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BARCELONATECH
Facultat d'Òptica i Optometria de Terrassa

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REPEATABILITY OF THE SUBJECTIVE REFRACTION

MERITXELL VÁZQUEZ LÓPEZ

JAUME PUJOL
CARLES OTERO MOLINS
ÒPTICA I OPTOMETRIA

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Facultat d'Òptica i Optometria de Terrassa

GRAU EN OPTICA I OPTOMETRIA

El/s Sr./Srs. Carles Otero y Jaume Pujol, com a tutor/s i director/s del treball,

CERTIFICA/CERTIFIQUEN

Que el Sr./Sra. Meritxell Vázquez López ha realitzat sota la seva supervisió el treball: *Repeatability of the subjective refraction*, que es recull en aquesta memòria per optar al títol de grau en Òptica i Optometria.

I per a què consti, signo/em aquest certificat.

Sr/a Carles Otero	Sr/a Jaume Pujol
Tutor/a del TFG	Director/a del TFG

Terrassa, 12 de juny de 2017

GRAU EN OPTICA I OPTOMETRIA

REPEATABILITY OF THE SUBJECTIVE REFRACTION.

RESUM

ABSTRACT

Nowadays refractive error is considered a healthy problem in the world. An accurate refractive exam is vital for obtain the best visual acuity and do correctly other visuals exams.

Mainly there are three types of refractive error; myopia, hyperopia and astigmatism. In addition to this, there is presbyopia that consist in a physiologically decrease in the accommodative ability.

The sample of this study consist in 10 patients which age are between 18 and 30 years. Only patients without ocular pathology where examined. On the other hand, the refractive exam consists in a subjective exam starting with a binocular autorefractometer (WAM-5500). The subjective exam starts firstly monocular and later binocular with the biocular and binocular balance. About the statistical analysis, before using SPSS statistics version 22.00 tests, we transform the sphere and astigmatism value into the orthonormal space to compare the results correctly. In all cases, a p-value less than 0.05 was considered to be statistically significant, and a 95% confidence interval was considered.

The statistical analysis of this study conclude, with a p-value>0.05 in Wilcoxon Signed-rank test, that there are agreement between both measurements. Instead of this, the study data was not normal distributed. The objective and importance of the present study is to know the repeatability of this refractive method.

RESUM

Actualment, l'error refractiu és considerat un problema de salut a nivell mundial. Un examen refractiu precís és vital per obtenir la millor agudesa visual possible i portar a terme correctament altres exàmens visuals.

Principalment, hi han tres tipus de error refractiu; miopia, hipermetropia i astigmatisme. D'altra banda, trobem la presbícia la qual consisteix en una disminució fisiològica de la capacitat d'acomodació.

La mostra d'aquest estudi consisteix en 10 pacients els quals es troben en un rang d'edat entre els 18 i els 30 anys. Només pacients sense patologies oculars han sigut examinats a l'estudi. Altrament, l'examen refractiu consisteix en un examen subjectiu partint d'un autorefractómetre binocular (WAM-5500). L'examen subjectiu s'inicia monocularment i després binocularment amb els equilibris biocular i binocular. En relació a l'anàlisi estadístic, abans d'utilitzar els test de SSPS statistics versió 22.00, hem transformat el valor d'esfera i astigmatisme a l'espai ortonormal per comparar els resultats correctament. En tots els casos un p-valor de 0.05 ha sigut considerat estadísticament significant i, s'ha considerat un 95% d'interval de confiança.

L'anàlisi estadístic d'aquest estudi conclou, amb un p-valor>0.05 en el test de Wilcoxon Signed-rank, que hi ha concordança entre les dues mesures. En contraposició, les dades han resultat seguir una distribució no normal. L'objectiu i la importància d'aquest estudi és conèixer la repetibilitat d'aquest mètode de mesura de la refracció.

RESUMEN

Actualmente, el error refractivo está considerado un problema de salud a nivel mundial. Un examen refractivo preciso es vital para obtener la mejor agudeza visual posible y llevar a cabo correctamente otros exámenes visuales.

Principalmente, hay tres tipos de error refractivo; miopía, hipermetropía y astigmatismo. Del mismo modo, nos encontramos con la presbicia la cual consiste en una disminución fisiológica en la capacidad acomodativa.

La muestra del estudio consta de 10 personas las cuales se encuentran entre los 18 y los 30 años de edad. Únicamente pacientes sin patologías oculares han sido examinados en el estudio. Por otra parte el examen refractivo consiste en un examen subjetivo partiendo de un autorrefractómetro binocular (WAM-5500). El examen subjetivo se inicia monocularmente y posteriormente binocularmente con los equilibrios biocular y binocular. En relación al análisis estadístico, previo a utilizar los test de SPSS statistics versión 22.00, hemos transformado el valor de esfera y astigmatismo al espacio ortonormal para comparar los resultados correctamente. En todos los casos un p-valor de 0.05 ha sido considerado estadísticamente significativo y, se ha considerado un 95% de intervalo de confianza.

El análisis estadístico de este estudio concluye, con un p-valor>0.05 en el test de Wilcoxon Signed-rank, que hay concordancia entre las dos medidas de error refractivo. En contraposición, los datos han resultado seguir una distribución no normal. El objetivo y la importancia de este estudio es conocer la repetividad de este método de medida de la refracción.

THE REPEATABILITY OF THE SUBJECTIVE REFRACTION

Abstract

Purpose. Nowadays refractive error is considered a healthy problem in the wold. An accurate refractive exam is vital for obtain the best visual acuity and do correctly other visuals exams. Mainly there are three types of refractive error; myopia, hyperopia and astigmatism. In addition to this, there is presbyopia that consist in a physiologically decrease in the accommodative ability. The objective and importance of the present study is to know the repeatability of this refractive method.

Method. The sample of this study consist in 10 patients which age are between 18 and 30 years. Only patients without ocular pathology where examined. On the other hand, the refractive exam consists in a subjective exam starting with a binocular autorefractometer (WAM-5500). The subjective exam starts firstly monocular and later binocular with the biocular and binocular balance.

Results. About the statistical analysis, before using SPSS statistics version 22.00 tests, we transform the sphere and astigmatism value into the orthonormal space to compare the results correctly. In all cases, a p-value less than 0.05 was considered to be statistically significant, and a 95% confidence interval was considered. In this study we work with median and interquartile range, obtaining very similar medians between both sessions. It can be seen in the J0 of right eye, the median value of the first session is 0.04 and in the second session 0.

Conclusion. The statistical analysis of this study conclude with a p-value>0.05 in Wilcoxon Signed-rank test that there are agreement between both measurements. Instead of this, the study data was not normal distributed.

Keywords: Autorefractor, Refractive Exam, Refractive Error, Repeatability.

1. Introduction

Several studies suggest that subjective refraction is a global visual health challenge[1]. An accurate refractive exam is essential to ensure the best visual acuity for the patient. Therefore, the first step in any visual exam is a refractive examination. If the result of the refraction exam is not correct, the rest of exams will not probably be correct.

Emmetropia is the refractive state of the eye, with relaxed accommodation, when the conjugated point of the retina, or remote point, is situated in the infinity. A refractive error is the alteration of eye's refractive power in which, without accommodation, the remote point is not at infinity. The purpose of the optical correction is emmetropia.

Eye's refractive state depends on the corneal power, the lens power, the anterior chamber's depth and the axial longitude of the eye.

There are three kinds of refractive errors: myopia, hyperopia and astigmatism.

Myopia is the condition in which, without accommodation, the image of an object placed at infinity is focused in a point before the retina (Figure 1). This means that the back focal point of the eye (F' in Figure 1) is in front of the retina[2].

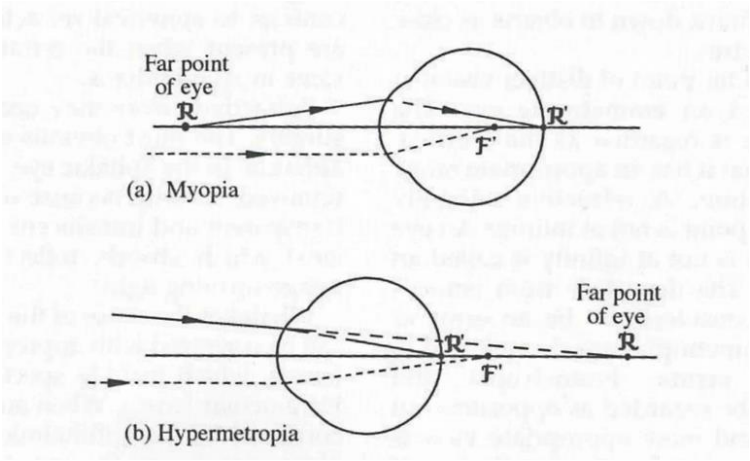

Figure 1. *The (a) myopic and (b) hypermetropic eyes and their far points.*

Then, the image created in the retina is defocused and patients experience blurred vision. The remote point of myopic people is closer than infinity. It explains why the accommodation range in myopic eye is lower than emmetropic eye. Myopia can be classified into three types. First, axial myopia occurs when the eye's axial length is longer than normal. Second, refractive myopia is produced by a change in the refraction index of the ocular media. Third, curvature myopia is produced by a decrease in the curvature radius of eye's refractive surfaces. Besides of this, there are several classifications of myopia, for example, simple or pathological myopia and congenital or acquired myopia. Pathological myopia consists in an elevate refractive error (>6D) and it causes pathological ocular problems such as retinal detachment[3]. This type of myopia is also called severe or magna myopia, and it represents approximately the 10% of all myopia types[3]. Congenital myopia alludes to people who born with this refractive error.

In hyperopia, the focused image of a distant object without accommodation lies behind the retina (Figure 1). Therefore, the image on the retina is blurred[4]. The remote point of a hyperopic eye is situated behind the retina. Young people can compensate this error by accommodation. The etiology of hyperopia is similar to myopia. It is accepted that exist a hereditary component. Hyperopia can also be classified according to several features. Probably one of the most relevant classifications of hyperopia, because of its clinical implications, is based on the accommodative use. Total hyperopia can be regarded as the

manifest and latent components. The part of the manifest hyperopia that can be overcome by accommodative effort is referred to as facultative hyperopia. Absolute hyperopia refers to the total hyperopia, the combination of manifest and latent component. The latent component is the hyperopia that patients cannot accept in his subjective refraction. With increase in age and loss in amplitude of accommodation, the manifest component of total hyperopia increases at the expense of the latent component. Similarly, the absolute component of manifest hyperopia increases at the expense of the facultative component[2].

Typically, the refractive error is dependent upon meridian and it is called astigmatism. It is produced because one principal meridian has a reduced radius of curvature and thus, higher refractive power. Then, in the other principal meridian, which is usually perpendicular to the first, the radius of curvature is greater. Its most common cause is a deformation of the cornea (external astigmatism)[2]. Internal astigmatism is due to a deformation of the ocular lens and is harder to quantify[4].

In most patients, the astigmatism has a congenital origin[3]. However, there are many possible acquired causes[3]. The front surface of the cornea provides about two thirds of eye's refracting power and the most eye's astigmatism[5]. There are several classifications of astigmatism. For example, depending on the angle between the meridians, astigmatism can be either regular (the main meridians are perpendicular and the power is constant along the meridian) or irregular (the main meridians are not perpendicular and the power may change along the meridians). Regular astigmatism can be easily corrected with lenses as the other refractive errors while irregular astigmatism is more difficult to compensate[3]. Astigmatism may also be classified according to the axis direction: with-the-rule, against-the-rule and oblique astigmatism. With-the-rule astigmatism is usually associated with a cornea that is steeper along the vertical meridian than along the horizontal one. It requires a correcting lens whose negative cylinder axis is within ±30º degrees from the vertical meridian. On the other hand, against-the-rule astigmatism is usually associated with a steeper cornea along the horizontal meridian than along the vertical one. A lens whose negative cylinder axis is within ±30º of horizontal meridian is required to compensate it. Finally, oblique astigmatism is referred to astigmatism with axes more than ±30º from the horizontal and the vertical meridian[2].

The accommodative ability decreases physiologically with the age and then, presbyopia occurs. Presbyopia is the difficulty that people have in performing close tasks because of the age-related decrease in amplitude of accommodation[2]. Presbyopia is typically developed around the fourth decade of age but there is certain variability depending on individuals, their refractive error, their ethnicity, etc[3]. The presbyopia correction is typically called addition and consists in adding positive power lenses for near vision to the correction for far vision. An important aspect in presbyopia correction is the clear vision interval. This interval is the distance between the most distant point and the

nearest point that patients can see clearly using the addition. When more powerful the addition is , more tight will be this clear vision interval [3].

There are several measurement techniques to find the refractive error of patients. Typically, the refractive error is firstly determined objectively with either an autorefractometer or with retinoscopy. Then, the objective refractive error is the starting point for the subjective refraction exam. The subjective exam is performed firstly monocular and finally binocular to equalise the accommodative states of both eyes.

There are several studies that analyse the autorefraction and retinoscopy methods to find the most correct refraction, especially in children[6],[7]. One of the most important aspects to consider is the control of the accommodation during refractive tests. This is especially relevant in children. The most used methods to control accommodation are cycloplegia and optical fogging[6],[7]. Hopkins et al.[7] showed that the use of cycloplegia elicits a more positive spherical power than using optical fogging in school-aged children. However, some of the drawbacks of using cycloplegia are the cost, the required time until accommodation is paralyzed, discomfort of the child with mydriasis and the cost[7]. Autorefraction or retinoscopy measurements using a noncycloplegic control of the accommodation have been shown to underestimate the hyperopic refractive state of children[7]. This underestimation is referred to a latent error[7]. The optical fogging consists in adding a high positive power lens in front of the eyes to relax accommodation. This method showed less positive spherical power than cycloplegia but have the advantage that a shorter time is required[7]. The results of the refraction using optical fogging may change due to variations in the latent hyperopia component[7]. The difference between measurements with clycloplegia and with optical fogging suggests that clycloplegia is the best method to control the accommodation[7]. Regarding the differences between autorefraction and subjective refraction, Choong et al. [6] found marked differences between autorefraction and subjective refraction using a noncycloplegic method. They found differences in sphere, astigmatism and axis. These differences are relevant in the case of children, who will have to do an accommodative effort if they are minus overcorrected. This effort predisposes the children to myopic progression[6]. There is a tendency of minus overcorrection when cycloplegia is not used in autorefraction measurements. This tendency disappears when cycloplegia is used [6].

There is controversy about which is the best refractive exam. It is known that there are differences between autorefraction and subjective refraction. According to Asiedu et al. [8] there is agreement between retinoscopy, subjective and autorefraction. The agreement between retinoscopy and subjective is better in the spherical power. Instead of that, for the total astigmatism there is satisfactory agreement between retinoscopy and autorefraction. Anyway, retinoscopy is the only method for obtain the total astigmatism[8]. The study indicates that autorefraction might be a suitable substitute of objective refraction (retinoscopy). Therefore, autorefraction might be a starting point for a subjective method of refraction.

The WAM-5500 is a binocular open-field autorefractor and keratometer. It determines refraction by measuring the size and shape of the retinal image of a target after reflection from the retina through the optics of the eye[9]. The guideline of the autorefractor is the plus sphere and the minus cylinder power with the best visual acuity[9]. This autorefractor includes additional features to measure accommodation and a system to alter the vergence demand of near targets[9]. The minimum pupil diameter for refraction measurement is 2.3 mm[9]. With WAM-5500 autorefractor we can have a slight negative cylinder. Respect the axes of the astigmatism the WAM autorefractor is very exactly, the 70% of WAM axes were within ±20º of the subjective axes found by an optometrist[9]. Furthermore, there is a significant underestimation of hyperopia that can be justified by a not fully relaxed accommodation[9].

The objective of the present study is to analyse the intrasession repeatability in the measure of the noncycloplegic subjective refraction.

2. Methods

Study population

The study population consisted of 10 people between 18 and 30 years old. Patients were examined by a final course student of Optometry. Patients with any ocular pathology were excluded to participate in the study.

Procedure

All subjects receive a verbal explanation of the nature of the study. The refractive error of both right and left eyes was measured. Noncycloplegic autorefraction were performed using the WAM-5500 autorefractor. This was followed by noncycloplegic monocular and binocular subjective refraction. Monocular subjective refraction was performed until best-corrected visual acuity was achieved. Then, the biocular balance was performed with a target of visual acuity 0.5 decimal for all patients. The subjective refraction was finished with the binocular balance. Visual acuity measurements at 6 m using a screen with normal letters optotypes were performed by the same optometrist. All measurements were performed twice in each patient in different days. The examiner did not see the results of the subjective refraction until the end of the two measures.

Statiscal Analysis

Before the statiscal analysis, the value of sphere and astigmatism was transformed to the orthonormal space to compare correctly the two results of sphere and astigmatism[10]. The statistical analysis of the results was performed using the software SPSS Statistics version 22.0 and Excel for windows. In all cases a p-value less than 0.05 was considered

to be statistically significant. In addition, in all cases a 95% confidence interval was considered. The Shapiro-Wilk test was performed to check the normality of all the variables. The Wilcoxon Signed-Rank test and the Bland and Altman plots were used to analyse the repeatability of the subjective refraction measurement.

3. Results

First, all parameters were transformed into the orthonormal space to compare them correctly. In the orthonormal space, the sphere is represented by an M and the astigmatism by a J0 and J45. For simplicity, we will only analyse the J0 component of astigmatism.

Parameters			Median	IQR (Q3-Q1)
Session1	RE	M	-0.44	1.935
		J0	0.04	0.225
	LE	M	-1.065	4.755
		J0	0.08	0.403
Session 2	RE	M	-0.32	2.038
		J0	0	0.17
	LE	M	-1.13	4.853
		J0	0.11	0.275

Table 1. *Descriptive statistics table. Median and interquartile range of the variables M and J0 of both eyes.*

Then, by means of the Shapiro-Wilk test, we obtained that all data were not normally distributed (p>0.05).

Wilcoxon Signed-rank test

	M_RE1/M_RE2	J0_RE1/J0_RE2	M_LE1/M_LE2	J0_RE1/J0_RE2
Z	-1,075	-1,590	-0,085	-0,866
Sig.	0,282	0,112	0,932	0,386

Table 2. *Wilcoxon Signed-rank test. The file test shows the p-values from the comparison of both sessions and the Z value.*

Consequently, a nonparametric test (Wilcoxon signed-rank test) was used to determine whether there were not statistically significant differences between the values of both

sessions (sig. or p-value>0.05). A p-value>0.05 means a none statistically significant divergence between the two measures of sphere and astigmatism.

	M_RE	J0_RE	M_LE	J0_LE
SD Within subject	0.129	0.036	0.157	0.121

Table 3. *Standard deviation within subject for each variable.*

We have calculated the precision and agreement of each variable in both sessions. As it can be seen, the within-subject standard deviation is small (less than 0.25 D). It indicates that there is agreement between the two measurements of sphere and astigmatism for each patient.

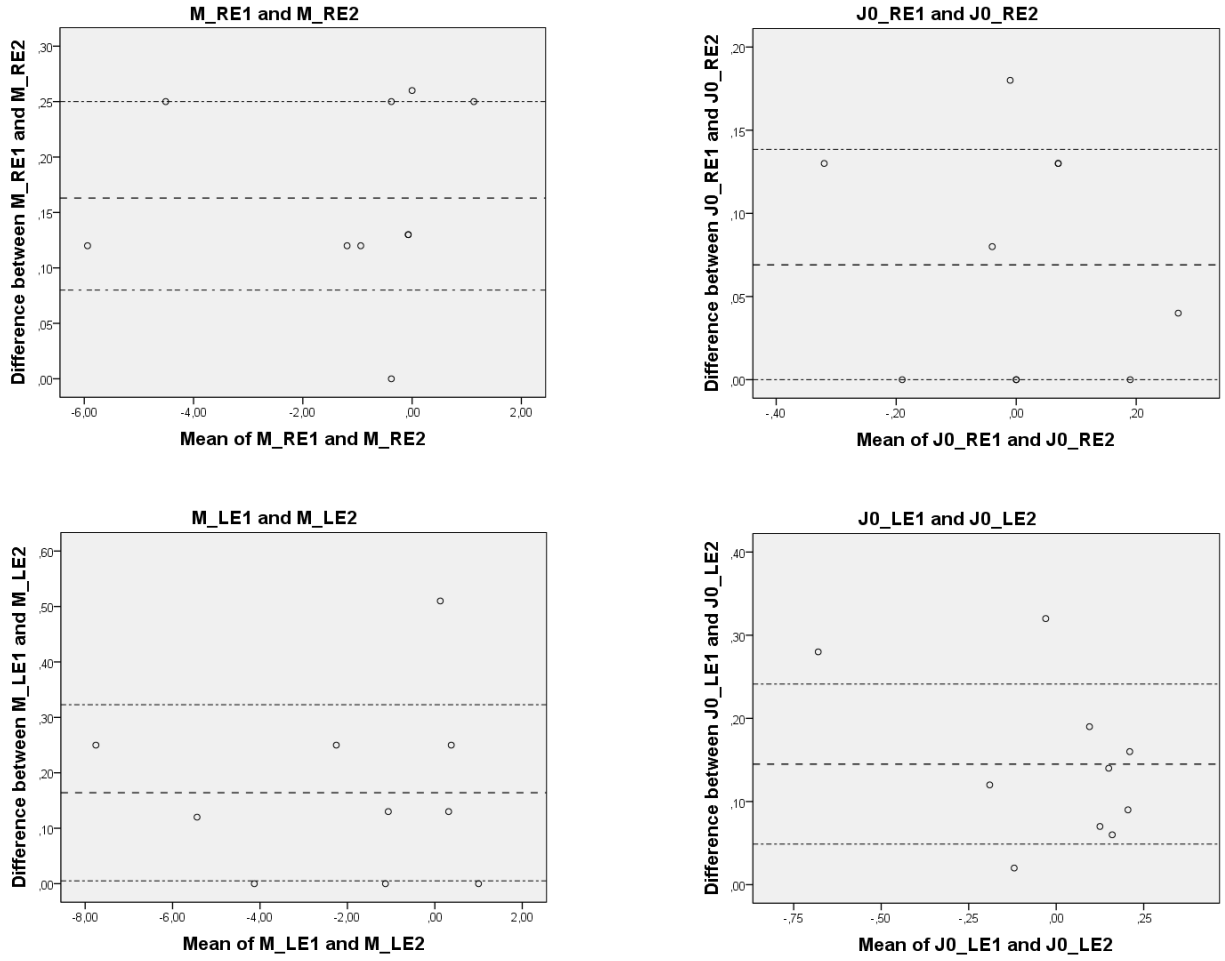

Figure 2. *Bland and Altman plots showing the mean of the differences and the corresponding 95% Limits of Agreement.*

Finally, the Figure 1 shows the Bland and Altman plots for the four comparisons. As it can be seen, the difference between the two measurements of every variable is slight, because

the Y axis scale goes only until 0,40D. Moreover, it can be observed that the plots do not show any recognizable pattern and therefore the differences did not vary in any systematic manner over the range of measurements.

4. Discussion

In the present study, we explored the repeatability of refractive error measurements. It can be deduced from our results that good agreement between either sessions or measures exists. It can be possible because both measurements were done exactly with the same technique. In addition to that, there is a large list of factors that affect the comparison of a measurement as; the condition of the patient, the patient's collaboration, the hour of the day at we do the measure and others.

Pujol et al. 2017[11] study compare the inter and intraexaminator variability. In this study 52 patients were examinated. The study tell about the precision that there is a difference intraexaminator for the M (sphere) component about a 0,034±0,195D. In addition, this intraexaminator difference has not significantly importance. On the other hand the difference of the interexaminator has worst results but these are acceptable, were lower than 0.25D. The difference was using a subjective refraction starting with retinoscopy. In our study we eliminate the interaxaminator variability because all of measures were do it by the same optometrist. In comparison with our study the difference between either measures or sessions was not significantly different too, because we obtain a P-value>0.05 in Wilcoxon Signer-Rank test.

Likewise, the result of this study abide by the initial idea. The results that we have obtained seem logic because, the technique of the measurement and the instruments, were the same in spite of the variability in ocular conditions and the state of the patient. The sample size of this study is too small therefore we cannot provide robust conclusions. In any case, this pilot study can help to better define the research question of further similar studies.

5. Conclusion

The refractive error is the starting point of an optometric exam, if this is not correct in the other test will probably obtain wrong results. At present, there are different ways to find the refractive error of a patient and, studies like this, help to find the importance and repeatability of each technique.

Nowadays, a lot of specialist are using autorefractometer. Instead of this, professionals need to know how trustworthy and which repeatability have this instrument for use it in their clinical practice. The importance of this study is the verified repeatability of the refractive error method starting with an autorefractometer, in our study WAM-5500.

It would be worthwhile in future studies to compare different autorefractometers and compare the repeatability of the technique used in this study with different age patients.

The principal conclusion is the fact that repeatability of refractive error measurement is high.

Ethical and social commitment

As it is indicated in the regulations, in the final degree's project it can include a section talking about the social and moral commitment cross-cutting remit. In this section we will analyse the article in an ethic way and the legal and social implications of our study.

At the first, the objective of this study is to compare and improve a way for find the best refractive error in a patient with an existent method. The visual health have a crucial importance in the population. For this reason, the search and innovation in health science have an important impact in the population's quality life. In this way, there are a direct relation between the principal objective of the study and the fourth principles of bioethic.

About the legal side, is important to reflect that the 10 patients included in this study doesn't had to firm an informed consent because they were participants in the study too. Another important aspect is the safety of the patients. In all of tests we have carry of the patients, furthermore, the methods used in this study aren't dangerous for them.

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