

Comparison of estimates of best correlated visual acuity between measurements with a digital chart and a commercial letter chart.

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Contents

1 Abstract	4
2 Introduction	5
2.1 Visual acuity	5
2.1 Definition of visual acuity.....	5
2.2 ETDRS chart.....	5
2.3 Digital charts	6
2.3.1 The AxAnlvls chart.	7
2.4 Aims and purposes.....	8
3 Methods.....	9
3.1 Recruitment	9
3.2 Subjects	9
3.2.1 Sample size estimation	10
3.3 Equipment.....	10
3.4 Examination procedure.....	10
3.4.1 ETDRS	10
3.4.2 Digital chart.....	11
3.4.3 Definition of visual acuity.....	11
3.5 Statistical analysis	12
3.5.1 Analysis model for best corrected visual acuity.....	12
3.5.2 Hypotheses.....	12
3.5.3 Statistical analysis	12
4. Results.....	13
4.1 Subject Characteristics.....	13
4.2 BCVA difference between the AnAxlvls digital chart and the ETDRS chart as a function of visual acuity class	13

4.3 Estimate of variance components for BCVA and Anova results	14
4.4 Examination time for the two charts	15
5. Discussion.....	16
5.1 Main findings and interpretation.....	16
5.2 Differences in design of charts.....	16
5.3 Method	17
5.4 Strengths and limitations.....	18
5.5 Conclusions	18
6 Acknowledgements.....	20
7. References	21

1 Abstract

Purpose: To provide a comparison of performance between a digital chart and the gold standard ETDRS chart, with regards to visual acuity.

Methods: 12 adults aged ≥ 55 were enrolled and had their visual acuity measured twice using both charts. Four subgroups were created depending on measured visual acuity. Analysis of variance was used to examine systemic difference between the charts.

Results: No systemic difference was found (Test statistic=152.23, significance level $F_{1:8:0.95} = 7.57$). There is difference between the two charts at visual acuity levels (Test statistic=0.17, significance level $F_{3:8:0.95} = 5.42$). The mean difference in examination time was 47 seconds shorter for the digital chart.

Conclusion: There was no significant systemic difference between the two charts. There was significant difference in performance depending on visual acuity level. The digital chart has a shorter examination time compared to the ETDRS chart.

2 Introduction

2.1 Visual acuity

Assessment of visual acuity is the most common measurement when assessing visual function.

Visual impairment is connected to decreased function and general reduced quality of life. (1)

Deterioration of visual acuity is common among various diseases and conditions, of varying severity, within the ophthalmology field(2). Its assessment is also standard method of quantifying severity of ocular diseases, efficacy of interventions, and impairment of central visual function. (3)

2.1 Definition of visual acuity

Through using optotypes as targets, visual acuity is determined. Visual acuity is defined as the visual angle subtended by the width of the line depicting the smallest perceived optotype. This is called the Minimum Angle of Resolution (MAR) (Figure 1). (4)

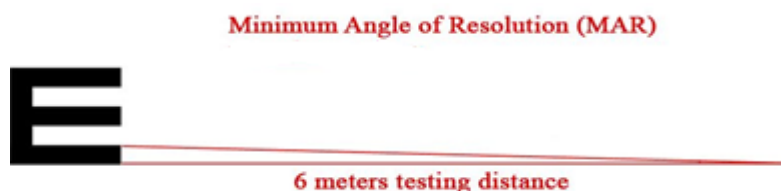


Figure 1. Standard optotype for definition of visual acuity.

MAR is expressed in arc minutes. The 10th log of MAR is used to express MAR, thus logMAR is the unit that describes visual acuity. (5)

Clinically, visual acuity measurement uses multiple rows of prepressed letters, also known as optotypes. There are several different kinds of charts of this type. Commonly, the optotypes become increasingly smaller for each row. The task of the examinee is to read as far along the chart from a standardized distance as possible whilst simultaneously having their optics adjusted with best possible glass correction. (6)

2.2 ETDRS chart

In 1982, Ferris et al, presented charts intended to facilitate measurement of visual acuity in the clinical setting (7). A few years later, these same charts was adopted by the Early Treatment Diabetic Retinopathy Study (8,9). The chart has become known as the ETDRS chart and is today recommended as the gold standard of visual acuity determination for scientific purposes(10).

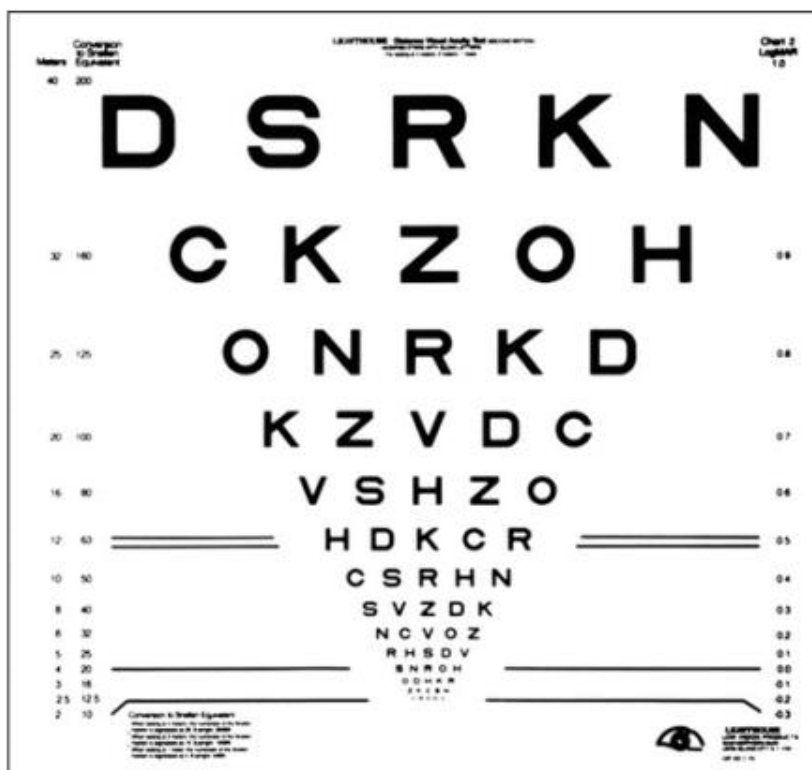


Figure 2. ETDRS chart.

The design removes unwanted factors such as legibility of optotypes, varying difficulty of optotypes, consistent spacing between letters and rows massively reducing the crowding effect, albeit not eliminating it completely, and as such, the only variable left is letter size(7).

The main limitation is the remaining portion of the crowding effect. The crowding is the effect that makes an object harder to discern when surrounded by other objects in its vicinity, in this case, other letters(11,12). This contributes to a reduced performance on visual acuity assessments. It is also more pronounced in the elderly, as well as in certain conditions, such as macular degeneration and amblyopia (13).

Furthermore, the ETDRS chart does not have a standardized testing protocol, particularly when it comes to termination of examination. As such, the measurements of acuity may vary depending on what termination protocol is applied to the examination. (14)

2.3 Digital charts

With the general advancement of digitalization, the same is true for the measurements of visual acuity. Recent years have shown an emergence of digital charts used for measurements and aim to improve existing charts. They provide a plethora of options to swiftly change testing protocol. This include, among others, the option to change letters being examined, or changing the order by which

they appear(15). By their digital nature, adjustment depending on testing distance can be made without changing the visual acuity levels available for testing. They also have the option of displaying fewer letters at a time (for instance, only showing the row being examined instead of the whole chart), reducing the time taken for locating and fixating upon a letter (16).

2.3.1 The AxAnlvls chart.

The chart used in this project is a digitalized system developed by Per Söderberg at the Gullstrand laboratory, Ophthalmic, Dept. of Neuroscience, Uppsala University. It introduces a novel method of displaying optotypes. Optotypes are initially read from left to right, each one representing an increasingly smaller optotype, and provides the ability to display the optotype on its own, to eliminate the crowding effect. Additionally, it contains a dial chart designed with the intent to facilitate identification of the axis of astigmatism. This dial chart was not evaluated in this study, as the object of comparison, the ETDRS chart, does not have a dial chart.

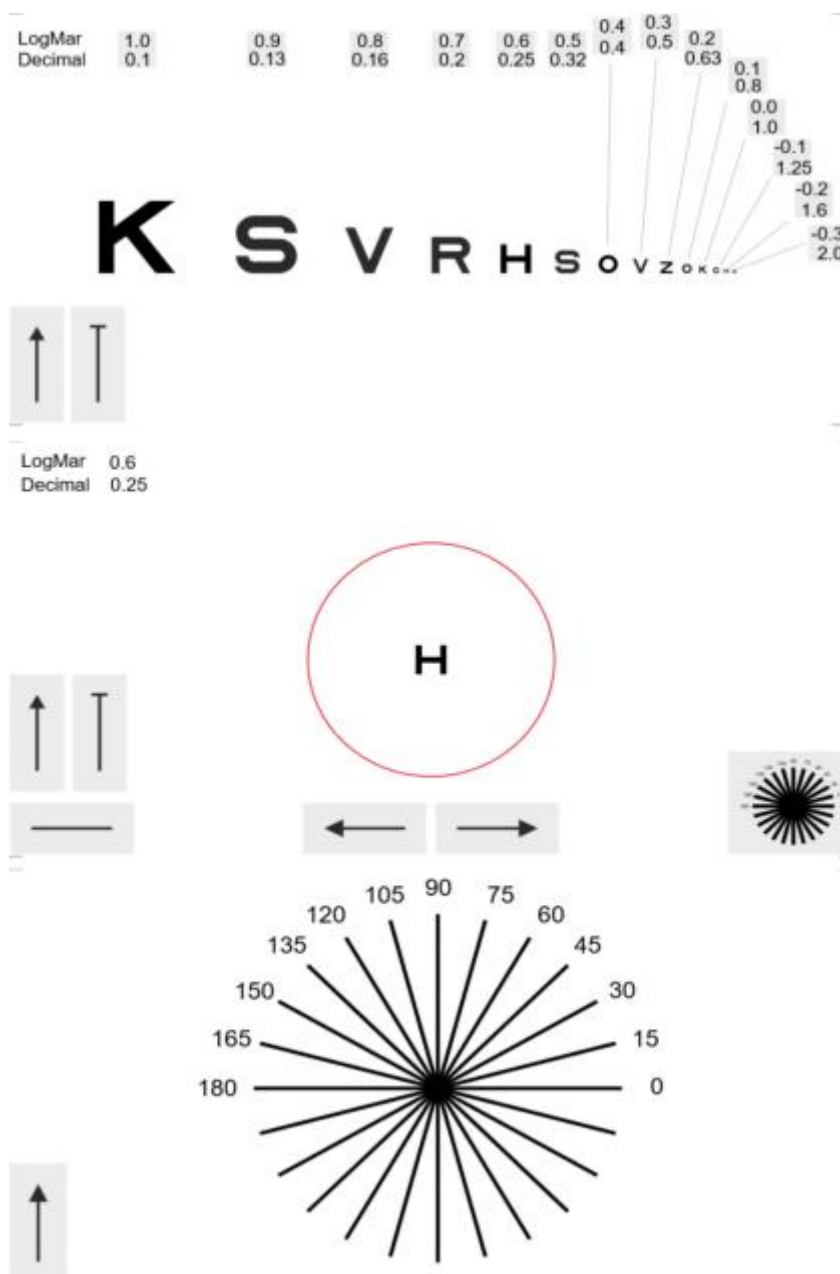


Figure 3. The AxAnIvIs chart.

2.4 Aims and purposes

The purpose of this project was to provide a comparison between the ETDRS chart and the AxAnIvIs system. The selected variables were level and variation of measurement as well as level and variation of time required for examination of visual acuity.

The study aimed to answer the following three questions:

- 1) Is there systematic difference of estimated visual acuity between the charts at different levels of visual acuity?

- 2) Is there difference of estimated visual acuity in the precision of the estimate of visual acuity between the charts?
- 3) Is there a difference in time for examination between the charts?

3 Methods

3.1 Recruitment

All subjects were recruited from the eye clinic at Akademiska Sjukhuset, Uppsala. Criteria for inclusion were; age ≥ 55 and no underlying condition strongly associated with change in visual acuity within 1 month (Table 1). All patients were recruited during a regular appointment at the clinic. No financial compensation was offered although culinary treats were offered during visits.

Variable	Criteria
Age (years)	≥ 55
Visual acuity (LogMAR)	[1.0;-0.1]
Diagnosis	No ocular disease strongly considered to cause change of visual acuity within one month

The study conformed with the Declaration of Helsinki. Informed consent was obtained from all subjects before enrollment. Ethical approval was obtained from Etikprövningsnämnden.

3.2 Subjects

Subjects were divided into 4 classes with regards to best corrected visual acuity (VA class). These were, as denoted in LogMAR: [1.0-0.8], [0.7-0.5], [0.4-0.2], [0.1 - -0.1]. Determination of VA class was based upon previous examination values found in the patients' medical history, so long as these values were not older than 2 years. The order of inclusion was predetermined such that one subject from each class would be included and examined before the second subject of any group were examined. When a subject meeting inclusion criterion and being of the right VA class was found, they were given a brief outline of the project and its aims and purposes and subsequently invited to participate. Time expected each visit was estimated to be a maximum of 30 minutes. This was repeated for all 16 subjects. The primary goal for this was to eliminate possible confounding factors such as examiner skill improvement due to repeated examinations.

As to eliminate possible change of visual acuity, a limit of time until second appointment was set at 1 month. As such, not having an underlying condition strongly associated with change in visual acuity was an inclusion criterion.

3.2.1 Sample size estimation

A previously completed ST project estimated the variance for measurements within these systems. With these measurements in mind, the variance of difference was estimated. To demonstrate a difference of one resolved step on the ETDRS chart, with a power of 0.8, the sample size was estimated to be 10. Furthermore, to allow subgroup analysis between the classes with respect to gender, 16 subjects would have to be included. As such, the study aimed to include 16 participants (8 females and 8 males) of four visual acuity levels (described below).

3.3 Equipment

The ETDRS chart used is a commercial 4m backlit chart (produced by Preisler Instrument AB, Sweden), placed in normal room illumination. The AxAnIvIs chart is custom made with a custom algorithm for visualization, made to be placed at 4m. Room illumination is controlled to be the same for all examinations, as difference in room illumination is a cause for variance in measurement, despite the charts being backlit(17).

3.4 Examination procedure

All subjects met with the same examiner. The examiner was a student enrolled in the medical program at Uppsala University, previously having completed the ophthalmology course. As such, the examiner has previously determined visual acuity with refraction. Additionally, the examiner was given opportunity to determine visual acuity during a sit-in with a senior eye specialist at the clinic. Accordingly, the examiner was given ample experience to independently conduct examinations of visual acuity, but being inexperienced, improvement of ability during the data collection was expected and corrected for as previously described.

All examinations were conducted in the same research room at the eye clinic in Akademiska Sjukhuset. All subjects completed refraction of one eye using both the digital chart and the standard ETDRS chart during both occasions. Both the charts and the order of presentation were changed upon second visit. Additionally, examinations were conducted such that half of the subjects completed the ETDRS chart first and the digital chart second upon their first visit, and vice versa for the other half. Room illumination was controlled to be identical for all occasions.

3.4.1 ETDRS

Examination of the ETDRS chart was conducted as follows. The patient was equipped with examination spectacles blocking the eye not being examined. After the spectacles were ensured a comfortable fit, time of examination was measured using the examiner's cellular phone. The patient was then presented with the ETDRS chart and asked to read aloud the top row of letters. Upon reading all five letters without errors, they were asked to read the subsequent row. Upon error, the

patient was presented with a spherical lens of strength depending on the level of visual acuity where the error occurred in the chart. For LogMAR 0.5 and above, a -1 diopter concave lens was selected and for LogMAR 0,4 and below, a -0,5 diopter concave lens was selected. The lens was then held in front of the patient's eye and asked if the lens offered improvement. If yes, the lens was then inserted to the examination spectacles and the examination continued. If no, the same procedure was repeated with a convex sphere of strength as described. Importantly, once a concave or convex lens has been used, its opposite would not be tried again. Upon another error, the same procedure with regards to LogMAR level is repeated until addition of a lens no longer offers improvement. In that case, a concave cylindrical lens of -0,5 diopter was held in front of the patient's eye in four angles; 0, 45, 90 and 135 degrees respectively. The patients were asked to determine which, if any, angle of the lens offered improvement and if so, the lens was inserted into the spectacles and examination continued. Upon error, another -0,5 concave cylindrical lens was held in front as previously described. Upon completion of LogMAR -0,1 or neither cylindrical nor spherical lens offering improvement, the examination was concluded. Time for examination was recorded as well as best corrected visual acuity including measurement of correction.

3.4.2 Digital chart

Examination with use of the digital chart is conducted as follows. The subject is equipped with examination spectacles blocking the eye that is not being examined. After being ensured a comfortable fit, time of examination is measured using the examiner's cellular phone. The subject is then asked to start reading letters aloud, from left to right. Upon hesitation and/or error, the last correctly identified letter is selected for examination using the software. As a single letter is placed in focus, a lens of strength corresponding to current size of letter is added, identical to the procedure described for ETDRS above.

Identical to the ETDRS method, when LogMAR -0,1 is reached, or neither cylindrical nor spherical lens longer offers improvement, examination is concluded. Time for examination, strength of correction and visual acuity is recorded.

3.4.3 Definition of visual acuity

For the ETDRS chart, the visual acuity is determined to be that of the last fully completed row, and for the digital system, the last correctly identified optotype.

3.5 Statistical analysis

The primary response variable was best corrected visual acuity (BCVA), denoted as LogMAR. The secondary response variable was time, denoted in seconds.

The explanatory variables were ETDRS visual acuity level (class) at inclusion, visual acuity charts, and occasions.

3.5.1 Analysis model for best corrected visual acuity

Visual acuity, x_{ijkl} , can be determined using the population mean, μ , a term for the fixed factor chart type, α_i ($i=1,2$), a term for the fixed factor ETDRS visual acuity level at inclusion, β_j ($j=1,2,3,4$), and a term for random variation among subjects, $C_{k(j)}$ ($k=1,2,\dots,12$), a term for interaction between chart type and ETDRS visual acuity level at inclusion, $\alpha\beta_{ij}$, a term for interaction between chart type and subjects, $\alpha C_{ik(j)}$ and a term for random variation between occasions defined as a measurement error, $\varepsilon_{l(ijk)}$, resulting in the following equation (Eq. 1).

$$x_{ijkl} = \mu + \alpha_i + \beta_j + C_{k(j)} + \alpha\beta_{ij} + \alpha C_{ik(j)} + \varepsilon_{l(ijk)} \quad \text{Eq. 1}$$

3.5.2 Hypotheses

Following the equation above, the following null hypotheses are able to be tested.

- 1) H_{01} : There is no systematic difference of estimated visual acuity between the AxAnlvIs chart and the ETDRS chart.
- 2) H_{02} : There is no systematic difference between the charts depending on visual acuity level.

3.5.3 Statistical analysis

Using Eq. 1, a nested of analysis of variance on the outcome of measured visual acuity resulted in Table 2.

Table 2. Model of analysis for measured visual acuity	
Source	Mean Square
Charts	MS ₁
Visual acuity classes	MS ₂
Subjects	MS ₃
Charts x Visual acuity classes	MS ₄
Charts x Subjects	MS ₅
Occasions	MS ₆

This allows the testing of the two hypotheses, $H_{01} = MS_1/MS_5$, $H_{02} = MS_4/MS_5$.

Considering the limited sample size, the significance level was set to 0,05 and the confidence coefficient to 0,95.

4 Results

Many patients were identified as potential subjects, based upon age and latest visual acuity measurements fetched primarily through assessment of medical records but also through personal conversation at the clinic. However, an overwhelming majority were excluded due to current eye pathology. As the nature of their primary visit to the clinic includes a medical examination from a practitioner, many had been given pupil dilating eye drops, excluding them from participation. In total 13 patients were enrolled in the study. 1 patient revoked their participation before the second visit and therefore had all their data removed.

4.1 Subject Characteristics

Enrolled in the study were 7 women and 5 men. Ages ranged from 56 to 85 (Median = 70). Almost all participants had some form of ocular pathology. However, these pathologies were not recorded. Patients were screened from active ocular pathology that would exclude them for participation and no further assessment was made. The median time between first and second visit was 5 days.

4.2 BCVA difference between the AnAxlVIs digital chart and the ETDRS chart as a function of visual acuity class

The mean difference of logMAR between the AnAxlVIs digital chart and the ETDRS chart as a function of visual acuity class was estimated to **-0,15 ± 0,06 (95% CI)** for class 1, **0 ± 0,07 (95% CI)** for class 2, **-0,06 ± 0,11 (95% CI)** for class 3, **-0,02 ± 0,08 (95% CI)** for class 4 (Figure 4).

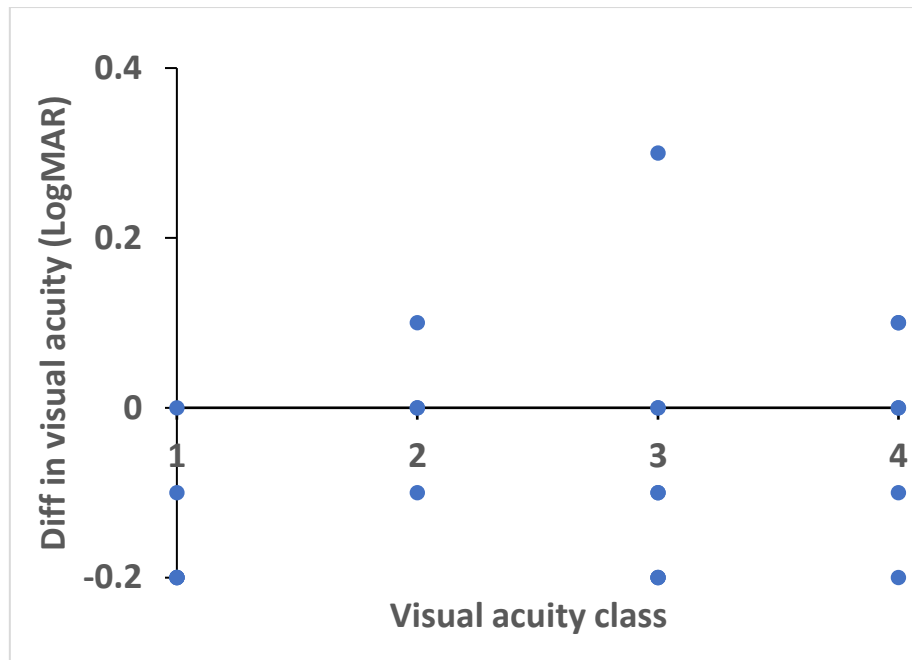


Figure 4 illustrates the visual acuity difference measured between the charts depending upon the visual acuity class.

Overall, the average difference was estimated to be $-0,0625 \pm 0,05$ (95% CI) logMAR between the charts.

4.3 Estimate of variance components for BCVA and Anova results

For a nested analysis of variance (ANOVA) to be valid, it is required that the groups be of equal sizes. As this was not the case, an artificial member of class 2 was created through the average of the existing two patients. As class 3 had one too many for analysis and accordingly one was excluded at random.

The analysis showed that there is no difference between the two charts (Test statistic=152.23, significance level $F_{1,8,0.95} = 7.57$). However, it showed that there is a difference between the charts at different visual acuity levels (Test statistic=0.17, significance level $F_{3,8,0.95} = 5.42$). A possible reason for this can be the small sample size, as mentioned in the discussion.

Estimates of variance components were estimated in Table 3.

Source	Variance component
Subjects	0,00199
Charts x Subjects	0,00826
Occasions	0,01031

As shown above, the variance of occasions is around 5 times higher than that of subjects.

4.4 Examination time for the two charts

The average difference in examination time was estimated at -48 ± 30 s (95% CI) (AxAnIvIs examination time – ETDRS examination time) (Figure 5).

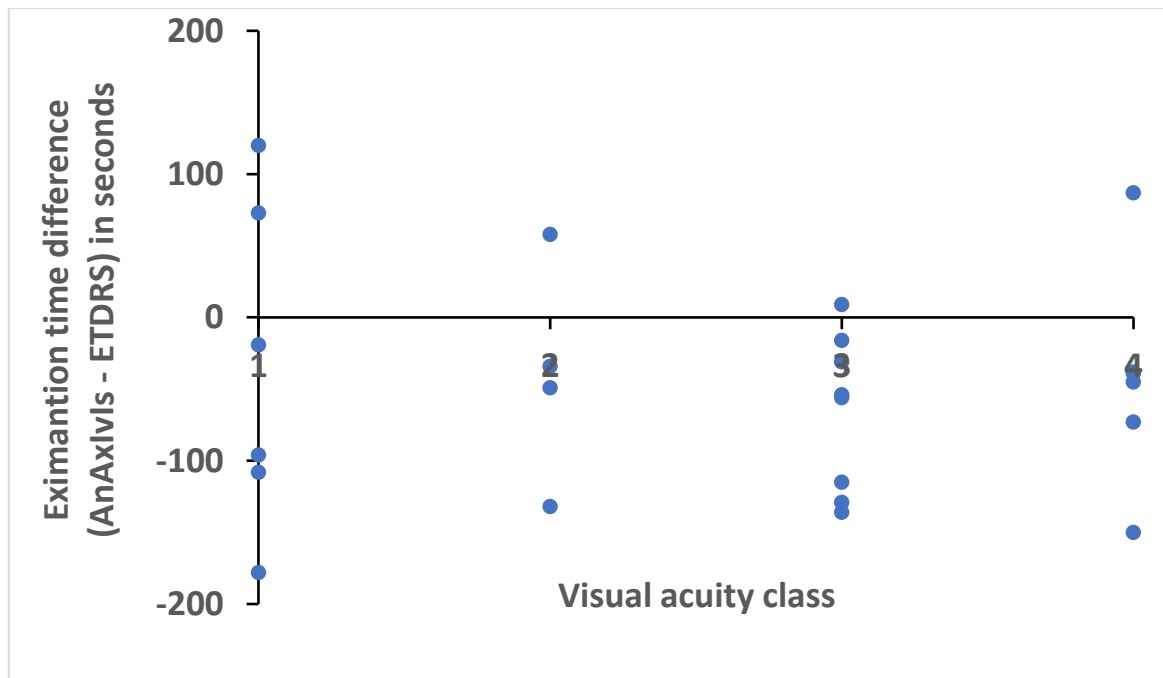


Figure 5 The scatter plot illustrates the examination time difference at different visual acuity classes.

5 Discussion

5.1 Main findings and interpretation

The main findings are that overall, the AxAnIvIs performs equally to ETDRS, and does so at a faster rate. However, for class 1 there was a significant difference where the patients performed better on the AxAnIvIs chart. This finding was unexpected and is perhaps explainable by the small sample size.

With regards to the nested analysis of variance, there was a five times higher variance among occasions with regards to BCVA compared to that of subjects, which also was unexpected. As the nature of the examination is bound to be subjective, the variance of subjects should in theory be higher than that of occasions. One possible explanation for this is the learning curve of the AxAnIvIs chart. As the ETDRS chart resembles the kind of chart commonly used and the AxAnIvIs is a novel concept, one would anticipate a greater change in understanding of the AxAnIvIs between the first and second visit. However, this would only be expected to affect time spent, not the outcome, due to the AxAnIvIs binary outcome at each level.

A significant difference of estimated visual acuity was identified for class 1, not for the other classes and not overall either. This implies that there is a significant difference in performance at this visual acuity level, but considering the small sample size, and the small difference, more research is needed to fully appreciate if there is a difference.

5.2 Differences in design of charts

The most prominent change in design between the two charts is that while the ETDRS displays five optotypes, the AxAnIvIs only displays one. The first implication is that the task difficulty would be different between the ETDRS and AxAnIvIs due to only having to identify one optotype as opposed to five. As such, one could argue that surely the AxAnIvIs would prove an easier task than ETDRS. There exist other digital charts that also have a reduced number of optotypes compared to the ETDRS, that have been shown to be equal to the ETDRS. As such, reduced number of optotypes does not by itself imply a difference in difficulty.

The other implication of having single optotypes as opposed to the ETDRS of five is that it reduces the crowding effect, making letters harder to discern, also posing a potential difficulty of communication, as the examiner and the patient may be discussing a different optotype. This was particularly evident when examining patients with macular degeneration, as they had relatively intact focused vision, but reduced peripheral vision, making the examination harder as it was hard to discern which optotype they were trying to discern on the ETDRS chart. This effect could be implied

as a reason as to why the patients on average performed better when being examined by the AxAnIvIs chart.

The design of having a digital chart makes it suitable for clinical work. The design displays fewer letters overall, and by having only one letter per level it leaves a binary choice, as opposed to the ETDRS where solving four out of five letters would still disqualify the patient, eliminating some frustration for both patient and examiner.

With regards to routine clinical practice, the ETDRS chart is not among the most commonly ones used. The most used chart is the Snellen chart, which has been shown to be significantly different with regards to variability to the ETDRS chart. This implies that since the ETDRS and the AxAnIvIs is equal, the AxAnIvIs could replace the Snellen chart.

5.3 Method

All patients were aged 55 or older, designated mainly because of the ETDRS chart used for reference also had the same age requirement. It also represents, roughly, the average patient in eye clinic. The method of refraction represents a commonly used method in clinical practice and is as such, highly subjective.

As the order of patients was predetermined by visual class, to correct for examiner improvement during the study, this limited the number of possible subjects into the study.

A larger number of patients were screened for potential inclusion into the study. However, since the study was conducted right after the outbreak of COVID-19 in Sweden, a common reason for declining participation was due to hesitancy of visiting the hospital solely for research purposes. This was exacerbated by the guidelines at the time, which deemed all people aged 70 or above as a risk group, adding yet another reason of hesitancy towards participation. At the time, the clinic also showed a decline in the number of patients visiting, as cancellation fees were waived and the retained free slot of time was not actively filled with another patient, opposed to the routine before the pandemic outbreak.

This was both limiting the amount of exposure the study got toward potential subjects, as well as hypothetically skewing the proportion of potential candidates to those fulfilling exclusion criteria, as one would have more motivation to visit the hospital for treatment compared to routine examination of current eye health.

As such, subgroup analysis by gender was impossible for this study, since it required 16 subjects to be enrolled.

With regards to finding subjects depending on visual acuity, no significant difference was subjectively experienced by the examiner, although raw data was not recorded.

The reasons of exclusion of participation in the study was not recorded, severely limiting the clinical implications of the study as the data of the subjects not recorded simply does not exist. The author has a general feeling for reasons of exclusion but no raw data to support this.

5.4 Strengths and limitations

The strengths of this study include having all measurements performed by a single examiner, providing protection from examiner variation. The exclusion criteria included having an ocular disease strongly correlated with change in visual acuity within 30 days, and as such, change in visual acuity between visits were corrected for. The study included patients both with ocular disease and without, a fairly large span of age, as well as patients with difference in visual acuity, making the analysis resemble that of the population. Additionally, the order of subjects was predetermined by visual acuity, which corrected for examiner skill improvement during the data collection. However, as the examiner in this case was a previously untrained student, the change of skill would be expected to change more rapidly than that of an experienced examiner. This can perhaps explain why the variance of occasions was so much higher than the variance of subjects.

The most significant limitation of the study is the small sample size. Given more time, it would have been preferable to have at least 16 subjects, and if possible, more, to provide more accurate analysis and to be able to analyze subgroups within the cohort. The author would estimate that the unfortunate timing of the pandemic greatly limited the exposure the study got, as well as deterring participation.

Another limitation is that the exclusion of potential subjects was not recorded. This would provide greater insight into the exposure and subsequent enrollment that the study acquired. Also recording underlying eye pathology of subjects would have been useful. Although the sample size of this study would not allow for subgroup analysis, this data could potentially have been used in combination with existing and future studies of the AxAnIVIs chart to provide deeper analysis of the chart's performance.

5.5 Conclusions

The nested analysis of variance showed no significant difference between the results of the two charts, implying that there is no systemic bias. With regards to visual acuity depending on visual class, significant different was found for class 1, implying that it is not suitable to use this chart for

this subgroup. The examination time was found to be systemically lower for the AxAnIvIs chart, making it more desirable for clinical work. However, based upon the results of this study, this is not recommended to the finding of bias in class 1. As the sample size is limited, more research is warranted to see if the same effects occur on a large cohort.

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