Validation of Nidek TONOREF II Auto Refractor- Pilot Study

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Abstract

The purpose of the study is to validate the Nidek Tonoref II automated refractometer machine.

Methods

A prospective study was performed on Fifty five subjects of any age group were included in the study; Static retinoscopy was performed first followed by Nidek Tonoref II auto refractor. The reliability between the Static retinoscopy and the auto refractor was measured using paired t test.

Results

Among the fifty five subjects twenty six were males and twenty nine were females. Their mean age was 45 with +/- 18.8 standard deviation. The spherical equivalent of the mean refractive error in retinoscopy is 0.39 with +/- 1.5 Standard deviation and the auto refractor is 0.17 with +/-1.7 standard deviation. The Mean difference in spherical equivalent between retinoscope and autorefractor: 0.22 (0.61). The measurement of agreement for the validity was statistically significant (P<0.01).

Conclusion

The study shows that there is good estimation of spherical error between retinoscopy and auto refractor but not with cylinder power. There is an over estimation with cylindrical error and it is variable in Nidek TONOREF II automatic refractometer. The AR- reading should not be prescribed straightaway without carefully checking the acceptance subjectively. Automatic refractors are probably a helpful aid to the professional, but they do not and should not replace the art of clinical refraction.

Keywords

Retinoscopy; autorefractometer; spherical error; cylindrical error

Introduction

Refraction, the determination of the refractive error of an eye, is an essential part of eye care. Refraction is used clinically to determine the spectacle prescription so that the best possible acuity can be achieved. The objective refraction function measures spherical powers, cylindrical powers and cylinder axis. Automatic refractors have gained importance in recent years because of the busy clinical schedule and the increasing faith of patients in sophisticated mechanical devices [1]. Many such refractometers, both subjective and objective, are now available, with steadily improving designs and claims to accuracy. One of the latest objective models is the Nidek TONOREF II auto refractometer, which was recently installed in our centre. In view of several reports in the literature on the reliability and accuracy of various types of autorefractors. The TonoRef II is NIDEK’s 2nd generation 3-in-1 pretesting instrument is with combined autorefractor, autokeratometer and non contact tonometer [2]. The TonoRef II features the Pupil Zone Measuring Method which expands the refraction measurement area.
Materials and Methods

Subjects of any age who came to the general outpatient department were included in the study. From 2 mm up to 4 mm in diameter, depending on the patient's pupil size, to get the most accurate measurement. It also uses a Super Luminescent Diode which uses a sharper, clearer measurement ring to penetrate cataracts and IOLs in the objective measurement process.

According to Wubbolt S et al in his study “Comparisons of manual and automatic refractometry with subjective results” [3] concluded that the Auto Refractometer provides measurements with the smallest deviation compared to the subjective method. Here it has to be taken into account that the measurements for the sphere have an average deviation of +0.2 diopter. In comparison to retinoscopy the examination of children with the RM-A 7000 is difficult. An advantage of the Auto Refractometer is the fast and easy handling, so that measurements can be performed by medical staff.

Accuracy of the autorefractor power refractor in clinical work a comparative study by Schittaowskiet all [4] suggest that the best accuracy compared to retinoscopy had Retinomax K-plus followed by RK-5. Power Refractor had the biggest deviations of the tested devices. Power Refractor may be a useful device for screening small children and handicapped people because of the one meter observing distance. For a precise refraction especially in children a retinoscopy under cycloplegic conditions is still necessary.

SchimdtBacher et al found that retinoscopy in cycloplegia is still the method of choice when determining refraction in children [5]. Autorefractors quickly provide results for comparison which coincide with retinoscopy in 50-60% in spherical equivalent and in 80-90% in cylindrical values. The Pediatric Autorefractor is not suited for everyday clinical routine due to a low success rate of 50% and tight measuring range of +5.0 to -7.0 D in spherical equivalents.

Steele G et al found that even though the Retinomax Plus and the Sure Sight appear to agree with each other and with the results of cycloplegic retinoscopy [6] for determining sphere and cylinder power, interpretation of the data should be considered as screening only because the actual magnitude of sphere and cylinder may vary from the actual magnitude. These results suggest that either device may be useful only as screening tools for assessing refractive error in pre-school children.

Subjects with amblyopia, strabismus, nystagmus and other ocular pathologies were excluded from the study. Subjects who were not co-operative for the assessment were also excluded. Fifty five subjects with mean age of 45, with standard deviation +/-18.8 were studied. The comprehensive eye examination includes detailed history, visual acuity, objective refraction, subjective acceptance and then NidekTonoref II auto refractor was performed. The principle of NidekTonoref II is fine measurement beams are projected on the fundus of the patients eye by a projecting optical system and then computations is performed by capturing the reflected beams as a ring image to measure the refractive errors (Sph, Cyl and axis) of the patients eye [7]. The Super Luminescent Diode and a highly sensitive CCD device provide sharper and clearer images than LED. The TonoRef II also features 3D Alignment to make measurements simple for even new operators. Simply align the head with the patient's eye and the TonoRef II will take over: tracking the patient's eye until optimal positioning is achieved and acquisition is triggered [8].

Statistical analysis

Descriptive analysis was done using MS Excel and SPSS version 15. The values were assessed for right eye and the Spherical equivalent was taken for the refractive error. Refractive error was defined as Emmet rope (-0.50 D to +0.50 D), Myope less than 0.50 D and Hyperope more than 0.50 D based on retinoscopic values.

Results

Of the 55 patients 26 were males and 29 were females. Their mean age was 45 with +/- 18.8 standard deviation. The mean difference and standard deviations (SD) in spherical equivalent data, cylindrical power and axis are depicted in Table 1. The comparative analysis for various types of refractive error is given in Table 2. The spherical equivalent of the mean refractive error in retinoscopy is 0.39 with +/- 1.5 Standard deviation and the auto refractor is 0.17 with +/-1.7 standard deviation. The Mean difference in spherical equivalent between retinoscope and autorefractor: 0.22 (0.61).

Table 1: Comparison of errors between Retinoscope and Autorefractor

<table>
<thead>
<tr>
<th></th>
<th>Retinoscope</th>
<th>Autorefractor</th>
<th>P value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spherical</td>
<td>0.78</td>
<td>0.68</td>
<td>0.29</td>
</tr>
<tr>
<td>Cylinder</td>
<td>-0.77</td>
<td>-1.02</td>
<td>0.006</td>
</tr>
<tr>
<td>Sph equivalent</td>
<td>0.39 (+1.6)</td>
<td>0.17(+1.7)</td>
<td>0.01</td>
</tr>
</tbody>
</table>
Paired t test

Paired t test showed that there is significant difference between retinoscope and autorefractor in cylindrical values ($p = 0.006$) and mean spherical equivalent values obtained ($p = 0.01$) but not with spherical error ($p = 0.29$). So there is good estimation of spherical error and not with cylinder. There is over estimation with cylindrical error.

Table 2: Relationship with refractive error

| Ref Error | Emmetropia | | | | | | Hyperopia | |
|-----------|------------|------------------|------------------|------------------|------------------|------------------|------------------|
|           | Mean Difference (SD) | p value | Mean Difference (SD) | p value | Mean Difference (SD) | p value | |
| Sph error | 0.22 (0.79) | 0.19 | -0.11 (0.72) | 0.62 | 0.06 (0.43) | 0.46 | |
| Cyl Error | 0.25 (0.42) | 0.01 | 0.41 (0.70) | 0.08 | 0.17 (0.80) | 0.32 | |
| SEQ       | 0.35 (0.74) | 0.03 | 0.09 (0.52) | 0.58 | 0.15 (0.50) | 0.16 | |

Paired t test showed that there is no difference in values obtained in spherical error in all refractive error types, in cylindrical error and spherical equivalent there is difference noted in emmetropia and not in myopia and hyperopia. This shows that the cylindrical error is variable in autorefractor.

Graph 1: Measures of agreement

**Discussion**

On clinical refractive assessment 20 out of 55 eyes showed no cylindrical error, whereas only 10 eyes showed purely spherical error on the AR. It seems that the cylindrical values obtained on the AR may often not be of clinical significance in many eyes. The value of the cylindrical component obtained on the AR, like those for the spherical component and spherical equivalents, are also skewed towards more minus or less plus when compared with clinical refractive data.

This observation has also been made earlier on the SR III subjective refractor [9]. Again, like the spherical data, the skew deviation for cylinder power towards greater minus is more pronounced in emmetropic, low myopic, and low hypermetropic groups [10]. The difference in agreement between the AR and clinical data on the cylindrical component in the various age groups was not significant. This is to be expected, as the cylindrical power in a given eye is unlikely to be influenced by accommodative effort, in contrast to the spherical component [11]. The mean difference of cylinder axis values determined clinically and on the AR was 43° with a standard deviation of ±9.850. The determination of axis by the AR appears to be quite reliable and accurate [12].

**Conclusion**

The study shows that there is good estimation of spherical error between retinoscopy and auto refractor but not with cylinder. There is over estimation with cylindrical error and it is variable in Nidek TONOREF II automatic refractometer. The AR- reading should not be prescribed straightforwardly without carefully checking the acceptance subjectively, or using it as a guideline in case the clinical refraction- presents difficulties. Automatic refractors are doubtless an invaluable aid to the specialist, but they do not and should not replace the art of clinical refraction.

**References**

3. Polse KA, Henton EK (1975) An automatic objective


