



Comparative Study of Corneal Thickness before and after FemtoLasik Surgery with Pentacam® AXL and Ultrasound Device (Tomey SP-100)

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Authors' contributions:

This work was carried out in collaboration among all authors. 'Author A' designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. 'Author B' managed the analyses of the study and the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Aims: The purpose of our research is to evaluate corneal thickness, pre-operative and post-operatively after FemtoLasik surgery, using "Pentacam® AXL" and Ultrasound device. To evaluate the correlation of the two devices and their interchangeability.

Sample and Study Design: Our data includes 70 eyes of patients, age 19- 59 years, who undergone Lasik surgery for myopia. The data concerned pre-operative and post-operative central corneal pachymetry using Ultrasound pachymeter (Tomey SP-100) and "Pentacam® AXL".

Methodology - Place and Duration of Study: University of West Attica Dept Biomedical Science Course Optics & Optometry in collaboration with Private Ophthalmology Clinic "Athens Ophthalmologiko" during the period between May 2018 until September 2018. In this study, a comparison of data taken with Pentacam and Ultrasound was performed concerning central corneal thickness before and after FemtoLasik to evaluate the correlation of these devices. All the FemtoLasik surgeries were performed by the same experienced surgeon in order to ensure good repeatability of surgical procedures and all the patients selected had healthy eyes with no other

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ophthalmic pathology or systemic disease and myopia ranging from -1.00 to 9.25 Diopters. All patients were measured one month after FemtoLasik having achieved 6/6 visual acuity.

Results: Central corneal thickness before FemtoLasik measured by ultrasound device had an arithmetic mean value of $552.43 \mu\text{m} \pm \text{SD } 26.95$. The thickness preoperatively with "Pentacam" had an arithmetic mean value of $556.26 \mu\text{m} \pm \text{SD } 27.82$. The corneal thickness after Lasik measured by ultrasound device had an arithmetic mean value of $493.21 \mu\text{m} \pm \text{SD } 36.30$, while for "Pentacam" the arithmetic mean value was $499.07 \mu\text{m} \pm \text{SD } 36.17$. The two devices correlate strongly (0.9218 and 0.9986 respectively with significant level $P < 0.0001$)

Conclusion: Our conclusions after statistical analysis are that Ultrasound pachymetry and "Pentacam" topography correlated strong.

Keywords: Central corneal thickness; refractive surgery; Lasik; depth of ablation; residual stromal bed; "Pentacam"; ultrasound; corneal flap.

1. INTRODUCTION

In Lasik surgery in recent years, the femtosecond laser is used to create a corneal flap instead of the microkeratome [1,2]. It is a laser that emits infrared with a wavelength of 1053 nm and pulses lasting $100 - 10^{-15}$ sec. The femtosecond laser makes photodissection, a process in which the tissue is transformed into plasma that in combination with high pressure and temperature creates cavities and separates the flap from the corneal [3,4].

Contraindications to performing Lasik are, collagen-related diseases, immunosuppression, autoimmune diseases, diabetes mellitus, severe atopy, and wound healing-related diseases [2-3]. Also, patients with unstable refractive condition, ocular pathologies of the anterior segment, severe dry eye, blepharitis, choroiditis or incipient cataract are not corrected with Lasik. Other contraindications for performing Lasik are pregnancy and lactation. Lasik is an absolute contraindication for eyes with a history of herpetic keratitis, and of course in keratoconus or *forme fruste* keratoconus, PMD (Pellucid marginal degeneration) [4]. Particular attention should be paid to individuals with neovascularization of about 1 mm within the keratomileusis zone [4].

A basic concept is that the cornea should not be flattened less than 33.00 Diopters and curved more than 52.00 Diopters when performing FemtoLasik for myopia and hypermetropia correction respectively. Also, all candidates for Lasik should have a constant refraction for at least 12 months with a difference less than 0.50 Diopters in the same period. Patients with very thin corneas are not good candidates [4].

It is very important in refractive surgery to calculate the flap thickness preoperatively in order to safely take a decision for performing the operation or not. The remaining corneal layer, calculated from the thickness of the flap, is crucial in order not to have Lasik post-operative complications due to very thin corneas or corneal ectasia. It is important to evaluate the correlation of the two devices in order to have information in their interchangeability. A lot of studies involving central corneal thickness measurement had been presented in order to establish the best device for this measurement preoperatively but also postoperatively. Pentacam, Orbscan, Ultrasound and OCT pachymetry are the most common devices used for this purpose [5-19]. Measuring corneal thickness plays a key role in corneal refractive surgery to correct myopia. It is a key factor in patient selection and laser operation. The aim of this study was to compare central corneal thickness measurements using Scheimpflug imaging (Pentacam® AXL) compared to pre-operative and postoperative ultrasound measurements in normal myopic patients.

2. METHODS AND MEASUREMENT DESIGN

Our research was conducted at Private Ophthalmology Clinic "Athens Ophthalmologiko", and the participants were 36 patients: men (38.69%) and women (61.11%). Patients ranged in age from 19-59 years with a mean of 38.03 years $\pm \text{SD } 10.354$ (Fig. 2). All participated voluntarily, maintaining their anonymity due to the protection of their personal data. Patients underwent refractive surgery with the FemtoLasik method. Patients with ocular disease, keratoconus, or previous refractive surgery were excluded from the study. Hyperopic patients were excluded from this research. The data of

two eyes that were finally operated by the PRK method were also excluded from the sample. The final sample concerns 70 eyes that underwent FemtoLasik surgery from May 2018 until September 2018.

The measurements of the central corneal thickness before surgery, were taken with an ultrasound device (Tomey SP-100) and with "Pentacam® AXL", (Wavelight Pentacam Oculyser). The Pentacam® AXL also determined the axial length of the eye as well as all the data of the anterior eye segment, from the anterior corneal surface to the posterior surface of the crystalline lens giving rapid and accurate results on corneal thickness and corneal topography. The ultrasound measurements were performed in collaboration with the ophthalmologist at the center. Measurements were also made for the cycloplegic refraction in order to evaluate the thickness of the flap, the size of the flap zone and the flap thickness. The flap actual thickness was recorded from the Laser report postoperatively. All the operations were performed by the same surgeon with the FemtoLasik method. The flap was separated with a femtosecond laser which was the FS 200 (Wavelight, Alcon).

The keratomileusis was performed with the excimer laser Allegretto Wave Concerto 500Hz (Wavelight AG Erlangen Germany). From the data we calculated other parameters that served us in our statistical analysis. Specifically, from the cycloplegic data we calculated the spherical equivalent from the relation:

$$Sph. Equivalent = D sph + \frac{1}{2} D cyl$$

In this sample the numerical average value of refractive error corrected was -4.05 Diopters ± 2.27. (Min. value: -1.00 Diopters / Max value: -9.25 Diopters)

The statistical analysis was performed at significance level p=0.05, which is considered particularly satisfactory for such measurements.

3. RESULTS

The sample consisted of 36 patients: men (38.69%) and women (61.11%) and their age distribution is illustrated in Fig. 1.

Pre-operative corneal thickness measured with ultrasound device and "Pentacam" topographer. The first comparison was made between the values of preoperative corneal thickness, measured by ultrasound (thickness before Ultrasound), and the values measured by topography (thickness before Pentacam) with Medcalc, for a 95% confidence interval. The thickness before Lasik measured by ultrasound device ranged from 500 m to 620 m, with a numerical average value of 552.43 μm ± SD 26.95 and median 553 μm. The thickness preoperatively with the topographic method "Pentacam® AXL" ranges from 495 μm to 612 μm, with an average value of 556.26 μm ± SD 27.82 and a median of 563 m. Table 1 shows all this information.

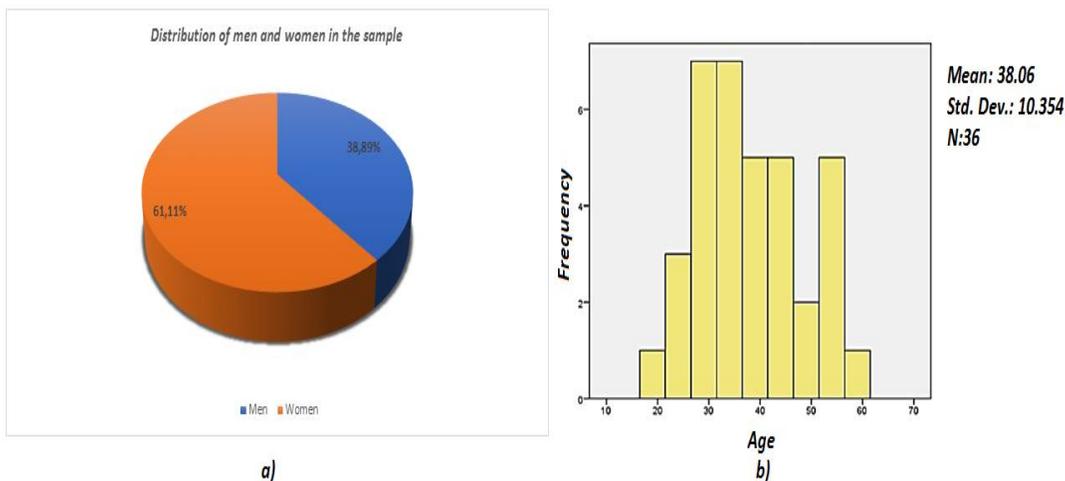


Fig. 1. a) Distribution of men and women in the sample b) Age distribution of men and women in the sample

The thickness after FemtoLasik measured by topographic method “Pentacam” ranges from ultrasound device ranged from 435.25 μm to 439.30 μm to 590.50 μm , with an average 588.14 μm , with a numerical average value of value of 499.07 $\mu\text{m} \pm \text{SD } 36.17$ and a 493.21 $\mu\text{m} \pm \text{SD } 36.30$ and median 481.1 μm . median of 490.5 μm . Table 2 shows all this The thickness preoperatively with the information.

Table 1. Corneal thickness before Lasik

Corneal thickness before Lasik	Pentacam	Ultrasound Tomey SP-100
Sample size	70	70
Arithmetic mean	556,2571	552,4286
95% CI for the mean	549,6237 to 562,8906	546,0023 to 558,8548
Variance	773,9619	726,3644
Median	563,00	553,00
Standard Deviation	27,8202	26,9511
Standard error of the mean	3,3251	3,2213
Paired samples t-test	Pentacam vs ultrasound	
Mean difference	-3,8286	
Standard deviation of mean difference	10,8641	
Standard error of mean difference	1,2985	
95% CI	-6,4190 to -1,23081	
Test statistic t	-2,948	
Degrees of Freedom (DF)	69	
Two-tailed probability	P = 0,0044	
Correlation	Pentacam and Ultrasound	
Correlation coefficient r	0,9218	
Significance level	P<0,0001	
95% Confidence interval for r	0,8767 to 0,9508	

Table 2. Corneal thickness after Lasik

Corneal thickness after Lasik	Pentacam	Ultrasound Tomey SP-100
Sample size	70	70
Arithmetic mean	499,0664	493,2159
95% CI for the mean	490,4408 to 507,6920	484,5611 to 501,8707
Variance	1308,6231	1317,4994
Median	484,1000	490,8500
Standard Deviation	36,1749	36,2974
Standard error of the mean	4,3237	4,3384
Paired samples t-test	Pentacam vs ultrasound	
Mean difference	5,8506	
Standard deviation of mean difference	1,9480	
Standard error of mean difference	0,2328	
95% CI	5,3861 to 6,3151	
Test statistic t	25,128	
Degrees of Freedom (DF)	69	
Two-tailed probability	P < 0,0001	
Correlation	Pentacam and ultrasound	
Correlation coefficient r	0,9986	
Significance level	P<0,0001	
95% Confidence interval for r	0,9977 to 0,9991	

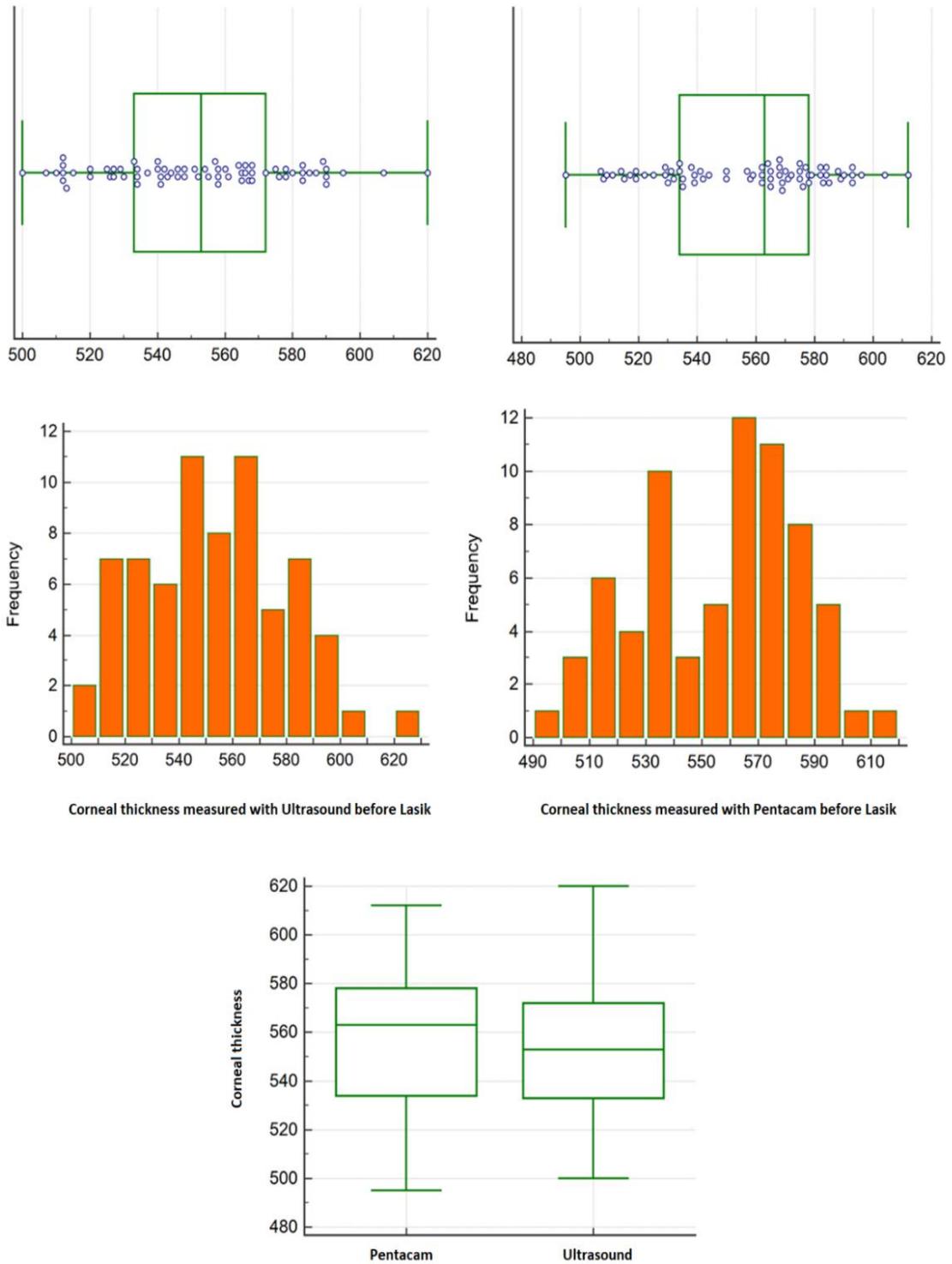


Fig. 2. Box-and-whisker plot and histogram plot with corneal thickness measurements of ultrasound and pentacam respectively before Lasik. Comparison box-and-whisker plot

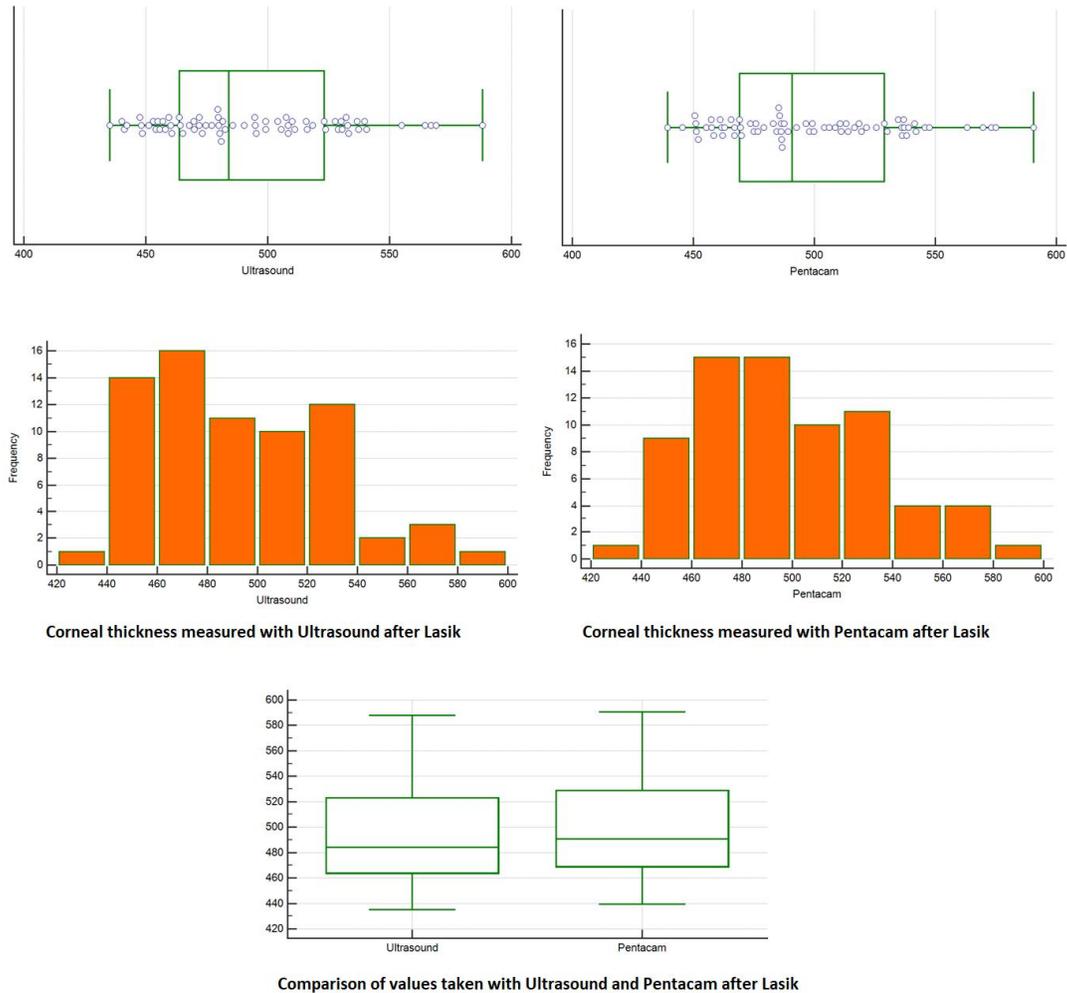


Fig. 3. Box-and-whisker plot and histogram plot with corneal thickness measurements of ultrasound and pentacam respectively after Lasik. Comparison box-and-whisker plot

Compare to other studies were Ultrasound gives higher results than Pentacam, in this study Pentacam gives slightly higher values than Ultrasound device [20].

4. CONCLUSION

The limits for the choice of refractive surgery method are being re-examined. The full interpretation of corneal ectasia is still incomplete. Careful examination of patients may reveal risk factors for the occurrence of ectasia. Corneal thickness is a key consideration of pre-operative screening, as patients with reduced corneal thickness are excluded from refractive surgery. For the FemtoLasik technique, the required minimum

residual corneal thickness after flap cross-section should be at least 250-300 μm . Safety limits must be observed and monitored so that the risk of post-operative complications, such as post-operative ectasia due to high percentage tissue degradation that will affect the biochemical stability of the cornea, remains low. PRK (Photo Refractive Keratectomy) could be a safer choice in patients with thin corneas than the FemtoLasik technique which is more "invasive". The results of this study between the measurements obtained by Pentacam and Ultrasound pachymetry in normal myopic eyes showed no significant differences in corneal thickness readings. Both devices measurements for central corneal thickness correlate strong for measurements taken before

and after Lasik refractive surgery. The correlation coefficient between them before and after FemtoLasik were 0.9218, 0.9986 respectively with significant level $P < 0.0001$. The mean difference was $-3.8286 \mu\text{m}$ and $5.8506 \mu\text{m}$ respectively before and after Lasik which is statistically insignificant ($P = 0.0044$ and $P < 0.0001$).

CONSENT AND ETHICAL APPROVAL

As per international standard or university standard guideline participant consent and ethical approval has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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