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Refraction in Children: A Comparison Between "Naive" Refraction to the Plusoptix A12 Portable Auto-Refractometer and Refraction at the Fixed Auto-Refractometer in Cycloplegia: About 52 Cases

Said Iferkhass*, Fatine Elalami, Nihad Elhalouat, Anas Bouassal, Aziz Elouafi, Abdelkader Laktaoui

Ophthalmology Department, Military Hospital My Ismail, Meknes, Morocco

Email address:
Said224@yahoo.fr (S. Iferkhass), fatineelalamii@gmail.com (F. Elalami), elhalouatnihad8@gmail.com (N. Elhalouat), atta.anass@gamil.com (A. Bouassel), elouafi.aziz@gmail.com (A. Elouafi), laktaouia@gmail.com (A. Laktaoui)

*Corresponding author

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Abstract: The aim of our work is to compare the values obtained by the last generation portable auto-refractometer PlusoptixA12 without dilation to those provided by an automatic refractometer with cycloplegia: Canon (RK-F2), in children, in order to have an idea about its strengths and limitations. Our work is a Cross-sectional study conducted from June to November 2016, about 52 children (104 eyes), aged from 3 to 16 years. Each child had a measure of refraction with the Plusoptix (without cycloplegy). After that, three instillations of cyclopentolate hydrochloride were carried out (T0, T5, and T10 min). We retake the refraction after 45 minutes using a fixed auto-refractometer. The average spherical equivalent was 1.46 ± 1.10 for refraction with Plusoptix versus 1.94 ± 1.40 for cycloplegic auto-refraction with a statistically significant difference (average difference -0.48D ± 1.06 (P <0.001). The difference between the average spherical refraction was -0.42 ± 1.03; P <0.001). In the hyperopic group, the average difference between the two refractive methods was -0.61 ± 1.03 compared to 0.23 ± 0.59 for myopic patients. For cylinders, the difference of the average power between the two devices was -0.14 ± 0.38 (P <0.001). There was no statistical significance between the two instruments for the cylindrical axis (p: 0.087). In the light of results obtained, the Plusoptix can be used as an interesting method of screening for ametropia. But it is not a precise way for studying refraction in strabic and amblyopic population. Its results are more reliable for the myopic and astigmatic subgroups than hyperopic ones.

Keywords: Refraction, Plusoptix, Cycloplegia, Child

1. Introduction

Plusoptix is a portable auto-refractometer used to evaluate refraction with eccentric photo refraction. It permits simultaneous measurement of both eyes in less than a second, at a distance of one meter. It is easy to use and has been specifically designed for infants, children and non-cooperating patients [1-2]. But it has a major disadvantage that is its limited measuring range [3-5].

This study of 52 childrens (104 eyes), compare the refractive values obtained by the last generation of PlusoptixA12 without cycloplegia, to those provided by auto-refractometer with cycloplegia. In order to know its usefulness for the study of refraction and its place in detection of risk factors of amblyopia

2. Materials and Methods

Our work is a cross-sectional study, carried out in the pediatric ophthalmology department of My Ismail military hospital in Meknes, during 6 month from June to November 2016.

It concerns 52 children, or 104 eyes. The mean age of our sample were 9.5 ± 3.6 years with extremes ranging from 3 to 16 years with a sex ratio H / F to 1.

Each child has a measure of refraction with Plusoptix A12 (4 values, the average value represented the final result). Then three instillations of cyclopentolate hydrochloride (Skiacol® 0.5%) are carried out (T0, T5, and T10 min). We retake the refraction after 45 minutes using a fixed auto-refractometer.

The majority of our patients were cooperating: 48 (92%). The 4 others had difficulty to set the target: to remedy this, we have used another source of attraction (candy, drawing).

Binocular measurement was performed for 39 patients (75% of cases). For strabismus, the measurement was monocular.

In our study, 30 children already had an optical correction before (57% of cases). 16 (30%) had strabismus. Two children (3%) had nystagmus. The measurement was impossible for three patients with a refraction exceeding the capacity of the device: (strong bilateral myopia of -8 DS, unilateral strong myopia of -9.50DS and pseudophakia)

Three degrees of severity of ametropia were adopted: Hyperopia was considered as: Low if its value is less than +1.75 DS, moderate from +2 to +3.25 DS, and high beyond +3.50 DS.

Myopia was considered as: Low for refraction less than 3D, Moderate from 3 to 6D, and high for refraction beyond 6D.

Astigmatism was considered to be: Low if refraction is less than 0.75 diopters, average from 1 to 2 diopters, and high above 2 diopters.

Children with contraindications to cyclopentalate and children under one year of age were excluded from the study.

Statistical data were generated using SPSS software version 21. The descriptive data were presented as mean, standard deviation and frequency. A paired test and a regression analysis of the curve estimate were performed to compare cycloplegic refraction to that obtained by PlusoptiX A12. A statistically significant difference was defined by a value of $p < 0.05$. (The data were analyzed in absolute values).

3. Result

Under cycloplegia, low ametropia accounted for 60.2% of all types of ametropia combined, followed by moderate ametropia, which accounted for 24.7%, while high ametropia accounted for only 15.1% of cases. In Plusoptix A12: low ametropia accounted for 65.6%, moderate 21.1% and high 13.3%.

For the comparison of the two refractive measurement methods (Table 1), the mean value of spherical equivalents is: 1.94 ± standard deviation (SD) of 1.40 for cycloplegic refraction, 1.46 ± 1.10 for refractive Plusoptix. That is a difference of -0.48 ± 1.06. Which means that the spherical equivalent obtained from the Plusoptix was, on average, 0.48 D less than that obtained under cycloplegia.

Table 1. *Comparison of the spherical equivalent and mean values of spherical and cylindrical ametropia, and the axis of astigmatism between the two cycloplegic and non-cycloplegic methods.*

	Cycloplegic refraction	Non-cycloplegic refraction	Average difference between the two methods of refraction:	Degree of significance
Spherical equivalent +/-DS	1,94±1,40	1,46 ±1,10	-0.48±1.06	0.00
Spherical ametropia of all types +/-DS	2,17±1,62	1,75±1,21	: -0.42±1.03	0.00
spherical hyperopic component+/-DS	2,29±1,66	1,68±1,15	-0.61±1.03	0.00
spherical myopic component+/-DS	1,73±1,23	1,97±1,57	0.23 ±0.59,	0.121
cylindrical ametropia+/-DS	0.80±0.89	0.95±0.97	: 0.14±0.38	0.00
mean value of the axis of astigmatism+/-DS	63.44±69.27	69.05±68.95	5.60 ±31.89	0,08

This difference was statistically significant with a significance level p: <0.001. (Pearson correlation coefficient (r): r = + 0.66, p <0.001), so that the Plusoptix refraction is significantly and positively correlated with cycloplegic refraction.

The Bland-Altman plot represents the concordance between the two types of refraction with respect to the spherical equivalents. The limits of approval varied between: [-2.56; 1.59] (Figure 1)

In strabismic children, the mean difference in spherical equivalents from the two types of refraction was -1.11 ± 1.28, with a significance level p <0.05.

The mean value for all types of spherical ametropia is 2.17 ± 1.62 for cycloplegic refraction, 1.75 ± 1.21 for Plusoptix refraction. The mean difference between the two methods of refraction was -0.42 ± 1.03. This difference was statistically significant with a significance level p: <0.001. (r = + 0.77, p <0.001, the Plusoptix refraction is significantly and positively correlated with cycloplegic refraction). The Bland-Altman plot represents the concordance between the two types of refraction with respect to spherical values. The limits of approval varied between: [-2.45; 1.60] (Figure 2)

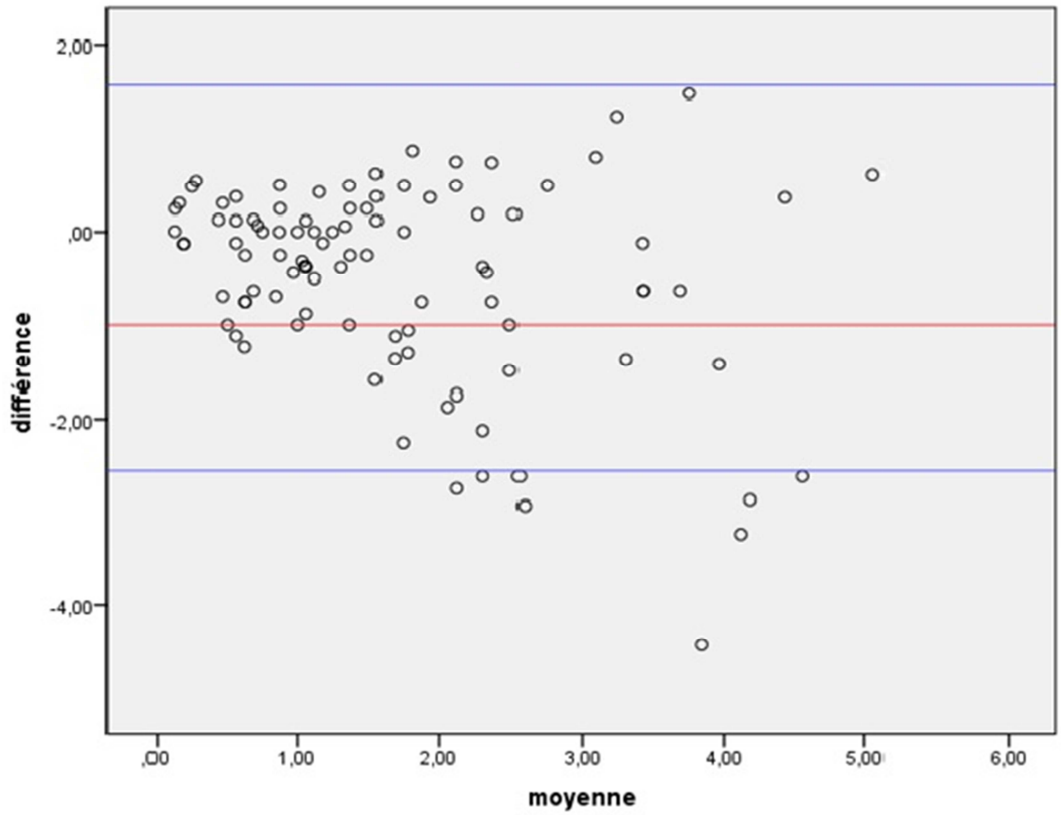

Figure 1. *Bland-Altman graph showing the concordance between the two types of refraction, with regard to the spherical equivalent.*

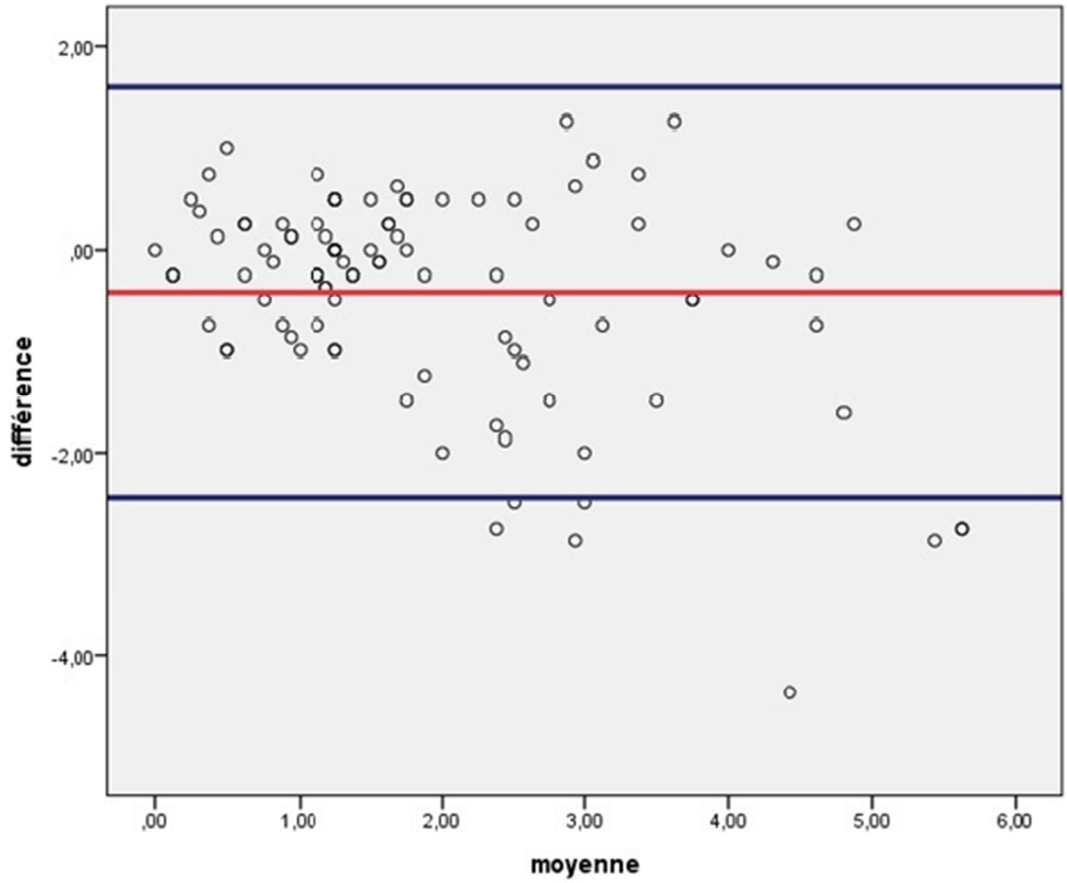

Figure 2. *Bland-Altman graph showing the concordance between the two types of refraction, with regard to spherical values.*

We divided the data into two subgroups to examine the precision of Plusoptix separately for myopia and hyperopia

The mean value for the hypermetropic spherical component is 2.29 SD ± 1.66 for refraction with skiacol, 1.68 ± 1.15 for refraction at Plusoptix. The average difference between the two methods of refraction: -0.61 ± 1.03. This difference was statistically significant with a degree of significance p: <0.001. (r = + 0.78, p <0.001, the Plusoptix refraction is significantly and positively correlated with cycloplegic refraction).

The mean value (in absolute values) for the myopic spherical component is 1.73 ± 1.23 for cycloplegic refraction, 1.97 ± 1.57 for refraction with Plusoptix. The average difference between the two types of refraction: 0.23 SD ± 0.59, this difference was not statistically significant with a degree of significance p: 0.121> 0.05.

(r = + 093, p <0.001, the Plusoptix refraction is significantly and positively correlated with cycloplegic refraction)

The average value (in absolute values) for cylindrical ametropia is 0.80 ± 0.89, for refraction with cycloplegic, 0.95 +/- 0.97 for refraction at Plusoptix. The average difference between the two methods of refraction: 0.14 ± 0.38, this difference was statistically significant with a degree of significance p <0.001. (: r = + 0.92, p <0.001),. The Plusoptix refraction is significantly and positively correlated with cycloplegic refraction). the Bland-Altman graph compares the averages of the measurements with their differences and shows the agreement between the two types of refraction with respect to the cylindrical refraction, with limits of agreement between: [-0.59; 0.89] (figure 3)

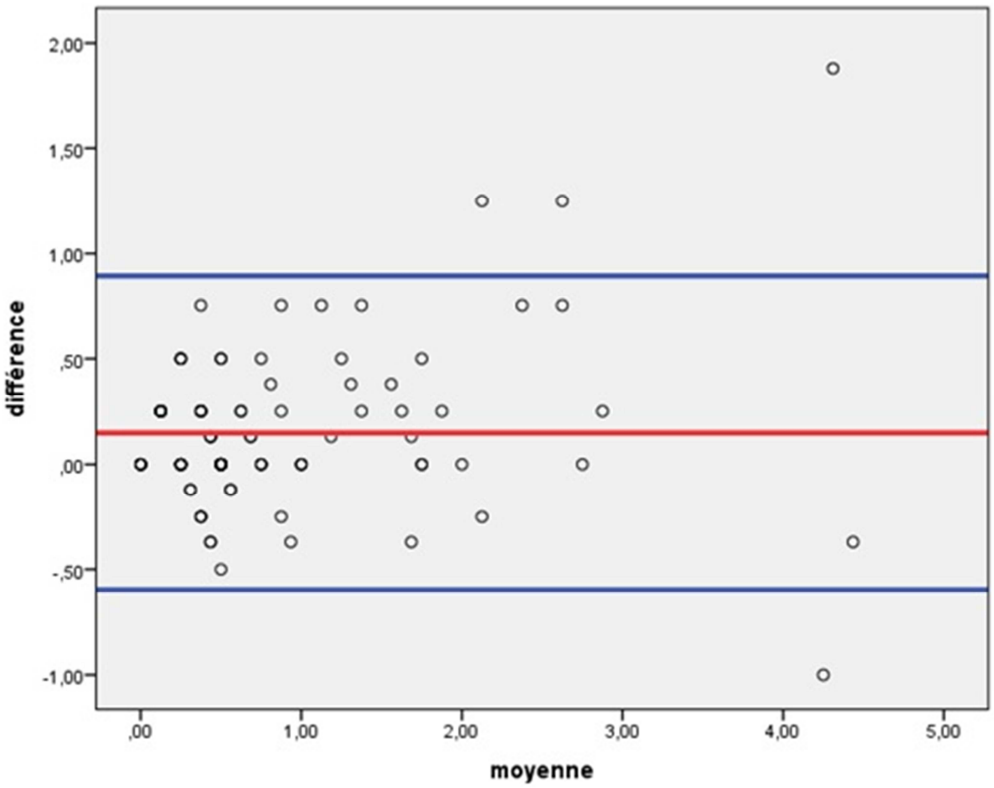

Figure 3. *Bland-Altman graph showing the concordance between the two types of refraction, with regard to astigmatism.*

The mean value of the axis of astigmatism is 63.44 +/- 69.27 for cycloplegic refraction, 69.05 +/- 68.95 for refraction with Plusoptix. The average difference from two types of refraction: 5.60 ± 31.89, this difference was not statistically significant with a degree of significance p: 0.087> 0.05. (r = + 0.89, p <0.001), the Plusoptix refraction is significantly and positively correlated with cycloplegic refraction).

4. Discussion

In this study, children were examined with the newest generation of Plusoptix: the PlusoptiX A12. To our knowledge, it has only been tested to date in a single study [6].

The age of our patients was between 3 and 16 years old. Other authors have conducted studies to compare Plusoptix with cycloplegic refraction over approximate age groups [6-7-8]

We saw in our work that 30% of children had strabismus. This high prevalence could be explained by the very specific recruitment related to pediatric ophthalmology and strabology specialized consultations within our department.

This result is similar to what Xiao-Ran Yan found in his study about the performance of Plusoptix A09 to detect risk factors for amblyopia in Chinese children [9], and what AH

Dahlmann-Noor and al. [10] found. They noticed respectively 35.4% and 29.6% cases of strabismus in their series. These results are superior to those found by Payerols and Brian W. [8-11], who report respectively only 9.4% and 5% cases.

In our series, with cycloplegia, astigmatism was the most frequent refractive abnormality, it was found in 86.12% of the eyes examined, followed by hyperopia then myopia with respectively 79.4% and 19.6%. For Plusoptix, the same distribution was observed: astigmatism was present in 91% of the eyes examined, hyperopia in 77% and myopia in 15% of cases.

Miri Fogel-Levin [6] found in his series that hyperopia was the most common refractive abnormality with a prevalence of 68.5% followed by myopia 17.9% and astigmatism 13.4%.

In this study, the average spherical equivalents obtained in Plusoptix were 1.46 ± 1.10, and those obtained using cycloplegic refraction was 1.94 ± 1.40.

The average difference between the two instruments was -0.48 ± 1.06, which means that the spherical equivalent obtained from Plusoptix was 0.48 D less than that obtained with cycloplegia. Thus, it can be concluded that Plusoptix tends to underestimate hyperopia and overestimate myopia. Our results are consistent with those obtained by Millicent W. Peterseim, Demirel and Mirzajani [1,12, 13], who respectively reported an average difference of -0.47 ± 0.07, -0.25, and -0.22 ± 0, 75 (Table 2). In practice these average differences are not negligible in the case of children requiring total optical correction.

Table 2. *Comparison of the results of our study with those of the literature with regard to the spherical equivalent.*

	Average ES/ Cycloplegic ± DS	Average ES/ plusoptix ± DS	Average difference ± DS	P (degree of significance)	R (corrélation)
Fogel-Levin and al (2016) [6]	0.68 ± 2.63	0.25 ± 1.3			
Payerols and al. (2016) [8]	1.06± 2.04	0.54 ±1.82		0.04	
Demirel and al (2013) [1]	-0.25	0.125	-0.25	< 0.001	
Ayse YK and al. (2010) [7]	2.14 ± 2.29	1.15 ± 1.65		<0.001	
MIllicent W. Peterseim and al. (2014) [12]			-0.47 ± 0.07	< 0.001	0.89
Ali Akbar and al. (2011) [14]	1.30 ± 0.99	0.96 ±0.82	-0.16 ± 1.0	0.01	
Mirzajani and al (2012) [13]			-0,22±0,75		
Our study (2016)	1.94 ± 1.40	1.46 ± 1.10	-0.48 ±1.06	< 0.001	0.66

In 2011, the study by Ali Akbar et al [14], about screening for risk factors of amblyopia in preverbal children using Plusoptix, the mean difference in spherical equivalent was -0.16 ± 1.0. A negative difference was also reported by Erdurmus et al [15], who found a difference of -0.63

Analysis of our data shows that for strabismic children, the average difference of spherical equivalents between the two methods of refraction was -1.11D, and for hyperopia exceeding 3D, the mean difference reached -1.54D, with a correlation coefficient not exceeding 0.54.

In our work, 75% of values of spherical equivalents provided by Plusoptix A 12 were less than ± 1.00 D from those obtained by auto-refractometer under cycloplegia. These results are consistent with those obtained by Erdurmus et al [15], who included a cohort of healthy children aged from 9 months to 14 years, and found that in 82% of cases, spherical equivalents obtained with Plusoptix CR03 were less than ± 1.00D from those obtained by cycloplegic retinoscopy.

The difference between the two refractive methods with respect to spherical equivalents was statistically significant with a significance level p: <0.05. The same result was reported by all the studies found in the literature. Based on the Pearson correlation coefficient (r), the Plusoptix refraction was significantly and positively correlated with cycloplegic refraction (r = + 0.66, p <0.001). This same finding was reported by Millicent W. Peterseim et al [12] in 2014, with a correlation coefficient of 0.89

In practical terms, this difference of -0.48 ± 1.06 is quite important especially for children requiring total optical correction. In addition, this mean difference in spherical equivalents between the two methods of refraction was -1.11 in our strabismus patients and reached -1.54 in hyperopic patients exceeding 3D. Thus, we can concluded that although the plusoptix is reported as an effective tool for screening risk factors for amblyopia, it is limited in the refractive study in this at-risk population.

In our series, the average spherical values (in absolute values) obtained in Plusoptix was 1.75 ± 1.21, and those obtained using cycloplegic refraction was 2.17± 1.62.

The mean difference between the two methods of refraction was -0.42 ± 1.03, this negative value indicates an underestimation of hyperopia and an overestimation of myopia by Plusoptix in comparison with cycloplegic refraction. This result is close to that obtained by Millicent W. Peterseim and al. [12], which was -0.64 ± 0.08. Demirel and al. [1], in their study to compare Plusoptix S08 to refraction under cycloplegia, reported a difference of -0.25.

On the other hand, for Fogel-Levin et al [6], the mean difference between the spherical values was positive of the order of 0.29 SD ± 0.89. (Table3).

In our work, the degree of significance (p) was less than 0.05, and therefore the difference between Plusoptix and cycloplegic refraction with respect to spherical values was statistically significant. Demirel, Fogel-Levin, Payerols, and Millicent W. Peterseim [1-6-8-12] also reported a statistically significant difference.

However, Paff and colleagues [16] reported that the agreement between PlusoptiX S08 and the cycloplegic refractometer was moderate. For Choi et al [17], the plusoptix A8 gives slightly farsighted readings than the modern auto-refractometer (nidek AR800)

Table 3. *Comparison of the results of spherical value in our study to those in literature.*

	Average S/ Cycloplegic ± DS	**Average S / Plusoptix ± DS**	**Average difference ± DS**	**P (degree of significance)**	**R (corrélation)**
Fogel-Levin and al (2016) [6]	0.88 ± 1.5	0.58 ± 1.4	0.29±0.89	<0.001	0.81
Payerols and al.(2016) [8]	1.77± 2.20	1.27 ±2.07		0.044	
Demirel and al (2013) [1]	0	+0.50	-0.25	< 0.001	
Demirci and al (2013) [19]	0.16 ± 1.44	0.27 ± 1.64			
Ali Akbar and al. (2011) [14]	1.64 ± 1.06	1.38 ±0.95	0.05 ± 1.05	0.43	
Millicent W. Petzrseim and al (2014) [12]			-0.64±0.08	< 0.001	
Mirzajani and al (2012) [13]			-0.16±0.75		
Our study (2016)	2.17 ± 1.62	1.75 ± 1.21	-0.42 ±1.03	< 0.001	0.77

Gilmartin L. M [18], in his study comparing Plusoptix S04 with cycloplegic refraction performed by an ophthalmologist, admitted that the acceptable difference between Plusoptix values and cycloplegic refraction should be ± 1.00D for the sphere. This acceptable difference was reached in 67% of cases; the remaining 33% differed by more than 1.00. Of those cases that were not within acceptable standards, 7 had a difference of 1.25 or 1.50. For the 7 other cases, the difference was much more important, it reached values between 4 and 6 D. According to Ali Mirzajani [13], 82% of the spherical values were at ± 1 D.

Regarding to our series, the difference of ± 1.00 D acceptable was reached in 79.5% of cases, the remaining 20.4% differed by more than ± 1.00 D: 9.2% had a difference of 1.25 D or 1.50 D. For 11.2%, the difference was between 2.75D and 4.5D. This is another argument that Plusoptix can be used as a screening method but not for the study of optical refraction.

Demirci G. et al. [19] showed that spherical measurements of Plustopix S08 were strongly correlated with cycloplegic retinoscopy measurements and those of the cycloplegic autorefractometer. The same authors consider Plusoptix S08 a very safe, easy-to-use and reliable screening refractive method.

We divided the data into two subgroups in order to examine the precision of Plusoptix separately: myopia, defined as <0 sphere, and hyperopia, defined as a ≥0 sphere.

With regard to hyperopia, the average difference between the two types of refraction: -0.61± 1.03, this negative value confirms the previous suspicions concerning the underestimation of hypermetropia by the Plusoptix, which is probably the result of accommodation caused by the fixation of a nearby target.

The difference was statistically significant with a significance level p: <0.001. (r = + 0.78, p <0.001). The Plusoptix refraction is significantly and positively correlated with cycloplegic refraction. This Pearson coefficient remains higher than those obtained by Fogel-Levin et al [6,] and Payerols et al [8] which were respectively 0.62 and 0.52.

For the hypermetropic spherical component, 10% of the results were identical, 33% of the PlusoptiX A12 values were at 0.25 D, 13.5% at ± 0.50, 12.5% at ± 0.75 of the cycloplegic refraction. As a result, 78.8% of the results were ≤ ± 0.75 of cycloplegic refraction.

For hyperopia exceeding 3D, the mean difference was much larger reaching -1.54 ± 1.19, with a correlation coefficient not exceeding 0.54. Based on these results, we can conclude that the performance of Plusoptix decreases when it comes to hyperopia> 3D.

The mean difference between the two types of refraction for myopia is: 0.23 ± 0.59, this difference was not statistically significant with a degree of significance p: 0.121. In the study made by Fogel Levin [2] comparing Plusoptix A12 to cycloplegic refraction, the mean difference was negative (-0.048 ± 0.55), this difference was not statistically significant. The Pearson Correlation Coefficient is of (r = + 093, p <0.001), which means that there is an excellent correlation between the Plusoptix results and the cycloplegic refraction with respect to the myopic component. This correlation coefficient is very close to that obtained by Payerols et al [8] which was 0.91.

On the other hand, it is better compared to that reported by Fogel-Levin [6] which was 0.85.

With regard to myopia, about 11% were identical, 30% of the Plusoptix A 12 results were 0.25 DS and 35% to 0.5DS of the results of refraction under cycloplegia. Thus, 75% of the results were ≤ ± 0.5 of the cycloplegic refraction.

According to our results, Plusoptix tends to underestimate hyperopia and overestimate myopia; it gives results closer to cycloplegic refraction with respect to the myopic spherical component compared to the hypermetropic component.

This conclusion was also made by Payerols et al [8]. paff, et al [16] who found that the average difference between the two methods of measuring refraction was higher with hyperopia than with myopia and that Plusoptix was more accurate in myopic children compared to hyperopic. This can be explained by the fixation of the child that can stimulate accommodation and cause myopia fixation. Schimitzek and Lagrèze [20] showed that without cycloplegia, the refraction of hyperopic children is underestimated and cycloplegia improves refractive accuracy.

In our work, the average difference between the two means of measuring the refraction with respect to the cylinder was 0.14 ± 0.38, this positive difference indicates an overestimation of the cylindrical results by Plusoptix, this value is pocket of that reported by Mirjazani [13], which compared Plusoptix S08 to cycloplegic retinoscopy, noted a difference of 0.13 DC ± 0.44. Ayse YK et al [7] also noted a positive difference of 0.48 ± 0.38. As for Ali Akbar [14] and Demirel [1], they found a negative difference with

respectively -0.43 ± 0.58 and -0.25DC. In our stady, the difference was statistically significant (p <0.001), which is consistent with previous studies (Fogel Levin [6], Demirel [1], and Ali akbar [14]).

On the other hand, in the study conducted by Payerols et al [8] in France, concerning the precision of Plusoptix A09 in children aged 1 to 12, there was no significant difference in the average value of the cylinder between the two methods (p: 0.69). Based on the Pearson correlation coefficient of 0.92, we can conclude that the correlation between the two methods was positive and strong; the same result was reported by Fogel-Levin et al [6], with a coefficient of Pearson of 0.91.

In the Gilmartin L. M. [18] study, using Plusoptix S04, the acceptable difference of 0.75 D was found in 90% of cases. The remaining 10% had a difference that ranged from 1D to 3.5D. In our series, the results were better with Plusoptix A12, and the acceptable difference was found in 95% of cases. The remaining 5% had a difference between 1 and 2 D.

For the axis of astigmatism, we found a difference of 5.60 ± 31.89 between Plusoptix and cycloplegic refraction, this difference was not statistically significant with p: 0.087 and the Plusoptix results were strongly and positively correlated with those obtained under cycloplegic refraction.

Payerols et al [8] also noted a statistically insignificant difference with p: 0.28.. The same observations were made by Ayse YK [7] for the mostoptix S04.

Amblyopia is the main cause of decreased visual acuity in children, refractive vices being the most important cause.

In order to define children with risk factors for amblyopia, the recommendations of the American Association of Pediatric Ophthalmology and Strabology (AAPOS) [21] were used.

In our work, Plusoptix has proven to be a good tool for screening risk factors of amblyopia with a sensitivity of 82.5%, specificity 94%, a positive predictive value of 75% and a negative predictive value of 96.4% against 98.9%, 96.1% and 90% respectively for Fogel-Levin [6].

5. Conclusion

The Plusoptix A12 is a very interesting tool for screening ametropia, mainly in pediatric ophthalmology. It provides results relatives to those under cycloplegia: these results are more reliable for the myopic and astigmatic subgroups than for the hyperopic ones. It's limited in the refractive study in this at-risk population.

It has several advantages: a considerable time saving, a simultaneous measurement of the two eyes, eviction of refraction under sedation as well as cycloplegia. It is also used to eliminate false myopia in young adults, and provides information about microtropia and crystalline opacities and also measures refraction in case of nystagmus.

It has a good sensitivity and specificity in detection of the risk factors of amblyopia, whose values are respectively 82.5% and 94%.

However, it remains less efficient when it comes to high ametropia or strabismus at wide angle, and limited in the refractive study in at-risk population.

Conflict of Interest

None.

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