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COMPARISON OF ESTIMATES OF VISUAL ACUITY  
BETWEEN MEASUREMENTS WITH A DIGITAL CHART AND  
THE ETDRS CHART

By: Mikaela Lundvall

Supervisor: Zhaohua Yu

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**Title: Comparison of estimates of visual acuity between measurements with a digital chart and the ETDRS chart**

**By: Mikaela Lundvall**

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## 1 Populärvetenskaplig sammanfattning

Ett av de viktigaste måtten för att bedöma en persons synförmåga är synskärpa. Synskärpa mäts med hjälp av syntavlor med symboler (optotyper) där patienter ombeds identifiera optotyperna, vanligtvis bokstäver. Många av de syntavlor som används idag är av flera skäl problematiska; de är stora och deras design försvårar på flera sätt undersökningen för patienten. Digitala syntavlor har utvecklats för att minska de problem som associerats till de klassiska syntavlorna.

I den här studien jämfördes en ny digital syntavla, AxAnIvIs, med den syntavlorna som är standard att använda inom forskning, ETDRS. Syftet med studien var att undersöka om det finns en systematisk skillnad mellan tavlorna i uppmätt synskärpa, om det finns en skillnad i uppmätt synskärpa beroende på synskärpenivå samt om det finns en skillnad i undersökningstid. 14 personer  $\geq 55$  år deltog i studien. Deltagarna undersöktes med båda syntavlorna vid två olika tillfällen. De delades in i fyra grupper utifrån vilken synskärpa de hade vid första tillfället. Vid varje mätning utfördes en refraktion och bästa korrigerade synskärpa uppmättes. Resultatet av studien visade ingen statistisk signifikant skillnad mellan syntavlorna, inte heller någon statistisk signifikant skillnad mellan syntavlorna beroende på synskärpenivå kunde ses. Undersökningstiden var ca 30 s kortare med AxAnIvIs, vilket sannolikt beror på designskillnader mellan syntavlorna. För att kunna implementera AxAnIvIs i kliniken behöver fler studier med fler deltagare göras. Även studier där deltagarna har specifika ögonsjukdomar, eller där optotyperna byts till en annan typ bör göras för att se om AxAnIvIs kan användas på fler sätt och på fler patientgrupper.

## 2 Abstract

**Purpose:** To compare the performance of a digital system for measuring visual acuity, the AxAnIvIs system, to the gold standard ETDRS chart.

**Methods:** 14 adults  $\geq 55$  years had their best corrected visual acuity measured twice using both the ETDRS chart and AxAnIvIs system. Subjects were divided into subgroups, visual acuity classes, depending on the measured visual acuity. An analysis of variance was used to examine if there was a systematic difference between the charts.

**Results:** Similar visual acuity results were recorded from both charts. No systematic difference between the charts was found (Test statistic = 0.0474,  $F_{1,8,0.95} = 7.57$ ), and there was no statistically significant difference between the charts depending on visual acuity class (Test statistic = 0.33,  $F_{3,8,0.95} = 5.42$ ). The mean difference in examination time was 37 s shorter for the AxAnIvIs system.

**Conclusion:** There was no significant difference between the two charts, and no significant difference between the charts depending on visual acuity class. The AxAnIvIs system have shorter testing time compared to the ETDRS chart.

### 3 Background

#### 3.1 Visual acuity

Visual acuity is the most commonly used measurement in the clinic for assessing visual function. A visual acuity reduction is attributable to several different diseases and problems of the eye with varying degree of severity (Pollock et al., 2012). Visual acuity impairment have been linked to reduced quality of life and decreased function (Chou et al., 2016).

Visual acuity is a measurement of the ability to discriminate two adjacent stimuli separated in space, i.e. the finest spatial detail that can be resolved (Falkenstein et al., 2008). It is measured by having the subject identify optotypes, usually letters, on a chart at a standardised testing distance (Ferris & Bailey, 1996). It is defined as the smallest angle at which objects can be distinguished (Snellen, 1862). For small angles, the visual angle ( $\alpha$ ) is the angle subtended at the eye by a component line of an optotype ( $D$ ) at the testing distance ( $d$ ):

$$\tan \alpha = \frac{D}{d} \quad (1)$$

For optotypes, the component line is one-fifth of the height of that optotype (Green, 1905). For the optotype at recognition threshold, i.e. the smallest optotype that can be distinguished, the visual angle is the minimum angle of resolution (MAR),  $\alpha_0$ , and defines visual acuity as

$$\text{Visual acuity} \equiv \log_{10} \alpha_0 \quad (2)$$

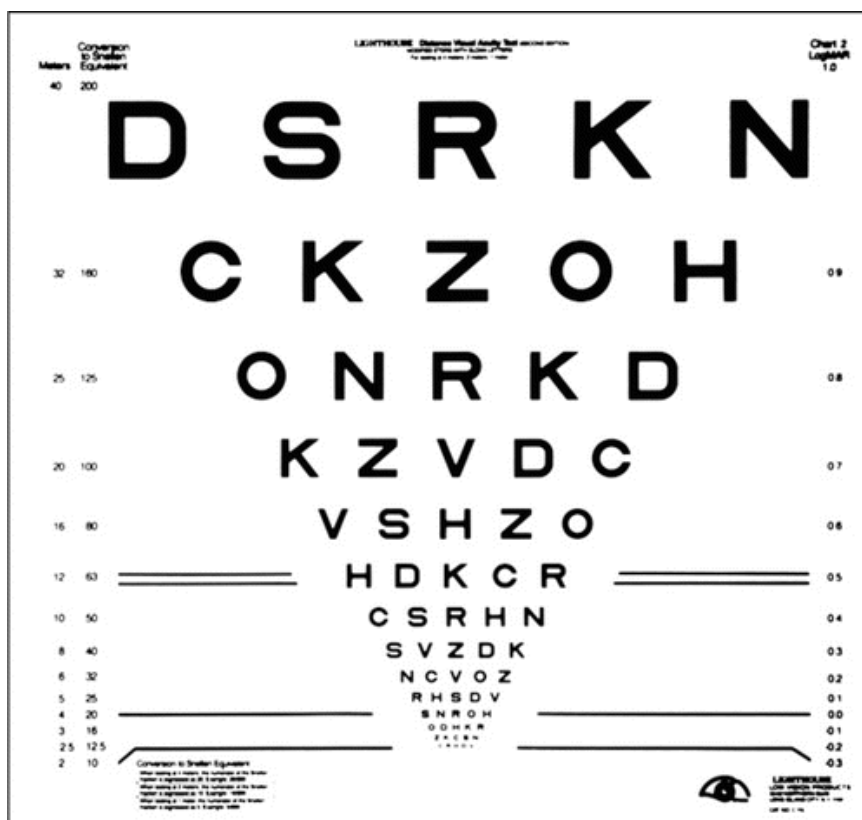
MAR is measured in arc minutes and visual acuity is usually expressed as logMAR, the logarithm to the base of 10 of MAR (Westheimer, 1979).

The design of a chart or optotype used in measuring visual acuity can cause measurement bias. The progression of optotype size from one line to the next on the chart, the number of optotypes on each line, the design of the optotype and differences in legibility of the optotypes being used are some factors that can cause bias (Hazel & Elliott, 2002; Kaiser, 2009; Lim et al., 2010; McMonnies, 1999; Plainis et al., 2013). When using letters as optotypes, some letters have been shown to be more difficult to identify and to differentiate from other letters, especially C from O and R from K (Alexander et al., 1997; Elliott et al., 1990). An ideal measurement system for visual acuity should not be influenced by these biases and it should give a result that is precise and that can be reproduced (Kaiser, 2009).

#### 3.2 ETDRS chart

The ETDRS chart (Figure 1) is a visual acuity chart developed by Ferris et al. (Ferris et al., 1982) based on principles by Bailey and Lovie (Bailey & Lovie, 1976) and was first used in

the Early Treatment Diabetic Retinopathy Study (Early Treatment Diabetic Retinopathy Study Research Group, 1985).



**Figure 1.** ETDRS chart.

It provides standardisation of testing and measuring visual acuity by its design. The letters used are equally legible, it uses a logarithmic progression of size of letters (a difference of 0.1 log units per line), each row has the same number of letters, the lines are of equal difficulty and it has consistent spacing between letters and rows to control for the visual crowding effect. All these factors of the design make the letter size the only variable on the chart (Bailey & Lovie, 1976; Ferris et al., 1982). It is the recommended chart for use in clinical research (Ferris & Bailey, 1996).

It has some limitations compared to other charts, the chart itself is large and requires more space and the examination time is increased (Rahimy et al., 2015). There is also no universally applied rules for when to stop a testing procedure and therefore the measured visual acuity varies with the set termination rule for the test (Bailey et al., 1991; Carkeet, 2001).

### **3.3 Digital charts and systems**

In recent years digital charts have become more common. Measuring visual acuity with computer-based technologies have advantages in research and in the clinic compared to other

charts. They can for example provide the choice to make changes to different parameters, such as choice of optotype and randomisation of optotypes (Bailey & Lovie-Kitchin, 2013). There are several different sets of optotypes in use in clinical practice. The most common for adults are letters, especially Sloan letters, for children the HOTV-optotypes. For illiterate patients and small children tumbling E, Landolt ring or symbols are used (Grimm et al., 1994). To be able to easily change between them is a major advantage compared to traditionally used charts. Other known advantages are that they minimise the localisation element of the test task, i.e. the position of an optotype on a chart is easier to locate and fixate on when there are fewer interfering optotypes on the chart. All visual acuity levels can also be tested without adjustment of the screen or testing distance (Jolly et al., 2019).

Another advantage with digital charts is that they more effectively can control the crowding effect than traditional charts can by displaying fewer letters. Crowding is the phenomenon where an object that is recognisable on its own becomes harder to recognise when surrounded by other objects (Leat et al., 1999; Levi, 2008; Whitney & Levi, 2011). If a letter is in close proximity to other letters or contours the ability to correctly identify it decreases, which can result in a reduction in visual acuity (Bouma, 1970; Pluháček & Siderov, 2018). Older adults are more susceptible to the crowding effect than younger adults, that is also true of persons with macular degeneration and amblyopia (Bailey & Lovie, 1976; Scialfa et al., 2013).

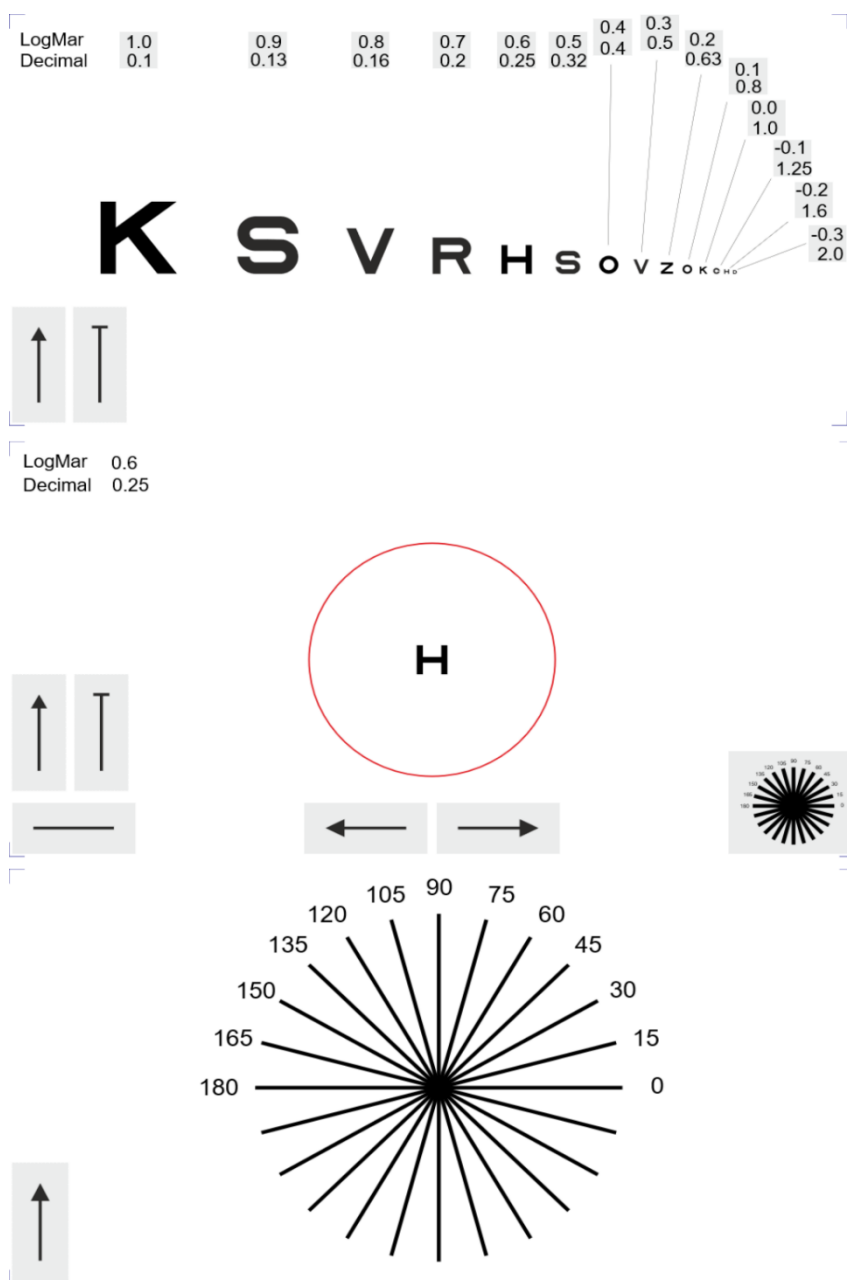
The best-known digital systems are the electronic visual acuity (EVA) and the COMProg. EVA is an electronic visual acuity measurement system that is approved by the US Food and Drug Administration (FDA). One adaption of EVA, the E-ETDRS, displays single letters on a screen, five letters of each logMAR-level are presented. Another adaptation of EVA, the EVA-SL, displays a single line of the ETDRS chart (five letters) on a screen (Jolly et al., 2019). COMProg uses a thresholding technique by alternating between displaying a single letter and a single line of five letters. The system allows for some changes to the variables, e.g. spacing between letters, number of letters per line and use of crowding bars (Laidlaw et al., 2008).

The visual acuity measurements with digital charts and systems have been shown to agree well with the ETDRS chart (Bastawrous et al., 2015; Beck et al., 2003; Bokinni et al., 2015; Hirano et al., 2017; Jolly et al., 2019; Laidlaw et al., 2008; Rhiu et al., 2016; Rosser et al., 2003; Shah et al., 2011). However examination time between digital charts and the ETDRS chart have varied; for some digital charts the examination time is increased (Laidlaw et al., 2008) and for others decreased (Bokinni et al., 2015). Few digital charts have been

shown to have shorter examination time with no adverse effect on visual acuity measurements.

### 3.3.1 AxAnIvIs

The AxAnIvIs chart is a digital visual acuity system developed by Per Söderberg, Gullstrand laboratory, Ophthalmic, Dept. of Neuroscience, Uppsala University. The system uses a custom-made algorithm for optotype visualisation. Optotypes decrease in size horizontally in one line (Figure 2 Upper) and can be displayed on their own (Figure 2 Middle), to minimise the visual crowding effect of presenting multiple letters on multiple lines.



**Figure 2.** AxAnIvIs chart. Upper: Optotypes in one line decreasing horizontally from left to right side. Middle: A highlighted optotype within a red circle. Lower: a dial chart for estimating the axis of astigmatism.



### **3.4 Aim of study**

The aim of this study is to determine if there is a systematic difference of estimated visual acuity between the AxAnIvIs system and the ETDRS chart at different levels of acuity, and to determine if there is any difference of estimated visual acuity in the precision of the estimate between the two charts. The project aims to answer the following questions:

1. Is there a difference of estimated visual acuity in the precision of the estimate between the two charts?
2. Is there a systematic difference of estimated visual acuity between the AxAnIvIs system and the ETDRS chart at different level of visual acuity?
3. Is there a difference in the time taken between the two charts?

## 4 Method

This study conformed with the Declaration of Helsinki, and informed consent was obtained from the participants before participation. Ethical approval was obtained from Etikprövningsnämnden. Subjects were recruited primarily from Ögonmottagningen Akademiska Sjukhuset, Uppsala. Each participant was tested using both the ETDRS chart and the AxAnIvIs system on two separate occasions.

### 4.1 Subjects

All subjects who met the following inclusion criteria: aged equal to or older than 55 years, and visual acuity between 1.0 and -0.1 logMAR, and no ocular disease strongly considered to cause visual acuity to change within one month where asked to participate. One eye of each subject was assessed.

Each potential subject's visual acuity was measured with the ETDRS chart before they were asked to participate in the study. If a potential subject complied with the inclusion criteria and their visual acuity corresponded to the next subject required, they were asked to participate in the study. After informed consent was obtained, subjects were enrolled in the study. The measured visual acuity was used to assign each subject to a subgroup, visual acuity class (Table 1).

**Table 1.** Visual acuity classes.

Visual acuity class	Visual acuity (logMAR)
1	[1.0 0.8]
2	[0.7 0.5]
3	[0.4 0.2]
4	[0.1 -0.1]

To minimise systematic errors one subject from each visual class was recruited before another subject in the same visual acuity class (as the already recruited subjects) was recruited (i.e. the first four subjects all belonged to different visual acuity classes, the next four subjects belonged to different visual acuity classes etc.).

#### 4.1.1 Sample size estimation

An ST project estimated the variance for visual acuity measurements with the ETDRS chart and the AxAnIvIs system. The variance for ETDRS was 0.0199 (arc minutes)<sup>2</sup> and for AxAnIvIs 0.0249 (arc minutes)<sup>2</sup>. Based on these variances, the variance for difference between measurements with the two charts was calculated. To demonstrate a difference of 1

resolved step on the ETDRS chart (0.1 logMAR) at the power of 0.8, the estimated sample size was 10. To allow for an equal number of subjects in each visual acuity class and an equal number of men and women, 16 subjects was set as the sample size.

## 4.2 Charts

Two systems for measuring visual acuity was used, the ETDRS chart and the AxAnIvIs system. The ETDRS chart (Preisler Instrument AB, Sweden) is a commercial 4 m backlit chart placed in room illumination. The AxAnIvIs system is a custom-made digital chart, with a custom-made algorithm for optotypes visualisation, placed at 4 m. Room illumination was controlled to be the same for all examinations.

## 4.3 Testing protocol

All visual acuities were measured by a single examiner and denoted in logMAR. Every second subject was measured with the ETDRS chart first and the AxAnIvIs system second on the first occasion, on the second occasion the order of the systems was reversed. The other subjects were measured with the AxAnIvIs system first and the ETDRS second on the first occasion, on the second occasion the order of the systems was reversed.

### 4.3.1 Definition of resolved vision

For the ETDRS chart, visual acuity was defined as the last correctly read full row of optotypes. With the AxAnIvIs system, visual acuity was defined as the last correctly read optotype.

### 4.3.2 Visual acuity estimation and best corrected vision

The visual acuity chart was presented to one eye of the subject, with the other eye covered. For the ETDRS chart the subject was asked to read full lines from top to bottom to the smallest perceivable without refractive correction, for the AxAnIvIs system the subject was asked to read from left to right to the smallest perceivable optotype without refractive correction (Figure 2 Upper). The last optotype that the subject read correctly was highlighted (Figure 2 Middle). Spherical lenses were then added, if visual acuity was more than 0.4 logMAR, 1.0 diopter spherical lenses were added and if visual acuity was less than or equal to 0.4 logMAR, 0.5 spherical diopter lenses were added, until best corrected visual acuity was achieved.

To correct for astigmatism with the ETDRS chart a cylindrical lens (-1.0 diopter if  $> 0.4$  logMAR, 0.5 diopter if  $\leq 0.4$  logMAR) was positioned at 0, 90, 45 and 135 degrees. With the AxAnIvIs system, a dial chart was presented to estimate the axis of astigmatism (Figure 2 Lower). The angle was then adjusted by the subject if needed for both systems. Then

cylindrical lenses were added until best corrected visual acuity was achieved. When the optical defect is corrected with cylindrical glass, the optics become more myopic. Therefore, as a final step +0.5 diopter spherical lenses was subsequently added until best corrected visual acuity was achieved. For each occasion the best corrected visual acuity, the examination time, spherical error, cylindrical error and axis angle, if the dial chart was used and if the dial chart was useful were recorded.

#### 4.4 Statistical analysis

The primary response variable was best corrected visual acuity (logMAR), the secondary response variable was examination time (s). The explanatory variables were ETDRS visual acuity class at inclusion, visual acuity chart and occasion. For statistical analysis MATLAB v9.7 (Mathworks Inc., Natick MA, USA) and IBM SPSS Statistics v26.0 (IBM, Armonk NY, USA) was used. The statistical analysis aimed to test the following null hypotheses and the corresponding alternative hypotheses:

1. H<sub>01</sub>: there is no systematic difference of estimated visual acuity between the AxAnIvIs system and the ETDRS chart  
     H<sub>1</sub>: there is a systematic difference of estimated visual acuity between the AxAnIvIs system and the ETDRS chart.
2. H<sub>02</sub>: there is no systematic difference between the charts depending on visual acuity class.  
     H<sub>2</sub>: there is a systematic difference between the charts depending on visual acuity class.

Visual acuity,  $x_{ijkl}$ , can be estimated according to the following equation:

$$x_{ijkl} = \mu + \alpha_i + \beta_j + C_{k(j)} + \alpha\beta_{ij} + \alpha C_{ik(j)} + \varepsilon_{l(ijk)} \quad (3)$$

where  $\mu$  is the population mean,  $\alpha_i$  is a term for the fixed factor chart type ( $i=1,2$ ),  $\beta_j$  is a term for the fixed factor ETDRS visual acuity class at inclusion ( $j=1,2,3,4$ ),  $C_{k(j)}$  is a term for random variation among subjects ( $k=1,2,3$ ),  $\alpha\beta_{ij}$  is a term for interaction between chart type and visual acuity class at inclusion,  $\alpha C_{ik(j)}$  is a term for interaction between chart type and subjects, and  $\varepsilon_{l(ijk)}$  is a term for random variation between occasion ( $l=1,2$ ) defined as a measurement error.

The outcome of measured visual acuity was analysed with a nested analysis of variance (ANOVA) according to Equation 3 ( $\alpha = .05$ ), resulting in table 2. The test statistic for hypothesis 1 is  $MS_1/MS_5$ , for hypotheses 2  $MS_4/MS_5$ .

**Table 2.** Analysis model for the measured visual acuity.

Source	Mean square
Charts	MS <sub>1</sub>
Visual acuity classes	MS <sub>2</sub>
Subjects	MS <sub>3</sub>
Charts x Visual acuity classes	MS <sub>4</sub>
Charts x Subjects	MS <sub>5</sub>
Occasions	MS <sub>6</sub>

If there was significant systematic difference between charts but not between charts depending on visual acuity class, the average difference between the two charts would be estimated as CI (0.95) for the mean difference and would be the calibration factor between the two charts. If there was significant systematic difference between the charts and between charts depending on visual acuity class, a regression model for the difference between the charts as a function of visual acuity class would be established and the calibration factor between the charts would be estimated as the regression coefficients.

## 5 Results

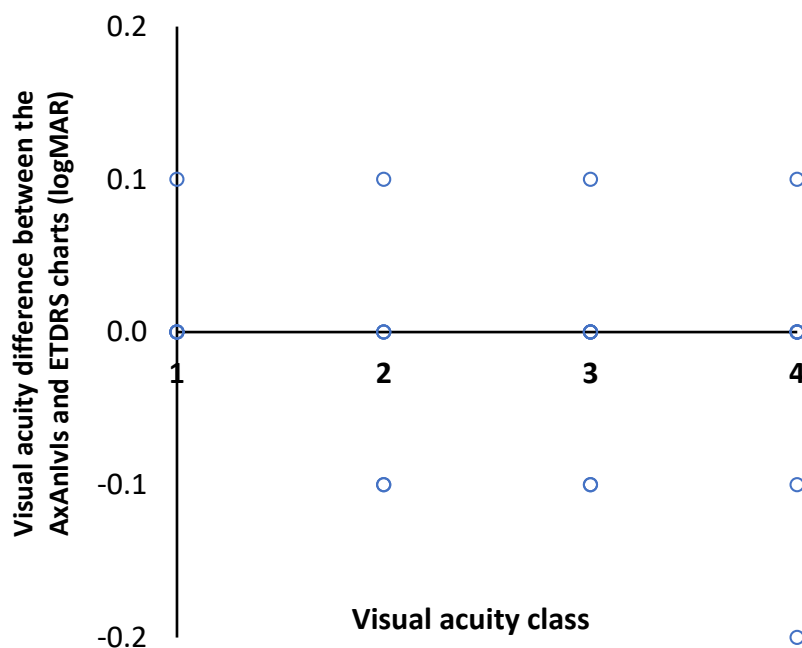
Altogether 85 patients were identified as potential subjects. 52 had eye diseases that excluded them from the study, 19 had been given pupil dilating drops prior to the exam and were therefore excluded. In total 14 patients were enrolled in the study.

### 5.1 Subject characteristics

Eight of the subjects were men and six were women. The age of the subjects ranged from 55 to 85 years ( $Mdn = 64.5$ ). Almost a third of the subjects (29 %) had no ocular disease, half (50 %) had diabetic retinopathy, nearly a third (29 %) had astigmatism, almost a fifth (21 %) had age-related macular degeneration and one seventh (14 %) had glaucoma. The median time between first and second visit was 10 days.

### 5.2 Difference between the AxAnIvIs system and the ETDRS chart as a function of visual acuity class

The mean visual acuity difference between the AxAnIvIs digital chart and the ETDRS chart at the different visual acuity classes was estimated as 0.02 logMAR (95% CI [-0.02, 0.06]) at visual acuity class 1, -0.02 logMAR (95% CI [-0.1, 0.06]) at visual acuity class 2, -0.01 logMAR (95% CI [-0.06, 0.04]) at visual acuity class 3, and -0.03 logMAR (95% CI [-0.1, 0.04]) at visual acuity class 4. Figure 3 shows a scatter plot of visual acuity difference between the charts at the different visual acuity classes.



**Figure 3.** Visual acuity difference between the AxAnIvIs system and the ETDRS chart.

### 5.3 Estimates of variance components for visual acuity results

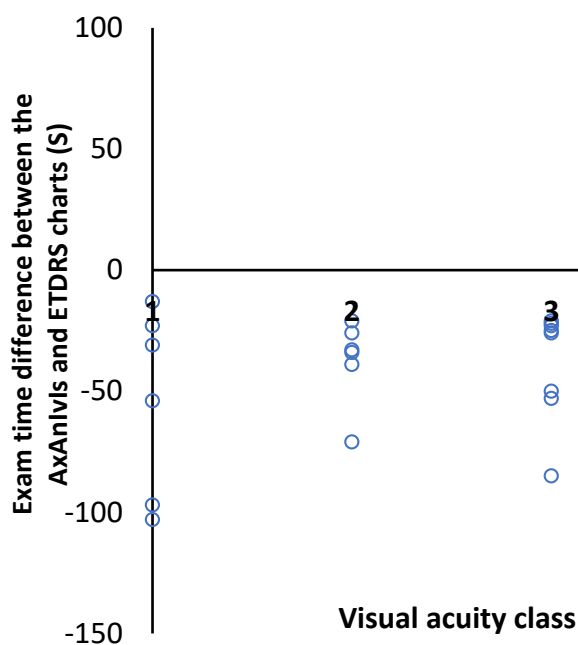
A nested ANOVA showed no significant difference of visual acuity estimates between the two charts (Test statistic = 0.0474,  $F_{1,8,0.95} = 7.57$ ). There was no significant difference between the two charts depending on visual acuity class (Test statistic = 0.33,  $F_{3,8,0.95} = 5.42$ ). Estimated variance components for random factors in the model (Equation 3) can be seen in Table 3.

**Table 3.** Estimate of variance components.

Source	Variance component
Subjects	0.0026
Charts x subjects	0.0010
Occasions	0.0019
Error	0.0000

### 5.4 Examination time

The mean examination time difference was estimated as -37 s (95% CI [-52, -22]). Figure 4 shows the examination time difference at the different visual acuity classes in a scatter plot (AxAnIvIs examination time - EDTRS examination time).



**Figure 4.** Difference in examination time between the AxAnIvIs system and the EDTRS chart.

## 6 Discussion

### 6.1 Main findings and interpretation

The difference between the measurements of visual acuity with the AxAnIvIs system and the ETDRS chart was small for all visual acuity classes. The differences for each visual acuity class are smaller than one resolved step (0.1 logMAR) on the ETDRS chart, which indicates that the precision of the estimate of visual acuity are equal between the two charts.

When comparing the means between groups, the statistical analysis showed no statistically significant difference between the two charts, i.e. no systematic bias could be identified. Furthermore, there was no statistically significant difference between the two charts depending on visual acuity class. The findings in the current study is consistent with previous research that has shown that many digital charts measurements of visual acuity are equal to the measurements with the ETDRS chart. Since no significant difference was found, the AxAnIvIs system can be used as a replacement of the ETDRS chart.

The examination time was decreased for the AxAnIvIs system compared to the ETDRS chart. That is expected since the AxAnIvIs displays fewer letters than the ETDRS chart, the better the acuity the larger the difference in number of letters shown will be decreasing the examination time. It also displays fewer letters in total than the digital chart that has previously been shown to be faster than the ETDRS chart. The dial chart used in the AxAnIvIs system to correct for astigmatism also saves time compared to positioning a lens at four different angles with the ETDRS chart. The largest difference was observed in visual acuity class 1, the class with the lowest vision. Most of the subjects in that class had age-related macular degeneration, an ocular disease with effects on central vision, known to be more susceptible to the crowding effect, making it more difficult to identify the optotypes. Since the crowding effect on the AxAnIvIs chart is very small, even patients with age-related macular disease will find it easier to identify optotypes. This could explain why the examination time was more decreased than in the other visual acuity classes.

This study did not find a significant difference between the charts and further research, with a larger sample size, is needed to be able to validate the AxAnIvIs chart. Further research is also needed to see if the general design of the chart can be used with other optotypes (other than letters), to be able to use it in other population groups, e.g. small children.



## 6.2 Chart design and its implications

The major design difference between the two charts is that the AxAnIvIs system displays only one optotype per acuity level. This could imply that the difficulty of the task (identifying optotypes) varies with each acuity level. The task could be more difficult on some levels because some letters are more difficult to identify than others. On the ETDRS chart the task difficulty is controlled to be the same on all levels. Furthermore, compared to the ETDRS chart the overall task difficulty could be easier since fewer letters must be identified for each acuity level. This study could not prove these differences, which suggests that there is no difference in task difficulty, even though there in theory should be. Previous research with other digital charts with fewer optotypes per line have not been able to identify these differences, which indicates that fewer letters per line does not necessarily make the task easier. Furthermore, fewer letters per line does not have an impact in the precision of the estimate when compared to the ETDRS chart, not for the AxAnIvIs system and not for other digital charts previously shown to be equal to the ETDRS chart.

Another effect caused by the different numbers of optotypes per line is the difference in crowding. The ETDRS chart is designed to control for the crowding effect but does not eliminate it. The AxAnIvIs system have no crowding effect since only one optotype is displayed. Since previous research has shown that crowding reduces visual acuity, visual acuity measurements between the charts should, in theory, therefore not be the same since the AxAnIvIs system would systematically overestimate visual acuity compared to the ETDRS chart. However, the result of this study could not provide enough evidence to support this, indicating that the difference in crowding between the ETDRS chart and The AxAnIvIs system is small or negligible for the measurements.

The design of the AxAnIvIs system makes it useful in routine clinical work. Compared to other digital charts, it displays fewer letters in total, making it more user friendly and the results easier to calculate. The design decreases the examination time, which this study shows, making it useful for visual acuity screening in the clinic where time is limited. It should not be used to evaluate treatments, for those purposes a more exact measurement of visual acuity should be used where visual acuity can be measured on a more detailed scale. For example, the ETDRS chart where visual acuity is estimated based on the number of letters read correctly. The AxAnIvIs chart could however be used to replace the Snellen chart, which is the chart most frequently used in routine clinical practice where an exact and precise measurement of visual acuity is not crucial for the management of patients.

The Snellen chart has been shown to have more variability in its measurements compared to the ETDRS chart (Ricci et al., 1998). The design of the AxAnIvIs chart deals with many of the problems that the Snellen chart has, reducing the variability in measurements.

### **6.3 Method discussion**

Participants was aged 55 years or older, resembling the average patient at an ophthalmic clinic. The refractive method used in the study is a standard subjective refraction, a commonly used method in clinical practice.

Many patients at the clinic was screened for potential participation, however because of the study design only potential subjects that corresponded to the next desired subject could be enrolled. This resulted in a large discrepancy between the number of screened patients and number of enrolled subjects. A minimum sample size, calculated from data from a previous study, was 10 subjects. For this study, to be able to make subgroup analysis, e.g. based on gender, 16 subjects had to be enrolled. This could not be done during this study. Subjects in visual acuity class 1 was especially hard to find since most of the patients at the clinic with acuity 1.0-0.8 logMAR were at the clinic for treatment, making them unable to participate in the study.

### **6.4 Strengths and limitations**

A strength of this study is that a single examiner performed all testing and examiner-based variation was therefore controlled for. The subjects had a range of visual acuities, and some subjects had an ocular disease while others did not, which makes the sample of this study resemble the population. The study also had pre-defined parameters for visual acuity classes, allowing for subgroup analysis. Furthermore, the study design dealt with some factors that are known to increase variability between tests. Since the testing procedure included a refraction before each measurement, uncorrected refractive error was controlled for. Potential subjects with ocular disease with acuity change within one month was excluded, decreasing the risk for large variability in measurements between the first and second testing occasion. Room illumination was controlled, limiting the effect of variable lighting conditions, which is known to increase variability.

The main limitation of the study is the small sample size. The sample size estimation, based on a previous project, set a minimum sample size of 10 subjects. This study had 14 participants which, according to the estimation should be enough to find a difference between the charts. Nevertheless, the study could not provide enough evidence to reject the null hypotheses. A larger sample size would have increased the probability of finding a

difference. Another consequence of the small sample size was that assumptions based on certain subject characteristics, such as gender or ocular disease, could not be made.

## **6.5 Conclusions**

There is no significant difference between the estimates of visual acuity between the two charts, which suggests no systematic bias. There is also no statistically significant difference between the two systems depending on visual acuity class. The AxAnIvIs can therefore be used as a replacement of the ETDRS chart. The examination time with the AxAnIvIs system is half of a minute shorter than that with the ETDRS chart, which makes it more desirable in routine clinical work.

## **7 Acknowledgments**

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