A COMPARISON OF THE DIATON, ICARE, AND GOLDMANN METHODS OF TONOMETRY

by

Amanda Marie Hodge and Rebecca April Motz

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 2011

A COMPARISON OF THE DIATON, ICARE, AND GOLDMANN METHODS OF TONOMETRY

by

Amanda Marie Hodge and Rebecca April Motz

Has been approved
May, 2011

APPROVED:

, Faculty Advisor

ACCEPTED:

_____
Faculty Course Supervisor

A COMPARISON OF THE DIATON, ICARE, AND GOLDMANN METHODS OF TONOMETRY

by

Amanda Marie Hodge and Rebecca April Motz

Has been approved
May, 2011

APPROVED:

, Faculty Advisor

ACCEPTED:

_____
Faculty Course Supervisor

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

A COMPARISON OF THE DIATON, ICARE, AND GOLDMANN METHODS OF TONOMETRY

We, Amanda Marie Hodge and Rebecca April Motz, 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.

ABSTRACT

Background: To determine if the Diaton and Icare tonometers are as accurate and reliable as Goldmann Applanation tonometry. *Methods*: Intraocular pressure was measured in 140 eyes of 70 participants by means of three methods. Additionally, the Pachmate, using ultrasound, was utilized to measure pachymetry on all eyes in the study. Measurements were taken in the order of: Goldmann, Icare, Diaton. *Results*: Goldmann was shown on average to measure IOP 0.49 millimeters higher than the Icare. One standard deviation of the Icare measurements was 2.38 millimeters, while two standard deviations was 4.76 millimeters. When comparing the Diaton and Goldmann, Goldmann measured IOP 1.21 millimeters higher on average. One standard deviation of measurements with the Diaton was 3.45 millimeters, while two standard deviations was 6.90 millimeters. *Conclusions*: We can recommend Icare as a safe alternative to Goldmann tonometry, but the same cannot be said for the Diaton. We can only recommend that the Diaton be used as a screening device of IOP in healthy individuals without known history of above normal IOP or glaucoma.

ACKNOWLEDGEMENTS

We would like to thank Dr. Dean Luplow for taking the time to advise us during the course of the study in addition to assisting with organization of materials for our day of data gathering. Also, we would like to thank Dan Harris from Icare Finland Oy and Roman Iospa from BiCOM. Icare graciously donated the probes for use with the Icare tonometer. Diaton donated a tonometer for use in the study. Without the help of these two companies we would have been unable to do this research study. Additionally, we would like to thank the Michigan College of Optometry for donating the use of the Pachmate, Icare tonometer and various other supplies used during the data gathering process.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ILLUSTRATIONS

Introduction

Currently the Diaton and Icare are being used to measure intraocular pressure (IOP), however, it is unsure how accurate and reliable they are in comparison to the gold standard method of Göldmann applanation.

This study was performed to determine if the Diaton tonometer is as accurate and reliable as Goldmann and to determine if the Icare tonometer is as accurate and reliable as Goldmann.

Because the Diaton is a new instrument being used to measure IOP, there is limited available research about its accuracy and reliability. Two research studies have shown that the Diaton is an accurate way to measure IOP, while other studies have shown that it should not be used to replace Goldmann but may be used as an IOP screening device in healthy individuals.

A study done by Yuehua et al. showed that on average the Diaton reads IOP 1.62 mmHg lower than corneal thickness corrected Goldmann applanation tonometry [1]. Another study performed by Mustafa et al. found the Diaton readings to be lower than corneal thickness corrected Goldmann applanation tonometry. This study also showed that thin central corneal thickness seems to affect the measurements obtained by Diaton, a transpalpebral measurement instrument [2]. Waisbourd et al. also noted this conclusion in a study. His study showed that transpalpebral tonometry measured higher IOP relative to Goldmann for thinner corneas and that it measured lower IOP relative to Goldmann for thicker corneas [3]. These studies concluded that the Diaton is useful as a screening device of IOP, but should not be used to replace Goldmann [1,2,3]. A study done by Sandner et al. concluded that the Diaton readings correlate well with Goldmann readings. However, because the study showed that in more than 10% of the measurements there was a difference between Goldmann and Diaton of greater than 3 mmHg, it was concluded that the Diaton may be a helpful screening device, but not a replacement for Goldmann tonometry [4].

The following studies show the Diaton to be as accurate and reliable as Goldmann tonometry: Nesterove A.P, M.D. et al. and R. S. Davidson et al. [5,6]. The study by R. S. Davidson et al. showed that 83% of measurements taken with the Diaton and Goldmann were within 2 mmHg of each other. It was also concluded that it would be useful to consider incorporating the Diaton into routine eye examinations for measuring IOP [6].

While there has been very little research on the accuracy and reliability of the Diaton tonometer in comparison to Goldmann applanation tonometry, there has been more research comparing the Icare tonometer to Goldmann. The majority of studies performed have compared the Icare to Goldmann in patients with a wide range of IOP and in patients with a previous diagnosis of glaucoma or ocular hypertension. Additionally, the majority of studies did not factor corneal thickness into the readings of IOP with the Icare tonometer but did take this into consideration with Goldmann readings.

The following studies found the Icare to measure IOP an average of 0.4-2.2 millimeters higher than corneal thickness corrected Goldmann applanation tonometry: Johannesson et al. and Muttuvelu et al. [7,8]. There have been two studies performed in which a higher average difference between readings with the two instruments was found. A study by Lopez-Caballero et al. found that the Icare measured IOP to be 3.4 millimeters higher than Goldmann tonometry on average [9]. Additionally, Poostchi et al. found the Icare to measure IOP 3.36 millimeters higher than Goldmann [10]. The previous two studies were performed on glaucoma patients.

Several studies have concluded that the differences in IOP between Goldmann and Icare are clinically non-significant. The following are examples of those studies: Anthony Josephson et al., Scuderi et al., Vandewalle et al. [11,12,13]. In a study by Rehnman et al., 45 glaucoma patients were studied. The patient's IOP was measured with Icare and Goldmann and it was then determined whether the difference between the two measurements would alter the management and treatment of these patients. In this study, using the Icare tonometer would have changed the management or treatment of 18% of these patients as compared to using Goldmann tonometry [14]. Munkwitz et al. performed a study comparing the Icare to Goldmann tonometry. In the study of 75 eyes of 75 patients, the authors concluded that the Icare was a good alternative to Goldmann at lower IOP levels while it did not correlate well with Goldmann at higher IOP levels [15].

In many of the studies comparing Icare to Goldmann, researchers have found that the Icare is more accurate at lower IOP levels than higher IOP levels. Additionally, many studies have found that the Icare is less accurate in patients with increased central corneal thickness due to the fact that the Icare is dependent on corneal thickness.

The current study was done to determine if the Diaton tonometer is as accurate and reliable as Goldmann tonometry and to determine if the Icare tonometer is as accurate and reliable as Goldmann tonometry. The current study will contribute to voids found in past published studies concerning the reliability and accuracy of the Icare tonometer in comparison to Goldmann applanation tonometry. This study compares corneal thickness corrected Icare tonometer values with corneal thickness corrected Goldmann applanation tonometry values. This will remove the factor of corneal thickness, which has complicated the comparison between the two instruments in past studies. This study uses the Central Corneal Thickness Adjustment in IOP table produced by the following studies: Ehlers et al. (1975), Stodtmeister (1998), and Doughtry and Zaman (2000). This table can be found in Appendix A. Additionally, the current study will analyze the reliability and accuracy of the Icare tonometer in a very specific population. 90% of patients are within the age range of 21-25 years, while the complete age range is 21-49 years of age. All patients are healthy without evidence of glaucoma. Therefore, with this patient base, the study will focus on using the Icare tonometer as a screening tool for young and healthy patients as compared to using the instrument to influence management and treatment of patients at risk for or diagnosed with glaucoma.

The following questions are to be addressed by this study. Is the Diaton tonometer as accurate and reliable as the Goldmann tonometer? Is the Icare tonometer as accurate and reliable as the Goldmann tonometer?

Methods

Within the current study, 140 eyes of 70 participants were included and examined. Each participant was required to sign a consent form in which permission was given to perform the necessary tests and in which participants were guaranteed protection of privacy. After signing the consent form, each individual patient was tested at five separate stations. The stations included: instillation of anesthetic (fluress) in both eyes (OU), Goldmann measurement OU, Pachmate measurement OU, Icare measurement OU and Diaton measurement OU. The results gathered from each patient were recorded in a spreadsheet in which each participant was assigned an identification number in order to protect personal identification.

The participants in the study were between the ages of 21 and 49 with 90% being between 21 and 25 years old. The study was comprised of 30 males and 40 females. Age and sex have no direct effect on IOP and therefore were not included in the results and analysis of data. The participants included optometry students and optometrists at The Michigan College of Optometry as of September, 2010. No participant with a previous diagnosis of ocular hypertension or glaucoma was included. Also, participants were excluded if there were visible signs of eyelid or corneal pathology.

The instrumentation used to conduct the study includes: Fluress, Goldmann tonometer, Diaton tonometer, Icare tonometer, and Pachmate. Fluress is an ophthalmic solution that consists of 0.25% Fluorescein Sodium and 0.4% Benoxinate Hydrochloride. These ingredients constitute a dye and an anesthetic, respectively. Goldmann applanation is considered the gold standard of IOP measurement. A prism probe is used to apply pressure (applanate) to the cornea thus causing formation of visible mires within the biomicroscope. A dial is rotated until the inner edges of the mires align. The Diaton tonometer is used to measure IOP transpalpebrally, which is through the eyelid. Therefore no anesthetic is needed. The Diaton is placed along the eyelid margin, which is in line with the corneal-scleral junction. The Icare tonometer uses rebound technology. It measures the intraocular pressure by bouncing a small plastic tipped probe against the central cornea. Because it does not rest on the cornea an anesthetic is not necessary. The Pachmate is a type of handheld pachymeter, which measures central corneal thickness using ultrasound technology during contact with the cornea. Due to the fact that corneal contact is used, anesthetic is instilled prior to measurement.

The data was analyzed with calculation of average, mode, median, one standard deviation, and two standard deviations. First, the difference between corneal thickness corrected Goldmann tonometry and corneal thickness corrected Icare tonometry in each eye. This was done for all eyes included in the study. The average of these calculations was subsequently computed. As a result, a positive average demonstrates that Goldmann measurements are on average higher than Icare measurements. The same process was completed for Goldmann and Diaton measurements. Once the average was calculated, the mode, median, and one and two standard deviations were calculated.

Results

The results of the current study include the following statistics for each comparison: average, mode, median, one standard deviation, and two standard deviations. The two comparisons performed were: Icare tonometry versus Goldmann applanation tonometry and Diaton tonometry versus Goldmann applanation tonometry. To arrive at the results, the gathered raw data was inserted into various formulas. For example, the pachymeter results for each eye were rounded to the nearest five microns. The corneal thickness correction factor was calculated using the Central Corneal Thickness Adjustment in IOP table produced by the following studies: Ehlers et al. (1975), Stodtmeister (1998), and Doughtry and Zaman (2000). See Appendix A for the Central Corneal Thickness Adjustment in IOP table. After the correction factor was calculated for each eye, all Goldmann and Icare measurements were re-calculated using the same correction factor for each measurement. Using the corneal thickness corrected values for Goldmann and Icare and the Diaton values, the following were calculated: difference in IOP between Goldmann and Icare (with a positive number indicating that the Goldmann measurement was higher), difference in IOP between Goldmann and Diaton (with a positive number indicating that the Goldmann measurement was higher).

Using the differences between Goldmann and Icare and the differences between Goldmann and Diaton for each of the 140 eyes, average, median, mode, and standard deviations were calculated. It was found that on average Goldmann measured the IOP to be 0.49 millimeters higher than the Icare tonometer. Both the median and mode of the difference in IOP between Goldmann and Icare was one millimeter. Additionally, one standard deviation of the difference between the two instruments was 2.38 millimeters. Two standard deviations of the difference was 4.76 millimeters. See appendix C for a table containing statistics of the comparison between Icare and Goldmann.

The results of the comparison of Goldmann and Diaton showed that on average, Goldmann measured the IOP to be 1.21 millimeters higher than the Diaton tonometer. Both the median and mode of the difference in IOP between Goldmann and Diaton was one millimeter. Additionally, one standard deviation of the difference was 3.45 millimeters. Two standard deviations of the difference between the instruments was 6.90 millimeters. See appendix C for table containing statistics demonstrating the comparison between Goldmann and Diaton.

This current study also surveyed the participants regarding the comfort during IOP measurement from a patient perspective of the Icare tonometer and the Diaton tonometer. Of the respondents, 69% reported that they preferred the Icare tonometer over the Diaton tonometer.

Discussion

To determine the usefulness of the Icare tonometer and the Diaton tonometer, the current study used two qualifications to determine if the variation in accuracy and reliability of the instruments are clinically significant. If two standard deviations are greater than the daily fluctuation of IOP in a non-glaucoma patient the value is clinically significant. According to the article, IOP Fluctuation: What's the Connection, the normal daily fluctuation of IOP is two to six millimeters in a normal individual [16]. Therefore, if two standard deviations of the measurements for a particular instrument is greater than six millimeters, the reliability of that instrument indicates that the instrument should not be used as a replacement for Goldmann applanation tonometry. Additionally, the accuracy of the instruments was analyzed. This was done by first comparing the average Goldmann measurement minus the average measurement using the other instruments. Then, the resulting difference was determined to be clinically significant or non-clinically significant. The qualification used for the determination of clinically significant or non-clinically significant was set by the researchers before the collection of data. It was determined that it is safe to use the Icare or the Diaton as a substitute for Goldmann tonometry if the average difference between the two instruments was less than 1 millimeter. Additionally, it was determined that it is safe to use the Icare or the Diaton as a screener for IOP in healthy young patients if the average difference was less than 2 millimeters.

After establishing the criteria for clinically non-significant and clinically significant, the collected data was analyzed. In the comparison of the Icare with Goldmann, it was determined that the average difference between the instruments (0.49 millimeters) was clinically non-significant. Therefore, the average denotes that the Icare is within standards to use it as a replacement for Goldmann. Additionally, two standard deviations of the measurements for the Icare tonometer (4.76) is clinically non-significant because 95% of the patients were within the normal daily fluctuation of IOP. The chart in appendix D was created to demonstrate the differences between Goldmann and Icare (after being corrected for corneal thickness). The chart shows the range of differences between the two instruments. The range in differences between the two instruments is negative five to positive eight, despite 95% of the participants having a range within 4.76 millimeters of average.

In the comparison of the Diaton with Goldmann, it was determined that the average difference between the instruments (1.21 millimeters) was clinically significant. The average shows that the Diaton tonometer is acceptable for use as a screener of IOP, however it is not accurate enough to use as a replacement for Goldmann tonometry. Additionally, two standard deviations of the measurements for the Diaton tonometer (6.90) is clinically significant because 95% of the patients were not within the normal daily fluctuation of IOP. The chart in appendix E was created to demonstrate the differences between corneal thickness corrected Goldmann and Diaton. The chart shows the range of differences between the two instruments. The range in differences between the two instruments is negative 8.5 to positive nine.

The methods used and design of the current study may have had a negative impact on the results of the study, thus affecting the conclusions drawn. Specifically, examiner proficiency and familiarity in use of the Diaton and Icare prior to the collection of the data may have been a factor contributing to study weakness. The examiners limited this factor during the collection of data because each of the two examiners used one instrument during the entire collection process. Additionally, time of day at which patients were tested varied for each patient. Collection of data took place between 8:00am and 5:00pm. This factor was not limited by methods used by the examiners. Lastly, during use of the Pachmate, Icare and Diaton, three measurements were taken with each instrument on each eye. The averages of the readings were used in analysis of the results. It may have been more beneficial to use the average of more than three measurements in order to increase accuracy.

REFERENCES

1. Yuehau et al. Transpalpebral measurement of intraocular pressure using the Diaton tonometer versus standard Goldmann applanation tonometry [Internet]. Graefes Archive for Clinical and Experimental Ophthalmology Journal, 248: 1765-1770. May 2010 - [cited 2011 Jan 30]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20495818
2. Mustafa et al. Central corneal thickness and Diaton transpalpebral tonometry [Internet]. Graefes Archive for Clinical and Experimental Ophthalmology Journal, 246: 881-889. Feb 2008 – [cited 2011 Jan 30]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18286299
3. Waisbourd et al. Comparison of the transpalpebral tonometer TGDc-01 with Goldmann applanation tonometry [Internet]. European Journal of Ophthalmology, 20: 902-906. Nov 2010 – [cited 2011 Jan 30]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20306444
4. Sandner et al. Measurement of the intraocular pressure with the "transpalpebral tonometer" TGDc-01 in comparison with applanation tonometry [Internet]. Graefes Archive for Clinical and Experimental Ophthalmology Journal, 243:6, 563-569. Dec 2004 – [cited 2011 Jan 30]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/15614540

5. Nesterov et al. Clinical comparison of the Diaton and the Non0contact Tonometers with the Goldmann applanation tonometer in glaucoma patients [Internet]. ESCRS Meeting, London. Sept 2006 – [cited 2011 Jan 30]. Available from: http://escrs.org/EVENTS/06LONDON/sessiondetails.asp?id=157&category=Free&sessiondate=10/09
6. R. S. Davidson et al. Comparison of the Diaton Transpalpebral Tonometer Versus Goldmann Applanation [Internet]. Diaton Comparison Trials [cited 2011 Jan 30]. Available from: http://tonometerdiaton.com/index.php?do=home.Comparison_Study_Diaton_Tonometer_Goldmann
7. Johannesson et al. Pascal, icare and Goldmann Applanation Tonometry – A Comparative Study [Internet]. Acta Ophthalmologica Journal 86:6, 614-621. 2008 – [cited 2011 Jan 9]. Available from: http://onlinelibrary.wiley.com/doi/10.1111/j.1600-0420.2007.01112.x/pdf
8. Muttuvelu et al. Precision and Accuracy of the icare Tonometer – Peripheral and Central IOP Measurements by Rebound Tonometry [Internet]. Acta Ophthalmologica Journal. 2010 – [cited 2011 Jan 9]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20840218

9. Lopez-Caballero et al. Rebound Tonometry in a Clinical Setting. Comparison with Applanation Tonometry [Internet]. Archived Society Espanol Oftalmol Journal 82:5, 273-278. 2007 – [cited 2011 Jan 9]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/17516263
10. Poostchi et al. The icare Rebound Tonometer: Comparisons with Goldmann Tonometry, and Influence of Central Corneal Thickness [Internet]. Clincal Experiment Ophthalmology Journal 2009:7, 687-691. 2009 – [cited 2011 Jan 9]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19788665
11. Josephson, Anthony. Goldmann Applanation Tonometry versus icare Rebound Tonometry [Internet]. Optician Online, 29-30. 2009 – [cited 2011 Jan 9]. Available from: http://www.icaretonometer.com
12. Scuderi et al. Validity and Limits of the Rebound Tonometer (icare): Clinical Study [Internet]. European Journal of Ophthalmology, Sep 2010. 2010 – [cited 2011 Jan 9]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20853257
13. Vandewalle et al. Comparison of icare, Dynamic Contour Tonometer, and Ocular Response Analyzer with Goldmann Applanation Tonometer in Patients with Glaucoma [Internet]. European Journal of Ophthalmology, 19:5, 783-789. 2009 – [cited 2011 Jan 9]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/19787598

14. Rehnman et al. Comparison of Rebound and Applanation Tonometry in the Management of Patients Treated for Glaucoma or Ocular Hypertension [Internet]. Ophthalmic and Physiologic Optics Journal, 28:4, 382-386. July 2008 – [cited 2011 Jan 9]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18565094
15. Munkwitz et al. Comparison of the icare Rebound Tonometer and the Goldmann Applanation Tonometer over a Wide IOP Range [Internet]. Graefes Archive for Clinical and Experimental Ophthalmology Journal, 246:6, 875-879. Jun 2008 – [cited 2011 Jan 9]. Available from: http://www.ncbi.nlm.nih.gov/pubmed/18196259
16. Rhee, Douglas. IOP Fluctuation: What's the Connection [Internet]. Review of Ophthalmology, 16:4. 2009 – [cited 2011 Jan 23]. Available from: http://www.revophth.com/content/d/glaucoma_management/i/1217/c/22924/

APPENDIX A

TABLE 1: Central Corneal Thickness versus Adjustment in IOP

Central Corneal Thickness (Microns)	Adjustment in IOP (mm Hg)
445	+7
455	+6
465	+6
475	+5
485	+4
495	+4
505	+3
515	+2
525	+1
535	+1
545	0
555	-1
565	-1
575	-2
585	-3
595	-4
605	-4
615	-5
625	-6
635	-6
645	-7

APPENDIX B

ILLUSTRATIONS 1-4: Instruments Used in the Study

Goldmann Applanation Tonometer

Diaton Tonometer

Icare Tonometer

Pachmate

APPENDIX C

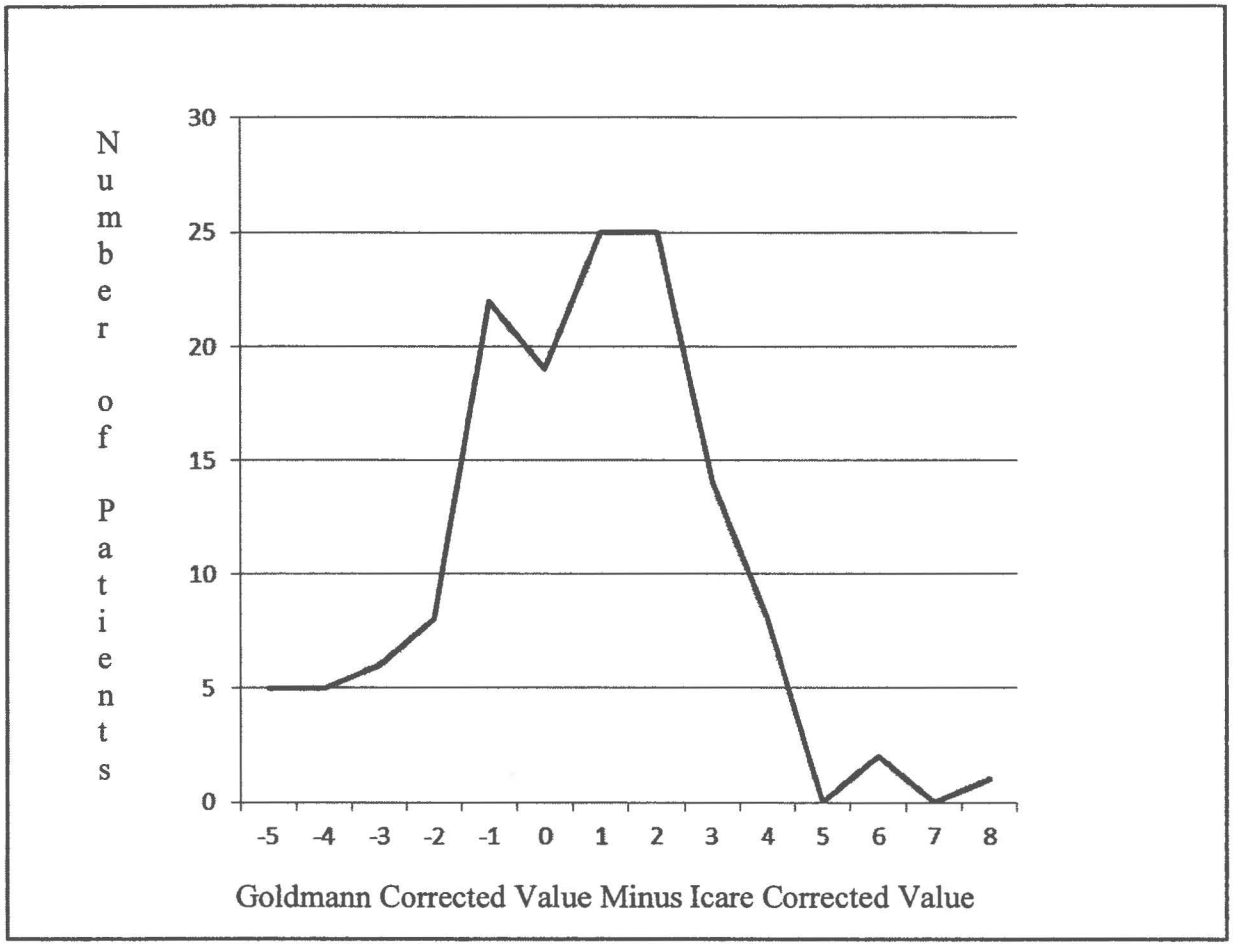
TABLE 2: Statistics Derived from the Data

Statistics			
Goldmann versus Diaton		Goldmann versus Icare	
Average	1.21	Average	0.48
Median	1.00	Median	1.00
Mode	1.00	Mode	1.00
One standard deviation	3.45	One standard deviation	2.38
Two standard deviations	6.90	Two standard deviations	4.76

APPENDIX D

FIGURE 1: Goldmann versus Icare

Goldmann Versus Icare



APPENDIX E

FIGURE: Goldmann versus Diaton

Goldmann Versus Diaton