COMPAIRING CORNEAL PACHYMETRY READINGS FROM PACHMATE AND OPTOVUE IVUE OCT

by

Anthony A. Sesto

Has been approved

1 May, 2016

APPROVED:

[redacted]

Faculty Advisor:

ACCEPTED:

[redacted]

Faculty Course Supervisor

Ferris State University
Doctor of Optometry Senior Paper
Library Approval and Release

COMPAIRING CORNEAL PACHYMETRY READINGS FROM PACHMATE AND OPTOVUE IVUE OCT

I, _Anthony Sesto___, hereby release this Paper as described above to Ferris State University with the understanding that it will be accessible to the general public. This release is required under the provisions of the Federal Privacy Act.

[redacted]

Doctoral Candidate(s)

5/3/16

Date

COMPAIRING CORNEAL PACHYMETRY READINGS FROM PACHMATE AND OPTOVUE IVUE OCT

By

Anthony A. Sesto

This paper is submitted in partial fulfillment of the
requirements for the degree of
Doctor of Optometry

Ferris State University
Michigan College of Optometry

May, 2016

COMPAIRING CORNEAL PACHYMETRY READINGS FROM PACHMATE AND OPTOVUE IVUE OCT

by

Anthony A. Sesto

Has been approved

____ May, 2008

APPROVED:

_____

Faculty Advisor:

ACCEPTED:

Faculty Course Supervisor

Avesh Raghunandan OD, PhD
Course Coordinator

Ferris State University
Doctor of Optometry Senior Paper
Library Approval and Release

COMPAIRING CORNEAL PACHYMETRY READINGS FROM PACHMATE AND OPTOVUE IVUE OCT

I, _Anthony Sesto ___, hereby release this Paper as described above to Ferris State University with the understanding that it will be accessible to the general public. This release is required under the provisions of the Federal Privacy Act.

_____

Doctoral Candidate(s)

_____

Date

ABSTRACT

Background: This study compared optical to ultrasound corneal pachymetry for measuring the central corneal thickness of a human eye. Corneal pachymetry is the process of measuring the thickness of the cornea. Ultrasound corneal pachymetry has been considered the "gold standard" for measuring corneal thickness for many years. This study compared a Pachmate® ultrasound pachymeter to an Optovue® iVue optical coherence tomography (OCT).

Methods: This research looked at the data from 136 healthy corneas of patients from Mason Family EyeCare. The data was collected using the Optovue® iVue OCT then Pachmate®. Performing it in this order ensured there that there was no alternation of the cornea from applanation of the ultrasound probe. The information from the Optovue iVue® OCT was compared to that of the Pachmate® to see if it was a viable alternative option to take corneal thickness readings.

Results: Corneal thickness readings from the Optovue® iVue OCT ranged from 445 to 618 μm with an average of 525.63 μm and the reading from the Pachmate® ultrasound pachymeter ranged from 469 to 658 μm with an average of 555.44 μm. The difference (Pachmate® minus Optovue® iVue) between each individual reading from the two methods ranged from -1 to 65 μm with an average 29.80 μm.

Conclusion: The data collected and analyzed shows that there is a statically significant difference between the two different pachymetry methods with a $p=0.000$. These results suggest the Optovue® iVue OCT underestimates the pachymetry reading as compared to the Pachmate®

ACKNOWLEDGEMENTS

1) Dr. Philip Walling, OD Michigan College of Optometry my advisor for helping and guiding me though my project
2) Drs. Glen and Chad Linsley, ODs Mason Family EyeCare for allowing me to collect data from their practice
3) Dr. Robert Buckingham, OD for performing the statistical analysis of the collected data
4) Dr. Vandana Rajaram, OD for assisting with the interpretation of the data

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

FIGURE Page

CHAPTER ONE

INTRODUCTION OF COMPAIRING PACHYMETRY READING

How might the instrumentation used to take corneal pachymetry (or central corneal thickness) measurements influence clinical decision making? This is an important question because having accurate corneal pachymetry measurements can start, stop or alter treatment of a patient. Corneal pachymetry is widely used in medical eye care to help diagnose and monitor many ocular diseases.

One disease where corneal pachymetry is widely used to assist in diagnosis is glaucoma. The Ocular Hypertension Treatment Study (OHTS) is a study that stated many risk factors for developing glaucoma, one of them being a person's corneal pachymetry measurement. According to the OHTS if a person has a corneal pachymetry measurement of less than 555 μm they are at a higher risk of developing glaucoma then a person with a corneal pachymetry measurement of greater than 555 μm.[1] The reason why a person with a corneal pachymetry of less than 555 μm is at greater risk is because the equipment used to measure intraocular pressure (IOP) is calibrated to a corneal thickness of 555 μm. This means that for a person with thinner than 555 μm corneas, the IOP is being falsely measured lower than it actually is. It is the opposite for if a person that has a corneal thickness greater than 555 μm; their IOP will actually be lower than what is measured.

According to the Glaucoma Foundation and other sources the conversion ratio of corneal thickness to IOP is 20 μm (corneal thickness):1 mmHg (IOP).[2] For example, if a

person has a corneal thickness of 515 μm their IOP would be 2 mmHg greater than what is measured. It works the opposite way when a person's corneal thickness is greater. This is important because it could be the information needed in order to start a person on glaucoma medication or postpone treatment and watch them closer to see if any glaucoma damage is occurring. Corneal pachymetry is not only used to help the management of glaucoma but in many other ocular disease managements.

Other ocular diseases where corneal pachymetry measurements can assist with the management are: corneal edema, Fuchs' corneal dystrophy, keratoconus, and others. Corneal edema can occur when the cornea is not getting enough oxygen, which is needed to allow the corneal pumps to pump out extra fluid. It could also be caused from a corneal dystrophy. Instances where the cornea is not getting enough oxygen could be from contact lenses, pressure patching, etc. Having the corneal pachymetry readings before a person wears contacts, or if they are patched and taking them after, can prove if they are experiencing corneal edema or not.

Fuchs' corneal dystrophy occurs when the pumps in the corneal endothelium cannot keep up with the fluid entering entering the cornea causing corneal edema. If a person has Fuchs' corneal dystrophy, corneal pachymetry can assist in the diagnosis because a person with these conditions will have thicker corneal pachymetry measurements in the morning than in the evening. The treatment for Fuchs' corneal dystrophy is a hypertonic solution drop. Corneal pachymetry can assist to see how effective the treatment or if it needs to be adjusted. Keratoconus is a genetic condition that affects the structure of the cornea, and because of that, the cornea can experiencing corneal edema due to the change. Also keratoconus can cause thinning of the cornea over

time, so having corneal pachymetry measurements when the patient is first diagnosed and using those measurements while following the person can help tell if that person's cornea is thinning or not. Corneal pachymetry is used not only in ocular disease management but also in pre/post surgical consultations such as Laser Assisted in Situ Keratomileusis (LASIK).

When a person seeks a LASIK consultation there are many factors that are considered to determine if the person is eligible or not. Corneal pachymetry to determine central corneal thickness is just one of the procedures that must be performed. Knowing the corneal thickness is important because according to Eye Surgery Education Council there needs to be 250 μm corneal stromal bed left over after surgery to prevent any post-surgical complications to cornea.[3] (The 250 μm stromal bed equation can be found on the Eye Surgery Education Councils website.) When is comes to LASIK corneal pachymetry is one of the most important procedures and that it must be performed accurately and according to the book Ophthalmology written by M. Yanoff. To calculate stromal bed thickness only ultrasonic and not optical devices are allowed.[4]

After realizing how important corneal pachymetry measurements were to the diagnosis, management and treatment of corneal diseases, the investigators of this report were curious how different corneal pachymetry devices would vary in their measurements from one another. Knowing how important corneal pachymetry measurements are this report compares two corneal pachymetry devices that use different methods to acquire the measurement. One of them is an ultrasound device named Pachmate® which is considered to be the gold standard in pachymetry readings and the other is an optical device named Optovue® iVue.

CHAPTER TWO

METHODS

Background: Sixty-eight people from Mason Family EyeCare volunteered their information to be used in this IRB approved study (Appendix A). The people were not recruited for this project. Instead of recruiting people for the project the data was gathered from people who were already going to have corneal pachymetry because it was medically indicated. All persons whose data were used in this project were educated on the procedures the same as they would be in their normal eye exam. The data collected from each person was based on fact that they had normal healthy corneas (meaning they did not have any corneal disease or dystrophy), they were compliant in their contact lens wear regiment, and they did not have any previous injury that caused large amounts of scaring of the cornea.

Procedure: Each person who was having corneal pachymetry performed had the optical device Optovue® iVue OCT scan first then they had the ultrasound Pachmate®. It was done in this manner to eliminate any corneal distortions caused by the ultrasound Pachmate® device. When performing the Optovue® iVue OCT scan, it was carefully completed to show central alignment and of 'good' scan quality, which was produced from the machine. When performing the Pachmate® applanation the patients were numbed using 1 drop proparacaine in each eye. Then, the applanation was performed. Each Pachmate® applanation had to be within the standard deviation of +/- 5 μm (which

is recommended from the company), to ensure that each measurement was accurate. If the Pachmate® applanation was not with in +/- 5 μm, then the applanation was performed again until it made that criteria.

Devices: Pachmate® is an ultrasound pachymeter that gets its measurements by applanating the cornea. Pachmate® can measure cornea thickness ranging from 200 to 1100 μm with an accuracy of +/- 5 μm. Once the Pachmate® probe touches the cornea it takes twenty-five measurements using high frequency sound waves of 20MHz.[5] Optovue® iVue OCT uses light waves to take its pachymetry measurements. OCT does this by taking eight radial line scan at 6mm lengths. The horizontal line is scanned eight times for averaging. Each of the radial lines contains 1,024 A-scans and the horizontal line contains eight times as many. [6]

CHAPTER THREE

RESULTS

Corneal thickness readings from the Optovue® iVue OCT ranged from 445 to 618 µm with an average of 525.64 µm and the reading from the Pachmate® ultrasound pachymeter ranged from 469 to 658 µm with an average of 555.45 µm (Table 1). The difference (Pachmate® minus Optovue® iVue) between each individual reading from the two methods ranged from -1 to 65 µm with an average 29.80 µm.

Table 1 – Descriptive Statistics

Descriptives

			Statistic	Std. Error
OCT Reading	Mean		525.64	3.564
	95% Confidence Interval for Mean	Lower Bound	518.59	
		Upper Bound	532.69	
	5% Trimmed Mean		524.96	
	Median		522.00	
	Variance		1727.403	
	Std. Deviation		41.562	
	Minimum		445	
	Maximum		618	
	Range		173	
	Interquartile Range		61	
	Skewness		.271	.208
	Kurtosis		-.550	.413
Pachmate	Mean		555.45	3.737
	95% Confidence Interval for Mean	Lower Bound	548.06	
		Upper Bound	562.84	
	5% Trimmed Mean		554.85	
	Median		552.00	

Variance	1899.420	
Std. Deviation	43.582	
Minimum	469	
Maximum	658	
Range	189	
Interquartile Range	65	
Skewness	.277	.208
Kurtosis	-.594	.413

A Shapiro-Wilk test was accomplished to evaluate normalcy of the distribution of readings for both pachymetry instruments. Table 2 reveals that the data is normally distributed.

Table 2 Shapiro-Wilk Test for Normality

Tests of Normality

	Shapiro-Wilk		
	Statistic	df	Sig.
OCTReading	.981	136	.052
Pachmate	.981	136	.055

The data was evaluated for outliers. The Box and Whiskers plots in Figure 1 and 2 reveal the lack of outliers.

Figure 1 Box and Whiskers Plot for OCT Reading

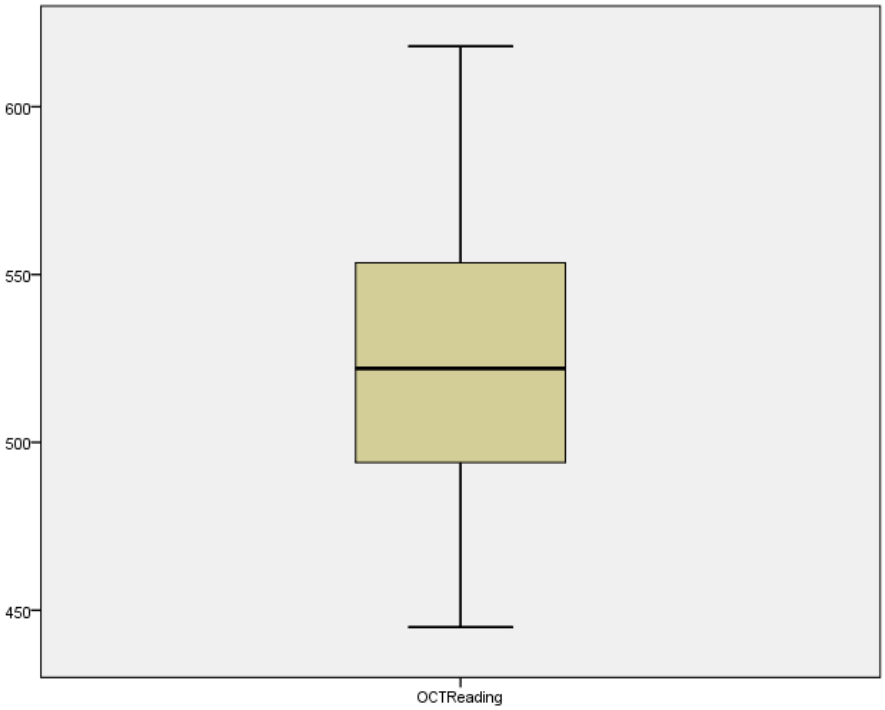
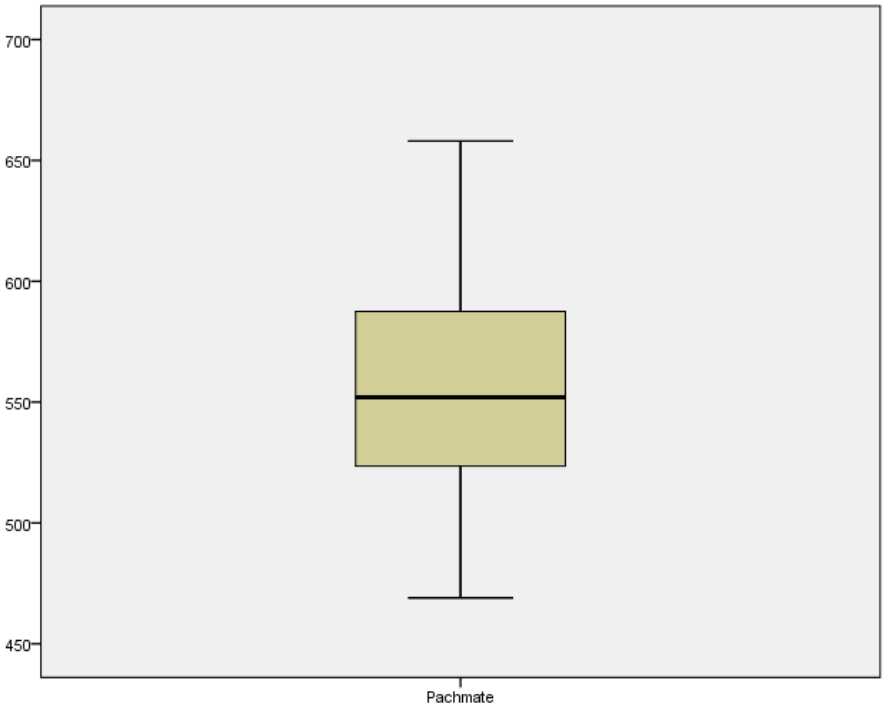


Figure 2 Box and Whiskers Plot for Pachmate



A Pearson's Correlation Coefficient revealed a highly statistically significant correlation with R equal to .957 (Table 3)

Table 3 – Pearson Correlation Coefficient

Paired Samples Correlations

		N	Correlation	Sig.
Pair 1	OCT Reading & Pachmate	136	.957	.000

A paired samples t-test was conducted to compare the pachymetry readings of the Optovue® iVue OCT and the Pachmate®. Table 4 reveals there was a statistically significant difference in the pachymetry readings for the Optovue® iVue OCT (M=525.64, SD=41.562) and the Pachmate® (M=555.45, SD=43.582); t(135)=-27.466, p = 0.000. With the mean difference of -29.809, these results suggest the Optovue® iVue OCT underestimates the pachymetry reading as compared to the Pachmate®.

Table 4 – Paired Samples T-Test for OCT Reading ad Pachmate

Paired Samples Test

		Paired Differences					t	df	Sig. (2-tailed)
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			
Pair 1	OCT Reading - Pachmate	-29.809	12.656	1.085	-31.955	-27.662	-27.466	135	.000

Since there was a difference between the two methods of pachymetry, a stepwise linear regression analysis was performed on the data set. A linear regression would allow a clinician to predict the pachymetry reading from either instrument if the clinician knew one of the two readings. Table 5 reveals the Model Summary for the Pachmate®. In statistics, the term "Model" defines a mathematical relationship between variables such as a regression equation.[8] In linear regression, the SPSS software will develop a model

or regression equation. The model summary in Table 5 includes items such as the Adjusted R Square and the Standard Error of the Estimate for the pachymetry readings. The Adjusted R Square for the pachymetry data was .915 which means that the independent variable, Optovue® iVue OCT reading, in the linear regression equation accounts for 91.5% of the variance in the dependent variable, Pachmate® reading.

Table 5 – Linear Regression Model Summary

Model Summary

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate	Change Statistics				
					R Square Change	F Change	df1	df2	Sig. F Change
1	.957[a]	.916	.915	12.703	.916	1455.124	1	134	.000

a. Predictors: (Constant), OCT Reading

Table 6 reveals the stepwise linear regression coefficients for the Pachmate® readings. The table includes the model, coefficients, and significance of the coefficients for the data. The stepwise linear regression equation reveals that for the data the regression equation is Pachmate reading = 28.009 + [1.003 (Optovue® iVue OCT reading). Using this linear regression equation, 91.5% of the variance in the dependent variable, Pachmate® reading, is explained.

Table 6 - Linear Regression Coefficients for Pachmate Readings

Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients	t	Sig.
		B	Std. Error	Beta		
1	(Constant)	28.009	13.870		2.019	.045
	OCT Reading	1.003	.026	.957	38.146	.000

a. Dependent Variable: Pachmate

CHAPTER FOUR

DISCUSSION

The data collected and analyzed in this study shows that there is a statically significant difference between the two different pachymetry methods with a p=0.000. These results suggest the Optovue® iVue OCT underestimates the pachymetry reading as compared to the gold standard Pachmate®. If a clinician is using a Optovue® iVue OCT to measure pachymetry they can use this study to calculate the approximate amount a Pachmate® measurement would be by adding the mean difference of 29.809 μm as a rough estimate. If a clinician wants to convert their Optovue® iVue OCT measurement to Pachmate® exact an equation was developed using the data from this study: Pachmate reading = 28.009 + [1.003 (Optovue® iVue OCT reading). In a clinical setting it would not be necessary to use the equation vs. adding 29.809 μm because it may not change the decision of the clinician.

When researching this topic, it was found that company of Carl Zeiss performed their own study like this one that compared the measurements between their OCT and Pachmate®. It reveled that the Zeiss OCT measurements were about 10 μm thinner than Pachmate®. More information can be found in the Zeiss OCT manual.[10]

When performing patient care or managing any disease it is important to have all the information to assist in clinical decision making. If a piece of information is missing it could influence a clinician to either monitor, start or stop treatment for any condition.

This study was conducted to help clinicians with that decision that they have to make every day.

REFERENCES

1. Gordon, M. O. (2002). The Ocular Hypertension Treatment Study. *Archives of Ophthalmology Arch Ophthalmol, 120*(6), 714.
2. Drake, M. V., M.D. (2011, April 3). The Importance of Corneal Thickness. Retrieved January 28, 2016, from http://www.glaucoma.org/glaucoma/the-importance-of-corneal-thickness.php
3. Steinert, R., MD, Koch, D., MD, Lane, S., MD, & Sulting, R., MD. (n.d.). LASIK Surgery Screening Guidelines For Patients. *The Eye Surgery Education Council,* 1-4. Retrieved January 27, 2016.
4. Yanoff, M., & Duker, J. S. (2014). *Ophthalmology* (4th ed.). Saunders.
5. Pachymeter. (n.d.). Retrieved February 07, 2016, from http://dghtechnology.com/product/pachmate-2/
6. Optovue - iVue - SD-OCT - Optical coherence tomography. (n.d.). Retrieved January 28, 2016, from http://www.optovue.com/products/ivue/
7. Radford, S. W., Lim, R., & Salmon, J. F. (2004). Comparison of Orbscan and Ultrasound pachymetry in the measurement of central corneal thickness. *Eye, 18*, 434-436. Retrieved January 28, 2016.
8. Glass, G. V., & Hopkins, K. D. (1996). *Statistical methods in education and psychology* (3rd ed.). Needham Heights, MA: Allyn and Bacon.
9. Keppel, G., & Wickens, T. D. (2004). *Design and Analysis: A Researcher's Handbook* (4th ed.). Upper Saddle River, New Jersey: Prentice Hall.

10. CIRRUS HD-OCT. (n.d.). Retrieved March 4, 2016, from http://www.zeiss.com/meditec/en_us/products---solutions/ophthalmology-optometry/glaucoma/diagnostics/optical-coherence-thomography/oct-optical-coherence-tomography/cirrus-hd-oct.html

APPDENDIX A

IRB APPROVAL LETTER

FERRIS STATE UNIVERSITY

Institutional Review Board for Human Subjects in Research

Office of Research & Sponsored Programs, 220 Ferris Drive, PHR 308 · Big Rapids, MI 49307

Date: January 8, 2016

To: Dr. Philip Walling and Anthony Sesto
From: Dr. Gregory Wellman, IRB Chair
Re: IRB Application #151204 *(Comparing corneal pachymetry reading from Pachmate and an Optovue automated OCT)*

The Ferris State University Institutional Review Board (IRB) has reviewed your application for using human subjects in the study, "*Comparing corneal pachymetry reading from Pachmate and an Optovue automated OCT*" (#151204) and determined that it meets Federal Regulations *Exempt-category 1E*. This approval has an expiration date of three years from the date of this letter. **As such, you may collect data according to the procedures outlined in your application until January 8, 2019**. Should additional time be needed to conduct your approved study, a request for extension must be submitted to the IRB a month prior to its expiration.

Your protocol has been assigned project number (#151204), which you should refer to in future correspondence involving this same research procedure. Approval mandates that you follow all University policy and procedures, in addition to applicable governmental regulations. Approval applies only to the activities described in the protocol submission; should revisions need to be made, all materials must be approved by the IRB prior to initiation. In addition, the IRB must be made aware of any serious and unexpected and/or unanticipated adverse events as well as complaints and non-compliance issues.

This project has been granted a waiver of consent documentation; signatures of participants need not be collected.

As mandated by Title 45 Code of Federal Regulations, Part 46 (45 CFR 46) the IRB requires submission of annual reviews during the life of the research project and a Final Report Form upon study completion. Thank you for your compliance with these guidelines and best wishes for a successful research endeavor. Please let us know if the IRB can be of any future assistance.

Regards,

Ferris State University Institutional Review Board
Office of Research and Sponsored Programs

Version 1.2015