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In vitro measurement of central thickness in hydrated soft contact lenses using different instruments, brands, and optical designs: a pilot study

Mediciones in vitro del espesor central de lentes de contacto hidratadas con diferentes instrumentos, marcas y diseños ópticos: un estudio piloto

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ABSTRACT:

The central thickness of contact lenses is a parameter related to oxygen permeability and comfort. However, its value is not usually reported in the lens specifications of different laboratories. In this pilot study, the central thickness of several soft contact lenses of different spherical powers, additions, and materials was measured with two different devices, the Rehder electronic thickness gauge model ET-3 and the Nikon V-12B profile projector, to study whether different measurement conditions (with the lens in air or immersed in saline solution) affected the results. First, the lenses were measured with the ET-3 device, and then the thickness of a central section of each lens was measured with the Nikon V-12B projector. Bland-Altman and correlation analyses were performed. The results of the Bland-Altmann analysis suggest that both instruments and measurement methods are interchangeable. Statistical analysis of the results of multifocal lens measurements suggests that central thickness changes significantly only in high-power lenses, independent of other factors. This work presents the first validation study of a method for measuring the central thickness of contact lenses immersed in saline solution, which could prevent evaporation and the potential reduction of their properties.

Key words: central thickness, contact lens, ET-3 device, V-12B projector, optical design.

RESUMEN:

El espesor central de las lentes de contacto es un parámetro relacionado con la permeabilidad al oxígeno y la comodidad. Sin embargo, su valor no suele reportarse por los fabricantes. En este estudio piloto, se midió el espesor central de varias lentes de contacto blandas de diferentes potencias esféricas, adición y materiales con dos dispositivos diferentes, el medidor de espesores electrónico Rehder modelo ET-3 y el proyector de perfiles Nikon V-12B, para estudiar si las diferentes condiciones de medición (con la lente al aire o sumergida en solución salina) afectaban los resultados. Primero, se midieron las lentes con el dispositivo ET-3 y, posteriormente, se midió el espesor de un corte central de cada lente con el proyector Nikon V-12B. Se realizaron análisis de Bland-Altman y de correlación. Los resultados del análisis de Bland-Altmann sugieren que ambos instrumentos y métodos de medición son intercambiables. El análisis estadístico de los resultados de las lentes multifocales medidas sugiere que el espesor central cambia significativamente solo en lentes de alta potencia, independientemente de otros factores. Este trabajo presenta un primer estudio de validación de un método para medir el espesor central de lentes de contacto sumergidas en solución salina, lo que podría prevenir la evaporación y la posible reducción de sus propiedades.

Palabras clave: espesor central, lente de contacto, dispositivo ET-3, proyector V-12B, diseño óptico.

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1. Introduction

Contact lens central thickness is a parameter related to oxygen permeability and comfort [1,2]. Central thickness of single vision contact lenses is greater for positive lenses than for negative lenses, due to geometry and design structure[1], and several publications confirm that contact lenses with greater central and edge thicknesses decrease oxygen transmissibility and corneal sensitivity, while increasing scleral vascularization[3,4], particularly in the middle-aged population.

There are different multifocal contact lens designs available in the market that are used to compensate for distance, intermediate and near vision of presbyopic patients by the principle of simultaneous vision[5]. However, the central thickness value for each contact lens prescription is typically not included in the lens specifications provided by individual laboratories, and the only data available is for a -3.00 D single vision contact lens [1]. For researchers who would like to examine a larger variety of contact lenses in greater depth and gain a better understanding of the relationship between thickness value and other lens or ocular features, this information is limited.

In the recent years, Optical Coherence Tomography (OCT) and the Rehder Electronic Thickness Gauge (ET- 3) (Castro Valley, CA) devices were used as reference metrics to measure contact lens thickness in-vivo and in-vitro respectively[6,7]. OCT is useful for checking thickness variations when the lens is on the eye, although the device's resolution and the normal saccadic motions of the eyes may make data collection delicate. However, the ET-3 is made especially to measure the thickness of contact lenses both in air and ex vivo [8]. The sensor of the device moves with a constant speed, and the pressure applied is uniformly distributed inducing a precision of ±2 µm[6,9,10]. Nevertheless, there are no studies available that report correlations between the ET-3 instrument with any other device that could be also used to measure contact lens thickness in-vitro. In this way, a comparison with the Nikon Profile Projector V-12B was made in this research. This device has been used to measure the total contact lens diameter[11] but there are no reports about measurements of contact lens central thickness. Although the ISO standard 18369-3[8] describes the contact lens thickness measurements with the lens in air, there is no gold standard described for measuring the lenses immersed in saline solution. The V-12B Nikon projector measurements could provide an alternative approach to determining the thickness of soft contact lenses in saline solution. The use of Nikon projectors is extended in several scientific fields such as odontology[12,13] or otorhinolaryngology[14], and they may also be beneficial for optical applications.

This pilot study aims to evaluate whether the central thickness measurements of contact lenses in air and in saline solution are comparable. This last situation approaches more to a contact lens fit on eye. Since the two situations are different, the devices and the accuracy of both measurements' procedures would be also different and explained in the following sections.

The primary objective of this pilot study was to compare the central thickness measurements obtained using the Rehder Electronic Thickness Gauge (ET-3) and the Nikon Profile Projector V-12B for soft contact lenses with variation of spherical powers, additions, and materials.

Another objective of this pilot study was to compare the thickness values across different contact lens brands. Therefore, a secondary goal was to assess the central thickness measurements of contact lenses with different central powers from different commercial contact lens brands.
With these two objectives in mind, the structure of this work is as follows. After the introductory chapter, the equipment compared is detailed to validate the use of central thickness measurement with contact lenses immersed in saline solution (with the V-12B) as well as in air (with ET-3 device). Subsequently, a comparison of devices and methods was conducted, followed by an analysis of central thickness measurements for various contact lenses with different designs, powers and brands.

2. Materials and methods

2.1. Instruments

2.1.1. Rehder Electronic Thickness Gauge model ET-3

The Rehder Electronic Thickness Gauge model ET-3 (Castro Valley, CA) is a device specifically used by industries and researchers to measure the thickness of soft contact lenses and other soft materials[10].
The sensor features a steel bar that moves at a constant speed toward a steel sphere carrier, where the contact lens is positioned. It is programmed to regulate compression upon contact with the sample, ensuring a consistent and controlled pressure application to the contact lens. This fact enhances measurement precision by maintaining an accuracy of approximately ±2 µm. Additionally, this instrument plays an important role in performing periodic calibrations, enhancing the reliability of the measurements. [6,9,15].

2.1.2. Nikon Profile Projector V-12B

The Nikon V-12B projector is typically used in industrial and quality control environments to measure small, micrometer-scale intervals. It consists of lenses arranged in a telecentric system, allowing for precise measurements of both horizontal and vertical distances while maintaining image sharpness. Image focus is attained by adjusting the vertical position of the instrument's objective lenses. The large circular screen displays the magnified image of the sample. Although the device includes various color filters, conventional lighting was used in this study [16].
Figure 1 depicts an example of the ET-3 device and the Nikon Profile Projector V-12B.

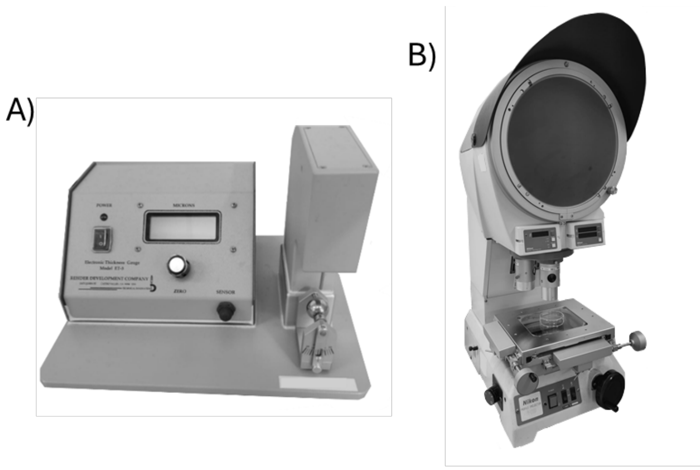

Figure 1. Example of A) ET-3 device and B) Nikon Profile Projector V-12B

2.2. Contact lens selection and measurements

A total of twenty commercial contact lenses with different powers (spherical and multifocal), materials and from different manufacturers were measured. A selected heterogeneous variety of spheres, and addition values of the contact lenses sufficient for the comparison between instruments was selected to ensure a comprehensive comparison over a large range of powers commonly prescribed and used by the population (with low, medium and high values). All the multifocal contact lenses had a centre-near aspheric design (the addition is at the centre of the optic zone of the contact lens), while the single vision contact lens had an aspheric design. Since one of the objectives of the study is to assess whether thickness influences lens design, this selection enables a meaningful comparison across different brands, designs, and power values. The main characteristics of these contact lenses are depicted in Table 1.

Each contact lens was measured three times under repeatability conditions; that means the data were taken without moving the lens between measurements. After each measurement, the measurements were reset to zero. The temperature control was set to 21°C. All measurements were conducted by the same operator, with contact lenses handled using tweezers, and both devices set the measurement units to micrometers. In order to alter and manipulate the contact lens as little as possible, measurements were first taken using the ET-3 device. The ET-3 instrument was initially calibrated to zero when the steel vertical bar made contact with the steel sphere. The contact lens was then placed on the steel sphere and carefully centered with tweezers, ensuring alignment with the steel bar at the lens's center. Since the contact lenses were soft, they naturally conformed to the sphere's shape. Special care was taken to prevent air bubbles from forming between the lens and the sphere. These bubbles were removed before any measurement.

After carrying out the measurements with the ET-3 devices, the contact lens was cut with a razor blade[17] and the remaining central slice was taken for the next set of measurements (Figure 2A). Then, the central thickness of this slice was measured transversely at the centre of the long edge with the Nikon V-12B projector (Figure 2B).

Table 1. Characteristics of the commercially available soft contact lenses used in this study

Name of the brand	Xtensa Rx	Clariti 1 day MF	1 DAY ACUVUE MOIST MF	Dailies Total 1 MF
Manufacturer	mark'ennovy, Spain	Coopervision, USA	Johnson& Johnson, USA	ALCON, USA
Nominal sphere values (D)	-3.00, +3.00, -10.00	+3.00, +3.00, -6.00, +5.00	-9.00	+3.00, -9.00
Addition	-	LOW HIGH	LOW MED HIGH	LOW MED HIGH
Lens design	Aspheric	Centre-near aspheric	Centre-near aspheric	Centre-near aspheric
Lens geometry	Single vision	Multifocal	Multifocal	Multifocal
Material	Methafilcon	Somofilcon A	Etafilcon A	Delefilcon A
Water content	55%	56%	58%	> 80% from core to surface, approaching 100% at the outermost surface
Base curve (mm)	8.5	8.6	8.4	8.5
Diameter (mm)	14.4	14.1	14.3	14.1
Fabrication process	Lathed	Molded	Molded	Molded

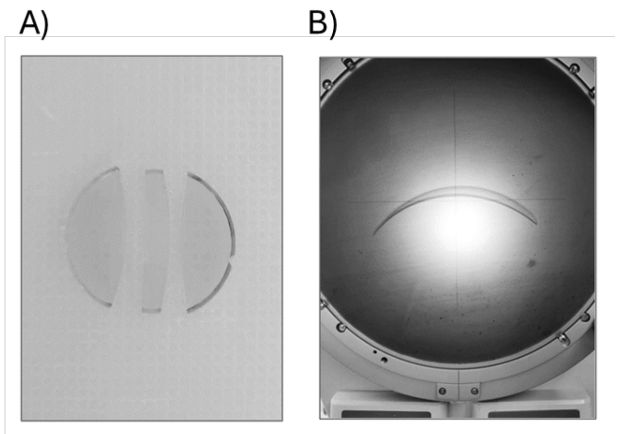

Figure 2. A) Schematic contact lens central slice cut with a razor blade. B) Contact lens displayed on the Nikon V-12B projector screen.

The contact lens was positioned transversally in a petri dish filled with saline solution (buffered saline, pH 7.2), with its inner surface aligned at the centre of the cartesian axis displayed on the screen. At this stage, the system was set to zero, and the reference axis were gradually moved from the inner surface of the lens to the outer surface. The measurement was completed once the axis reached the highest point of the lens. The entire process was being controlled on the projector screen (Figure 2B). The contour illumination option was applied in order to enhance the projection of the contact lens thickness silhouette.

Special consideration was taken to make a proper centration of the contact lens on the sphere of the ET-3 device and an accurate cutting at the centre of the contact lens for the V-12B projector measurements. Due to the potential for greater variability in the method used with the V-12B projector, resulting from contact lens centration and handling, all measurements were conducted by a trained operator with experience in contact lens manipulation and equipment operation.

2.3. Statistical analysis

The statistical analysis was performed with the programs Statgraphics Centurion XVIII® and MATLAB. General linear model statistical test (GLM), and the Bland-Altman analysis were carried out. These analyses are widely used in the literature for statistical assessments as well as for clinical trials [18–20].

The Bland-Altman analysis is considered as a gold standard valid method to make comparisons between instruments in the scientific field [21–26]. This analysis is simple to calculate and interpret, making it a valuable tool for comparing measurement results between two methods or devices. In this study, the differences between the results from each instrument were analyzed, with potential bias estimated through the mean difference. Repeatability was assessed by calculating the standard deviation of the differences within the 95% limits of agreement. The Bland-Altman plot was generated using a MATLAB toolbox [27]. The instrument with the lowest standard deviation values would have the more repeatable measurements.

The General Linear Model (GLM) is a robust method for conducting analysis of variance (ANOVA). In this study, the selected factor was the "instrument." With GLM statistical methods can be obtained for the analysis of a parameter that is statistically dependent on other qualitative and/or quantitative variables. In this study, these methods were used to determine whether variations in the central thickness of the measured lenses differ significantly based on their power or brand, potentially reflecting the influence of contact lens optical design.

3. Results

3.1. Comparison between devices

To perform the Bland-Altman analysis, the normality of the differences between thickness measurements from both devices was first assessed using the Kolmogorov-Smirnov test implemented in MATLAB. The results indicated that the differences followed a normal distribution. Next, each pair of values was examined to identify and exclude potential outliers, considering only pairs whose differences fell within 95 % of the normal distribution. Out of the 20 lenses, only one was discarded.

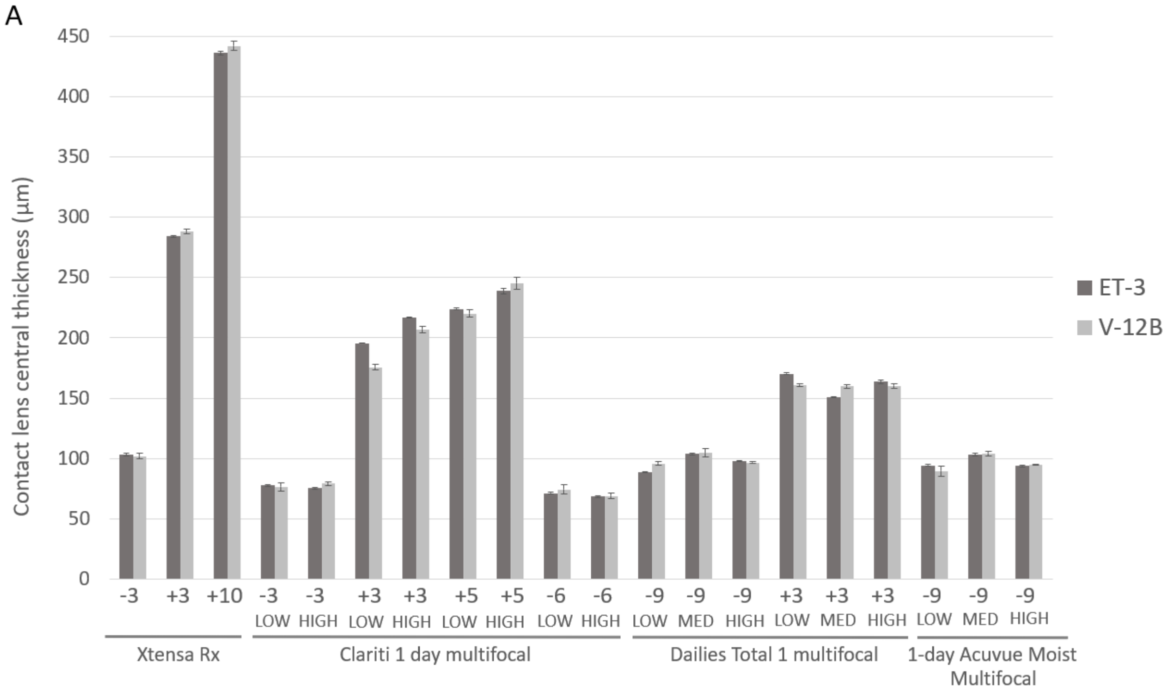

Figure 3. Comparison of all the contact lens central thicknesses per sphere, addition and brand

The correlation between the ET-3 and the V-12B devices was evaluated with MATLAB and results are shown in Figure 4A. The linear fitting equation of the correlation analysis is V-12B = 1.006(0.9778, 1.034)·ET-3 – 0.3913(-5.32, 4.538), with a coefficient of determination (R^2) of 0.9971. The values in parentheses gave the 95% confidence levels of the fitting parameters.

A Bland-Altman plot was also performed and the results are depicted in Figure 4B. There was a horizontal bias line close to zero (0.47 µm) with no statistical significance ($p>0.05$). A T-test was also carried out in MATLAB. This analysis indicated that the distribution of differences followed a normal distribution with a mean of zero that cannot be discarded. It could be observed that the data did not follow any tendency between the limits of agreement (dashed lines).

In the repeatability analysis, the standard deviation of the ET-3 device measurements was 0.72 µm, while the standard deviation results obtained from the V-12B projector was 2.40 µm. Thus, the ET-3 measurements demonstrated greater repeatability.

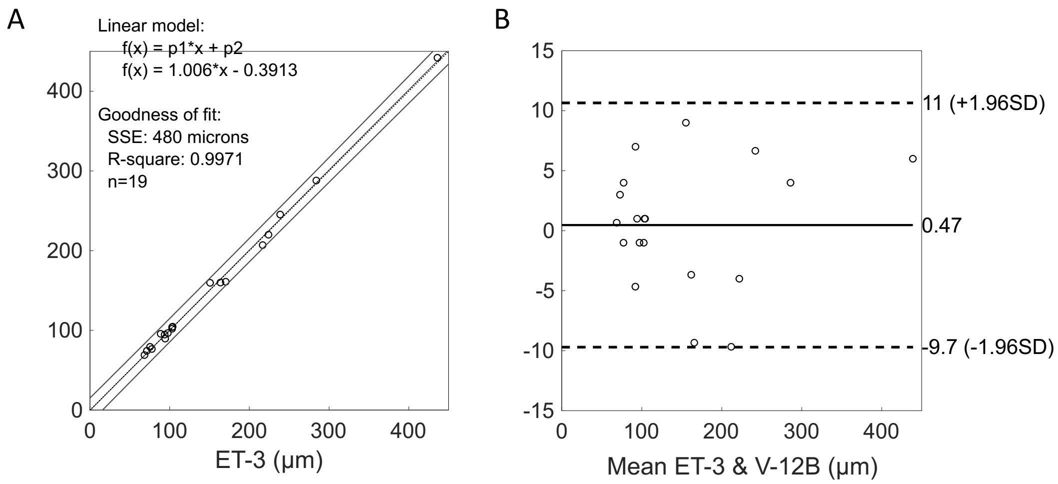

Figure 4. A) Correlation fitting plot, B) Bland-Altman diagram representation

3.2. Central thickness dependence on design and brand parameters

For the analysis of the GLM models, three different factors were selected. One numerical (spherical power) and two other qualitative ones (type of instrument and lens brand). The factors ('brand', 'sphere power' and 'instrument') were independent following the results of the statistical analysis. The GLM analysis showed no statistically significant differences between instruments at 95% confidence, confirming the results of the Bland-Altmann analysis.
Despite the reduced sample of contact lenses, a more detailed statistical analysis was also carried out to see if different commercial brands (with different optical designs) use different central thicknesses for contact lenses with similar sphere and addition in multifocal contact lenses. The analysis was made between 1-day Acuvue Moist MF and Dailies Total 1 MF of +3.00 D spherical power, and it showed statistically significant differences ($p<0.05$). However, Dailies Total 1 MF and Clariti 1 day MF with -9.00 D of spherical power were compared, and no statistically significant differences were found. Further comparisons under the same conditions were not possible due to differences in lens power and design.

4. Discussion

This pilot study aimed to evaluate the correlation between two different devices, the ET-3 and the V-12B projector, when measuring the central thickness of single vision and multifocal soft contact lenses. The Bland-Altman analysis revealed that all lens values, except one, fell within the limits of agreement and did not follow any trend. The horizontal bias was close to zero, indicating similar results between the two instruments. Furthermore, linear regression analysis demonstrated a correlation index close to 1, confirming a strong correlation between the devices. Based on these findings, it was concluded that the ET-3 and V-12B instruments were interchangeable with each other.

ET-3 use is extended in healthcare field to measure contact lens thickness in air. It has been demonstrated that the more time the contact lens is exposed in air, the more dehydrated it will be[6,8]. This fact may affect the final results of the study by maybe obtaining thinner thickness values than the original ones expected when the lens is immersed in saline solution. The contact lens could also have moved from the established zero location if measurements take too much time or if the spherical steel surface becomes slippery when the contact lens is still moist. Besides, the measurements obtained with the ET-3 device are extremely sensitive to small air bubbles that could emerge between the back surface of the contact lens and the steel sphere. This fact should be carefully monitored.

After taking the measurements with the ET-3, a small indentation in the central zone of some lenses was observed in the screen of the V-12B Nikon projector. To our knowledge, this is the first time that this indentation caused by the ET-3 device in contact lenses is reported, and this fact is thanks to the possibility of visualizing the lens with the V-12B projector at a microscopic level. These indentations could have been provoked by the repeated number of measurements over the same central zone of the contact lens, in which they may have caused a slightly deeper indentation. This fact was observed in general, regardless of the power and the lens brand. The thickness measurement of these indentations could be considered for future studies. Considering that the indentation generates a small step in the centre of the lens and that the device units are the micrometers, the measurements with the V-12B could be affected. Nevertheless, the procedure followed in this study can be accepted since the operator detected first the position of the indented mark, and then measured the central thickness with the V-12B as close as possible to that location but not in the indentation itself (This may introduce a minor bias when comparing measurements from both instruments on the same contact lens).

In terms of thickness measurements with the V-12B projector, a central slice of the contact lenses was cut with a razor, as explained in sections above. Since this is a manual process, the lens may not be cut precisely through the cen, and the razor could create small protrusions on the lens. As a result, the central thickness measurement may be slightly inaccurate. In this study, it was observed that the measurements obtained with the V-12B projector had a greater standard deviation than the ones obtained with the ET-3 device. The primary factor contributing to this difference could be that the V-12B device is very sensitivity to vibration. In this instrument, the contact lens is immersed in saline solution, and a crank must be rotated to measure its thickness. This manual movement may more indirectly the contact lens petri dish, transmitting vibrations to the lens and potentially affecting the measurements. Furthermore, the contact lens needs to be cut in order to visualize the shape profile, so the main disadvantage would be that the contact lens cannot be experimentally reused after completing the measurement.

Literature publications and reviews reported other studies which analyzed contact lens thickness with similar devices but based on different measurement principles. Lira and collaborators [1] measured the central and peripheral thickness of single vision spherical soft contact lenses with an electronic thickness gauge and reported that there were remarkable differences between lens powers. A similar conclusion was reported by Vincent et al.[28] regarding scleral contact lenses. Tankam and colleagues[29] used the Gabor-Domain Optical Coherence Microscopy (GD-OCM) with a precision of 0.2 microns to measure the edge thickness and the shape of multiple contact lenses. As their results were not reported for contact lens central thickness, the precision value cannot be directly compared with the values for ET-3 nor V-12B Nikon projector obtained in this study.

González-Mejióme and collaborators[30] reported in-vivo contact lens thickness measurements results with OCT techniques and showed that there was a significant decrease of the contact lens thickness by 2% after a 90-minute wear. Thus, it would be interesting for future research to measure the lenses on eye with OCT and compare the results with the measurements obtained from ET-3 or V-12B. Chan et al.[31] highlighted the importance of the temperature parameter in the dehydration of the contact lens on eye, that could be linked to changes related to contact lens thickness as well.

In recent years, several software systems have been developed to measure the contact lens thickness on eye, as well as the shape and the anterior and posterior curvatures[32]. Similar to the OCT, the results of this publication could be compared with innovative programs for a more detailed analysis of contact lens thickness.

In the present study, the correlation between multifocal contact lenses and single vision contact lens thicknesses was not made, since lenses of several powers, additions and designs were measured. The main objective was to perform a first study to obtain a relationship between two devices that are useful for measuring contact lens central thicknesses and to show that the V-12B Nikon projector can be applied to measure contact lens thicknesses. These contact lenses can vary in their construction parameters depending on the type of material, base curve, optical design, etc. There may even be variability between different brands of similar contact lenses. To maintain the simplicity of the pilot study while obtaining a representative sample of contact lenses, a heterogeneous set of contact lenses was selected, limiting the sample to commercial contact lenses in common use. An attempt was made to obtain differences in materials, power, base curve, etc. The main characteristics of the lenses studied are shown in Table 1. In total, the proposed method was studied with 20 contact lenses. The repeatability of the measurements with the ET-3 device was greater than with the V-12B projector, nevertheless, both instruments were found interchangeable with each other.
Several advantages and disadvantages were observed for both devices. On one hand, ET-3 provided a wider measurement zone from the lens centre and provided a reference profile (steel sphere of the device). On the other hand, V-12B provided a more accurate centration technique as a microscopic tool is incorporated in the screen of the device. However, a more extensive study focused on thickness variations among lenses with similar powers and produced by different manufacturers, could be conducted in the future.

As there were significant differences in thickness between different brands of +3.00D sphere, but not with contact lenses of -9.00D sphere, the analysis of the measured contact lens sample may suggest that the brand had no impact on the thickness of negative lenses but did influence the thickness of positive lenses. It is well known that central thickness of negative lenses are thinner than positive lenses, according to geometrical optics principles. In positive contact lenses, the central thickness will vary more, as shown in Figure 3. This could be important when fitting a positive contact lens in a presbyopic patient with dry eye disease, for example, because the selection of the lens brand would be related to a concrete thickness that could eventually affect the comfort in some cases. Nevertheless, this conclusion just represents the results obtained for a specific spherical contact lens power and two different lens brands. Further research into this aspect can be developed in the future.

On the other hand, negative contact lenses are thinner in the centre of the lens than in the periphery according to their optical geometry. In Figure 3 the results of central thickness agree with that condition, and the values for contact lenses with different powers are quite similar. Whether the additions are high, medium or low, they did not influence the central thickness results, either for positive or negative sphere values.

Additional limitations of the method that could be used as a starting point for future work include further improvement and standardization of the lens sectioning method, increasing the number of contact lenses in a larger study, and comparing it with other in vivo thickness measurement methods, such as OCT, which would further contextualize the clinical relevance of the procedure.

5. Conclusions

To our knowledge, no literature has been found comparing the results obtained. Therefore, this paper introduces a novel approach in the evaluation of different devices for measuring contact lens thickness. This is also the first time the Nikon Profile Projector V-12B has been applied to contact lens thickness measurements in the field of optics.
The analysis demonstrated that both instruments—the Rehder Electronic Thickness Gauge ET-3 and the Nikon Profile Projector V-12B—are interchangeable and capable of providing repeatable thickness measurements. Regarding the central thickness of the multifocal contact lenses studied, the findings suggest that this parameter only changes significantly in contact lenses with high negative additions, regardless of the brand.

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