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Test-retest variability of visual acuity in a busy eye clinic

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Test-Retest Variability of Visual Acuity in a Busy Eye Clinic

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Acknowledgements

I would like to thank my supervisor, Dr Hemant Kana, Consultant Ophthalmologist at the St John Eye Hospital, Chris Hani Baragwanath Hospital for his support and assistance in the research project

I would also like to thank the eye clinic nursing staff for their patience and enthusiasm for the data collection.

ABSTRACT

OBJECTIVES

The main objective is to demonstrate and to quantify any variability between nurse measured and doctor measured visual acuity (VA) performed on the same patient under the same testing conditions in the out patients clinic at the St John Eye Hospital.

DESIGN

A prospective, cross-sectional study using adult patients presenting with visual acuity of at least 6/60 in one eye as measured on an illuminated Snellen chart.

The study was performed on patients aged 18 years and older.

STUDY METHOD

Patients who have had VA testing by the nurses but have not consulted with the doctors were randomly selected to have their VA re-tested by a doctor under the same testing conditions as the initial testing by the nurses. Both tests were performed using an illuminated Snellen chart.

STATISTICAL METHODS

Using a Bland-Altman analysis, a measurement error between the two observers was determined. The difference in measurements between observers for each patient was determined and each value was plotted on the y-axis. The mean difference in observations was in-turn calculated and plotted on the x-axis. The degree of disagreement with its 95% confidence interval (CI) was plotted on the graph.

RESULTS

The calculated difference in Early Treatment of Diabetic Retinopathy Study (ETDRS) letters between the observers ranged between 0 and 55 letters, which equates to 11 Snellen lines.

When the differences are averaged out, the mean difference was only 0.045 letters with a standard deviation of 9.62 letters and the 95% confidence interval (CI) of -55 to 70.

On performing the Bland-Altman analysis, the limits of agreement between the observers at the 95% CI were -18.79 letters (at lower end) and 19.70 letters (at the upper end), a total of 38.49 ETDRS letters.

CONCLUSIONS

The VAs measured at the St John Eye Hospital out patients department are not reproducible. Variability in measurement as found in the study was 38,49 ETDRS letters, an equivalent of 7,69 Snellen lines. This is not within the accepted limit of 2 Snellen lines or 10 ETDRS letters.

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List of Abbreviations

VA: Visual Acuity

CI: Confidence Interval

ETDRS: Early Treatment of Diabetic Retinopathy Study

Log: Logarithm

MAR: Minimal Angle of Resolution

OKN: Optokinetic Nystagmus

HREC: Human Research Ethics Committee

Obs: Observation

Std Dev: Standard Deviation

Min: Minimum

Max: Maximum

r: Correlation coefficient

N: Total number of subjects

Var: Variance

sd: Standard Deviation

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1.Introduction

Visual acuity (VA) testing is an integral part of any ophthalmologic assessment. VA measures the visual systems' minimal spatial discrimination between two objects in space, and represents the minimal angle of separation subtended by a single photoreceptor by the two objects that allow the objects to be perceived as distinct. This represents the state of the entire ocular system, including the visual pathways.

VA is used in clinical practice as a surrogate measure of ocular disease severity, change in disease over time, or to monitor response to therapy.[1,2,3]

VA can be measured using subjective or objective methods.[2,3,4]

1.1. Subjective Methods

The subjective methods of measuring VA generally entail the use of reading charts. The charts consist of letters or optotypes. Each successive line on the chart represents increasing or decreasing visual angle at a set distance.[1,2]

There are several types of reading charts available such as the Snellen, ETDRS, Bailey-Lovie, Landolt C and the illiterate E charts.[1,2,3]

The Snellen chart, which was introduced by Herman Snellen in the 17th century, is the most widely used chart in clinical practice since it is readily available and relatively quick to use [3] . Originally, Snellen constructed a set consisting of a block of letters for which the letter as a whole was five times as large as the strokes that formed the letter. The patient read the letters from an increasing distance until they could no

longer read the letters .[3] Over time this method was adapted such that the patient was moved instead of the numbers and the reading distance was set at 20 feet or 6 metres.[3] The results of this test are expressed in fractions where the numerator denotes reading distance and the denominator denotes the smallest line of letters read by the subject on a particular chart. The denominator is derived from population studies and is used as a reference for 'normal' vision. Thus normal vision came to be defined as 6/6 meters (or 20/20 in feet) meaning that at 6 meters the whole letter subtends the photoreceptors at 5 arc minutes and each stroke of the letter subtends at 1 minute of arc. [3]

The accurate measurement of vision using the aforementioned charts can be influenced by various factors including light intensity of the testing environment; number, size, contrast, shape and illumination of the optotypes; and the design of the test chart. Patient factors such as pupil size, presence of corneal pathology, state of dark adaptation, duration of exposure to the target, eye movements etc. can also affect the results obtained. [1,2,3]

Problems with the Snellen chart have been well documented and include the following:

i. The chart consists of rows of optotypes of decreasing size that are arbitrarily standardised to be read at 6 metres. [1,2,3,4]
ii. The variation in the number of letters per line and the spacing between the letters are arbitrary. As a result some lines have more letters than others resulting in visual crowding.[1,2,3]
iii. The progression of the size of the letters on the chart is irregular and there is lack of an accurate or standardized scoring system.[1,2,3]
iv. The variation in the ratio of the sizes of the letters between successive lines is arbitrary with large gaps between acuity levels at the lower end of the acuity scale.[3]

To overcome the aforementioned problems with the Snellen chart, Logarithm of the minimal angle of resolution (logMAR) based charts such as the Bailey-Lovie use optotypes that are more precisely sized and spaced with a logarithmic change in size between the lines to provide a more accurate quantitative evaluation of visual acuity . In these charts, there is a 0.10 log (logarithm) unit difference between each successive row on such that a value of 0.0 corresponds to MAR (Minimal Angle of Resolution)= 1.0 or 6/6 (Snellen equivalent).[1,2,5]

1.2. Objective Methods

The objective evaluation of visual acuity testing is limited to laboratory use and in preverbal children

These include:

1. Visual Evoked Potential

   This is the recording of electrical activity of the visual cortex created by stimulation of the retina.

   In this test, the eye is stimulated by a flash of light or a black and white checkerboard on a screen. The electrical impulses generated by the eyes in response to the stimulus are then recorded using electrodes connected to the scalp of the subject and to a computer. This response to stimuli is represented as a series of waves much like an electroencephalogram.[1,2,3]

2. Optokinetic Nystagmus (OKN)

   This is the presence of reflexive eye movements following presentation of a moving target in the visual field. These involuntary eye movements are controlled by the cortical and vestibular mechanisms of the brain and consist of a tracking phase where the eye matches the speed of the moving target followed by rapid jerk nystagmus in the opposite direction. OKN can be elicited clinically by presenting a rotating optokinetic drum to the patient. [2]

3. Preferential looking

   In infants, spontaneous visual fixation can be induced by specific stimuli. Infants prefer to look at patterned stimuli rather than uniformly bright objects.

   The types of stimuli that are commonly used include Teller cards, Cardiff acuity cards and Keeler cards.[1,2]

The subjective testing methods are widely used since the charts are readily available and are easy to use with minimal training required for the operator.

Cases where there is uncertainty on whether the subjective VA obtained is accurate or not present a real dilemma in clinical practice since the objective methods are often not available.

To compound matters, the reproducibility of VA testing on the Snellen chart is reported to be poor, with some authors reporting up to 13% of patients displaying discrepancies of two or more lines on re-testing under controlled conditions.[4,6]

All chart-based methods of visual acuity testing are subject to random probability of 'guessing' the correct optotype by the test subject. The random likelihood of this occurring is very low at 4% if a full-set 26 letter chart is used and goes up to 10% if a reduced letter set chart is used. [7]

This variability in Snellen measured VAs is clearly observed in situations where different operators test the same patient on the same day and get differing results. This is true for ophthalmologists in a large referral unit where VAs are often performed by clinic nurses or by a referring optometrist. The physician may get a different result on repeated VA testing on the same patient than what is initially presented to him/her.[7]

2. Literature review

Several papers in the literature have reported that results from visual acuity testing in clinical settings have a certain degree of inherent variability.[8,9,10]

In 1999, John Siderov and Annette L. Tiu were the first to quantify this inherent variability in a clinical setting (instead of clinical trial or laboratory setting) which they reported to be 8 letters on a LogMar based chart which is equivalent to 2 Snellen chart lines.[11] Several other papers have been published since then supporting this finding.[8,9,10]

In their 2007 paper, Ralph Becker et al further demonstrated that the lower the VA, the higher this variability is. They also demonstrated that incorrect VA measurement occurs frequently and this can also mimic low reproducibility of the visual acuity values in low vision. [7]

The question that this study seeks to answer is whether VAs measured under normal clinic conditions at the St John Eye Hospital are repeatable or reproducible. If they are not reproducible, is the variation observed the inherent "normal" variation of up to 2 Snellen lines as described in the literature? [8,9,10]

As discussed in the opening paragraphs, VA measurement using illuminated charts is a surrogate marker of the visual system's resolving power, therefore the true measure remains unknown. When two varying VA measurements are obtained from the same patient on test-retest, the 'real' VA will remain unknown. This problem is similar to comparing two different methods of measuring an unknown variable or comparing a new method of measurement against the accepted gold standard, where the measured values may differ significantly.[7,11, 12] The observed difference may be due to one of the measurement methods being more accurate than the other, measurement error or a random variation in the actual variable of interest.[7]

Furthermore, the of use Bayesian statistics in test re-test studies has been criticised (if not deemed incorrect) as it may lead to erroneous conclusions.[13] In publications by Bland & Altman it was argued that simply calculating the differences in

arithmetic/geometric means and plotting the values on a scatter plot will always show a difference between the two methods of interest even when there is none.[7,11,12]

They further argue that simply calculating correlation coefficient between the two tests of interest may also lead to incorrect conclusions since correlation does not mean agreement.

For example, if a manual thermometer were to be compared to a new electronic version, both instruments may show an increase in temperature when immersed in progressively hot water. This increase in readings will show a linear relationship, but the value of the increases may differ between them [10,11]. Hence one cannot conclude that 50 degrees celsius on the new thermometer is equal to 50 degrees celsius on the manual one but can say they both show an increase in temperature i.e. there is a correlation.

Another problem is that statistical manipulations using Snellen fractions is cumbersome and may lead to inaccuracies when geometric and arithmetic means are calculated.[7,11,12] It is argued that LogMAR units should be used in such studies as they are more amenable to statistical manipulations including application of Bayesian statistics where appropriate, and can be easily converted into other notations such as ETDRS letters and Snellen fractions using readily available conversion tables.[7,11-13]

Lastly, no study of this sort has been done at the St John Eye hospital. Thus it is unclear whether this variability exists and if so, whether it is in line with what has been reported in the literature as the acceptable level of 10 ETDRS letters or 2 Snellen lines.

Furthermore, no study on the variability of visual acuity has to our knowledge been reported from a large ophthalmology referral centre serving the indigent in South Africa and as such, the level of VA variability in such centers is unknown.

3. Study aim

The aim of this study was to quantify the variability in tested visual acuity in a busy, tertiary referral ophthalmology out patient clinic at the St John Eye Hospital where VA testing is performed by trained ophthalmology nurses.

4. Study objectives

The main objective was to re-test VAs (by the study physician) on a sample of outpatient clinic patients who have already had routine testing by the nursing staff under normal clinic conditions to assess the level of variability in measurements between the 2 observers.

5. Hypothesis

VA measurement performed by clinic nurses on any patient in the clinic will always be in agreement with VAs performed by the doctors. Any variation observed will be up to 2 Snellen lines as reported as the acceptable level of variability.

6. Experimental Procedure

6.1. Design

A prospective, cross-sectional study on adult patients presenting with visual acuity of at least 6/60 in one eye as measured on an illuminated Snellen chart.

The study only included patients aged 18 years and older.

6.2. Method

Patients who have had VA testing by the nurses but have not consulted with the doctors were sampled to have their VA re-tested by the study doctor in the same testing conditions as the initial testing by the nurses.

6.3. Inclusion criteria

Measurable VA on the Snellen chart

Age >18 years

6.4. Exclusion criteria

- Patients with VA less than 6/60 (Counting fingers, light perception or no light perception)
- Mentally incompetent patients
- Age less than 18 years

6.5. Outcome measures

Level of variability of visual acuity as measured on the Snellen chart

6.6. Sample of population

Patients over 18 years of age, presenting for scheduled or emergent consultation at the St John Eye Hospital's out patient clinic.

209 eligible patients were enrolled into the study. This assumed that the total number of patients seen at St John out patient clinic is 12 000 annually (based on historic data), in order to demonstrate an 80% correlation between nurse and doctor VA (variability of 2 Snellen lines or less) with a 95% confidence level and standard error of 0.02812.

6.7. Materials, equipment and facilities

Illuminated Snellen charts that are currently used at the St Johns Eye clinic were used. The charts consist of a Perspex box with Snellen optotypes/letters printed on 4 sides and mounted on a rotating, vertical arm. The box has an illumination source inside.

The optotypes on each side of the box range consist of either numbers, alphabets or tumbling E.

6.8. Data collection

Patient data and Snellen recordings were captured on ethics data capturing sheets (Appendix A) as approved by the ethics committee. The VAs were recorded as Snellen fractions.

Each patient's recording was assigned a case identity number to ensure anonymity.

Patient names and medical record numbers were not made available to any person other than the researcher (Dr B Khantsi) and research supervisor (Dr H Kana).

6.9. Data management and statistics

The Snellen fractions were recorded on the data capture sheet and then transcribed to an excel spreadsheet. The Snellen fractions were in turn converted into ETDRS letters using conversion a table[13]

The difference in ETDRS letters between doctor & nurse measurements for each patient was calculated together with the mean difference per patient.

The data was imported into Stata 12 statistical program for analysis.

A scatter plot of the nurse measured VA on the y-axis and the doctor-measured VAs on the x-axis was drawn. The line of equality, which represents the line on which all observations would fall if there is agreement between recordings, was imputed.

A Bland-Altman plot of the actual difference between the measurements per patient (y-axis) against the average difference per patient (x-axis) was drawn. The plot includes the 95% limits (upper & lower) of agreement and the standard t–test for the limits of agreement was performed.

6.10. Staff and administration

The study was carried out by Dr B Khantsi, a registrar in the Department of Ophthalmology at St John Eye Hospital and was supervised by Dr H Kana, a consultant ophthalmologist at the St John Eye Hospital.

6.11. Ethical considerations

Clearance from the Human Research Ethics Committee (HREC) and the

Postgraduate Committee was obtained prior to commencement of the study.

Consent to conduct the study at the St John's Eye Hospital was obtained from the Superintendent, Chris Hani Baragwanath Hospital.

All patients enrolled in the study were consented as per attached patient consent sheet (Appendix C)

All patient names, medical record numbers and identifiers were kept

confidential, with each patient assigned a reference number on the data capture sheets.

7. Study Results

7.1. Demographics

Recruitment was performed over a period of 5 months.

A total of 209 patients who fulfilled the study criteria were enrolled into the study. The baseline demographics were as follows:

Gender

Forty seven percent (47%) of the patients were male and fifty three percent were female (53%).

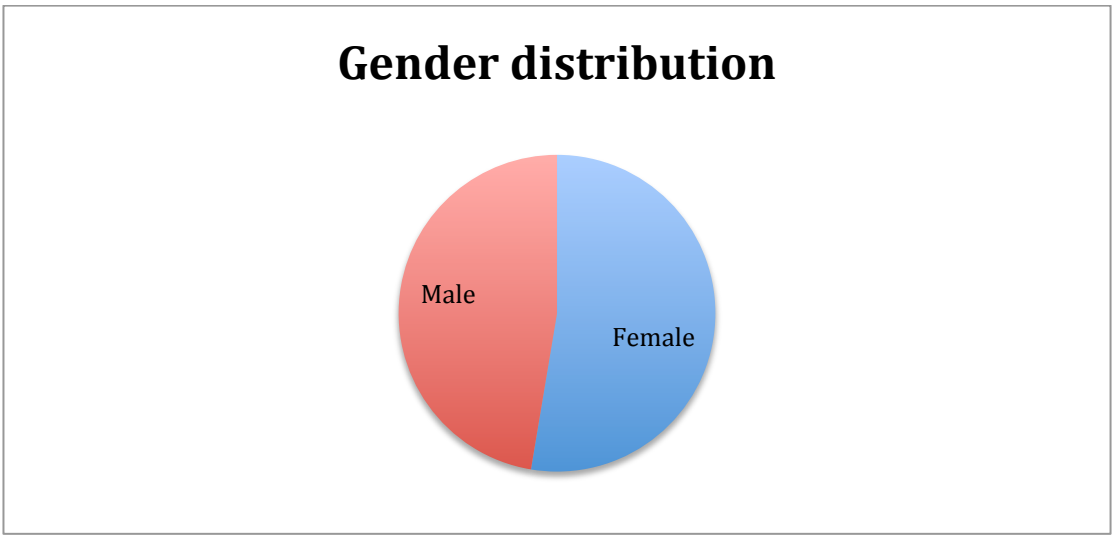


Figure 1 Gender distribution in the study population

Age

The mean age of the study recruits was 51 years with a standard deviation of 20.05 years.

The age distribution is depicted in the bar graph below

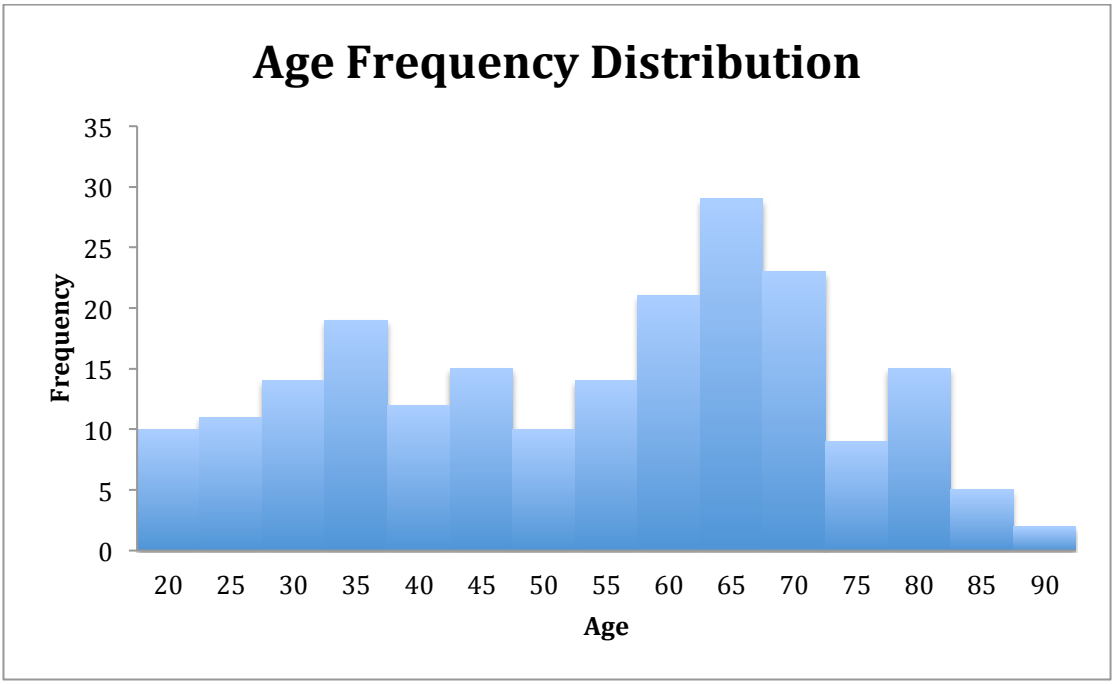


Figure 2 Age Frequency Distribution Chart

Ethnicity

Of the 209 patients, 196 (93.78%) were Black, 4 (1.91%) Caucasian, 6 (2.87%) Indian and 3 (1.43%) Coloured.

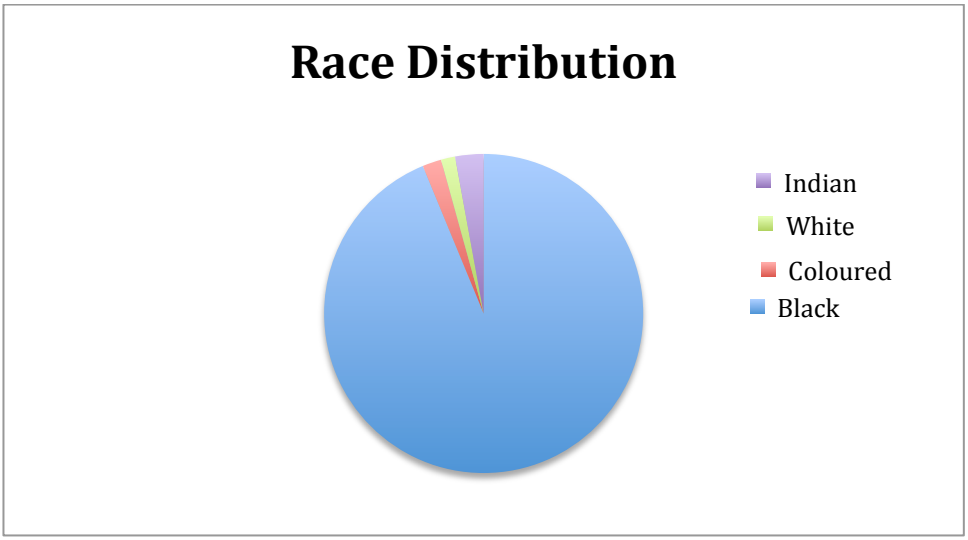


Figure 3 Race composition of the study population

A summary of the baseline demographics is displayed in table 1

Table 1

	Number	**Percentage (%)**
Age (mean)	51	
Male	99	47.37
Female	110	52.63
Black	196	93.78
White	4	1.91
Indian	6	2.87
Coloured	3	1.43

7.2. Data analysis

The visual acuity measurements were recorded into an excel spreadsheet and converted into ETDRS values using a conversion table[14]. The descriptive statistics were generated from the excel spreadsheet and the Bland-Altman analysis was performed in Stata statistical software v11

7.3. Statistical analysis

Nurse measured visual acuity

Table 2

Variable	*Obs*	*Mean*	*Std Dev*	*Min*	*Max*
Nurse VA	418	55.92105	29.44003	0	85

The mean VA was 55.92 letters and the standard deviation 29,44 letters (95% CI 0 to 85)

The frequency distribution chart, as depicted below, shows a slight skew towards the right.

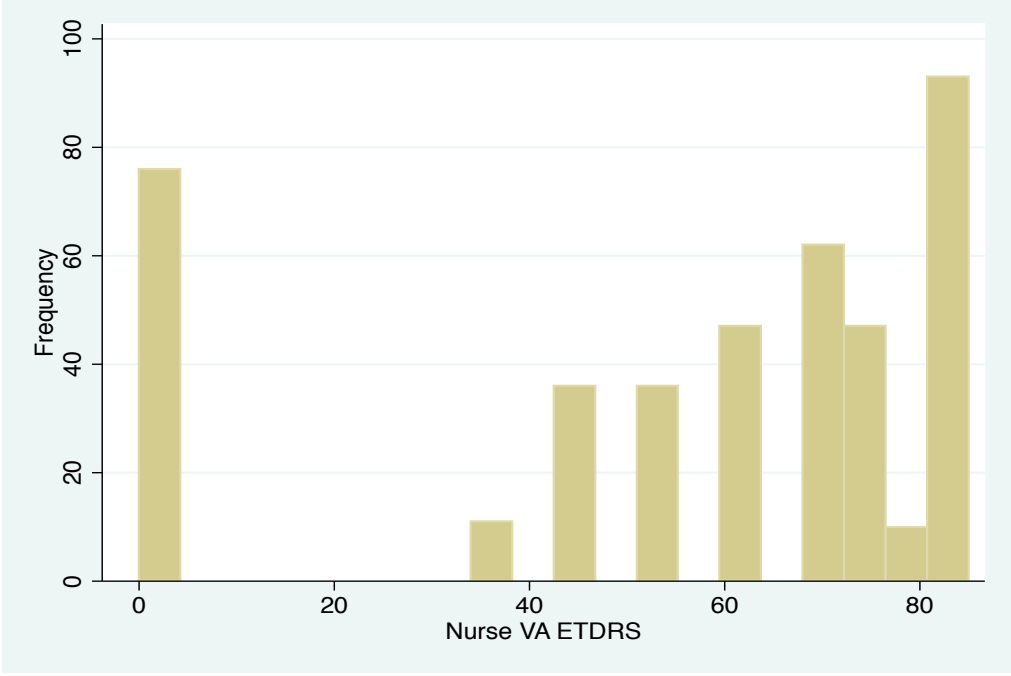


Figure 4 The frequency distribution of nurse measured VA

Doctor measured VA

Table 3

Variable	*Obs*	*Mean*	*Std. Dev*	*Min*	*Max*
Doctor VA	418	55.8756	28.4464	0	85

The mean VA was 55,87 letters with a standard deviation of 28,44 letters (95% CI 0 to 85)

The frequency distribution chart also showed a skew to the right.

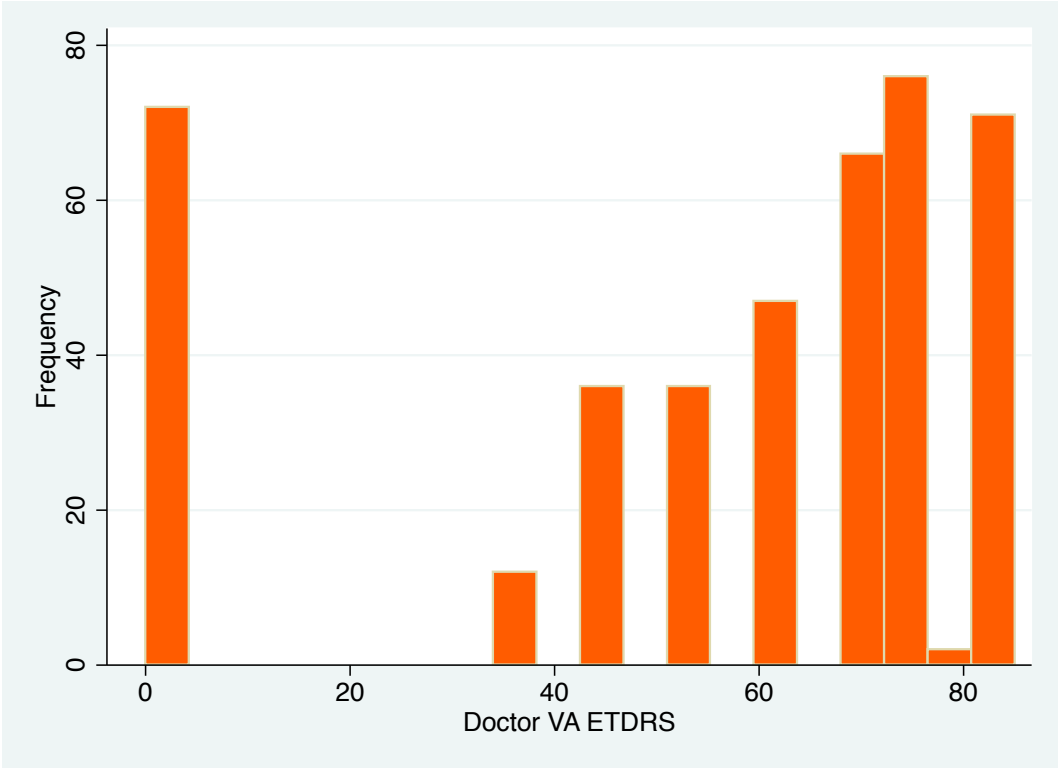


Figure 5 The frequency distribution of doctor measured VA

The mean difference in letters between the two groups was 0,045 letters with a standard deviation of 9,62 and 95% confidence interval of -55 to 70 letters.

Difference in means

Table 4

Variable	Obs	Mean	Std Dev	Min	Max
Diff	418	0.0454545	9.624875	-55	70

The above calculation, using the mean difference shows that there is very little variability between the two observers. This is further demonstrated by the wide confidence interval of -55 to 70 letters. When the results of the two groups are plotted on a scatter plot (nurse VA on y-axis and doctor VA on the x-axis), it becomes very clear that there is a variability in VA between the two groups.

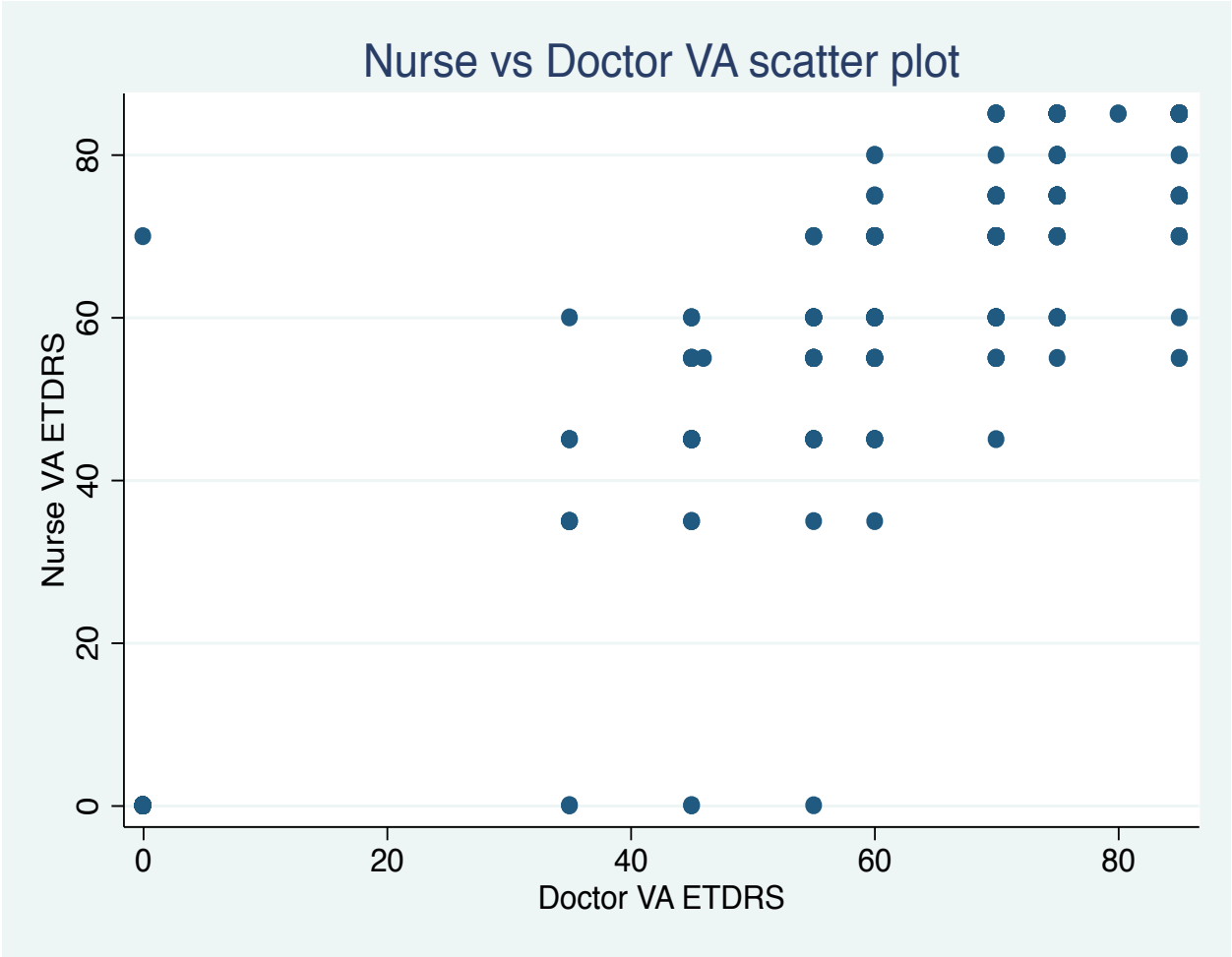


Figure 6 Scatter plot of nurse vs doctor measured VA

If the measurements recorded by the two observes were the same for each patient, scatter plot would be linear and not 'scattered'.

All the measurements would fall on a ‘line of equality ’ which indicates repeatability of each measurement.

The scatter plot with the line of equality is portrayed below:

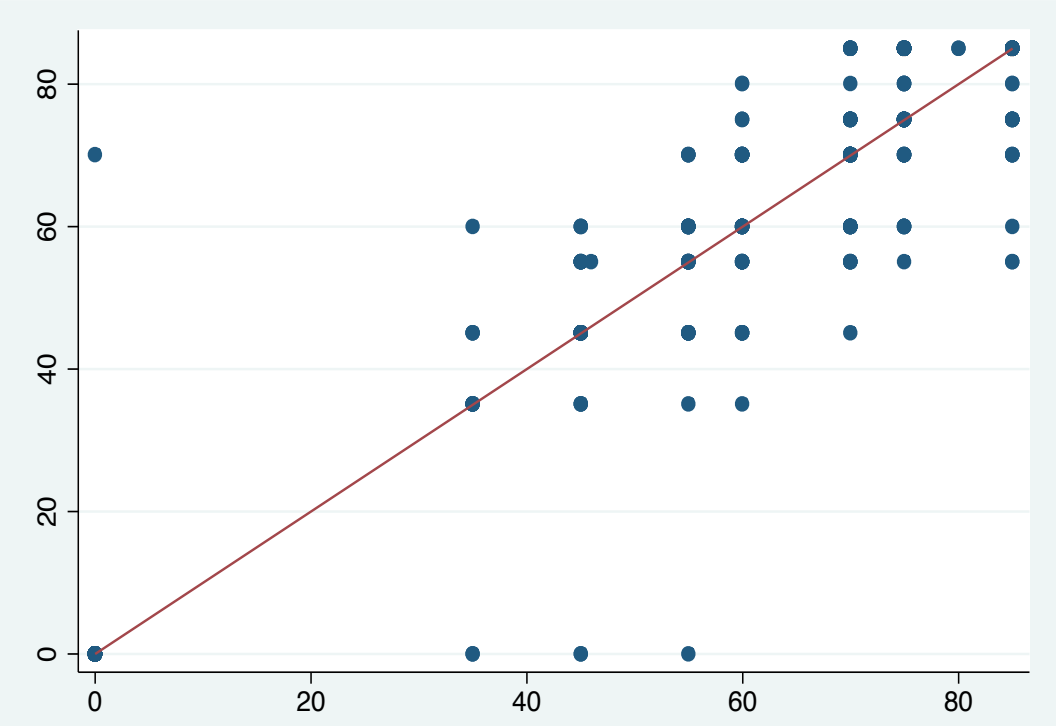


Figure 7 Scatter plot of nurse vs doctor measured VA with line of equality

Since not all the observations fall on the line of equality, we can assume that the VA as measured by the nurse for any given patient was not reproducible by the doctor on the same patient under the same testing conditions.

Bland-Altman Graph

As discussed earlier, a Bland-Altman plot is a scatterplot of the actual difference and the mean difference between two measurements. The difference is plotted on the y-axis, and the mean difference is plotted on the x-axis and the degree of disagreement with its 95% CI is plotted.

The mean difference and its standard deviation and confidence interval were converted to scalars in stata:

scalars:

r(N) = 418

r(sum_w) = 418

r(mean) = .0454545454545455

r(Var) = 92.63821669936779

r(sd) = 9.624874892660568

r(min) = -55

r(max) = 70

r(sum) = 19

The Bland-Altman plot is depicted below

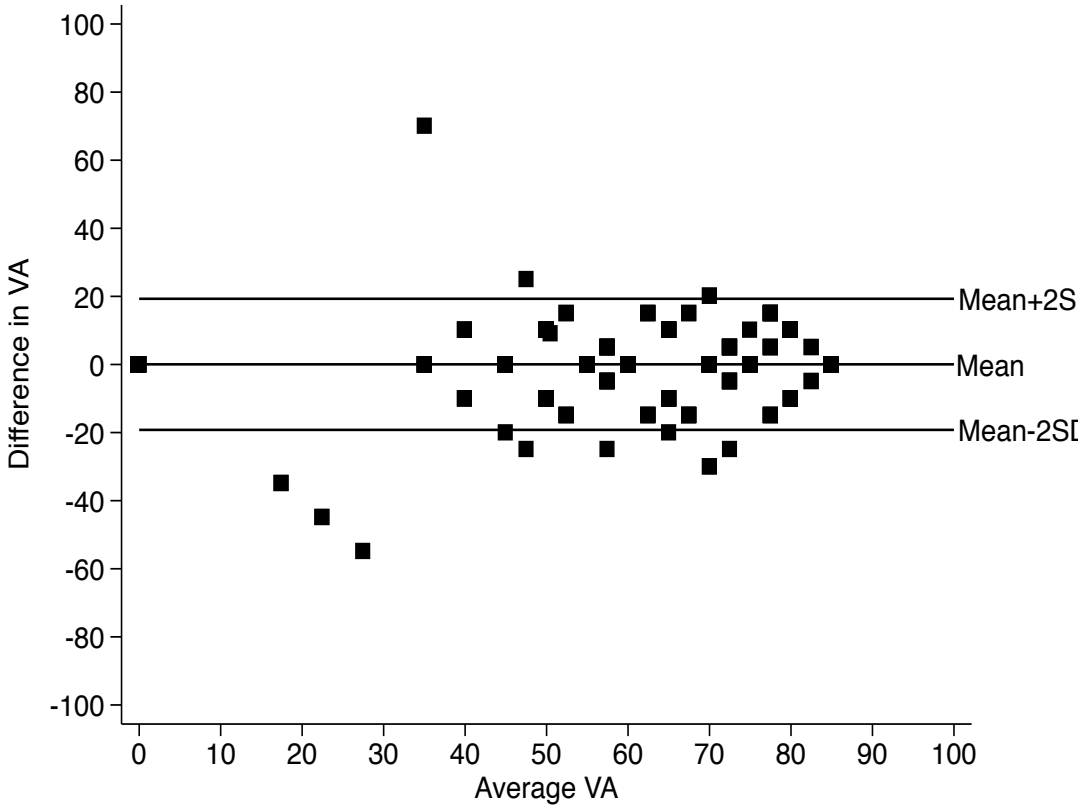


Figure 8 Blant-Altman plot

The above plot is a graphical representation of the following:

- The limits of agreement between the observers at the 95% CI were -18.79 letters (at lower end) and 19.70 letters (at the upper end), a total of 38.49 ETDRS letters
- The values beyond the limits of agreement are considered un-repeatable
- The values within the limits of agreement represent the inherent variability on re-testing
- We can say (with 95% confidence) that each patient's VA will vary by up to 38,49 letters on re-testing

8. Discussion

Variability in visual acuity on re-testing is well described in the literature. The primary assumption in this study was that any given patient's true VA is unknown, thus the measured VA is an approximation. Assuming that neither VA measurement is correct (or represents the patient's true VA), one can reasonably infer that the less variable the repeated measurements are, the closer they are to the true VA.

In busy eye care centers/clinics like at the St John Eye Hospital, VA is usually not tested by the treating physician due to time constraints except in specific clinical scenarios. The implication is that the vast majority of patients are being managed based on once off, potentially irreproducible VAs.

In cases where the patient's VA is re-tested by the treating physician, the most common assumption is that the second measurement is more accurate. As discussed earlier in the introduction, this sentiment is flawed.

A difference of less than 2 Snellen lines on re-testing implies that both measurements are reasonably close to the patient's true VA hence either value can be accepted as accurate. The implications are that if the difference is more than 2 Snellen lines, the VAs is meaningless. i.e., they do not reflect the patients VA and no meaningful management plans can be made for the patient.

This study aimed to measure the variability in visual acuity under normal clinic conditions at St John Eye Hospital (which is a busy, referral tertiary hospital) and to compare it with literature reports.

The study suggests that under the current VA testing conditions, the VAs are not re-producible. The variation was found to be 38.49 ETDRS letters, which is equivalent

to 7.69 Snellen lines. This is clearly much more than the acceptable limit of 2 Snellen lines.

The implications are that the VAs as currently measured at the institution do not reflect the patient's true VA and are as such, clinically meaningless.

The possible explanations for this large difference include:

- Bias on the part of the physician on re-testing, therefore better readings are obtained
- The VAs were not performed by the same group of nursing staff on every occasion
- Patient fatigue
- Patient learning effect (on re-testing)
- Unequal illumination of the Snellen chart boxes. This may have played a role since the luminance of illumination boxes in the VA testing room were not measured at baseline.

9. Study Limitations

- The nursing staff who performed VA measurements changed frequently during the study period. Even though this rotation in nursing staff may have played a role , the aim of the study was to assess VA variability under normal clinic conditions.
- Heterogeneity in the patient population may have made measuring VA inaccurate due to different literacy levels and language differences.
- The study did not look at the version of Snellen chart used by the testers i.e E-chart versus numbers or alphabets. This was left to the testers'dicretion.
- The use of pin hole testing was not mandated in the study. However, pinhole VA was performed on re-testing if it was done initially.

10. Conclusion

The study indicates the need to quantify VA variability in busy eye clinics to ensure the measured VAs are meaningful and are reflective of the patients' true VAs. This exercise could be undertaken annually as a means of quality control. It would be interesting to see if re-training of the nursing staff on VA measurement would have any impact on the results.

Appendix

Appendix A: Case Report Form

Appendix B: Information Sheet for Patients

Appendix C: Patient Consent Form

Appendix D: Information Sheet for Nurses

Appendix E: Turn-It-In Report

Appendix A

Case Report Form 1 ***Visual Acuity Correlations***			
Date			
Study ID			
Ethnic group	Black Indian Caucasian Coloured Asian Other		
Age (in years)			
Gender	Male Female		
Measurements			
	**Clinic VA (Routine method)*	***Study VA*	
Snellen's chart visual acuity			
Alternative acuity measure (type)			
Investigator	Name	Signature	Date

** Standard eye clinic visual acuity as performed by nursing staff*
*** Visual acuity performed by investigator under pre-specified conditions*

Appendix B

Information Sheet for Patients

Study Title: A Prospective Study on Visual Acuity Variability in a Large Eye Clinic

Hello,

I am Dr Boitumelo Khantsi. I am conducting a clinical study for the purposes of a master's degree. This clinical study is on the reading test, which the nursing sisters have already performed on you today. I would like you to participate in this study by having a second reading test performed by me, Dr Khantsi.

All information collected for the study will be kept strictly confidential to the study. Your name, hospital number, address or contact numbers will not be revealed to anyone. Your name will not appear in any report or publication about the study.

Participation in the study is voluntary. Even if you agree to participate, you are free to withdraw at any time during the study, and you do not need to give an explanation for doing so. Your medical care will not be compromised in any way. Remember that the treatment that you will receive will remain the same, whether you decide to participate in the study or not.

I am available to answer any questions you may have regarding the study during working hours here at the eye clinic, or you can contact me telephonically (011) 933 9771. I am reachable on 079 482 3665 after hours.

This study has been approved by the Human Research Ethics Committee of the University of the Witwatersrand. For further information on clinical study participant's rights, you can contact Prof PE Cleaton-Jones at the university of the Witwatersrand on 011 717 2301.

Thank you for taking the time to read this information sheet.

Yours sincerely

Dr B Khantsi, Registrar, Division of Ophthalmology, Department of Neurosciences

University of the Witwatersrand

Supervisor: Dr H Kana**,** Consultant Ophthalmologist**,** Division of Ophthalmology**,** Department of Neurosciences

University of the Witwatersrand

Appendix C

Patient Consent Form

Study Title: A Prospective Study on Visual Acuity Variability in a Large Eye Clinic

Investigator:
Dr B Khantsi, Registrar, Division of Ophthalmology, Department of Neurosciences
University of the Witwatersrand

Supervisor:
Dr H Kana**,** Consultant Ophthalmologist**,** Division of Ophthalmology**,** Department of Neurosciences
University of the Witwatersrand
Telephone: (011) 933 9771

Study ID | | | | Date | | | |

I have read the information sheet concerning this study (or have understood the verbal explanation) and I understand what will be required of me, and what will happen to me if I take part in it.
I understand that my participation in the study is completely voluntary. I understand that at any time I may withdraw from this study without giving a reason and without affecting my normal care and management.
My questions concerning this study have been answered by…….
I agree to take part in this study.

Signature……
Date……..
Name of investigator……
Signature…….
Date……

In case of illiterate patient:
I confirm that I have read the patient information sheet to the patient, and that I have answered all of his/ her questions. I confirm that the patient has voluntarily agreed to participate in this study.

Signature or finger print of patient…….
Name of witness…….
Signature of witness……..
Date……

Appendix D

Information Sheet for Nurses

Study Title: A Prospective Study on Visual Acuity Variability in a Large Eye Clinic

Good day,

I will be performing a clinical study on visual acuity (VA). For this study, I will be measuring VAs on patients who have already had routine VAs measurements in the clinic.

This means that during routine patient visits to the Ophthalmology clinic, you will conduct VA testing as per your normal routine then I will repeat it on consented patients. **This is by no means to evaluate your measuring of VAs**, but simply to quantify the inherent variability in measured VAs, i.e. to test the test itself.

The repeat VA test will only be done if patients agree to participate and join the study.

All information that is collected for the study will be kept strictly confidential to the study. Patient identity will not be revealed to anyone who is not a part of the study team. Patient names will not appear in any report or publication about the study.

Patient participation in the study is voluntary. In addition, patients are free to withdraw at any time during the study, without needing to give an explanation for doing so. Patients' medical care will not be compromised in any way.

I am available for any questions throughout the day in the clinic.

This study has been approved by the Human Research Ethics Committee of the University of the Witwatersrand. Should you require more information regarding clinical study participants' rights, you can contact Prof PE Cleaton-Jones at the university of the Witwatersrand on 011 717 2301.

Yours sincerely

Dr B Khantsi, Registrar, Division of Ophthalmology, Department of Neurosciences, University of the Witwatersrand.

Supervisor: Dr H Kana**,** Consultant Ophthalmologist**,** Division of Ophthalmology**,** Department of Neurosciences,

University of the Witwatersrand.

Appendix E

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ORIGINALITY REPORT

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SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

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	Publication	
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