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Research Article

Comparison of the Real Fluorogram vs the Fluorogram Simulated by Pentacam HR in the Adaptation of Rigid Gas Permeable Contact Lenses

Cesar Felipe Parra Corredor*

Optometrist, Santo Thomas University, Bucaramanga, Colombia

***Corresponding Author:** Cesar Felipe Parra Corredor, Optometrist, Santo Thomas University, Bucaramanga, Colombia.

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Abstract

Rigid gas permeable [RGP] contact lenses are an effective tool to correct refractive defects in patients with whose origin is corneal astigmatism. The evaluation and adaptation of the RGP contact lens fluorogram shows the relationship between the LC and the cornea, and is essential to determine the final LC.

Objective: To compare the actual fluorogram versus simulated by the Pentacam HR in adapting LC RGP.

Methodological Design: Type of descriptive observational study, corresponds to the area of research called evaluation study of diagnostic tests, the sample consists of 40 pairs of images that are extracted from tests on patients who meet the inclusion criteria. I began with an eye assessment where clinical data were obtained to calculate the ideal LC, define the parameters of LC test, to photograph the actual fluorogram and enter data LC test the software Pentacam HR for simulation fluorogram. Finally the photographic recording of images using a checklist as compared three experts in the field of contact lenses that met certain characteristics.

Keywords: *Fluorogram; Fluorescein Pattern; Contact Lenses Rigid Gas Permeable; Pentacam*

Introduction

Rigid gas permeable contact lenses [RGP] offer visual health professionals a correction option for those alterations that diminish the visual acuity of patients and that day by day are one of the great reasons why they go to optometry offices. In the process of evaluation and adaptation of a RGP contact lens several tests are performed to determine the parameters indicated for the final LC. One of these tests is the fluorogram or evaluation of the fluorescein pattern that shows the relationship between the LC and the cornea that in the case of LC RGP is indispensable [1]. Fluorograms are essential in the process of adapting LC RGP and are developed based on the principle of hyperfluorescence of staining under ultraviolet light exposure [2,3]. The normal evaluation of these patterns has been made with the slit lamp that in some cases given the corneal surface, requires the realization of this examination until finding an ideal pattern. Based on the results of these fluorograms the visual health professional decides what changes to the parameters of the lenses should perform to carry out the best adaptation of each patient, this test is developed invasively and its interpretation is subjective [2,4]. With continuous technological advances and improvements in health services, high-tech equipment has been developed that can now offer simulation of fluorescein patterns based on a series of computer programs under previously programmed base curve models of lenses. And the data of the corneal topography of the patient, this with the purpose of adapting RGP contact lenses with a prediction value when performed with the real fluorogram. One of the teams that have developed this technology is the Pentacam HR. This is a technological tool that makes it easier for the eye care professional to manage contact lens patients since it assesses the anterior segment of the eye in aspects such as corneal topography, corneal elevation maps, corneal pachymetry, camera analysis in 3D, simulation of fluorescein patterns or fluorograms among others. Based on the great advantages offered by this technology for the adaptation of contact lenses RGP the research question arises in order to know whether or not there is similarity between the fluorescein pattern or simulated fluorogram by the Pentacam HR and the real fluorogram in the adaptation of rigid gas permeable contact lenses? since it could be implemented as a support tool that will bring benefits for the patient of contact lenses and for the visual health professional.

Materials and Methods

A quasi-experimental quantitative study was applied that dealt with the evaluation of diagnostic tests in order to evaluate the concordance of the two evaluation methods, allowing the establishment of relationships between variables and evaluating the efficiency and effectiveness of the technology for medical use.

Population and sample

The study was conducted in patients who attended the Optometry Clinic of the Santo Tomas University of Bucaramanga and who were suitable for the use of RGP contact lenses. For the sample size it was calculated under the central limit theorem which indicates that a population of 30 subjects is significant. The final result was of 5 patients with 8 eyes suitable for the study, taking into account that each patient could be made 5 different adaptations in each eye, 40 pairs of images were obtained to compare.

For the selection of the sample, the patients had to meet the inclusion criteria and to determine this they were examined taking into account the anterior segment of the eyeball and the corneal topography. After having selected the patients suitable for the study, they were explained and presented the informed consent in order to have the authorization and be able to carry out the study.

Inclusion criteria

- Male or female patients with ages between 18 and 50 years of age.
- Patients with corneal astigmatism equal to or greater than 1.00 Dpt.
- Patients not users of RGP contact lenses.
- Patient suitable for the use of contact lenses.

Adaptations and test lenses

It was taken into account that each patient could be made 5 types of adaptations, flatten 0.75 diopters (dpt), flat 1.50 dpt, adjust 0.75 dpt, adjust 1.50 dpt and parallel. For the calculation of the base curve of the test lens was performed according to the corneal topography (See table 1). The specifications of the contact lens used were the following:

- Power: Neutral
- Diameter: 9.5 mm
- Previous face design: none
- Back face design: spherical
- Base curve: according to each patient adaptation

Patient	Eye	Topographic Keratometry	The Most Flat Meridian	Corneal Astigmatism
1	OD	43.30/44.90*19	43,3	1.60
2	OD	44.40/45.40*6	44,4	1.00
3	OD	41.60/44.00*0	41,6	2.40
3	OI	40.80/44.00*164	40,8	3.20
4	OD	42.30/45.40*7	42,3	3.10
4	OI	41.80/45.90*169	41,8	4.10
5	OD	41.00/43.90*25	41,0	2.90

Table 1: *Description of the topographic topographies that were carried out.*

Registration of fluorograms

Once the test lenses were chosen, the patients were taken a photographic record of the real fluorogram in the slit lamp, of each of the adaptations that were made to them. After this, contact lens data were entered into the Pentacam HR software to perform the simulation of the fluorogram corresponding to each adaptation.

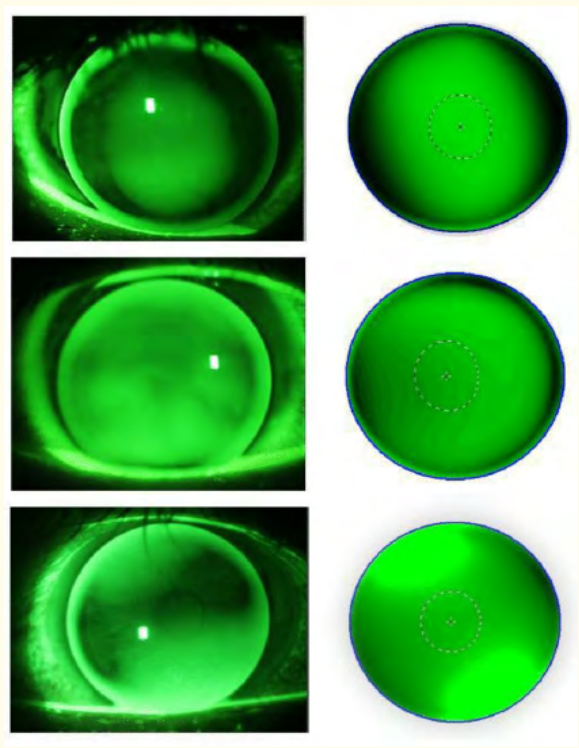

Figure 1: *Real fluorogram (left) and simulated fluorogram in Pentacam HR (right).*

Experts in contact lenses

For the analysis of the similarity between the real fluorogram and the simulated fluorogram, a checklist was made in which each expert consigned the analysis corresponding to each of the 40 cases presented to them, for which they should describe in the list to check each fluorescein pattern in terms of clarity and/or touch, in addition they had to say which pattern they observed between the options parallel, bowtie, flattened, oval, adjusted, double tap or irregular. They also had to say if the pattern they observed was mild, moderate or marked; After carrying out this analysis, according to the criterion and expertise of them, they had to say from 1 to 10 what degree of similarity the fluorograms observed in the two images were, being ten equal to identical and one to are different. The experts should have the following characteristics:

- Optometrists with graduate degrees in contact lenses
- Clinical experience greater than 10 years in contact lenses
- IACLE Fellow (International Association of Contact Lens Educators)

Data analysis

The data were analyzed according to the nature of the variable, for qualitative variables proportion and for quantitative variables measures of central tendency and dispersion. The statistical analysis was carried out with the Epi info version 3.5.1 and Stata 9.0 programs.

Results

Description of fluorograms by experts. The experts were asked to make a brief description of each of the patterns they observed, both for the real fluorogram and for the simulated fluorogram, and if they thought it was pertinent to say what aspects there was no similarity between the two fluorograms, analyze this information are collected and mention several characteristics in general about the real pattern as the variations in the sharpness of the image, the intensity of the light, the direction of the light, the intensity of the color and the decentralized location of the fluorogram in the photograph and of the simulated pattern by the Pentacam HR other aspects stand out as the Pentacam does not simulate the possible decentration that the lenses can present on the cornea, does not take into account the philosophy of adaptation of the anterior face of the contact lenses RGP. It also does not take into account the strength and tone of the eyelids, does not consider the tear volume in the simulation and does not take into account the weight of the RGP contact lenses. The Pentacam does not consider a dynamic fluorogram.

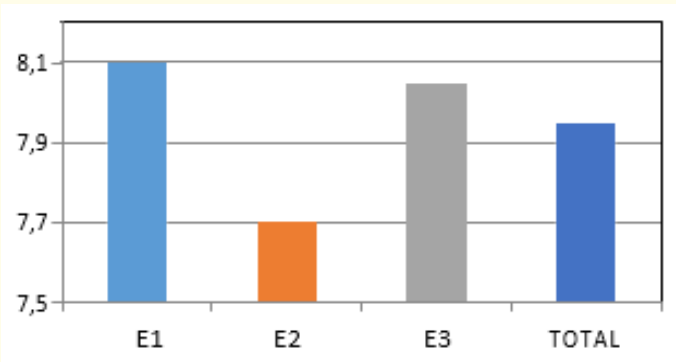

Figure 2: *Promments of each expert in the variable of similarity between fluorograms.*

Results of the qualitative variables. The statistical tool known as Chi^2 was used in the checklist. We analyzed the answers given for each case in the questions by each evaluator to know if there was a relationship between the answers given by the experts and the answers they had to give and it was obtained with a 95% reliability, that the answers given by the three experts in question no. 2 they relate one hundred percent to the answers they were expected to give and that the answers given in question no. 3 are 50% related to the answers

they had to give. The answers given by the evaluators in questions 2 and 3 of the checklist were expected to choose an exact pattern for each image, in some cases an evaluator placed two options so the answer that was left in the database was the most specific, for example, when I put the answer to question 2 in the following way: flattened-oval; it is understood that a flattened and oval pattern is obtained by performing a flattening, but not all the flattening is observed in an oval manner, therefore the oval pattern is a subclassification of the flattening, therefore the response that was taken was the most specific oval. For the answers to question 3 it was more difficult to determine the degree to which they observed the pattern they selected in question 2, however given the diopters for the adaptations as neutral, 0.75 and 1.50, they were expected to respond with the options moderate, marked and does not apply but as mentioned previously there is no exact way to quantify this since it is purely subjective analysis. Obtaining this relationship between the results of questions 2 and 3 of the checklist confirms the reliability of the results for question n° 4, in which the evaluators gave a score of 1 to 10 to the similarity between the fluorograms.

Results of the quantitative variables. It is observed that in 27 of the 40 pairs of images there is similarity in the responses of the three evaluators, the score found is equal to or greater than 7, values that are between the standard deviation that is 1.7 with respect to the median which is 8. The variations that we managed to highlight the most in terms of the similarity score is that, the patterns with the lowest score were mostly the flat ones of 1.50 dpt. Figure 3 shows the distribution of the scores given to the similarity between the fluorograms by the three experts in each of the 40 pairs of images. The total average of the results given by the evaluators to the similarity between the real fluorogram and the fluorogram simulated by the Pentacam HR is 79.5%; the score with the highest number of repetitions was 9 (35 times), almost 30% of the total images (see table 2).

Score Similarity	Absolute frequency	Accumulated Absolute Frequency	Relative frequency	Frequency Relative Acumulada
9	35	35	29,17	29,17
8	25	60	20,83	50,00
10	20	80	16,67	56,67
7	19	99	15,83	82,50
6	14	113	11,67	94,17
2	3	116	2,50	96,67
4	2	118	1,67	98,33
5	1	119	0,83	99,17
3	1	120	0,83	100,00

Table 2: *Frequency distribution of the results of the similarity of the fluorograms given by the experts.*

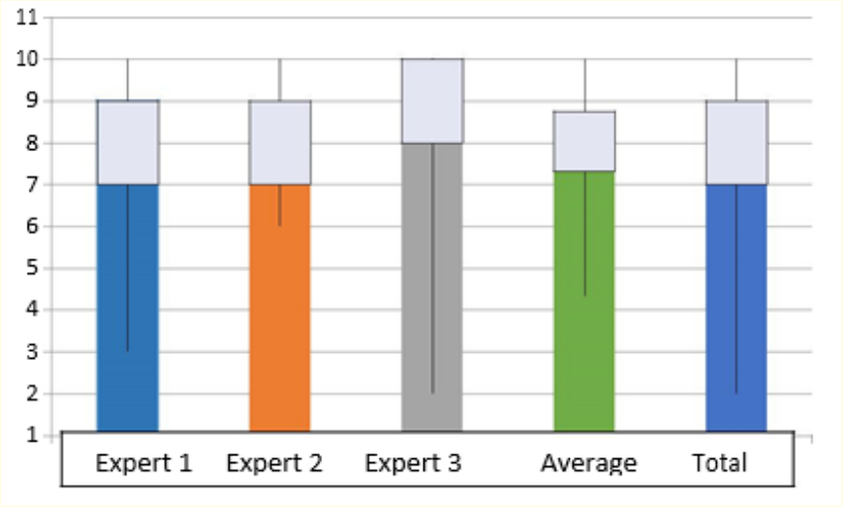

Figure 3: *Distribution of the similarity scores in the 40 fluorogram by the experts.*

Discussion

For the realization of this study we considered doing it starting with the adaptations of simpler RGP contact lenses with corneas without alterations of their corneal curvature such as keratoconos, corneal dystrophies, among others, in the bibliographic review that was carried out, three studies were found, where compared two methods of different adaptations of RGP contact lenses. In the first study carried out by Fink BA and collaborators entitled "A Comparison of Two Methods of Evaluating Cornea-to-Contact Lens Base Curve Fluorescein Patterns in Keratoconus" in 2001, the following were found as main results: according to the readings of the Fluorescein pattern slides by means of a photographic readers were obtained comparing the two evaluation methods with a weighted kappa value of 0.751. The evaluation of fluorescein patterns in a usual contact lens fitting performed in the repetitive tests of a comparison compared the photographic readers gave a weighted kappa value of 0.254 and a moderate value by the kappa 0.480 physicians [5]. In the study conducted by Nawtej SB., et al. Entitled "A comparison of a topography-based rigid gas permeable contact lens with a conventionally fitted lens in patients with keratoconus" performed in London in 2010, the following results were found: Levels of agreement percentage between the two adaptation techniques were between 74% and 100%.

The Kappa values varied between 0 and 0.6, indicating little agreement between the two adaptation techniques [6]. In the third and last study that was found in the database on the comparison of two methods of contact lens fitting, which was carried out by Sowjanya SJ entitled "Comparison of conventional method of contact lensing and software based contact lens fitting with Medmont corneal topographer in eyes with corneal scar "performed in Chennai, India in 2011 the following results were found: The parameters of contact lenses that were achieved using two different methods of adaptation showed a good correlation. The correlation coefficients, such as the comparison of the two methods in the base curve and the diameter were 0.96 [$P < 0.05$] and 0.94 [$P < 0.05$], respectively [7], based on these three studies and analyzing that given the sample of these investigations where they were patients with corneal alterations, such as keratoconus and corneal scars, it was determined that the research that was going to be carried out on the comparison of the fluorogram in adaptations of LC RGP had to be executed in healthy conditions of the patients, since in this way there is no record of having been done before.

Therefore, the specific results obtained in this study are not comparable with the specific results of the previously described studies; however, it can be analyzed that the similarity of the three teams that were used for the simulation of the adaptations versus the real adaptations had a good similarity, greater than 74%, and when compared with the results obtained in this study, in which the evaluators determined that the similarity of the Pentacam fluorogram versus the real fluorogram is 79.5%, with He deduces that although the variables were different, the similarities between the two techniques are similar.

The comparison that was obtained in the present study was given by a scale of similarity from 1 to 10, being 1 equal to "they are not equal" and 10 to "they are equal", to which each evaluator gave a response after making a prior analysis of the fluorescein pattern to determine the kind of pattern you observed and the degree to which you observed it, it should be remembered that this analysis is purely subjective, there is no standard to determine the degree to which the fluorescein pattern is observed more than by the experience of each evaluator.

The degree of similarity that the evaluators determined between the conventional fluorescein pattern and the pattern simulated by the Pentacam HR is 79.5% with a confidence interval of 95% [P value 0.00), given under normal conditions and/or healthy of the patients who participated and with simple parameters in common for the 29 RGP contact lenses. Given the results obtained, the use of the Pentacam HR could be suggested for the adaptation of RGP contact lenses, in patients that meet the characteristics described in the inclusion criteria of this study, however it is suggested to carry out this study again changing the parameters of the LC RGP, the design of the posterior face to aspheric and the design of the anterior face to lenticular since in this study the fluorograms with these characteristics were not evaluated in the LC RGP and they are certainly qualities of these lenses that are used daily to achieve successful adaptations in patients with a healthy anterior segment; it is also considered pertinent to carry out a new study, changing the adaptation techniques to only flattened 0.50 dpt and adjusted 0.50 dpt since the values we use in the adaptation classes that were carried out in this study, except for the parallel, are values that In daily adaptations, they are not performed because they can cause mechanical complications due to poor adaptation of RGP lenses such as SEAL, syndrome 3 and 9, or corneal abrasions, among others [8].

If we obtain favorable results in these studies, we could also consider applying the study to patients with corneal alterations such as mild keratoconus. Another observation is that once these new studies were reconsidered, three evaluators could be asked to participate because they have experience in the methodology of the study, while these studies should be carried out with equipment other than the Pentacam HR but also with she. After this it would be interesting to see the report of several clinical cases in which a patient will be adapted based on the fluorogram of the Pentacam HR, making a continuous follow-up to see if he had any mechanical complications or if on the contrary manages to carry out a successful adaptation. If favorable results are obtained, it would be possible to implement a high technology equipment such as the Pentacam HR in the RGP contact lens adaptation process, which would surely improve the approach and management of the patient, it would accelerate the process of adaptation to the patient. Submit a patient who is not well adapted in the first appointments and must attend the office repeatedly, we would not carry out processes in an invasive way with the patients, and clearly solving their needs with greater efficiency.

Conclusions

According to the characteristics obtained in the results, where the distribution of the data presents a negative asymmetry, with a median of 8 points in the comparison scale between the fluorograms with an interquartile range (IR) of 7 to 9 points given by the Three evaluators can affirm that there is a relevant similarity between the fluorescein pattern that simulates the Pentacam HR and the real fluorescein pattern for adaptations with patients that are constituted by a healthy anterior segment and RGP contact lenses with a spherical design.

As it is not found in the literature described the operation of the Pentacam HR, we can think that the contact lens module does not simulate an adaptation of rigid contact lenses with influential factors such as lens decentering, eyelid tone among others.

Although the Pentacam HR is a good prediction tool, it is necessary for a specialized professional trained in contact lenses to make the assessment and interpretation of these predictions so that the lens that is best adapted can be finally disposed.

With this research it was possible to identify the most influential factors when carrying out studies of this type, in which two tests whose interpretation is subjective and the analysis is complex must be compared, which is expected to facilitate the methodology and application for the future research done between the Pentacam HR and RGP contact lenses.

The simulation function of RGP contact lens fluorograms offered by the Pentacam HR could be used in the clinical practice of the Optometry Clinic of the Santo Tomas University to perform research and in the practice of the contact lens clinic and specialization Contact Lenses and Anterior Segment offered by the university.

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