UNDER PRESSURE: THE REUSABILITY OF THE ICARE REBOUND TONOMETER'S
DISPOSABLE PROBES

by

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UNDER PRESSURE: THE REUSABILITY OF THE ICARE REBOUND TONOMETER'S DISPOSABLE PROBES

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ABSTRACT

Background : This research study aims to evaluate the effect that disinfection of tonometer probes has on intraocular pressure measurements using the ICare tonometer. *Methods :* Intraocular pressure was measured six times in forty eyes using the ICare tonometer and a new tonometer probe. The probe from each eye was then disinfected using Hydrogen Peroxide, then re-tested six times on the same eye that it had measured previously, and the results were compared to find any difference. *Results :* The average reading from the unused probes was 15.14 with a standard deviation of 3.84, whereas the disinfected probes had an average reading of 14.76 with a standard deviation of 3.76 *Conclusion :* There was no statistical or clinically significant difference found in the intraocular pressure measurements taken with the ICare Tonometer using new versus disinfected probes.

TABLE OF CONTENTS

Page

LIST OF TABLES

v

LIST OF IMAGES

INTRODUCTION

Tonometry, the measurement of intraocular pressure (IOP), has become an essential component of any thorough eye examination. Intraocular pressure is especially useful in evaluating patients with glaucoma, a disease process associated with increased IOPs and peripheral visual field loss. Many methods of measuring IOP have been developed and each has its own advantages and disadvantages. Considerations associated with clinical tonometry include accuracy, convenience, cost and patient comfort. Currently used tonometers include the Goldmann tonometer, Perkins tonometer, tonopen, non-contact tonometer and recently the Icare tonometer, which uses rebound tonometry. This study will focus on the measurements from the Icare tonometer and the accuracy of unused probes versus probes that have been disinfected.

Normal IOP is considered to be anywhere in between 10.5 to 20.5 mmHg with the mean being 15.5 +/- 2.57 mmHg. Intraocular pressure normally fluctuates from 5 mmHg or more throughout the day and can be influenced by postural changes, straining, eyelid closure, systemic conditions, and drugs. IOP measurement is affected by the thickness of the cornea, with thin corneas (less than 540 microns thick) underestimating the pressure and thick corneas (greater than 540 microns thick) overestimating the pressure. IOP is generally found to increase with age and typically higher in persons of African descent.[1]

IOP can be measured by numerous methods and the main considerations are cost effectiveness, patient comfort, ease of use, accuracy and time effectiveness. Tonometers primarily exist in four classes: indentation, applanation, non-contact, and most recently rebound tonometry. Using a plunger to indent an anesthetized cornea, indentation tonometers indent the cornea and produce a tonometric value which can be converted to an approximation of the IOP. Because of the great force required to indent the cornea in such a way, indentation tonometers can result in the near doubling of IOP, thus limiting its use in clinical practice. Although indentation tonometers are inexpensive, they are rarely used because they are largely considered to be unreliable. Non-contact tonometers, in contrast, use a puff of air to flatten the unanesthetized cornea, and the time required to flatten the cornea is used to estimate the IOP. Although non-contact tonometers are conveniently performed without the use of anesthesia, these tonometers are less-frequently used because many patients dislike the startling puff of air. The gold standard of tonometric measurement is applanation tonometry, which uses a probe to merely flatten the anesthetized cornea. Applanation tonometers are conveniently mounted to slit lamps and widely used in clinical practice. The primary drawback to tonometry by applanation is the fact that the cornea must be anesthetized before IOP can be measured.[1]

Finally and most recently, rebound tonometry has been developed in the form of the Icare tonometer, one of the latest tech-savvy tonometers. Icare tonometers use small probes that make contact with the front of the eye and 'rebound' off of the cornea as speed of the probe is recorded before and after contact. Probe deceleration is the main

measurement that changes as a function of IOP. From the multiple measurements made by the tonometer, an accurate IOP can be quickly determined.[2,3]

Although making momentary contact with the cornea, the Icare tonometer's probes do not elicit enough corneal sensation to require the use of an anesthetic. It eliminates the need to instill any drops in the patients' eyes and is relatively comfortable for the patient. The probe is not only easy to use but the tonometer is extremely portable. The Icare tonometer's main hindrance is cost efficiency. Probes must be inserted into the device and removed after measurement, and a clean probe must be used on each individual patient. Although probes can be purchased in bulk to reduce cost, they are significantly more expensive to use than the other tonometers. Reusing probes could greatly reduce the cost of using the Icare tonometer and increase its use in eye care. The aim of this study is to analyze data measurements comparing the IOP measurements obtained using a new probe versus the IOP measurements obtained using the same probes after disinfection.

METHODS

Two sets of intraocular pressure measurements were preformed on twenty individuals using the Icare tonometer. Subjects of varying age, gender, and race were randomly selected for the data collected in this study. Because intraocular pressure can vary between an individual's two eyes, each of the forty eyes was considered to be a separate subject.

Prior to every reading, the individual was seated in an upright chair for at least three minutes prior to measurement to avoid any exertion during the readings. For the sake of consistency, each measurement was taken by the same tonometrist. Each patient was instructed to relax his or her eyelids and stare directly ahead as measurements were taken from the central cornea. Although clinicians generally record the average of the tonometer's six readings per eye, each of the six readings was specifically recorded to provide additional statistical insight.

The first tonometry reading was performed using an unused Icare tonometry probe. After the first set of readings was completed, each probe was soaked in three percent hydrogen peroxide for five minutes. After soaking, the probe was rinsed in sterile saline and allowed to air dry for one additional minute to avoid any corneal contact with the disinfectant. After disinfection and drying time, the probe was used again to measure the IOP on the same eye it had measured previously.

An important component of this experiment was developing a method for proper suspension of the end of the probes in the disinfectant. A Goldman tonometer's tip is thinner at the apex when compared to the base (see Image A), which allows it to be suspended using a hole larger than the apex but smaller than the base (see Image B). The Icare tonometer's probes, on the other hand, are very slender with a small circular cap at the end of the probe (see Image C). In order to soak the Icare tonometry probes, a new method of suspending the probes in disinfectant was developed. To soak the tonometry probes, the non-applanating end of the probe was inserted into a styrofoam holder (see Image D). The styrofoam holder was then inverted and rested on the edges of the glass, allowing the tip of the probe to be suspended in solution (see Image E). After being soaked in hydrogen peroxide for 5 minutes, the styrofoam holder was removed and the tip of the probe was quickly immersed in Opti-free contact lens solution to rinse off the hydrogen peroxide. The probe was then allowed to air dry with the probe's tip suspended in the air (see Image F). Once dried and disinfected, the same probe was used to re-measure the intraocular pressure from the same subject. Once again six measurements were made. The pre-disinfected and post-disinfected data were compared to determine if the disinfection process will in any way affect the resultant pressure reading.

In 1986, statisticians Bland and Altman proposed a method for assessing agreement between two methods of clinical measurement. Their alternative approach, based on graphical techniques and simple calculations, was specifically designed to evaluate clinical repeatability. This study utilized Bland-Altman analysis to determine if

there is a clinically significant difference between measurements by unused and disinfected probes.[4]

To utilize Bland-Altman, each individual measurement of intraocular pressure with a new probe was compared to the corresponding measurement in the same subject's same eye. In other words, Patient A's first IOP reading *with a new probe* in the right eye would be compared to Patient A's second IOP reading *with the exact same probe, now disinfected* in the right eye. Each pair of measurements forms the foundation for Bland-Altman analysis (See Table 1).

Bland-Altman analysis requires calculation of the difference between the two measurements as well as the average of the two readings. Also useful for further analysis is the standard deviation, or the average deviation from that mean. We utilized two different tables. The first was created by plotting the difference between the two measurements on the Y axis against the average of the two measurements on the X axis. The second is used to display the average of the differences as well as the 95% limits of agreement (See Table 2).

RESULTS

For the right and left eyes together, our mean IOP measurement with the unused probes was 15.14 mmHg with a standard deviation of 3.84. The measurement using disinfected probes was 14.76 mmHg with a standard deviation of 3.76. The correlation coefficient between the unused and disinfected probes for both eyes was 0.672.

For the right eye alone, the mean IOP measurement with the unused probes was 15.79 mmHg with a standard deviation of 3.96. The measurement using the disinfected probes was 14.72 with a standard deviation of 3.34. The correlation coefficient between the unused and disinfected probes for the measurements on the right eye was 0.598.

For the left eye alone, the mean IOP measurement with the unused probes was 14.49 mmHg with a standard deviation of 3.63. The measurement using the disinfected probes was 14.80 with a standard deviation of 4.15. The correlation coefficient between the unused and disinfected probes for the measurements on the left eye was 0.78.
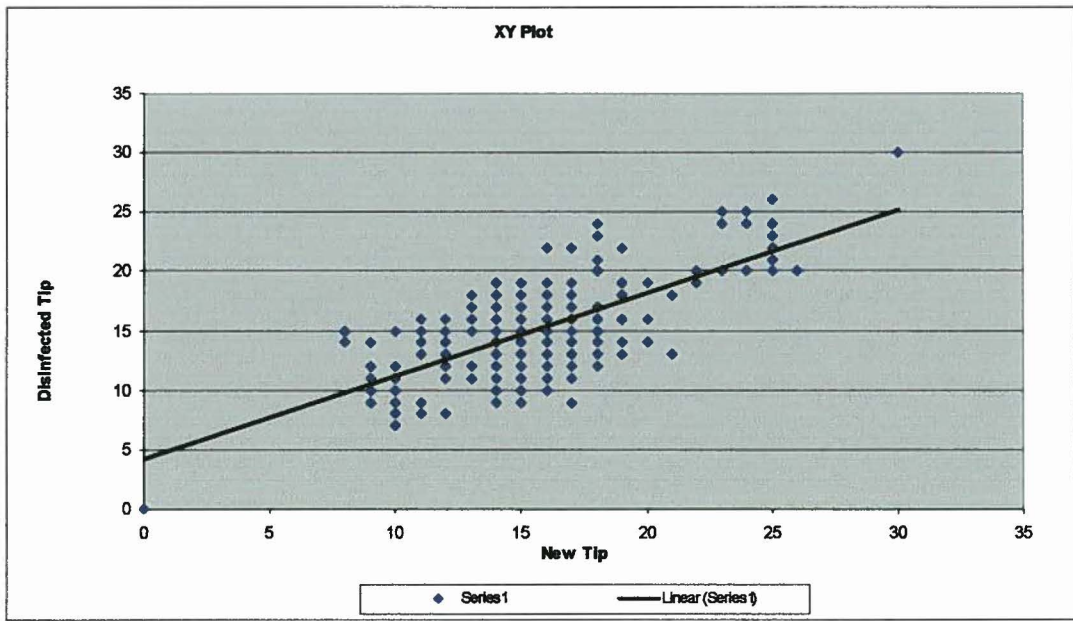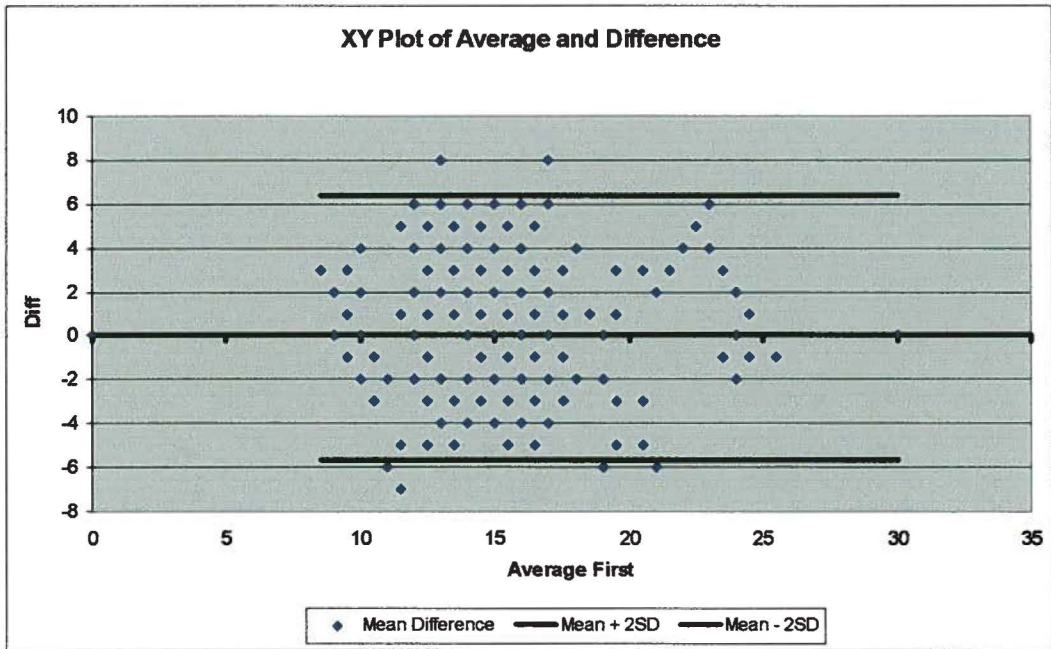
Table 1:Graph of Disinfected probes versus new probes

Table 2:Graph of Difference versus Average

DISCUSSION

The purpose of this project was to determine if disinfecting the probe of an Icare tonometer would affect its reading. The testing involved measuring using an unused probe and re-measuring the probe after disinfection on the same subject. The results of this test may have clinical significance on the possibility of disinfecting the probes and re-using them on another patient.

After data was collected and analyzed, it was found that there was no statistically relevant difference between the unused probes' measurements and the disinfected probes' measurements. The individual measurements were placed into two tables, the first comparing the initial measurement directly to the disinfected measurement. In Table 1, if the two measurements were exactly the same from the first measurement compared to the second, one would expect a slope of 1. The slope in this case was 0.78. The second table uses the Bland-Altman method for assessing agreement between two different methods of measurement. Table 2 shows that when comparing the methods, the pressure difference was between 0-8 mmHg for each measurement, with a standard deviation of 3.1.

The standard deviation of IOP measurements was 3.1, and the range was from 0-8mmHg. The key clinical issue is whether a difference of 3.1 mmHg on each measurement is an acceptable value. The IOP can fluctuate anywhere from 0-5 mmHg from its average value during the day according to normal diurnal variation.[1] On any

given measurement, the difference will be around 3mmHg, but can be as high as 8mmHg. This means that each probe can be disinfected one time and be re-used, without affecting the accuracy of the second measurement, if it is determined by the doctor that this deviation is acceptable.

One interesting finding was that when the eyes were separated into OD and OS readings, it was found that the OD readings after disinfection were approximately 1mmHg lower than the initial reading. The standard deviation was 3.32, which is higher than the standard deviation of the total. This was likely due to the fact that the OD was measured first in each individual, possibly leading to a higher initial measurement of the first eye. If this experiment were to be done again, it is recommended to measure the IOPs with the first eye being chosen at random.

Four questions are typically posed when analyzing a Bland-Altman graph: "How large the average discrepancy is between the two methods?", "Do any trends exist?", "Does the difference between methods change as the average increases?" and "Is there variability across the graph?" To answer them, we must look at the graph of the data compiled (see Table 2). The average discrepancy between the two methods is 3.1mmHg, ranging from 0-8 mmHg for each individual measurement. It is difficult to determine any trends in the data because most measurements fall within 10-19 mmHg. However, measurements obtained over 22 mmHg showed a closer agreement between the two measurements. As the average increases, the difference between methods appears to minimize. It would take many more measurements of higher IOPs to determine if this difference is significant.

10

A proper disinfection technique is necessary to effectively disinfect these probes. The method performed in this experiment was used to minimize contact of the probe with any other objects and maintain its proper disinfection. The probes proved to be delicate at times, and the metal end of the probe may be vulnerable to mechanical damage if not cared for properly. A hydrogen peroxide solution was selected as a disinfection technique due to its broad-spectrum microbe coverage and ease of use.[5,6] One must be sure to not allow hydrogen peroxide to make contact with the cornea, and a sterile water solution must be used to rinse the probe after disinfection. A one minute drying time was used to avoid any complications that may arise from a moist probe being used in the Icare tonometer. This technique worked well and provided accurate results.

CONCLUSION

The Icare Tonometer is a safe, accurate and convenient instrument for measuring IOP which does not require anesthetic. One of the issues in clinical use is the cost of repeated replacement of new probes for each patient. This study analyzed the measurements from the Icare tonometer using a new probe, and compared them with measurements made by the same probe on the same eye after disinfection. When comparing the IOP measurements of an unused Icare tonometer probe to a disinfected probe, no significant difference was found. The analysis comparing the two data sets reveals that the IOP measurement can differ by 3.1 mmHg on any given measurement, although the difference could be as high as 8mmHg. If this variation is deemed acceptable by clinicians, then the conclusion would be that the initial disinfection of an unused Icare tonometer probe using a 3% hydrogen peroxide solution will not affect the subsequent measurement of IOP.

REFERENCES

1. Yanoff, Myron, and Jay S. Duker. Ophthalmology. London: Mosby, 2003: 1431-1434.

2. Roberts, Dawn EC. Comparison of iCARE Tonometer with Pulsair and Tonopen in Domiciliary Work. Optometry In Practice. 2005: 6 33-39.

3. Martinez-de-la-Casa, Jose M., Julian Garcia-Feijoo, Alfredo Castillo, and Julian Garcia-Sanchez. Reproducibility and Clinical Evaluation of Rebound Tonometry. Investigative Ophthalmology and Visual *Science* 2005: 46 4578-580.

4. Altman DG, Bland JM. Measurement in medicine. The analysis of method comparison studies. The Statistician 1983; 32, 307-317.

5. Segal, William A., Johnathon R. Pirnazar, Max Arens, and Jay S. Pepose. Disinfection of Goldmann Tonometers after Contamination with Hepatitis C Virus. American Journal of Ophthalmology 131.2 (2001): 184-87.

6. Pepose, Jay S., Gerald Linette, Steven F. Lee, and Scott Macrae. Disinfection of Goldmann Tonometers Against Human Immunodeficiency Virus Type 1. Arch Ophthalmol. 107.7 (1989): 983-85.

APPENDIX A

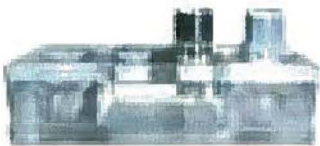LIST OF IMAGES

Image A: Goldmann tonometry tip

Image B: Common method of disinfection of Goldmann tonometry tips
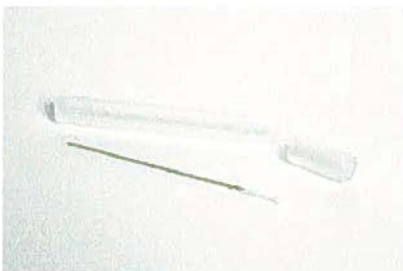

Image C: An Icare tonometry probe

Image D: Proposed method for soaking probes utilizing a piece of Styrofoam
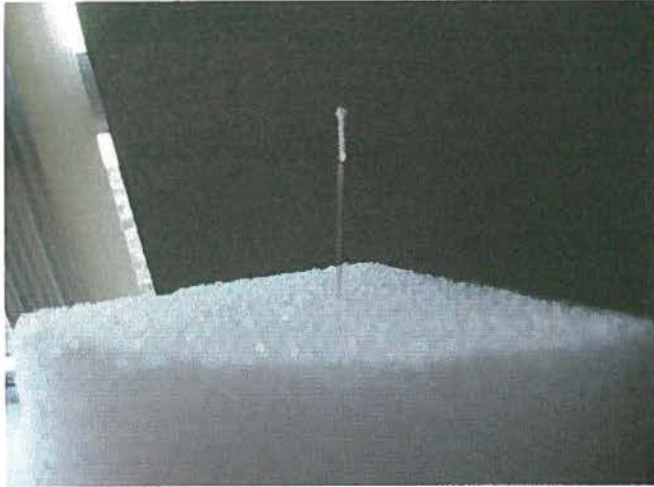

Image E: Icare tonometry probe suspended in solution

Image F: Air-drying the recently-disinfected Icare tonometry probe