THE EVALUATION AND THE EFFECT OF SURGICALLY INDUCED ASTIGMATISM IN PHACOEMULSIFICATION SURGERY

BY

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ABSTRACT

Three issues regarding surgically induced astigmatism (SIA) include the choice of SIA calculators, the relationship between SIA consistency with phacoemulsification technique variation, and the effect of SIA prediction error on toric IOL calculation. Phase I compared the individual SIA value and analysis report from SIAC, SIA2.1, SIA3.1, OC6.0 and VVC calculators. Mean difference and agreement between calculators were assessed. No significant differences in mean SIA between the calculators ($p = 0.71$) were found. The 95% limit of agreement between calculators ranged from -0.006 to 0.005D. OC6.0 and VVC reported astigmatism analysis according to Alpins method, whereas SIAC, SIA2.1 and SIA3.1 were based on Holladay method. Holladay method calculators provided surgeons' SIA centroid which is the actual SIA. SIAC and SIA3.1 provided subset analysis of SIA. SIA2.1 and SIA3.1 provided coherence analysis which is a clinically relevant value to evaluate SIA consistency. Thus, SIA2.1 were used in Phase II and III of this study for its suitability to the study objective. In Phase II study, the relationship between SIA consistency and phacoemulsification technique variation were evaluated. The actual SIA and coherence of four surgeons were calculated. A questionnaire (PTechSIA) was developed, validated and used to collect information on the surgeons' surgical technique. Input from the PTechSIA were used to quantify the surgeons' phacoemulsification technique variation using technique variation score (TVS). Strong negative correlation between SIA coherence and TVS (Spearman's r=-0.95, p=0.05) were found, indicating that a consistent phacoemulsification technique contributed to a better SIA consistency. In Phase III, we evaluated the surgeons' SIA prediction error and its effect on toric IOL selection. SIA prediction error was observed in all four surgeons. Two surgeons had a statistically significant SIA prediction error in X and Y value ($p < 0.01$). This error resulted in different toric IOL selection in 85% of subjects. Furthermore, underestimation of SIA had resulted in higher IOL toricity selection and vice versa. From the three-phase study, all issues were addressed accordingly. SIA calculator with centroid and coherence analysis are suggested to determine surgeons' actual SIA and monitor the SIA consistency. A consistent surgical technique contributes to a high SIA consistency, and SIA prediction error significantly affects toric IOL selection. These findings justified the clinical significance and relevance of SIA value.

خلاصة البحث

اللابؤرية الناجمة جراحيا (surgically induced astigmatism, SIA) لها تأثير مباشر على نتائج ما بعد الجراحة لعملية سحب الماء الأبيض بتقنية الفاكو. هناك ثلاث قضايا متعلقة بالـ SIA وهي: اختيار حاسبات SIA، والعلاقة بين اتساق الـ SIA مع تباين طرق سحب الماء الأبيض، وتأثير خطأ التنبؤ بالـ SIA على حساب العدسة البارزة (toric IOL) داخل العين. قارنت المرحلة الأولى للدراسة تقرير التحليل وقيمة الـ SIA الفردي لـ SIAC، و SIA2.1، و SIA3.1، و OC6.0، و VVC. تم حساب قياس القرنية لـ 80 شخصًا في الحاسبات، وتم تقييم متوسط الفرق والاتفاق بين الحاسبات. لم يتم العثور على فروق ذات دلالة إحصائية في متوسط الـ SIA بين الحاسبات (p=0.71). تراوح حد الاتفاق بنسبة 95٪ بين الحاسبات من -0.006 إلى 0.005 D. أبلغت OC6.0 و VVC عن تحليل للابؤرية وفقًا لطريقة ألباينس، واستندت SIAC و SIA2.1 و SIA3.1 على طريقة هولاداي. قدمت حاسبات طريقة هولاداي النقطة الوسطى لـ SIA الجراحين وهو الـ SIA الفعلي. قدم كل من SIAC و SIA3.1 تحليلا للمجموعة الفرعية للـ SIA. قدم SIA2.1 و SIA3.1 تحليلا للتماسك وهو قيمة ذات صلة إكلينيكية لتقييم اتساق الـ SIA. وبالتالي فقد تم استخدام SIA2.1 في المرحلتين الثانية والثالثة من هذه الدراسة لملاءمتها وفقًا لهدف الدراسة. تم في دراسة المرحلة الثانية تقييم العلاقة بين اتساق الـ SIA وتباين طرق سحب الماء الأبيض. تم حساب الـ SIA الفعلي والتمسك النهجي لأربعة جراحين. تم إنشاء استبيان والتحقق من صحته واستخدامه لجمع المعلومات حول الطريقة الجراحية للجراح. تم استخدام المدخلات من الاستبيان لتحديد تباين طرق سحب الماء الأبيض بين الجراحين من خلال طريقة تسجيل النقاط المعروفة باسم درجة اختلاف الطرق (technique variation score, TVS). تم العثور على علاقة سلبية قوية بين تمسك الـ SIA وTVS (r=-0.95 ، p= 0.05لسبيرمان)، مما يشير إلى وجود طريقة متسقة لسحب الماء الأبيض والتي ساهمت في اتساق أفضل لـ SIA. في المرحلة الثالثة ، قمنا بتقييم خطأ توقع الـ SIA للجراحين وتأثيره على اختيار العدسة البارزة داخل العين. تمت ملاحظة أخطاء في التنبؤ بالـ SIA عند الجراحين الأربعة كلهم. كان لدى اثنين من الجراحين خطأ تنبؤ ملحوظ (p<0.01) مع خطأ تنبؤ SIA حسابي بلغ 0.31 D و -0.44 D على التوالي. أدى هذا الخطأ إلى اختيار مختلف للعدسة البارزة داخل العين في 85٪ من المرضى، بالإضافة إلى أن التقليل من تقدير الـ SIA قد أدى إلى اختيار عدسة بارزة أعلى، والعكس صحيح. من خلال هذه الدراسة المكونة من ثلاث مراحل، تم النظر في المسائل المتعلقة بالـ SIA وفقًا لذلك. تم اقتراح حاسبات SIA مع نقاط مركزية للـ SIA وتحليل التمسك الـ SIA الفعلي للجراحين ومراقبة اتساق SIA. ساهمت الطرق الجراحية المتسقة في زيادة اتساق الـ SIA ، واتضح أن الخطأ في تنبؤ الـ SIA قد يؤثر بشكل كبير على اختيار العدسة البارزة داخل العين. بررت هذه النتائج الأهمية الإكلينيكية والعلاقة القوية لقيمة الـ SIA.

APPROVAL PAGE

I certify that I have supervised and read this study and that in my opinion, it conforms to acceptable standards of scholarly presentation and is fully adequate, in scope and quality, as a thesis for the degree of Master of Health Sciences (Optometry).

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DECLARATION

I hereby declare that this dissertation is the result of my own investigations, except where otherwise stated. I also declare that it has not been previously or concurrently submitted as a whole for any other degrees at IIUM or other institutions.

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Signature .... Date ....

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LIST OF SYMBOLS

%	Percentage
-	negative sign/ minus
µ	Micro
°	Degree
±	plus-minus
Hz	Hertz
α	Direction in degrees of the steeper corneal principal plane
ϕ	Direction in degree of the flatter corneal principal plane
M	Difference in power, expressed in diopters (D), between the steeper and the flatter principal corneal plane
X	X-axis value of astigmatic vector according to cartesian-coordinate based vector analysis
Y	Y-axis value of astigmatic vector according to cartesian-coordinate based vector analysis
Ω	The directions of planes under examinations using polar value methods
KP	The difference of dioptric components between two perpendicular keratometric/refractive planes using polar value methods
^{2}	Square
+	positive sign/ plus
x	multiply
>	more than
<	less than
≥	more than and equal to

=	equal to
√	square root
sin	sine
cos	cosine
tan	tangent
arctan	arc-tangent
Δ	difference/ detectable difference
®	registered
™	trademark
p	significant level
n_e	number of SMEs rating a measurement item as *"essential"*.
N	the total number of SMEs who are involved in the content validity process.
n	sample size required
$Z_{\alpha/2}$	95% confidence interval with significant level of 0.05
$Z_{1-\beta}$	power of study
σ	standard deviation
r	coefficient of correlation
J_0	Jackson cross-cylinder power, axes at 90° and 180°
J_{45}	Jackson cross-cylinder power, axes at 45° and 135°

LIST OF ABBREVIATIONS

ACD	anterior chamber depth
AE	angle of error
AL	axial length
ANOVA	analysis of variance
ATR	against the rule
BTCalc	Barrett Toric Calculator Version 2.0
CI	correction index
CVI	content validity index
CVR	content validity ratio
D	dioptre
DC	dioptric cylinder
DS	dioptric sphere
DTC	distance to centroid
DV	difference vector
ECCE	extracapsular cataract extraction
EDOF	extended depth of focus
FI	flattening index
HTAA	Hospital Tengku Ampuan Afzan
ICCE	intracapsular cataract extraction
ID	identification
IESC	International Islamic University Malaysia Eye Specialist Clinic

IIUM	International Islamic University Malaysia
IOS	index of success
IQR	interquartile range
K	keratometry
LASIK	laser in situ keratomileusis
LoA	limit of agreement
LRI	limbal relaxing incision
mm	milimetre
MSICS	manual small incision cataract surgery
OC6.0	Ophthalmology Calculator 6.0
PCI	partial coherence interferometry
PCIOL	posterior chamber intracocular lens
postop	postoperative
preop	preoperative
PTechSIA	Phacoemulsification technique related to SIA
RM-ANOVA	repeated measures analysis of variance
SD	standard deviation
SE	spherical equivalent
SIA	surgically induced astigmatism
SIA2.1	SIA Calculator Verson 2.1
SIA3.1	SIA Calculator Version 3.1
SIAC	SIA Calculator
SICS	small incision cataract surgery
SME	subject matter expert
SPSS	Statistical Package for the Social Science
SS-OCT	swept source optical coherence tomography

TIA	target induced astigmatism
TVS	technique variation score
U.K	United Kingdom
U.S.A	United Stated of America
VS	variation score
VVC	VECTrAK™ Vector Calculator Version 2.4.2
WHO	World Health Organization
WTR	with the rule
ZCalc	ZCalc Online IOL Calculator Version 1.5.1.201511251206

CHAPTER ONE

INTRODUCTION

1.1 STUDY BACKGROUND

Cataract is one of the leading causes of reversible blindness (Lundström et al., 2015; Salowi, Goh, Lee, Adnan, & Ismail, 2015). Management of cataract includes removal and replacement of cataractous lens with an artificial intraocular lens (IOL) through a surgery. There are various cataract surgery techniques such as intracapsular cataract extraction (ICCE), extracapsular cataract extraction (ECCE) and phacoemulsification. The aim of cataract surgeries is to restore functional vision to cataract patients.

Despite the ability to restore functional vision, residual astigmatism remains an issue in cataract surgery. It is one of the main causes for postoperative residual refractive error (Chang, Su & Chen, 2015; Hashemi et al., 2016; Nikose, Saha, Laddha & Patil, 2018; Yoon, Kim, Lee & Nam, 2013). Several strategies employed by ophthalmic surgeons to correct pre-existing corneal astigmatism includes implanting toric IOL and performing limbal relaxing incisions (LRI). In addition, surgeons must understand that residual astigmatism can also be induced by cataract surgeries' main incision, which is known as surgically induced astigmatism (SIA).

Surgically induced astigmatism has a direct impact on postoperative astigmatism outcome and serves as an important parameter in toric IOL calculation. It is defined as the changes in both magnitude and axis of the principle meridian of corneal curvatures following a corneal incision (Hill, 2008). This happens when the cornea flattens along the incisional meridian, thus inducing astigmatism with axis 90 degrees apart from the incision location (Figure 1.1). The amount of SIA is calculated as the difference between preoperative keratometry (K) and postoperative K. These astigmatic values are vectors that comprise of magnitude and direction, thus cannot be calculated using standard mathematical convention. Three accepted methods to calculate SIA is Naeser's polar method, Alpin's method and Holladay method of vector analysis (Hamer, Buckhurst & Buckhurst, 2017; Naeser, 2001). For clinical application of SIA, it has to be calculated using these valid calculation methods.

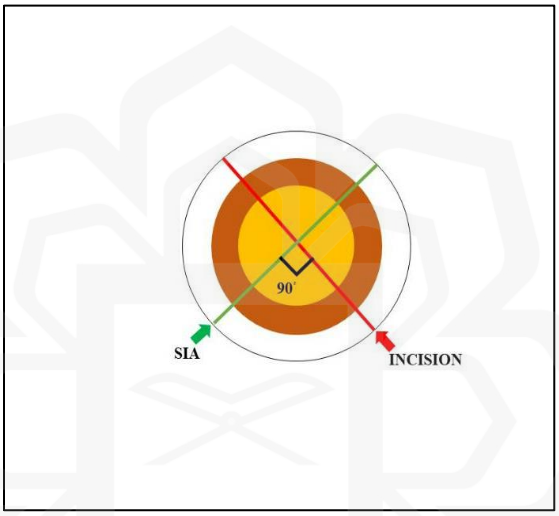

Figure 1.1 Corneal incision and SIA (Hill, 2008)

Various calculators are available to perform SIA calculation based on these methods. These calculators ease the process of SIA calculation, which can be tedious and prone to error if performed manually. However, the calculators provided different analysis report according to their respective calculation methods. To the best of our literature search, no study has compared the outcome between different calculators.

Previous studies have analysed various issues regarding SIA. It has been proven that multiple factors affected the magnitude of SIA such as incision size, incision location and corneal biomechanical properties (Chang, Su & Chen, 2015; Hashemi et al., 2016; Nikose, Saha, Laddha & Patil, 2018; Yoon, Kim, Lee & Nam, 2013). In addition to this established knowledge, recent studies have raised concerns on the large standard deviation of SIA (Tanito, Matsuzaki, Ikeda & Fujihara, 2017; Visser, Berendschot, Bauer & Nuijts, 2012), implying SIA inconsistencies. These studies recommended that surgeons maintain a consistent surgical approach to achieve a consistent and predictable SIA, as consistent SIA could improve toric IOL prediction accuracy (Clark, 2018; Gundersen & Potvin, 2016). However, no studies have been conducted to verify the relationship between surgical technique variations with SIA consistency.

For toric IOL calculation, surgeons have the option to use predicted SIA or actual (calculated) SIA. Several recommendations and guidelines on the SIA values to be utilised were available from previous studies (Barret & Abulafia, 2014; Alcon Online Toric IOL Calculator, 2015). It was observed that these recommendations were incongruent, thus indicating that a predicted SIA might not represent the actual SIA. Therefore, recent studies have suggested the use of actual SIA and postulated that its application improved postoperative refractive outcome (Clark, 2018; Gundersen & Potvin, 2016). However, some surgeons might still adhere to the predicted SIA guidelines and recommendations, which potentially could lead to SIA prediction error. As to date, no study has been conducted to evaluate the effect of the discrepancies between predicted SIA and actual SIA on toric IOL calculation.

In order to assist the surgeon to minimise postoperative residual refractive error for their patients, the issues on SIA need to be addressed**.** This study intended to evaluate the agreement between various SIA calculators and their clinical applications. In addition to that, the relationship between surgical technique variation with the consistency of SIA was explored. Subsequently, the SIA prediction error and its effect in toric IOL calculation were evaluated. Tackling these particular issues of SIA could contribute to the effort to achieve optimal postoperative vision in cataract surgeries.

1.2 JUSTIFICATION

Postoperative residual astigmatism remains as the main cause of patient's visual dissatisfaction (Chang, Su & Chen, 2015; Hashemi et al., 2016; Nikose, Saha, Laddha & Patil, 2018; Yoon, Kim, Lee & Nam, 2013). Surgically induced astigmatism is one of the crucial components in the planning of astigmatism correction (Clark, 2018; Gundersen & Potvin, 2016).

Several aspects of SIA were under-explored. The issue of SIA calculation remains a relevant concern. Due to the development of various SIA calculators which employs different methods and analysis report, an investigation is required to compare the outcome from different calculators and evaluate their suitable clinical application. In addition, the recommendations of applying a consistent surgical approach to achieve consistent SIA have not been verified through studies. A study is warranted to establish the relationship between surgical approach variations with SIA consistency. The discrepancies between predicted SIA and actual SIA have been evaluated in previous works. However, no study has evaluated the effect of this SIA prediction error on toric IOL selection, therefore, indicating a need for further investigation. Thus, this study is crucial to address these under-explored aspects of SIA.

1.3 THESIS STRUCTURE AND OVERVIEW

This thesis is structured into six chapters to address the issues in a stepwise manner. This is according to the nature of this study that was conducted in sequential phases.