelium.

Protocol for studying the predictive accuracy of formulae(42) has been established by veterans in the evolution and analyses of various formulae. They studied the spherical equivalent of the refractive outcome predicted by the formula and that actually achieved. It was advised to study a single type of Intraocular lens however if the other eye had a yellow lens the study warrants to include two types of lenses.

R. Sharma et al(43) compared the accuracy of the predictions of SRK–T and Haigis Formulae in 50 patients retrospectively. All the parameters were calculated using Zeiss IOL Master Scan, based on Partial Coherence . The patients who underwent phacoemulsification by a single surgeon with a temporal corneal incision and a standard Alcon Acrysof MA30 implant in the bag were studied. The pre–operative IOL power calculations were done using both SRK–T and Haigis formulae. The final implant power selection was based on SRK–T predictions. The patients were divided into 3 groups depending on the axial length (<22mm, 22–24mm, >24mm) and postoperative refractive outcomes were analysed at 4 weeks. The difference between the predicted value and the post–operative spherical equivalent obtained for both the formulae for the different axial length subgroups were analysed. Haigis formula had better

predictive accuracy than SRK–T in all axial length subgroups. Achieving the predicted post - operative refraction is a challenge in any cataract surgery and this makes the choice of IOL formula to be used for calculation very important

Mansur et al(44) in a prospective interventional clinical study of 70 eyes from 60 patients, who underwent uncomplicated phacoemulsification with IOL implantation between October 2015 and December 2017. Preoperative axial length (AL), corneal curvature (keratometry), and preoperative anterior chamber depth (preoperative ACD) were measured using Nidek AL-scan optical biometer. The IOL power was determined using both SRK/T and Haigis formulae. The difference between the predicted value and the postoperative spherical equivalent was calculated for both the formulae by the end of the follow-up (3 months postoperatively). The mean errors and the mean absolute errors of the two formulae were analyzed. There was no statistically significant difference between the mean error of the two formulas used in the overall performance. However, in eyes with axial length more than 25mm but was significant in eyes with an AL of more than 25 mm Haigis showed better predictive accuracy than SRK/T formula. There was a weak correlation between the mean AL, keratometry and the Haigis–SRK/T prediction differences.

Yang et al(45) investigated the effect of anterior chamber depth (ACD) on the refractive outcomes of four formulae (SRK/T, Holladay 1, Hoffer Q and Haigis

formulae) in axial lengths of all ranges. It was a retrospective study on patients who had uncomplicated cataract surgery. The axial length (AL) was categorised into four subgroups: short (< 22.00 mm), normal (22.00–24.49 mm), long (24.50–25.99 mm), extremely long (≥ 26.00 mm). Preoperative ACD was divided into three subgroups: < 2.5, 2.50–3.49, and ≥ 3.5 mm. Median absolute errors predicted by the SRK/T, Holladay 1, Hoffer Q and Haigis formulae were compared using the Friedman test. Post-operative analysis involved the Wilcoxon signed rank test with a Bonferroni adjustment. Correlations between ACD and the predictive refractive errors of the four formulas were analysed. In short eyes with an ACD < 2.5 mm, the Haigis formula revealed the highest Median absolute error. Therefore, in short axial length eyes Hoffer Q had better predictive accuracy compared to Haigis formula which was statistically significant. In normal axial length eyes with anterior chamber depth >2.5mm the Haigis formula significantly differed from the Holladay 1 and Hoffer Q formulae. In long eyes and extremely long eyes with an ACD ≥ 3.5 mm, the differences in Median Absolute Errors were statistically significant with the Haigis formula having the lowest Median Absolute Errors in both subgroups. In a total of 1123 eyes, refractive errors predicted by the Haigis formula showed a significant negative correlation with the anterior chamber depth.

Thus, the Hoffer Q formula is preferred over other formulae in short eyes with an ACD shallower than 2.5 mm. In short and normal eyes with an ACD < 2.5 mm the Haigis formula might underestimate ELP. The Haigis formula becomes

the preferred formula of choice in eyes with an AL ≥ 24.5 mm and an ACD ≥ 3.5 mm.

Wang JK, et al(37) evaluated the predictability of intraocular lens (IOL) power calculations using the IOL Master (Carl Zeiss) and different IOL power calculation formulae in eyes with a long axial length (AL) in Taiwan. The study included 68 eyes with an Axial length longer than 25.0 mm that underwent phacoemulsification with IOL implantation. Preoperative AL and keratometry measurements were obtained with the IOL Master (Group 1) or with applanation ultrasound and automatic keratometry (Group 2). The power of the implanted IOL was used to calculate the predicted postoperative spherical equivalence (SE) by various formulae: SRK/T, SRK II, Holladay 1 and Haigis. The predictive accuracy of the formula was analyzed by comparing the mean absolute error (MAE). AL measured by the IOL master was longer compared to applanation ultra-sound biometry. The use of optical or ultrasound biometry data in the SRK/T, SRK II, and Holladay 1 formulae resulted in similar accuracy of IOL power prediction in eyes with higher myopia. The IOL power calculated using the Haigis formula gave the best predictive accuracy of refractive outcomes in long eyes.

Thakur et al(46) compared the accuracy of Intraocular Lens (IOL) power calculation formulae in high axial myopia. 27 eyes of 22 patients with longer axial length between 26mm to 30mm were studied. The eyes were divided in to two groups. Group 1 consisted of AL 26-28mm consisting of 23 eyes and Group 2 had AL 28-30mm consisting of four eyes. The predictive accuracy of four formulae SRK-T, Hoffer Q, Haigis and Holladay 2 were compared. The predictive accuracy within ±1 D of the formulae in Group 1(axial length 26-28) is 88% with SRK-T, 87% with Hoffer Q, 88% with Haigis and 91% with Holladay 2. The predictive accuracy of SRK-T, Hoffer Q and Haigis was comparable for target refraction of ±1.0 D. Haigis and Holladay 2 gave better results for target refraction of ±0.5 D for Group 1 and Haigis and Holladay 2 performed better for Group 2.

Dharmil Doshi et al (47) studied the accuracy of Intraocular Lens (IOL) power calculation and the selection of the most appropriate formula in high myopic and hypermetropic patients. A prospective study was conducted on 80 consecutive patients who underwent phacoemulsification with monofocal IOL implantation. Preoperative keratometry was done by IOL Master. Axial length and anterior chamber depth were measured using A-scan machine ECHORULE 2 (BIOMEDIX). Patients were divided into two groups based on axial length (40 in each group). Group A with AL<22 mm and Group B with AL>24.5 mm. The IOL power calculation in each group was done by Haigis, Hoffer Q, Holladay-I, SRK/T formulae using the software of ECHORULE 2. The actual postoperative Spherical Equivalent (SE) and Absolute Error (AE) were calculated at one and

half months. The predictive accuracy of each formula in each group was analyzed by comparing the Absolute Error (AE). The Kruskal Wallis test was used to compare differences in the (AE) of the formulae. In Group A, axial length less than 22mm, Hoffer Q, Holladay 1 and SRK/T formulae were equally accurate in predicting the postoperative refraction after cataract surgery. The accuracy of these three formulae was significantly higher than Haigis formula. However, in Group B, axial length more than 24.5mm, Hoffer Q, Holladay 1, SRK/T and Haigis formulae were equally accurate in predicting the postoperative refraction.

The Comparative Study of Refractive Index Variations between Haigis, SRK/T and Hoffer-Q Formulas Used for Preoperative Biometry Calculation in Patients with the Axial Length >25 mm was a randomized clinical trial study performed in Isfahan University of Medical Sciences in 2012–2013. Haigis, Hoffer Q and SRK/T were studied and Haigis was found to have a better predictive accuracy than SRK/T and Hoffer Q(48). Further studies also proved that using optimized A constant instead of surgeon specific A constant in case of Haigis formula showed no statistically significant difference(49).

Thus, Haigis formula is suggested to have better predictive accuracy in longer axial length eyes. The current practice at our institution is SRK/T third generation formula in normal axial length eyes. The haigis formula which gives better prediction of the estimated lens position is to be studied in normal axial length eyes.

Further newer formulae like Olsen and Barett's universal formula have evolved. The Olsen formula(50) uses exact ray tracing and thick- lens considerations to account for the true physical dimensions of an eye's optical system. It uses the same technology employed by physicists to design telescopes and camera lenses. A key feature of the Olsen formula is accurate estimation of the IOL's physical position using a newly developed concept, the C-constant. The C-constant can be thought of as a ratio by which the empty capsular bag will encapsulate and fixate an IOL following in-the-bag implantation. This approach predicts the IOL position as a function of preoperative anterior chamber depth and lens thickness. Because this approach works independent of traditional factors such as eye length, keratometry (K), white- to-white dimension, IOL power, age, and gender, it can work in any type of eye, including those that have previously undergone refractive surgery. Its only requirements are accurate measurements of anterior chamber depth and lens thickness, both of which are provided by the LENSTAR optical biometer.

The Barrett Universal II(51) is an upcoming formula based on Gaussian principles or ray tracing. It contrasts from conventional formulae in that it analyses the change in principal planes that occur with different intraocular lens powers. It also modifies the calculation depending on whether the optic configuration alters from a biconvex to a meniscus lens. It identifies the changing versions that occur when a lens changes from a positive lens to a minus lens. The Barrett Universal II takes into account 5 variables. In addition to axial length, keratometry, and optical ACD, the formula takes into account

the lens thickness as well as white to white. The lens thickness adds additional accuracy to the prediction across all axial length ranges.

The Barrett Toric calculator predicts a posterior corneal curvature, which is different for each individual patient. It is based on a theoretical model, proposed to explain the phenomena of posterior corneal astigmatism and its tendency to be an against-the-rule effect vertically orientated in the majority of patients. For a toric intra ocular lens, besides keratometry, topography is always required. This is implemented in the Topcon Aladdin Biometer with precise interferometry. Precise control of the distance from the device to the patient's cornea adds another layer of accuracy. A device that contains keratometry and topography together is a tremendous advantage to the surgeon.

The Kane formula(52) is another new generation IOL calculation formula created using volumes of data sets from selected high-volume surgeons. This formula uses a combination of theoretical optics, thin lens formulas and 'big data' as quoted to make its predictions. The Kane formula uses the axial length, keratometry, anterior chamber depth, lens thickness, central corneal thickness and gender of the patient to tweak its predictive accuracy. The Hill-RBF method incorporated uses adaptive learning from a large dataset to predict refractive outcomes.

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Methodology

Methodology:

Study design:	Randomized control parallel trial with equal allocation in both arms
Study Population:	This is a hospital-based study. All patients with age related immature cataract presenting to outpatient department of Department of Ophthalmology – Schell campus, Christian Medical College, a tertiary care center, willing to participate in the trial and fulfilling the inclusion criteria
Inclusion criteria:	Patients above the age of 50 years Existence of age-related immature cataract No previous surgery of anterior or posterior segment Biometry for IOL power calculation possible by optical biometry using partial coherence interferometry

Exclusion criteria:	Non-correctable retinal or corneal problem Glaucoma Patient with psychiatric illness Traumatic cataract Corneal degenerations Squint High corneal astigmatism (more than 2.5D by keratometry)
Randomization:	Block randomization method Allocation concealment by Envelope which is opened after consenting the patient.
Blinding and masking	The optometrist checking the postoperative best corrected visual acuity at 6 weeks is blinded

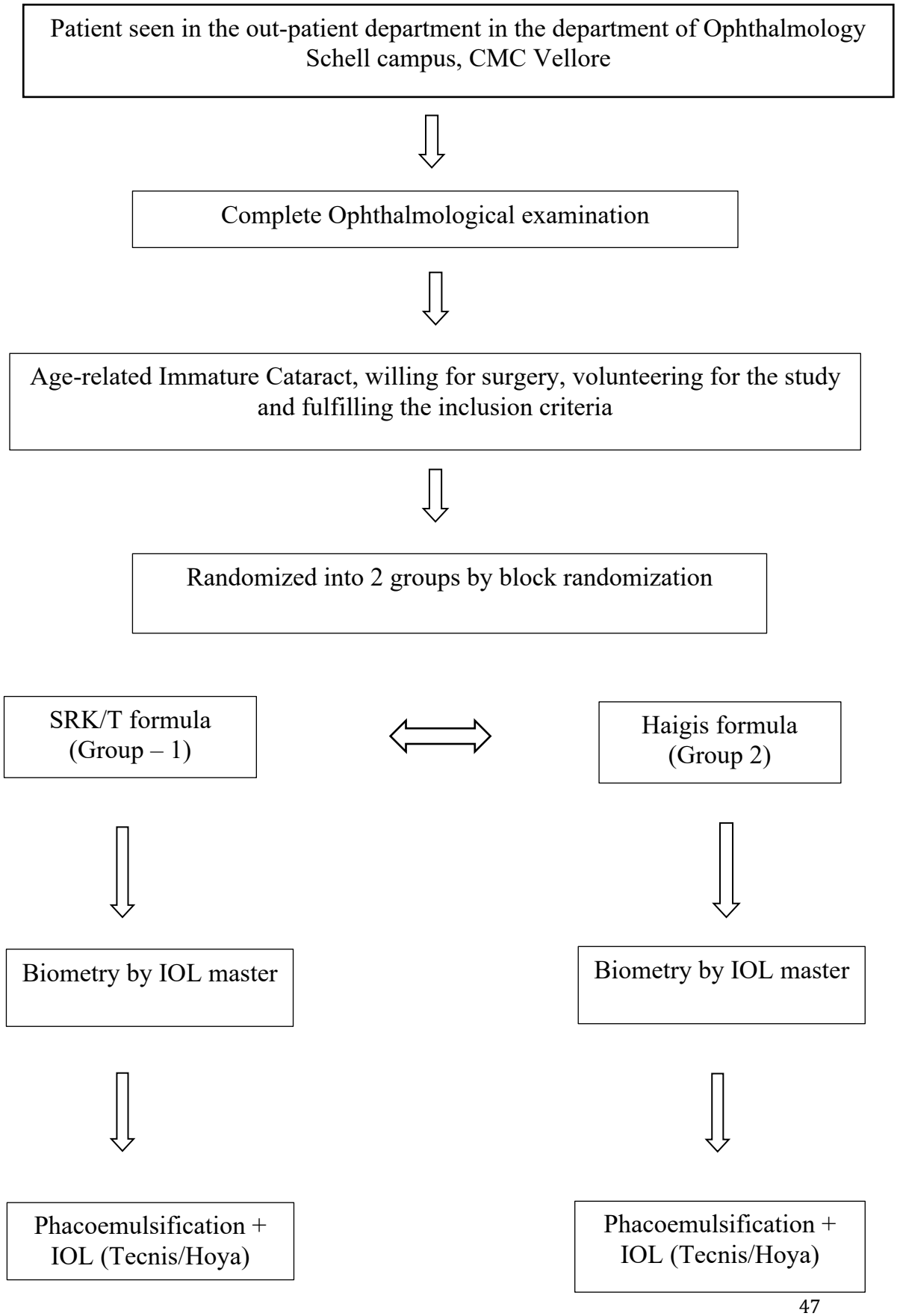
Patients of age >50 years, preoperative corneal cylinder value less than 2.5D diopter, the existence of age-related cataract confirmed by ophthalmologist, no previous surgery of anterior or posterior segment in the same eye and consenting for the study were selected. The exclusion criteria were non-correctable retinal and corneal problems affecting vision, other eye pathologies except cataract, surgical-related complication during surgery and post-operation and inaccessibility to patients after operation for re-visiting.

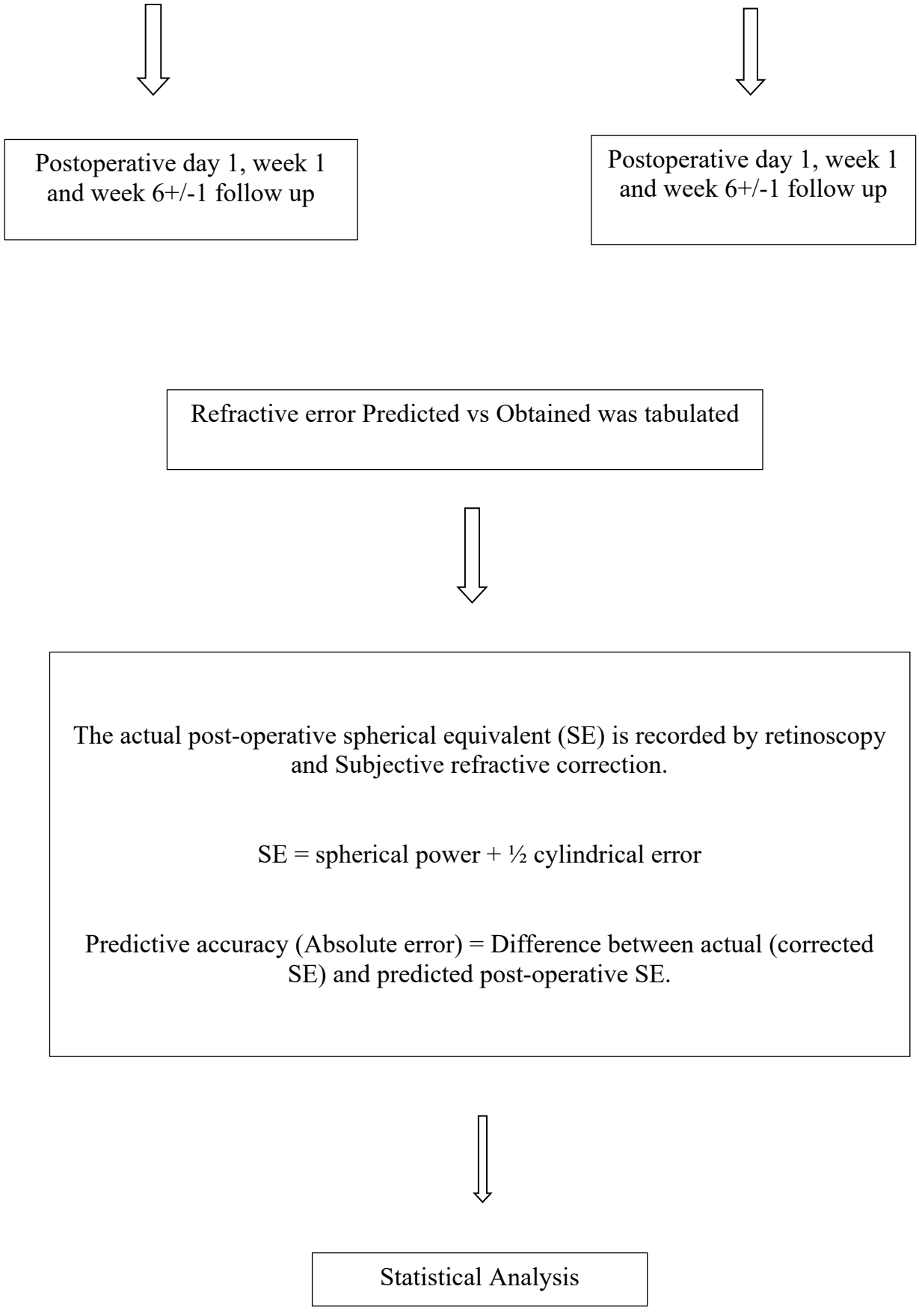
All patients underwent complete ocular examination including best corrected visual acuity, intraocular pressure (IOP) measurement, slit-lamp examination and fundoscopy. Biometry by IOL MASTER was done by three optometrists recruited for the study after randomizing the participants into two groups (SRK/T and Haigis groups) by block randomization.

Two experienced surgeons of same skill and technique performed all operation using standard phacoemulsification through a 2.8 mm clear cornea tunnel incision without suture with in the bag IOL implantation. The intraocular lens implant was restricted to two types of aspheric lenses proven to be superior – Tecnis and Hoya single piece foldable lenses. Only one eye of one patient was included in the study.

Patients were followed up for examination on the first post op day, after 1 week and then 6 +/- 1 weeks later. Best corrected visual acuity was done at 6 weeks (+/- 1) visit by two senior optometrists who were blinded to the formula used. The axial length and keratometry readings were also measured post-operatively at 6 weeks.

Diagrammatic Algorithm of the study:




Postoperative day 1, week 1 and week 6+/-1 follow up
Postoperative day 1, week 1 and week 6+/-1 follow up
Refractive error Predicted vs Obtained was tabulated
The actual post-operative spherical equivalent (SE) is recorded by retinoscopy and Subjective refractive correction.
SE = spherical power + ½ cylindrical error
Predictive accuracy (Absolute error) = Difference between actual (corrected SE) and predicted post-operative SE.
Statistical Analysis

Statistical Methods

Statistical methods and Sample size calculation:

The sample size was calculated using the formula below to compare the mean absolute error between the two groups. 'n' is the number of patients per arm, which is given by,

$$n = \frac{2s_p^2\left[Z_{1-\alpha/2} + Z_{1-\beta}\right]^2}{\mu_d^2}$$

$$s_p^2 = \frac{s_1^2 + s_2^2}{2}$$

Where,

s_1^2 : Standard deviation in the first group

s_2^2 : Standard deviation in the second group

μ_d^2 : Mean difference between the samples

α : Significance level

1- β : Power

S_1 = 0.75

S_2 = 0.46

μ^2_d = 0.6

α = 5%

1-β = 90%

$s^2_p = (0.75)^2 + (0.46)^2 / 2$

$= 0.3871$

$n = 2(0.3871)[1.96 + 1.282]^2 / 0.36 = 23$

n = 23 in each arm

In reference to the study done by Dharmil Doshi et al A Comparative Study to Assess the Predictability of Different IOL Power Calculation Formulas in Eyes of Short and Long Axial Length. J Clin Diagn Res JCDR. 2017 Jan;11(1):NC01–4.

Statistical methods:

Data entry was done on Microsoft excel

All analyses were done using Statistical Package for Social Services (SPSS) software Version 21.0 (Armonk, NY: IBM Corp).

Categorical variables were summarized using counts and percentages.

Normally distributed variables were summarized using mean and standard deviation. Skewed variables were reported as median and interquartile range

Chi square test was used to compare the proportions between the groups.

Two sample t-test was used to compare the means between two groups.

Kruskal Wallis, Mann-Whitney non-parametric tests were used to analyze multiple variables.

For all the analysis, 5% level of significance was considered to be significant.

Results

Results:

In this randomized control study, 70 eyes were recruited into two group by block randomization but only 59 eyes were taken for analysis in view of intraoperative complications, absenteeism for surgery and follow up.

Group 1 patients underwent IOL implantation based on SRK/T formula (29 patients) and Group 2 patients underwent IOL implantation based on Haigis formula (30 patients) which was 51% and 49% respectively. (Figure1)

There was a total of 30 men and 29 women which was distributed between the two groups as 18 men and 11 women in Group1 and 12 men and 18 women in group 2 (Table 1). Of the 59, 26 eyes were right and 33 were left. Group 1 had 15 right eyes and 14 left eyes whereas Group 2 had 11 right eyes and 19 left eyes. (Table 2)

The axial length ranged from 22.04 to 24.79 with majority of cases less than 24mm. Only 7 eyes had axial length between 24.00 – 24.99mm. (Table 3) However, the axial lengths were equally distributed between the two groups when categorized into 3 subgroups of 22.00-22.99, 23.00- 23.99 and 24.00 to 24.99. (Table 4)

The anterior chamber depth was measured for all patients irrespective of the formula used. They were sub grouped into 3 for analysis as ranging from 2.50 – 3.00mm, 3.00 – 3.50mm and > 3.50mm.(Table 5).

Two types of intraocular lenses were used with A constants of 118.8 and 118.9. (Tables 6,7). The corneal power of the eyes studied ranged between 41.2 to 47.61. Between the groups, Group 1 had corneal power ranging from 41.21 D to 46.56 and Group 2 had corneal power ranging from 41.42 to 47.6 (table 9). The overall baseline characteristics were studied, and the distribution was found to be statistically non-significant. (Table 10).

The actual refractive outcome (SE) was found to be myopic in both groups. (Table 11) In this study, by comparing the two Groups using Kruskal Wallis test, there was no statistically significant difference between the MAEs of the two formulae used with respect to axial length range 22.00mm – 24.99mm. (Table 14 and Table 15).

Fig.1 Distribution of eyes after randomization.

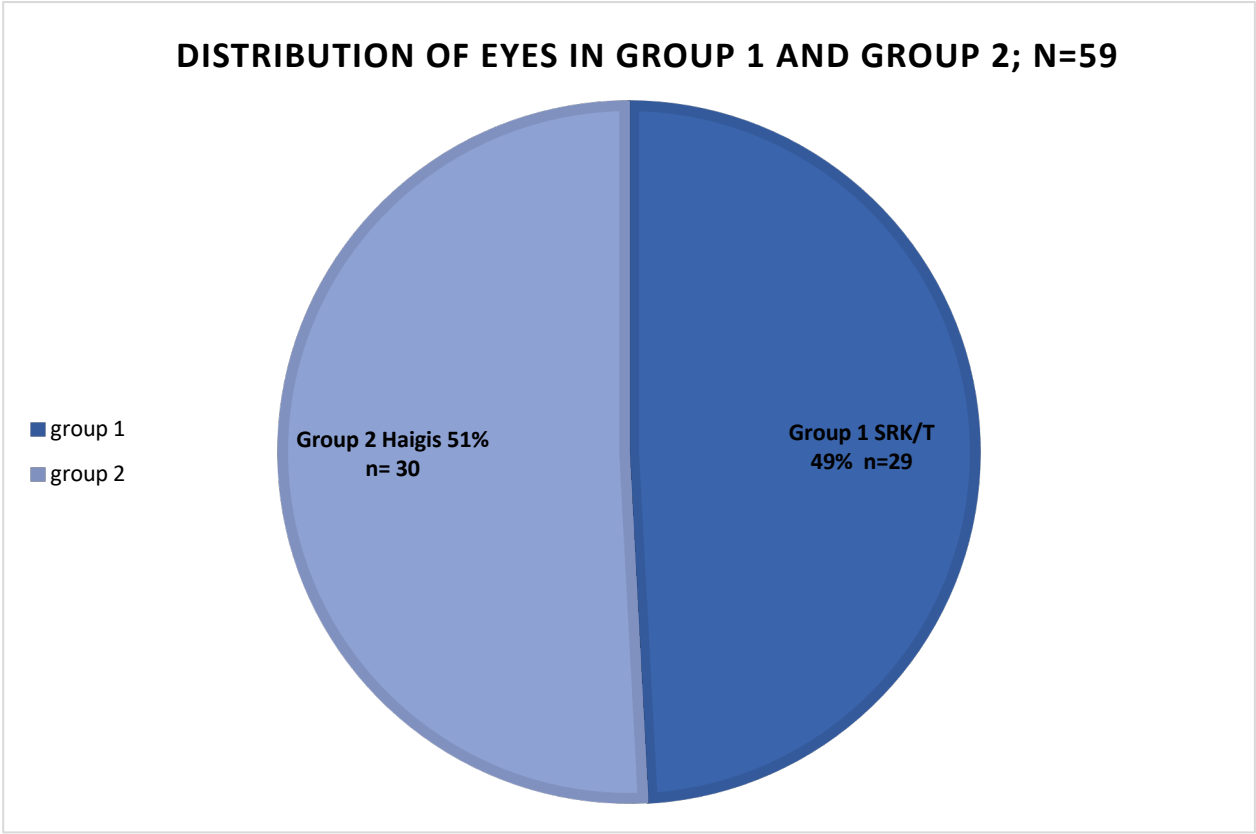


Table 1. Distribution of males and females in the two groups

	Group 1 – SRK/T (n=29)	Group 2 – Haigis (n=30)
Male	18 (62.1%)	12 (40%)
Female	11 (37.9%)	18 (60%)

Table 2. Distribution of eyes in the two groups

	Group 1 – SRK/T (n=29)	Group 2 – Haigis (n=30)
Right eye (n=26)	15 (51.7%)	11 (36.7%)
Left eye (n=33)	14 (48.3%)	19 (63.3%)

Table 3. Axial length range in all eyes.

Axial Length Range (mm)	Frequency (n=59)	Percentage (%)
22.00 - 22.99	26	44.1
23.00 – 23.99	26	44.1
24.00 – 24.99	7	11.9

Table 4. The axial length of eyes distributed in Groups 1 and Group 2

		AL 22.00-22.99 (n=26)	AL 23.00-23.99 (n =26)	AL 24.00-24.99 (n =7)	Total (n =59)
Group-1	Count	12(41.4%)	14(48.3%)	3(10.3%)	29
SRK/T	%within group	46.2%	53.8%	42.9%	
Group-2	Count	14(46.7%)	12(40%)	4(13.3%)	30
HAIGIS	%within group	53.8%	46.2%	57.1%	

AL – Axial Length in mm

Table 5. Anterior chamber depth in all eyes

ACD (mm)	Frequency (n=59)	Percentage (%)
2.50 – 3.0	16	27.1
3.0 – 3.50	31	52.5
>3.50	12	20.3

ACD – Anterior Chamber Depth

Table 6. Anterior chamber depth distribution in the groups

		ACD 2.50- 3.0 (n =16)	ACD 3.0-3.50 (n =31)	ACD >3.50 (n =12)	Total (N =59)
Group-1 SRK/T	Count	5(17.2%)	17(58.6%)	7(24.1%)	29
	% within group	31.3%	54.8%	58.3%	
Group-2 HAIGIS	Count	11(36.7%)	14(46.7%)	5(16.7%)	30
	% within group	68.8%	45.2%	41.7%	

ACD – Anterior Chamber Depth

Table 7. Distribution of intraocular lens type

IOL type	Frequency (n=59)	Percentage (%)
Tecnis	36	61%
Hoya	23	39%

IOL – Intra Ocular Lens

Table 8. Distribution of IOL type in the two groups.

		TECNIS (n =36)	HOYA (n =23)	Total
Group-1	Count	19(65.5%)	10(34.5%)	29
SRK/T	%within group	52.8%	43.5%	
Group-2	Count	17(56.7%)	13(43.3%)	30
HAIGIS	%within group	47.2%	56.5%	

Table 9. Average Corneal Power distribution between the two groups

	Group 1 (SRK/T)	**Group 2 (Haigis)**
Mean Average-K	44.31	44.12
Standard deviation	1.51	1.34
Range	41.21 – 46.56	41.42 – 47.61

Table 10. Baseline characteristics of the eyes studied

Parameter	Value
Gender, n (%)	
Male	30 (50.8%)
Female	29 (49.2%)
Age (years)	
Mean +/- SD	63.83 +/- 7.00
Eye operated, n (%)	
Right	26 (44.1%)
Left	33 (55.9%)
Axial length (mm)	
Mean +/- SD	23.16 +/- 0.69
Range	22.04 - 24.79
Keratometry (Diopters)	
Mean +/- SD	44.21 +/- 1.43
Range	41.21 – 47.61
Anterior chamber Depth (mm)	
Mean +/- SD	3.20 +/- 0.35
Range	2.60 – 4.08
IOL type, n (%)	
Tecnis	36 (69%)
Hoya	23(21%)
IOL power (diopters)	
Mean +/- SD	22.50
Range	16-26

SD: Standard Deviation

Table 11. The predictive refractive outcome and the absolute error in Group 1 and Group 2

Group		**Predicted refractive outcome**	**Actual refractive outcome (SE)**	**Absolute error (AE)**
Group 1	Mean	-0.28	-0.24	0.021
SRK/T formula	SD	+0.14	+0.46	0.44
	Range	-0.50 to +0.08	-1.00 to +0.63	-0.82 to+0.75
Group 2	Mean	-0.22	-0.59	-0.33
Haigis formula	SD	+0.18	+0.36	+0.38
	Range	-0.75 to +0.13	-1.50 to 0.00	-1.24 to +0.68

SD – Standard deviation

Table 12. Absolute error ranges across groups.

Absolute error group	**+0.25 to -0.25**	**+0.26 to +0.50 & -0.26 to -0.50**	**+0.51 to +0.75 & -0.51 to -0.75**	**+0.76 to +1.00 & -0.76 to -1.00**	**>+/-1.00**
Group 1 SRK/T (n=29)	11 (37.9%)	10 (34.5%)	7 (24.1%)	1 (3.4%)	0 (0.0%)
Group 2 Haigis (n=30)	11 (36.7%)	11 (36.7%)	4 (13.3%)	3 (10.0%)	1 (3.3%)

Table 13: Comparing the Absolute error (obtained – prediction) in each group to the other formula:

	Mean Absolute error (SRK/T)	**Mean absolute error (Haigis)**
Group 1 (SRK/T) n=29	+0.02	-0.73
SD	+0.44	+0.37

	Mean Absolute error (Haigis)	**Mean absolute error (SRK/T)**
Group 2(Haigis) n=30	-0.33	+0.31
SD	+0.38	+1.2
p - value	0.43	0.82

Table 14. Group 1 (n=29) where the lens was implanted by using SRK/T formula, the absolute error between SRK/T and Haigis for the same diopter lens is compared against various axial length groups

Axial length group		**Absolute error (SRK/T)**	**Absolute error (Haigis)**
22.00 – 22.99	Mean	-0.12	-0.77
	SD	+0.46	+0.19
	Range	-0.82 to +0.75	-1.08 to -0.50
23.00 – 23.99	Mean	+0.06	-0.71
	SD	+0.41	+0.52
	Range	-0.56 to +0.75	-1.54 to +0.66
24.00 – 24.99	Mean	+0.20	-0.68
	SD	+0.53	+0.19
	Range	-0.32 to +0.75	-0.88 to -0.49
p - value		0.43	0.82

Table 15. Group 2 (n=30) where the lens was implanted by using Haigis formula, the absolute error between SRK/T and Haigis for the same diopter lens is compared against various axial length groups

Axial length group		**Absolute error (Haigis)**	**Absolute error (SRK/T)**
22.00 – 22.99	Mean	-0.42	+0.58
	SD	+0.451	+1.87
	Range	-1.24 to +0.68	+0.11 to +0.71
23.00 – 23.99	Mean	-0.23	+0.66
	SD	+0.30	+0.34
	Range	-0.90 to +0.40	-0.26 to +1.21
24.00 – 24.99	Mean	-0.35	+0.38
	SD	+0.39	+0.48
	Range	-0.89 to +0.01	-0.26 to +0.90
p - value		0.27	0.19

Table 16. Group 1 (n=29) where the lens was implanted by using SRK/T formula, the absolute error between SRK/T and Haigis for the same diopter lens is compared against various Anterior Chamber Depth (ACD) groups

ACD group		Absolute error (SRK/T)	Absolute error (Haigis)
2.50 – 3.00	Mean	-0.03	-0.83
	SD	+0.35	+0.23
	Range	-0.44 to +0.48	-1.08 to -0.60
3.00 – 3.50	Mean	+0.51	-0.75
	SD	+0.48	+0.45
	Range	-0.82 to +0.75	-1.54 to +0.66
>3.50	Mean	-0.09	-0.63
	SD	+0.43	+0.26
	Range	-0.56 to +0.75	-0.91 to -0.18
p - value		0.73	0.53

Table 17. Group 2 (n=30) where the lens was implanted by using Haigis formula, the absolute error between SRK/T and Haigis for the same diopter lens is compared against various Anterior Chamber Depth (ACD) groups

ACD group		**Absolute error (SRK/T)**	**Absolute error (Haigis)**
2.50 – 3.00	Mean	-0.36	+0.63
	SD	+0.47	+0.27
	Range	-0.99 to +0.68	+0.11 to +0.93
3.00 – 3.50	Mean	-0.32	+0.56
	SD	+0.37	+1.88
	Range	-1.24 to +0.40	-0.26 to +0.71
>3.50	Mean	-0.32	+0.98
	SD	+0.27	+0.36
	Range	-0.75 to -0.07	+0.55 to +1.33
p - value		0.84	0.30

Table 18. Group 1 (n=29) where the lens was implanted by using SRK/T formula, the absolute error between SRK/T and Haigis for the same diopter lens is compared against various IOL groups

IOL type		Absolute error (SRK/T)	Absolute error (Haigis)
Tecnis	Mean	+0.18	-0.66
	SD	+0.42	+0.41
	Range	-0.64 to +0.75	-1.19 to +0.66
Hoya	Mean	-0.03	-0.87
	SD	+0.49	+0.28
	Range	-0.82 to +0.75	-1.54 to -0.53
p - value		0.89	0.91

Table 19. Group 2 (n=30) where the lens was implanted by using Haigis formula, the absolute error between SRK/T and Haigis for the same diopter lens is compared against various IOL groups

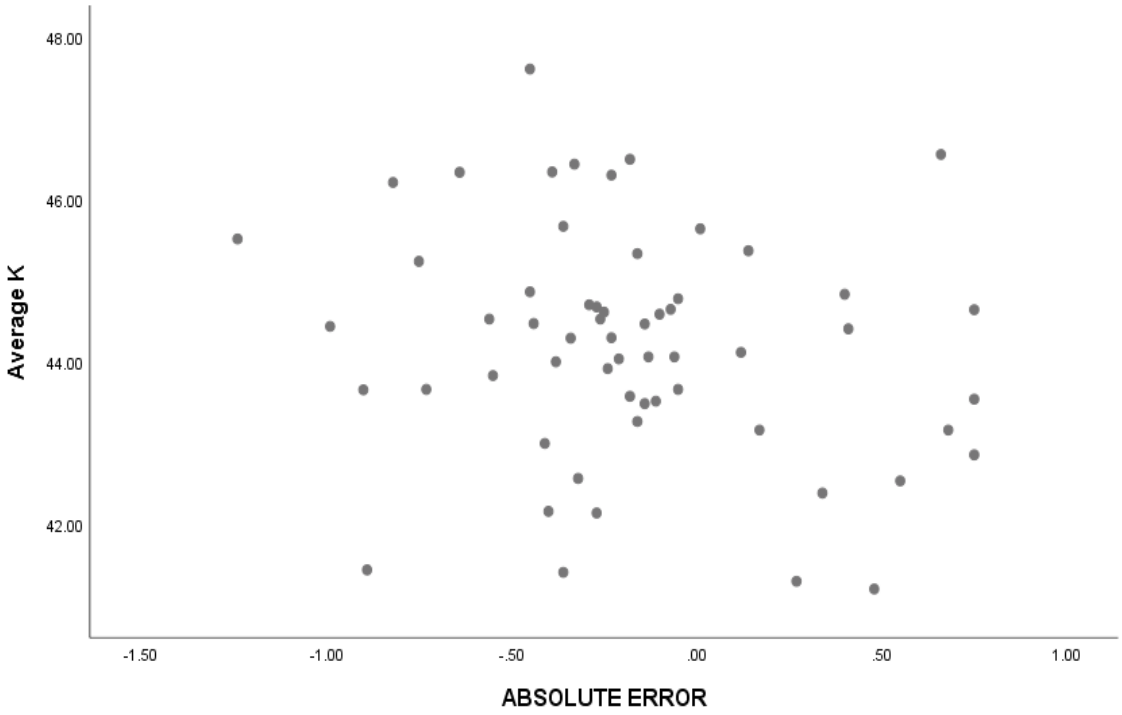
IOL type		Absolute error (SRK/T)	Absolute error (Haigis)
Tecnis	Mean	-0.28	+0.48
	SD	+0.39	+0.75
	Range	-0.90 to +0.68	+1.70 to +0.11
Hoya	Mean	-0.40	+0.59
	SD	+0.38	+0.42
	Range	-1.24 to +0.01	-0.26 to + 1.11
p - value		0.98	0.39

Table 20. showing comparison of measurement of axial length pre-operatively and post-operatively by IOL master

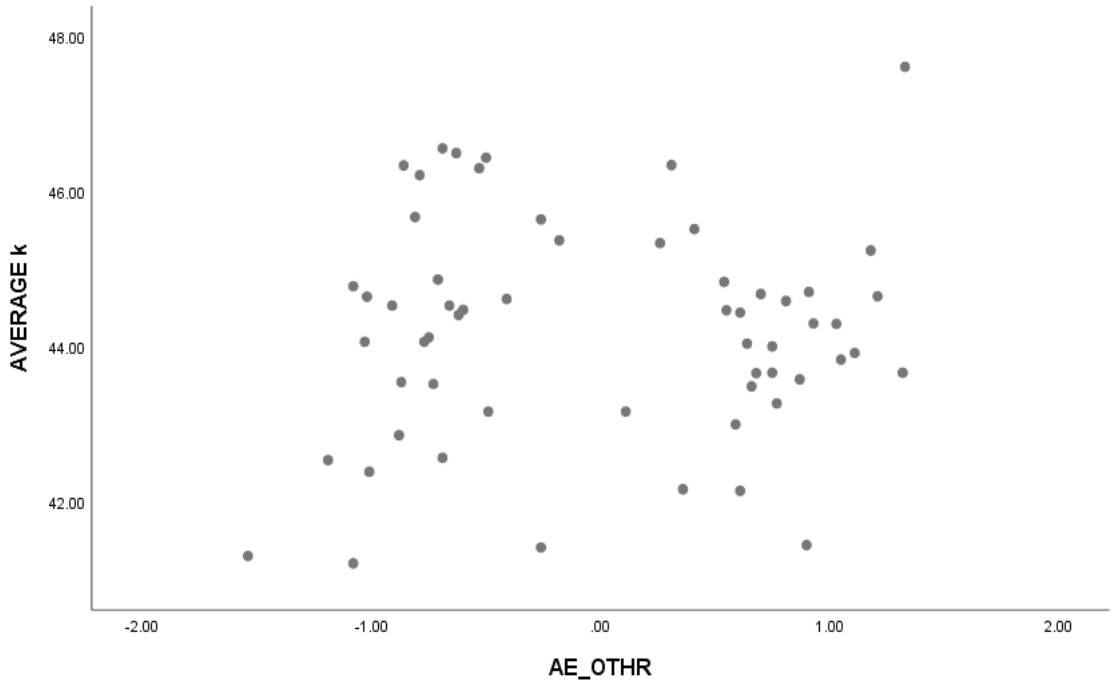
	Mean Axial Length mm	Standard Deviation	Standard Error Mean
Pre-operative measurement	23.16	0.69	0.09
Post-operative measurement	23.10	0.69	0.91

Paired samples test showed that the axial length measured post-operatively had a standard deviation of 0.06mm.

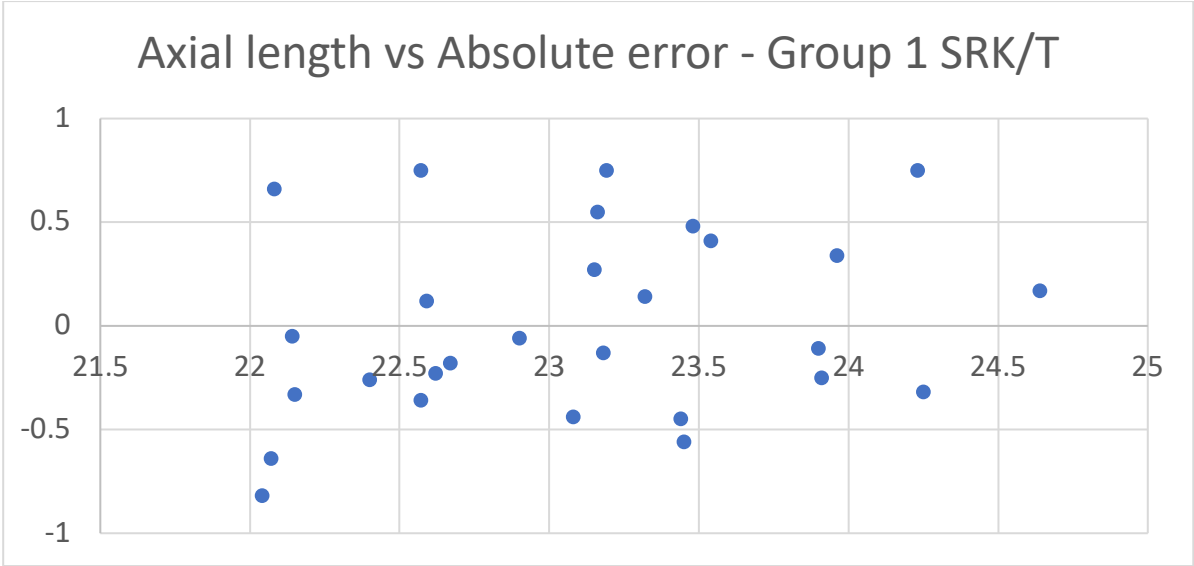
Graph 1. Showing the plot of absolute error using SRK/T formula in relation to corneal power. Absolute error is plotted against x-axis and Corneal power in diopters is plotted against y-axis



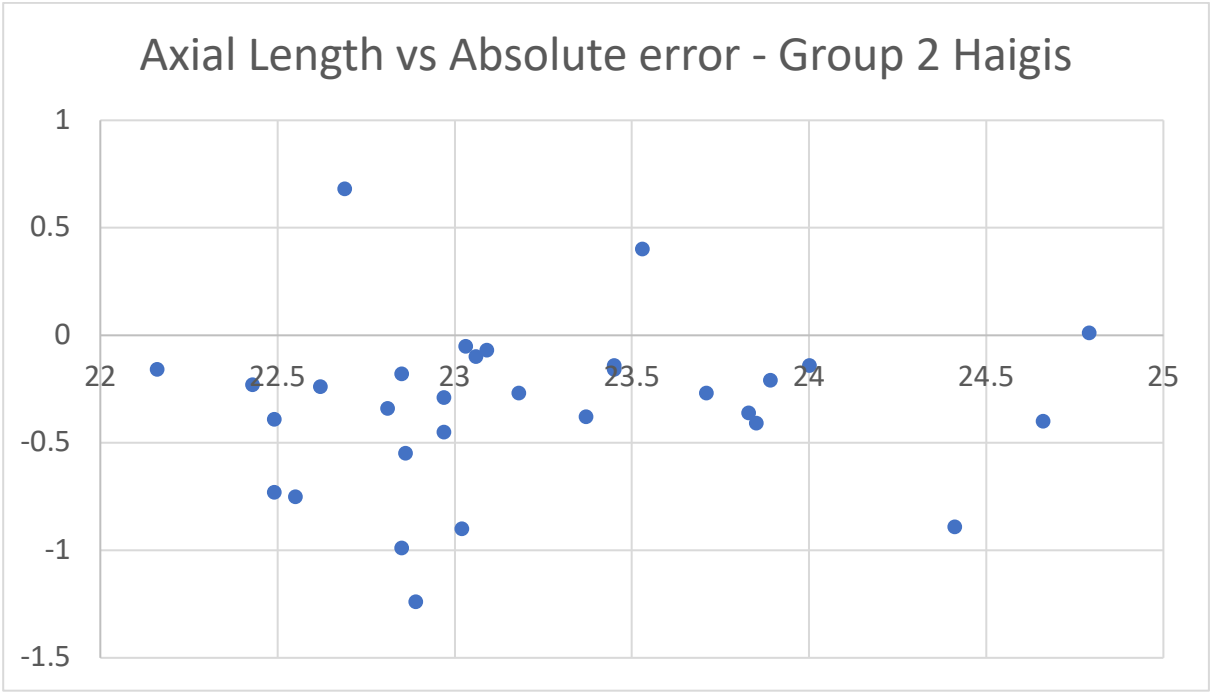
Graph 2. Showing the plot of absolute error using Haigis formula in relation to corneal power. Absolute error is plotted against x-axis and Corneal power in diopters is plotted against y-axis



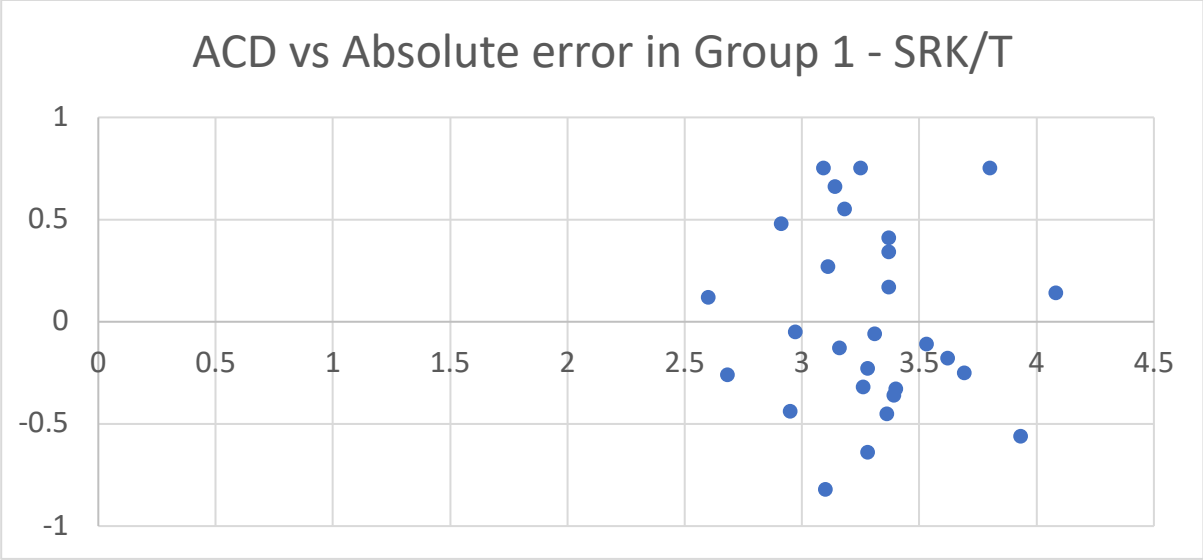
Graph 3. Showing Plot of axial length vs Absolute error in Group 1. Axial length along x-axis and absolute error along y-axis



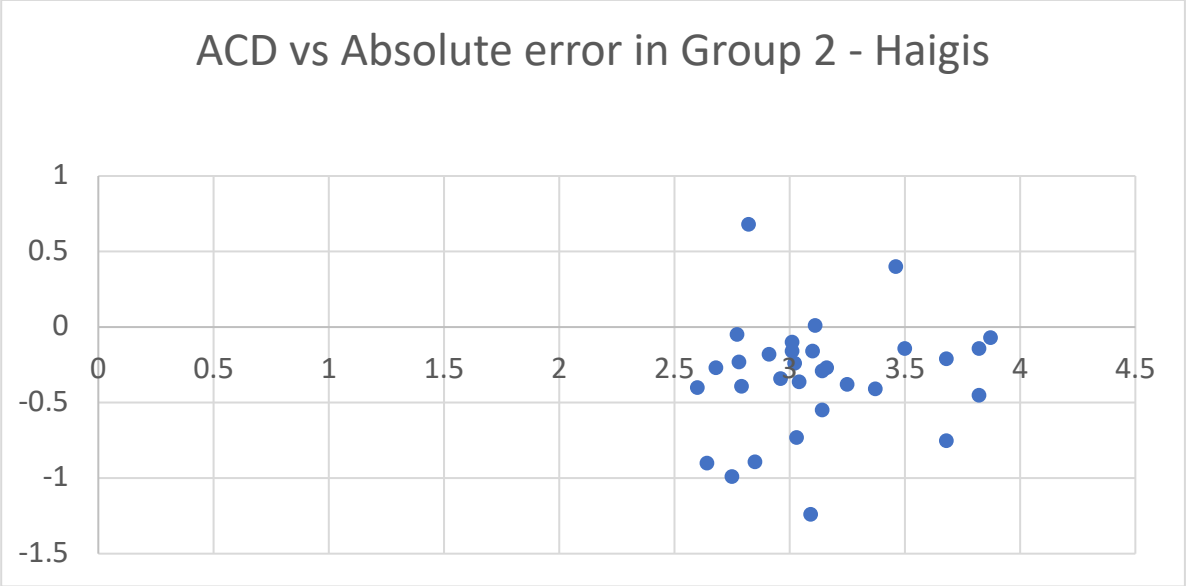
Graph 4. Showing Plot of axial length vs Absolute error in Group 2 Axial length along x-axis and absolute error along y-axis



Graph 5. Showing Plot of Anterior chamber depth vs Absolute error in Group 1. Anterior chamber depth along x-axis and absolute error along y-axis



Graph 6. Showing Plot of Anterior Chamber Depth vs Absolute error in Group 2. Anterior chamber depth along x-axis and absolute error along y-axis



Discussion

Discussion

Ever since the first theoretical formula for IOL power calculation was explained by Fedorov et al.(3) in 1967, others (Binkhorst, Holladay, Hoffer, Sanders) have attempted to create formulas to accurately predict refractive outcomes. Many authors have studied the predictive accuracy of various IOL power calculation formulae. In general, the belief among cataract surgeons is that formulae which include predicted IOL position are likely to be most accurate. Thus, the theoretical formulae have become increasingly popular, and formulae incorporating theoretical calculations with regression analysis data are very popular. The SRK/T formula was the first to use this approach and this has been followed by formulae attempting to predict the effective lens position (eLPo) and use it in calculations. The Haigis formula is one such calculation, though it has largely been superseded by the Barrett's Universal II formula. We have attempted to evaluate the Haigis formula and compare its predictability with the SRK/T formula that has been the mainstay of most IOL surgeons for some years now.

We decided to study eyes with "normal" axial length ie 22-24.99 mm. The Haigis formula has been documented to be more predictable in longer axial length eyes and is assumed to be accurate in this range of axial lengths also. We decided on a randomized controlled design to remove any surgeon or optometrist bias and collected data blind.

In this study we found that the actual refractive error obtained was myopic in both groups and the mean absolute error showed a similar performance in both

formulae. A study done by Wang and Chang(53) showed similar performance of the Haigis, Hoffer Q, Holladay 1, and SRK/T in medium eye length. In another study by Wang *et al.* (37), SRK/T and Haigis performed equally well and outperformed the Hoffer Q and Holladay 1 in 34 eyes with axial length ranging from 25-28 mm.

Predictive accuracy analyzed by Moschos *et al.* (54) and Roh *et al* (55) reported that the Haigis formula was more accurate than the other formulae in higher axial length eyes. However, Kapadia *et al.*(56), Maclaren *et al.* (57), Aristodemou *et al.* (58), and El-Nafees *et al.* (59) reported that the SRK/T formula was more accurate than the other formulae in long eyes.

In this study, we found that similar performance of SRK/T and Haigis (Mean absolute error : 0.021 for SRK/T and -0.33 for Haigis), with a little tendency of myopic shift for both SRK/T formula (Mean error = −0.24) and the Haigis formula (ME= - 0.59) (Table 10) . Doshi *et al.*(47) in their study reported that Haigis formula had a little tendency for hyperopic results while SRK/T found a myopic shift. However, Dalto *et al.* (60) found a significant myopic shift using the Haigis formula which is in agreement with our study.

In this study, we found that marginally higher proportion cases in the Haigis group had their refractive outcome within ± 0.50D (72.4% cases for SRK/T and 73.4% cases for Haigis formula (37.9% within ± 0.25, 34.5% within ± 0.50 for

SRK/T; 36.7% ± 0.25, 36.7% ± 0.50 for Haigis). 100% cases were within ± 1.0 D in SRK/T group and 96.7% cases in haigis group were within ± 1.0 D (Table12).

These results were similar to the study done by Sharma *et al.* (43) who achieved a prediction accuracy within 1.00 D of 78% for SRK/T formula, 86% for Haigis formula. Another study by El-Nafees *et al.* (59) achieved a prediction accuracy of 83.01% (for both SRK/T, Haigis) which is in agreement with our study. Kapadia *et al.* (56) achieved a prediction accuracy 67.85% for SRK/T formula and 68% for Haigis formula.

The results of our study have shown that the SRK/T formula has a performance similar to Haigis formula, with no statistically significant difference between the MAEs of the two formulae in the overall performance in normal axial length eyes. Doshi *et al.*(47) in their study found that in eyes with an AL of more than 24.5 (40 eyes), there was no statistically significant difference between MAE of Haigis, Holladay 1, Hoffer Q, and SRK/T formulae.

In this study, the prediction error of SRK/T and Haigis formulae was weakly, nonsignificant negatively correlated with AL and keratometry ($P>0.05$) This is in contrast to Dalto *et al.*(60) who reported a strong correlation between pre-operative keratometry and the difference between SRK/T and Haigis formulae predictability. Zhu *et al.*(61)in their study on 103 eyes with an AL of at least

26 mm found that the prediction error of SRK/T formula was positively correlated with AL and corneal astigmatism, while for Holladay and Haigis formulas, in addition to the previous two factors, the errors were also positively correlated with mean corneal curvature.

Kane *et al*.(62) who studied intraocular lens power formula accuracy with comparison of seven formulas on 3241 patients found that MAE of Haigis and SRK/T formulas were 0.420 and 0.413, respectively compared to 0.021 and -0.33 in our study. Kane et al did use retrospectively obtained data with no control of individual observer variation which may be responsible for the difference.

The inclusion of the measured ACD into the Haigis formula is said to allow for potentially increased accuracy(63). But in our study, there is no correlation between Anterior Chamber depth and the mean absolute error in either group. This is in contrast to a study done by Jeong et al(64) which concluded that ACD correlated significantly with errors of third generation formula. Our data does not support this conclusion.

Two types of IOL were used with A constants of 118.8 (Tecnis) and 118.9 (Hoya) and the absolute error was studied in the two groups. There was no correlation which is similar to a study done by Yunus(65) which established that

there is no statistical significance between absolute error and the type of IOL used.

The preoperative and post-operative measurements of axial length measured were analyzed and the difference was statistically non-significant which is similar to the study done by Lopez et al(66) which proved that there was no statistically significant difference in the axial length measured by IOL master in any grade of nuclear cataract pre and post operatively.

Overall performance of Haigis is similar to SRK/T formula raising the question of whether the quest for newer generation formulae is warranted in normal axial length eyes. The effective lens position, effect of anterior chamber depth, posterior corneal curvature (In Barett's II universal formula), lens thickness have been studied in various IOL calculation formulae. However in normal axial length eyes with no prior refractive surgeries it can be concluded that SRK/T is as good as fourth generation formulae. Given the extra measurements, time and expense of the additional parameters involved in the newer formulae, this conclusion is an important one.

Limitations and Conclusion

Limitations:

1) Single surgeon could not be employed due to constraints in time in order to achieve the sample size. However, two competent surgeons of similar skill ensured that the data was consistent.
2) Single type of Intraocular lens could not be used as presence of a yellow lens in the other eye warranted use of a yellow lens and vice versa. This is unlikely to have made any difference to the outcomes measured.
3) Absenteeism on day of surgery and follow up led to decrease in sample size
4) Intra-operative complications including sutures and posterior capsule rupture were excluded despite good visual outcome. This limited the amount of data but increased the accuracy of the study.

Conclusion:

1) SRK/T and Haigis formulae are equally good in predictive accuracy of refractive outcome post cataract surgery in normal axial length eyes. The need for sophisticated and newer fourth generation formulae is disputed.
2) There is no correlation between axial length and the refractive outcome within the axial length range studied
3) There is no relationship between anterior chamber depth and the refractive outcome in both the groups.
4) There is no correlation between average corneal power and the predictive refractive outcome
5) There is no relationship between the type of IOL used and the refractive outcome
6) The difference in pre-operative and post-operative measurements of axial length was statistically non-significant.

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Appendix

Appendix

I. Abstract

II. IRB Approval letter

III. Patient information sheet

IV. Informed Consent

V. Data collection sheet

VI. Data Sheet

ABSTRACT

TITLE: Predictive accuracy of intraocular lens power calculation formulae – SRK/T vs Haigis – a randomized control study

DEPARTMENT: Ophthalmology

NAME OF THE CANDIDATE: Dr. Swetha Ravichandran

DGREE AND SUBJECT: MS Ophthalmology

NAME OF THE GUIDE: Dr. Andrew Braganza

OBJECTIVES:

To compare the refractive status after cataract surgery between SRK/T vs Haigis formula calculated preoperatively using IOL master.

To study the effect of axial length on the predictive accuracy of SRK/T and Haigis formula

To study the effect of anterior chamber depth on the predictive accuracy of Haigis formula

METHODS:

Patients of age >50 years, preoperative corneal cylinder value less than 2.5D diopter, the existence of age-related cataract, consenting for the study and satisfying the inclusion, exclusion criteria were selected. All patients underwent complete ocular examination, Biometry by IOL MASTER was done by three optometrists recruited for the study after randomizing the participants into two groups (SRK/T and Haigis groups) by block randomization. Two experienced surgeons of same skill and technique performed all operation using standard phacoemulsification with in the bag IOL implantation. Patients were followed up for examination on the first post op day, after 1 week and then 6 +/- 1 weeks later. Best corrected visual acuity was done at 6 weeks (+/- 1) visit by two senior optometrists who were blinded to the formula used. The axial length and keratometry readings were also measured post-operatively at 6 weeks.

RESULTS:

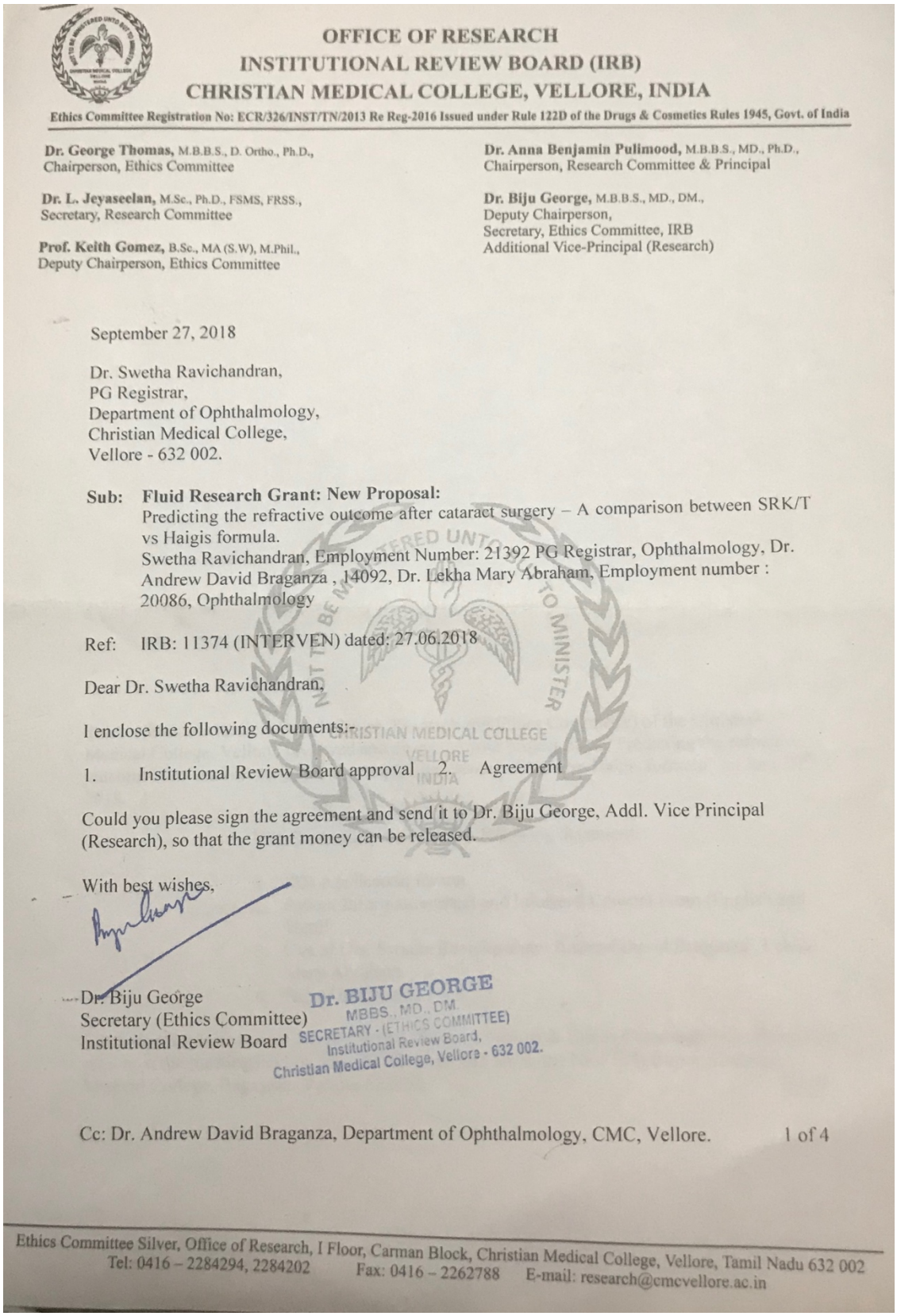
We found similar performance of SRK/T and Haigis (Mean absolute error : 0.021 for SRK/T and -0.33 for Haigis), with a little tendency of myopic shift for both SRK/T formula (Mean error = −0.24) and the Haigis formula (ME= - 0.59). Marginally higher

proportion cases in the Haigis group had their refractive outcome within ± 0.50D (72.4% cases for SRK/T and 73.4% cases for Haigis formula (37.9% within ± 0.25, 34.5% within ± 0.50 for SRK/T; 36.7% ± 0.25, 36.7% ± 0.50 for Haigis). 100% cases were within ± 1.0 D in SRK/T group and 96.7% cases in Haigis group were within ± 1.0 D. There was no correlation between axial length, keratometry or anterior chamber depth to the absolute error.

CONCLUSION:

SRK/T and Haigis formulae are equally good in predictive accuracy of refractive outcome post cataract surgery in normal axial length eyes. The need for sophisticated and newer fourth generation formulae is disputed.

IRB approval letter



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Ethics Committee Registration No: ECR/326/INST/TN/2013 Re Reg-2016 Issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. of India

Dr. George Thomas, M.B.B.S., D. Ortho., Ph.D.,
Chairperson, Ethics Committee

Dr. L. Jeyaseelan, M.Sc., Ph.D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., MA (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

September 27, 2018

Dr. Swetha Ravichandran,
PG Registrar,
Department of Ophthalmology,
Christian Medical College,
Vellore - 632 002.

Sub: Fluid Research Grant: New Proposal:
Predicting the refractive outcome after cataract surgery – A comparison between SRK/T vs Haigis formula.
Swetha Ravichandran, Employment Number: 21392 PG Registrar, Ophthalmology, Dr. Andrew David Braganza , 14092, Dr. Lekha Mary Abraham, Employment number : 20086, Ophthalmology

Ref: IRB: 11374 (INTERVEN) dated: 27.06.2018

Dear Dr. Swetha Ravichandran,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr. Andrew David Braganza, Department of Ophthalmology, CMC, Vellore. 1 of 4

Ethics Committee Silver, Office of Research, I Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788 E-mail: research@cmcvellore.ac.in

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Ethics Committee Registration No: ECR/326/INST/TN/2013 Re Reg-2016 Issued under Rule 122D of the Drugs & Cosmetics Rules 1945, Govt. of India

Dr. George Thomas, M.B.B.S., D. Ortho., Ph.D.,
Chairperson, Ethics Committee

Dr. L. Jeyaseelan, M.Sc., Ph.D., FSMS, FRSS.,
Secretary, Research Committee

Prof. Keith Gomez, B.Sc., MA (S.W), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
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Ref: IRB: 11374 (INTERVEN) dated: 27.06.2018

Dear Dr. Swetha Ravichandran,

The Institutional Review Board (**Silver**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Predicting the refractive outcome after cataract surgery – A comparison between SRK/T vs Haigis formula" on June 27th 2018.

The Committee reviewed the following documents:

1. IRB Application format
2. Patient Information sheet and Informed Consent Form (English and Tamil
3. Cvs of Drs. Swetha Ravichandran, Andrew David Braganza , Lekha Mary Abraham
4. No. of documents 1 – 3.

The following Institutional Review Board (Silver, Research & Ethics Committee) members were present at the meeting held on June 27th 2017 at 9.45 am in the New IRB Room, Christian Medical College, Bagayam, Vellore 632002.

Ethics Committee Silver, Office of Research, I Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 0
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Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. George Thomas	MBBS, D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB, Chennai	External, Clinician
Rev. Dr. T. Arul Dhas	MSc, BD, DPC, PhD(Edin)	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Additional Vice Principal (Research), Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore.	Internal, Clinician
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, CMC, Vellore	External, Scientist &Epidemiologist
Prof. Keith Gomez	BSc, MA (S.W), M. Phil (Psychiatry Social Work)	Student counselor, Loyola College, Chennai, Deputy Chairperson, Ethics Committee, IRB	External, Lay Person & Social Scientist
Dr. P. Zachariah	MBBS, PhD	Retired Professor, Vellore	External, Clinician
Dr. L. Jeyaseelan	MSc, PhD, FSMS, FRSS	Professor & Head, Biostatistics, Secretary (Research Committee), IRB, CMC, Vellore	Internal, Statistician
Dr. Jacob John	MBBS, MD, MPH	Professor, Community Medicine, CMC, Vellore	Internal, Clinician
Dr. Ashish Goel	MBBS, MD, DM	Professor, Hepatology, CMC, Vellore	Internal, Clinician
Dr. Suresh Devasahayam	BE, MS, PhD	Professor of Bio-Engineering, CMC, Vellore	Internal, Basic Medical Scientist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Dr. Prasanna Samuel	MSc, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician

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Mrs. Ilavarasi Jesudoss	M Sc (Nursing)	Deputy Nursing Superintendent, College of Nursing, CMC, Vellore	Internal, Nurse
Dr. Suceena Alexander	MBBS, MD, DM	Associate Professor, Nephrology, CMC, Vellore	Internal, Clinician
Dr. Shirley David	MSc, PhD	Professor, Head of Fundamentals Nursing Department, College of Nursing, CMC, Vellore	Internal, Nurse
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person

We approve the project to be conducted as presented.

Kindly provide the total number of animals enrolled in your study and the total number of withdrawals for the study entitled: "Predicting the refractive outcome after cataract surgery – A comparison between SRK/T vs Haigis formula" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 36,150/- INR (Rupees Thirty Six Thousand One hundred and fifty Only) will be granted for 1 year.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB: 11374 (INTERVEN) dated: 27.06.2018

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Patient information sheet

PATIENT INFORMATION SHEET- English

STUDY TITLE: Predicting the refractive outcome after cataract surgery – A comparison between SRK-T and HAIGIS

You are invited to take part in this research study carried out in the department of Ophthalmology, Schell Campus, Christian Medical College , Vellore. The information in this document is intended to enable you to choose whether or not to participate in this study.

Before you choose whether or not you wish to participate, please read the information provided below carefully and also discuss about it with your relatives if you wish to do so. If required feel free to make inquiries – don't feel rushed or pressured to make a speedy choice.

Before participating, clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

It is not mandatory to take part in this study and your decision to not take part will not affect your future medical care.

You can change your decision about partaking in the study whenever you like. Regardless of whether the study has begun, you can in any case quit. You don't need to give us a reason. In the event that you do quit, it won't influence the nature of treatment you get later on.

WHAT IS THE PURPOSE OF THIS STUDY?

Cataract is opacification of the lens and surgery is the only treatment which is definitive. The cataractous lens is removed and an artificial lens – Intraocular lens (IOL) of a suitable power in implanted. But the power of the IOL is very important as it determines the refractive error of the person after surgery and it remains so lifelong. Therefore, predicting the accurate refractive error and IOL power to be implanted is the main target in cataract surgery.

WHY HAVE I BEEN CHOSEN?

You have been chosen because you are diagnosed to have age related Immature Cataract and you need treatment ,it will be started whether you decide to take part in the study are not. It would help us in doing the study if you consent to enrol in the study..

WHAT WILL HAPPEN IF I TAKE PART?

If you take part in the study, you will be requested to provide the required clinical information, undergo routine eye examinations and the required clinical investigations,

all of which are non-invasive. In this study we are comparing 2 different formulae to predict the refractive error/IOL power. HAIGIS is a newer formula and SRK/T is the one currently employed in our

hospital. We will also analyze the effect of length of the eyeball, distance from the cornea to lens, refractive error post-operatively

EXPENSES AND PAYMENTS?

There are no additional expenses or payments.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Each participant in this study will have a vision assessment, both for near and distance, followed by basic eye examination.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

There are no risks involved in taking part in this study. All the examination procedures and tests to be done are completely non-invasive and pain free.

WILL MY TAKING PART BE KEPT CONFIDENTIAL?

All patient information is stored on password protected computer databases and in locked filing cabinets and will only be accessible to the research team.

WHAT IF THERE IS A PROBLEM?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you can contact the Principal Investigator or the Research Office at Carman Block, Bagayam, Vellore, 632002, email - research@cmcvellore.ac.in or researchothers@cmcvellore.ac.in, phone - 0416 2284294.

WHAT WILL HAPPEN TO ANY TEST RESULTS I GIVE?

The test results will be kept safe in the hospital’s patient information databases, which are password protected and accessible to only the members of the research team, who are medical professionals.

HOW WILL THE INFORMATION I PROVIDE BE USEFUL?

We plan to analyze the information collected and understand the condition, that is, presbyopia, in a better way. We will then publish the results in a health journal so others can read about it and learn from the results of the study, so that the new found information may be used to benefit others, the world over.

The personal information collected will still remain strictly confidential, and only the interpretations of the data will be published.

WHO HAS REVIEWED THIS STUDY?

The Institutional Review Board (IRB) of the Christian Medical College, Vellore, has reviewed this study.

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigation and your medical history). By signing this document, you will be allowing the research team investigators, if required, to access your medical information.

The results of clinical tests and therapy performed as part of this research may be included in your medical record. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

Thank you for reading this.
If you agree to enter the study, please sign the attached consent form. Contact Person (Principal Investigator)
DR. Swetha Ravichandran
Designation: P.G.Registrar
Department of Ophthalmology
Department of Ophthalmology, Schell Eye Hospital,
CMC, Vellore
Phone Numbers: 9003283073
Email ID: swetha4065@gmail.com

அறிவிக்கப்பட்ட முடிவு

தேவையான தகவல்
ஆய்வுக் கட்டுரை: கண்புரை அறுவை சிகிச்சைக்குப் பிறகு ஒளிவிலகல் விளைவுகளை முன்னறிவித்தல் - SRK-T மற்றும் HAIGIS
கண் மருத்துவம், ஸ்கெல் கேம்பஸ், சிறிஸ்டியன் மருத்துவக் கல்லூரி, வேலூர் ஆகிய துறைகளில் மேற்கொள்ளப்பட்ட இந்த ஆய்வில் பங்கேற்க நீங்கள் அழைக்கப்படுவீர்கள். இந்த ஆவணத்தில் பங்கேற்க வேண்டுமா இல்லையா என்பதைத் தெரிந்துகொள்ள உங்களைத் தூண்டுகிறது.
நீங்கள் பங்கேற்க விரும்புவாரா இல்லையா என்பதைத் தேர்வு செய்வதற்கு முன், தயவுசெய்து கவனமாக கீழே கொடுக்கப்பட்டுள்ள தகவலைப் படியுங்கள், அதை நீங்கள் விரும்பினால் உங்கள் உறவினர்களுடன் அதைப் பற்றி விவாதிக்கவும். தேவைப்பட்டால் விசாரணைகள் செய்யலாம் - விரைவாகத் தெரிவு செய்ய விரைந்து அல்லது அழுத்தத்தை உணரவில்லை.
இந்த ஆய்வில் பங்கு பெறுவதற்கு முன்பாக, ஆபத்துக்கள் மற்றும் பலன்களைப் புரிந்துகொள்வதற்கு முன், நீங்கள் சரியான முடிவு எடுக்கலாம். இந்த செயல்முறை 'தகவலறிந்த ஒப்புதல்' என்று அழைக்கப்படுகிறது.
இந்த ஆய்வில் பங்கு பெற வேண்டியது அவசியமில்லை மற்றும் பங்கேற்காத உங்கள் முடிவு உங்கள் எதிர்கால மருத்துவ சேவையை பாதிக்காது.
நீங்கள் விரும்பும் போதெல்லாம் படிப்பதில் பங்கெடுப்பது பற்றி உங்கள் முடிவை மாற்றிக்கொள்ளலாம். ஆய்வில் தொடங்கி விட்டதா இல்லையா என்பதைப் பொறுத்து, நீங்கள் எப்படியாவது வெளியேறலாம். எங்களுக்கு ஒரு காரணத்தைக் கொடுக்க தேவையில்லை. நீங்கள் வெளியேறுகிறீர்கள் என்றால், நீங்கள் பின்னர் பெறும் சிகிச்சையின் தன்மையை அது பாதிக்காது.
இந்த படிப்பின் நோக்கம் என்ன?
கண்புரை லென்ஸின் ஒடுக்குமுறை மற்றும் அறுவை சிகிச்சை மட்டுமே உறுதியானது என்பது மட்டுமே சிகிச்சை. கண்புரைக்குரிய லென்ஸ் அகற்றப்பட்டு, ஒரு செயற்கை லென்ஸ் - உள்வட்ட லென்ஸ் (IOL) பொருத்தப்பட்ட ஒரு பொருத்தமான சக்தி. ஆனால் ஐஓஎல் சக்தி மிகவும் முக்கியமானது, அறுவை சிகிச்சையின் பின்னர் நபரின் ஒளிவிலகல் சிக்கலைத் தீர்மானிக்கிறது மற்றும் அது வாழ்நாள் முழுவதும் உள்ளது.
எனவே, துல்லியமான கதிர்வீச்சு பிழை மற்றும் ஐஓஎல் ஆற்றலை கணிக்கப்பட வேண்டும் என்று கணிப்பதன் மூலம் கண்புரை அறுவை சிகிச்சையில் முக்கிய இலக்கு.

நான் ஏன் தேர்ந்தெடுக்கப்பட்டேன்?
நீங்கள் வயது தொடர்பான நோயெதிர்ப்பு கண்புரை நோய் கண்டறியப்பட்டிருப்பதால் நீங்கள் தேர்வு செய்யப்பட்டுள்ளீர்கள், உங்களுக்கு சிகிச்சையளிக்க வேண்டும், ஆய்வில் பங்கேற்க முடிவு செய்யலாமா இல்லையா என்பதைத் தொடங்குவீர்கள். நீங்கள் படிப்பில் சேர ஒப்புக்கொண்டால், படிப்பு செய்வதில் இது நமக்கு உதவும்.

நான் பங்கு பெற என்ன நடக்கும்?
இந்த ஆய்வில் பங்கேற்க நீங்கள் தேவையான மருத்துவ தகவல்களை வழங்க வேண்டும், வழக்கமான கண் பரிசோதனைகள் மற்றும் தேவையான மருத்துவ ஆய்வுகளுக்கு உட்படுத்தப்பட வேண்டும், இவை அனைத்தையும் ஊடுருவுகின்றன. இந்த ஆய்வில் நாம் 2 வெவ்வேறு சூத்திரங்களை ஒப்பிடுகிறோம், ஒளிவிலகல் பிழை / ஐஓஎல் ஆற்றல் ஆகியவற்றை முன்னறிவிக்க. HAIGIS ஒரு புதிய சூத்திரம் மற்றும் SRK / T தற்போது எங்கள் மருத்துவமனையில் பணியாற்றினார். நாங்கள் கண்ணிப்பின் நீளத்தின் விளைவுகளையும், கார்னியாவில் இருந்து லென்ஸுக்கு தூரத்திற்கு, தொலைதூரப் பிழையானது பிந்தைய இயக்கத்தாலும்

செலவுகள் மற்றும் பணம்?
கூடுதல் செலவுகள் அல்லது பணம் இல்லை.
எடுத்துக் கொள்ளக்கூடிய சாத்தியக்கூறுகள் என்ன?
இந்த ஆய்வில் ஒவ்வொரு பங்கேற்பாளரும் தொலைநோக்கு மற்றும் தொலைநோக்கு ஆகியவற்றிற்கான பார்வை மதிப்பீட்டைக் கொண்டிருக்க வேண்டும், அதன்பின் அடிப்படை கண் பரிசோதனை மேற்கொள்ளப்படும்.
எடுத்துக் கொள்ளக்கூடிய சாத்தியக்கூறுகள் என்ன?
இந்த ஆய்வில் பங்கு பெறுவதில் எந்த ஆபத்தும் இல்லை. அனைத்து பரிசோதனை நடைமுறைகள் மற்றும் சோதனைகள் செய்யப்பட வேண்டும் முற்றிலும் அல்லாத ஆக்கிரமிப்பு மற்றும் வலி இலவச.
என்னால் பொறுப்பேற்க இயலாது?
அனைத்து நோயாளிகளும் கடவுச்சொல்லை பாதுகாக்கப்பட்ட கணினி தரவுத்தளங்களில் சேமிக்கப்பட்டு பூட்டப்பட்ட தாக்கல் கேபினெட்டுகளில் சேமிக்கப்படும் மற்றும் ஆராய்ச்சி குழுவிற்கு மட்டுமே அணுக முடியும்.
ஒரு பிரச்சனை என்றால் என்ன?
இந்த ஆய்வின் போது நீங்கள் அணுகப்பட்ட அல்லது சிகிச்சையளிக்கப்பட்ட வழியின் எந்தவொரு அச்சத்தையும் பற்றி புகார் செய்ய விரும்பினால், நீங்கள் காரன் பிளாக், பாக்யம், வேலூர், 632002, மின்னஞ்சலில் முதன்மையான ஆராய்ச்சியாளர் அல்லது ஆராய்ச்சி அலுவலகத்தை தொடர்பு கொள்ளலாம் - ஆராய்ச்சி @ cmcvellore.ac.in அல்லது researchothers@cmcvellore.ac.in, தொலைபேசி - 0416 2284294.
எந்த டெஸ்ட் முடிவுகளை நான் பெற்றுக்கொள்வேன்?
சோதனை முடிவுகள் மருத்துவமனையின் நோயாளியின் தகவல் தரவுத்தளங்களில் பாதுகாப்பாக வைக்கப்படும், இது கடவுச்சொல் பாதுகாக்கப்பட்டு, மருத்துவ நிபுணர்களாக இருக்கும் ஆராய்ச்சி குழுவின் உறுப்பினர்களுக்கு மட்டுமே அணுகக்கூடியதாக இருக்கும்.
நான் பயன்படுத்தும் தகவலை எப்படி பயன்படுத்துவது?
நாம் சேகரிக்கப்பட்ட தகவலை பகுப்பாய்வு செய்ய திட்டமிட்டுள்ளோம், அதாவது, பிரபிமோபியா, சிறந்த முறையில். பிற்பாடு, ஒரு ஆரோக்கியமான இதழில் முடிவுகளை வெளியிடுவோம், எனவே மற்றவர்கள் இதைப் பற்றி படிக்கவும், படிப்பினையின் முடிவுகளிலிருந்து கற்றுக்கொள்ளவும், புதிய கண்டுபிடிப்புகள் மற்றவர்களுக்கு பயனளிக்கும் வகையில் பயன்படுத்தப்படலாம். சேகரிக்கப்பட்ட தனிப்பட்ட தகவல்கள் இன்னும் கண்டிப்பாக இரகசியமாகவே இருக்கும், மேலும் தரவின் விளக்கங்கள் வெளியிடப்படும்.
இந்த ஆய்வு எதைப் பற்றிக் கண்டறிந்தது?
வேலூர் மாவட்டத்தின் சிறிஸ்தவ மருத்துவக் கல்லூரியின் நிறுவன மதிப்பாய்வு வாரியம் (IRB) இந்த ஆய்வு ஆய்வு செய்துள்ளது.
உங்கள் மருத்துவ தகவல் (தனிப்பட்ட விவரங்கள், உடல் பரிசோதனை, விசாரணை மற்றும் மருத்துவ வரலாறு) பற்றிய தனியுரிமை தொடர்பாக நீங்கள் இரகசியத்திற்கு உரிமை உள்ளது. இந்த ஆவணத்தில் கையெழுத்திடுவதன் மூலம், உங்கள் மருத்துவத் தகவலை அணுக வேண்டுமெனில் ஆராய்ச்சி குழு விசாரணையாளர்களை அனுமதிக்க வேண்டும். மருத்துவ பரிசோதனைகள் மற்றும் சிகிச்சையின் முடிவுகள் பகுதியாக நிகழ்த்தப்பட்ட

अवगत सहमति

जांच शीर्षक: मोतियाबिंद चिकित्सा के बाद वर्तितः परिणाम की भविष्यवाणी - हैगिस अथवा ऐस-आर-के-टी फार्मूला की तुलना

सी-एम्-सी वेल्लोर की नेत्र विज्ञानं विभाग में होने वाली अनुसंधान अध्ययन में आपको निमंत्रण किया जा रहा हैं. इस दस्तावेज़ में दियी हुई जानकारी आपकी इस जांच में भाग लेना या ना लेना को तय करने में मदद करेगा.

इस जांच में भाग लेने से पहले कृपया नीचे दिई हुई जानकारी ध्यान से पड़े और चाहे तो रिश्तेदारों के साथ चर्चा करें. आराम से फैसला लें. कोई भी मज़बूरी या जल्दी नहीं हैं.

भाग लेने से पहले स्पष्ट रूप से समज लेना इस जांच में भाग लेने की विपत्ति और लाभ, ताकि आप आपके लिए सही फैसला ले सको. इस कार्यविधि का नाम "इन्फोर्मेड कंसेंट" है.

इस जांच में भाग लेना अनिवार्य नहीं हैं और भाग ना लेने से आपकी आने वाली इलाज में कोई भी प्रभाव नहीं होगा.

इस जांच में भाग लेने की फैसले को आप कभी भी बदल सकते हो. चाहे जांच शुरू भी हो जाये, आप कभी भी छोड़ सकते हो. कोई भी कारण देने की ज़रुरत नहि हैं. अगर आप ने जांच छोड़ दी तो इस कारण आपके इलाज में कोई प्रभाव नहीं होगा.

जांच की उद्देश्य
आँख में होने वाली अपराडिक्शन का नाम है मोतियाबिंद और इसका इलाज केवल शल्य-चिकित्सा है. प्रभावित हुई आँख की शीशा/लेंस को हटके उपयुक्त शक्ति वाली बनावटी लेंस अथवा "इन्ट्रा ऑक्युलर लेंस" दाखिल किया जाता है. यह लेंस की शक्ति काफी महत्वपूर्ण है क्यूंकि यही आँख में होने वाली त्रुटि को निर्धारित करता है और यह जीवन भर रहता है.

मुझे क्युं चुना गया हैं?
आपको इस लिए चुना गया है क्यूंकि आप में अपरिपक्व उम्र सम्बंदित मोतिबिन्द है और इसका इलाज ज़रूरी हैं. इलाज चाहे आप इस जांच में भाग ले या ले, शुरू किया जायेगा. अगर आप भाग ले नो इससे हमारी मदद होगी.

मेरे भाग लेने से क्या होगा?
अगर आप इस जांच में भाग लेने से सहमत हो तोः, आपसे रोगविशायाक जानकारी देने की बिनती किया जायेगा और सामान्य आँख की परीक्षा और उचित परिक्षण सहने की बिनती किया जायेगा. इस जांच में हम वर्तितः त्रुटि की भविष्यवाणी के दो सूत्र की तुलना कर रहे हैं. हैगिस सूत्र एक नया सूत्र है और यस-आर-के-टी सूत्र हमारे अस्पताल में इस समय उपयोग में हैं. हम इसके सिवाय नेत्रगोलक की लम्बाई, कनिनिका से लेंस की दूरी, चिकित्सा से पहले वाली वर्तितः त्रुटि, आदि की जांच भी करेंगे.

खर्चा एवं अदायगी
इस जांच में कोई भी खर्चा या अदायगी नहीं हैं.

भाग लेने का संभव लाभ?
जांच के हर प्रतिभागी की दृष्टि की निर्धारण की जाएगी (दोनों पास वाली और दूर की दृष्टि).

भाग लेने की विपत्ति?
कोई भी विपत्ति नहीं हैं. इस जाँच के सारे परीक्षा कोई हमला नहीं करेंगे.

मेरे जांच में भाग लेना गुप्तः रहेगा क्या?
मरीज़ सामंडित साडी जानकारी पासवर्ड के माद्यम से कंप्यूटर में और बंद मंत्रिमंडल में रखा जायेगा और ये केवल जांच की टीम पहुंच सकती है.

अगर कोई मुसीबत?
इस जांच के समय अगर आपके साथ गलत व्यवहार किया गया है तोः आप रिसर्च ऑफिस, कारमेन ब्लॉक, बगायम, वेल्लोर - 632002, ईमेल आई-दी - , फ़ोन नंबर - 0416 2284294 पे प्रदान अनुसूधन करने वाले से संपर्क कर सकते हैं.

मेरे दिए हुए परीक्षा का रिजल्ट का क्या होगा?
सरे रिजल्ट अस्पताल के मरीज़ों जानकारी की डेटाबेस में पासवर्ड के मॉडियम से सुरक्षित रहेगा.

मेरे दिए हुए जानकारी का उपयोग कैसा होगा?
आके दिया हुआ जानकारी की छान-बिन की जाएगी और आपकी परिस्थिति - प्रेस्ब्योपा - को बेहतर समझा जायेगा. इस जांच के परिणाम को कई सवस्तिया पत्रिका में प्रकाशित किया जाएगा ताकि दुनिया भर और लोग भी इसका लाभ उठाये. आपकी निजी जानकारी गुप्तः रखा जायेगा और केवल जांच के परिणाम प्रकाशित किया जायेगा.

इस जांच की समीक्षा किसने की है?
क्रिस्चियन मेडिकल कॉलेज, वेल्लोर की इंस्टीट्यूशनल रिव्यु बोर्ड (आई-आर-बी) ने इस जांच की समीक्षा की है.

आपके पास आपकी निजी जानकारी की गुप्तहि का अधिकार है. इस दस्तावेज़ को दस्तखांत करने से आप जांच करने वाली टीम को इस जानकारी का उपयोग करने का अनुमति दे रहें हैं.

आपका किया हुआ टेस्ट के रिजल्ट और इलाज का आपके मेडिकल रिकॉर्ड में दर्ज किया जायेगा. यह जांच, अगर सवस्तिया पत्रिका में प्रकाशित किया जाये तोः आपके सामंडित कोई भी जानकारी लिखी नहीं जाएगी.

इसे पड़ने के लिए धन्यवाद.

अगर आपको इस जाँच में छग लेना सामंडित है तोः कृपया नीचे दिया हुआ सहमति प्रपत्र दस्तखांट करें.

संपर्क व्यक्ति (प्रदान अनुसूधन):
डॉ. स्वेता रविचंद्रन
पि.जी. रजिस्ट्रार
नेत्र विज्ञानं विभाग
शैल नेत्र अस्पताल
सी.एम्.सी, वेल्लोर
फोन नंबर: 9003283073
ईमेल आई.दी - swetha4065@gmail.com

Informed consent:

CONSENT TO TAKE PART IN A CLINICAL TRIAL

Study Title: Predicting the refractive outcome after cataract surgery – A comparison between SRK-T and HAIGIS.

Study Number:

Participant's name:

Date of Birth / Age (in years):

I_____
_____, son/daughter of _____

(Please tick boxes) Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ] I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ] I understand that I will receive free treatment for any study related injury or adverse event but I will not receive and other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ] I understand that my identity will not be revealed in any information released to third parties or published [ ] I voluntarily agree to take part in this study [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Date: _____/_____/_____
Signatory's Name: _____ Signature: Or

Representative: _____
Date: _____/_____/_____
Signatory's Name: _____
Signature of the Investigator: _____
Date: _____/_____/_____
Study Investigator's Name: _____
Signature or thumb impression of the Witness:
_____ Date: _____/_____/_____
Name & Address of the Witness: _____

இந்த ஆராய்ச்சியின் ஒரு பகுதியாக நடத்தப்படும் மருத்துவ பரிசோதனைகள் மற்றும் சிகிச்சையின் முடிவுகள் உங்கள் மருத்துவ பதிவில் சேர்க்கப்படலாம். விஞ்ஞான கஞ்சிகைகளில் வெளியிடப்பட்ட அல்லது விஞ்ஞானக் கூட்டங்களில் வழங்கப்பட்டிருந்தால், இந்த ஆய்வின் தகவல்கள் உங்கள் அடையாளத்தை வெளிப்படுத்தாது.
இதை வாசிப்பதற்கு நன்றி.
ஆய்வுக்கு நீங்கள் ஒப்புக் கொண்டால், இணைந்த ஒப்புதல் படிவத்தில் கையொப்பமிடுங்கள்.

தொடர்பு நபர (முதன்மை விசாரணை)
டி.ஆர். ஸ்வேதா ரவிச்சந்திரன்
பதவி பெயர்: பி.ஜி.
கண் மருத்துவம் திணைக்களம்
கண் மருத்துவம், ஸ்கெல் கண் மருத்துவமனை,
CMC, வேலூர்
தொலைபேசி எண்கள்: 9003283073
மின்னஞ்சல் ஐடி: swetha4065@gmail.com

ஒரு மருத்துவ சோதனையில் பகுதி எடுத்துக்கொள்ள வேண்டும்

படிப்பு தலைப்பு:

ஆய்வு எண்:
பங்கேற்பாளரின் பெயர்:
பிறந்த தேதி / வயது (ஆண்டுகளில்):

நான் _____
_____, _____ மகன் / மகள்

(தயவுசெய்து பெட்டிகளை தேர்வு செய்யவும்)
இந்த ஆய்வின் படி எனக்கு தகவல் தாள் வாசித்திருப்பதைப் பிரகடனம் செய்துவிட்டு, எனக்கு இருந்த சந்தேகங்களை தெளிவுபடுத்தியிருங்கள். []
இந்த ஆய்வில் எனது பங்கேற்பு முற்றிலும் தன்னார்வமாகவும், என் வழக்கமான சிகிச்சை அல்லது என் சட்ட உரிமைகள் பாதிக்கப்படாமல் எந்த நேரத்திலும் பங்கேற்க தொடர்ந்து அனுமதி பெறும் உரிமை எனக்கு உண்டு என்றும் நான் அறிந்திருக்கிறேன்
எந்தவொரு ஆய்வு தொடர்பான காயத்திற்கோ தீங்கு விளைவிக்கும் நிகழ்வுக்கோ நான் இலவச சிகிச்சையைப் பெறுவேன் என்று புரிந்துகொள்கிறேன் ஆனால் நான் பெறமாட்டேன், மற்ற நிதி இழப்பீடு []
நான் விசாரணையில் இருந்து விலகினால் கூட, என் ஊழியர்கள் என் உடல்நலப் பதிவுகளை பார்க்கும் படி படிக்கும் ஊழியர்கள் மற்றும் நிறுவன நெறிமுறை குழு உறுப்பினர்கள் எனது அனுமதியைப் பெற மாட்டார்கள் என்பது எனக்கு புரிகிறது. இந்த அணுகலை நான் ஏற்கிறேன்

जांच में भाग लेने का सहमति पत्र:

जांच की शीर्षक:

जांच नंबर:

प्रतिभागी का नाम:
जनम दिन/उम्र:

मैं, _____, _____ का पुत्र/पुत्री

(कृपया डब्बे को टिक करें)

घोषित करता हूँ की दिया गया जानकारी पत्र को मैंने पड लिया है और सरे शक की समाधान हो चुकी है - [ ]

मैंने यह भी समाज रखा है की इस जाँच में भाग लेना मैंने अपने ही इच्छा से की हुई है और में कभी भी इस जांच से हट सकता हूँ और इस कारण मेरे इलाज पे कोई भी असर नहीं पड़ेगा - [ ]

में समजता हूँ की जांच के कारण हुई कोई भी हानि का इलाज मुझे बिलकुल मुफ्त में किया जायेगा लेकिन कोई भी नुक्सान भरापी पैसे के रूप में नहीं दिया जायेगा. - [ ]

मैंने समज रखा है की जांच के कर्मचारी और संस्थागत आचार नीति के सदस्यों को मेरे सवस्तिया रिकाईस को अवलोकन करने की अनुमति नहीं चाहिए. इस प्रवेश की अनुमति में देता हूँ - [ ]

मैंने समाज रखा है की मेरी पहचान अन्य पक्ष या प्रकाशित किये जाने वाले पत्र को दिए जाने वाले जानकारी में नहीं
रहेगा - [ ]

इस जांच में भाग लेने की सहमति मई अपने इच्छा से दे रहा हूँ - [ ]

प्रतिभागी की दस्तखांत/अंगूठा निशाँ:
तारीख:___/___/_____
नाम:
दस्तखांत:

या (अंगूठा निशान) -

प्रतिनिधि:
तारिख:
नाम:

अन्वेषक की दस्तखांत:
तारिख:
नाम:

गवाह का दस्तखांत/अंगूठा निशान:
तारिख:
नाम और पता:

Data collection Sheet:

DATA COLLECTION FORM

NAME AND HOSPITAL NUMBER:	
AGE:	SEX:
DIAGNOSIS	EYE TO BE OPERATED:
PREOPERATIVE BCVA	

AXIAL LENGTH:	
K-READING:	
SPECULAR COUNT:	
ANTERIOR CHAMBER DEPTH:	
FORMULA USED:	
IOL POWER AND TYPE USED:	

POSTOPERATIVE BCVA @1WEEK:

POSTOPERATIVE BCVA
@6 WEEKS +/- 1 week :

PREDICTED POST-OPERATIVE
SPHERICAL EQUVALENT:

PREDICTIVE ACCURACY OR ACTUAL POST-OPERATIVE ABSOLUTE ERROR[AE] SPHERICAL EQUIVALENT:

POST OP AL & K-READING:

SURGICAL COMPLICATIONS/
SUTURES ETC, IF ANY:

Data: