ORIGINAL ARTICLE/KLİNİK ÇALIŞMA

Comparison of Central Corneal Thickness Measurements of Nidek Al-Scan, Galilei G4 Dual Scheimpflug Analyzer and Cirrus HD-OCT

Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer ve Cirrus HD-OCT ile Yapılan Santral Kornea Kalınlığı Ölçümlerinin Karşılaştırılması*

Mehmet Serdar DERVİŞOĞULLARI[1], Yüksel TOTAN[2], İsa YUVACI[3], Fatma Betül GÜRAĞAÇ[4]

ABSTRACT

Purpose: To compare the central corneal thickness (CCT) measurements of three different devices.

Material and Methods: CCT was measured in one eye of 41 healthy subjects (age: 29.6±7.23 range:20-47), using the Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer and Cirrus HD-OCT (Cirrus Version 6.0). The agreement between the measurements of three devices was assesed using the one way ANOVA test. To assess the interexaminer reproducibility, two different examiners consecutively obtained CCT measurements in 23 eyes with Nidek AL-Scan, Galilei Dual Scheimpflug Analyzer and Cirrus HD-OCT.

Results: Mean±SD values for CCT using the Nidek AL-Scan, Galilei Dual Scheimpflug Analyzer and Cirrus HD-OCT were 541.04±34.91 µm, 541.56±31.05 µm, and 541.73±33.83 µm respectively. There was no statistically significant difference between these three devices at measuring CCT (p=0.98). Intraclass correlation between different observers was fine (>0.9 for each device) and Bland Altman plots of observers' measurements with each device showed good agreement.

Conclusions: Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer and Cirrus HD-OCT provide CCT measurements that are in agreement with each other and with the published values for CCT in human subjects. CCT measures from these instruments should be used interchangeably.

Key Words: Central corneal thickness, optical biometer, scheimpflug camera, optical coherence tomography.

ÖZ

Amaç: Bu çalışmada santral korneal kalınlığının (SKK) üç ayrı cihaz ile ölçümleri karşılaştırılmıştır.

Gereç ve Yöntem: Çalışmada ortalama yaşı 29.6±7.23 (değişim aralığı 20-47) olan 41 hastaya aynı gözlemci tarafından sağ gözlerine Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer ve Cirrus HD-OCT (Cirrus Version 6.0) ile SKK ölçümleri yapıldı. Üç cihaz ile elde edilmiş ölçümler one way ANOVA testi kullanılarak kıyaslandı. Ayrıca 23 hastada farklı iki gözlemci tarafından aynı cihazla SKK ölçümleri yapıldı ve her bir cihaz için gözlemciler arası tekrarlanabilirlik oranı değerlendirildi.

Bulgular: Ortalama SKK değerleri Nidek AL-Scan, Galilei Dual Scheimpflug Analyzer ve Cirrus HD-OCT için sırasıyla 541.04±34.91 µm, 541.56±31.05 µm ve 541.73±33.83 µm bulundu. Üç cihazin ölçümleri arasında istatistiksel olarak anlamlı fark tespit edilmedi (p=0.98). Farklı gözlemciler tarafından aynı cihazla yapılan ölçümlerde ise intraklas korelasyon değeri her bir cihaz için 0.9 dan büyük bulundu ve cihazların Bland Altman plotlarında tutarlılık izlendi. Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer and Cirrus HD-OCT provide CCT measurements that are in agreement with each other and with the published values for CCT in human subjects. CCT measures from these instruments should be used interchangeably.

Tartışma: Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer ve Cirrus HD-OCT ile ölçülen SKK değerleri istatistiksel olarak birbiriyle ve yayınlanan SKK değerleriyle tutarlı olup, klinik uygulamalarda bu üç alet SKK ölçümü bakımından birbirinin yerine kullanılabilir.

Sonuç: Cihazlar SKK ölçümünde birbiri yerine kullanılabilir.

Anahtar Kelimeler: Santral kornea kalınlığı, optik biyometri, scheimpflug, optik koherens tomografi.

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1. M.D Asistant Professor, Turgut Ozal University Faculty of Medicine, Department of Ophthalmology, Ankara/TURKEY
DERVISOGULLARI M.S., serdarderv@hotmail.com
2- M.D Professor, Turgut Ozal University Faculty of Medicine, Department of Ophthalmology, Ankara/TURKEY
TOTAN Y., ytotan@usa.net
3- M.D, Kayseri Training and Research Hospital, Eye Clinic, Kayseri/TURKEY
YUVACI İ., mdisay@hotmail.com
4- M.D, Turgut Ozal University Faculty of Medicine, Department of Ophthalmology, Ankara/TURKEY
GURAGAC F.B., abguragac@gmail.com

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Yazışma Adresi / Correspondence Adress: M.D Asistant Professor, Mehmet Serdar Dervişoğulları
Turgut Ozal University Faculty of Medicine, Department of Ophthalmology, Ankara/TURKEY

Phone: +90 312 203 50 95
E-mail: serdarderv@hotmail.com

INTRODUCTION

The accurate measurement of central corneal thickness (CCT) is important in clinical ophthalmology in many circumstances like contact lens associated cornea problems[1,2], refractive surgery[3-5] and glaucoma assessment.[6-11]

There are many techniques to measure CCT. Although ultrasound was traditionally regarded as the gold standard for CCT and other biometric measurements[12], interferometry has been shown to be more precise and more reliable than ultrasound.[13,14] Interferometry is the technology used in the relatively new Nidek AL-Scan (Nidek Co., Ltd. Gamagori, Japan) instrument. The Nidek AL-Scan uses optical low-coherence reflectometry to perform biometry of the entire eye and measures CCT, ACD, corneal curvature radius, white-to-white distance, axial length, and pupil size in 10 seconds.

The Galilei G4 Dual Sheimpflug Analyzer (Ziemer, Port, Switzerland) is a noninvasive diagnostic system based on a rotating dual Scheimpflug camera integrated with a Placido photographer. It captures slit images from opposite sides of the illuminated slit and averages the elevation data obtained from corresponding opposite slit images[15]. Cirrus high definition optical coherence tomography (HD-OCT) (Cirrus Version 6.0, Carl Zeiss Meditec, Inc., Dublin, CA) has a scan speed of 27.000 A-scans per second and an axial resolution of 5 ml. It may be advantageous for the posterior segment as well as the anterior segment and can be used as a reliable noncontact pachymeter when assessing glaucoma or cornea patients and in refractive surgery as a diagnostic imaging method.[16]

The reliability of the measurements obtained by any ophthalmic instrument could be determined to avoid misdiagnosis or erroneous treatment based on the readings. Cirrus HD-OCT and Galilei Dual Scheimpflug Analyzer have been shown to have good repeatability at measuring CCT[16,17] but there is no known assesment for Nidek AL-Scan's CCT measurements for repeatability. The aim of this study was to evaluate the agreement between CCT measurements obtained with Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer and Cirrus OCT and to find out if these devices can be used interchangeably. We also aimed to show the repeatability of CCT measurements with three devices.

MATERIALS AND METHODS

The study followed the tenets of the Declaration of Helsinki, and written informed consent was obtained from all participants after the nature of the study and possible consequences of the study were explained. The study protocol was approved by the local ethics committee.

All healthy subjects could achieve a visual acuity of 6/6 or better with spectacle correction. In all cases, uncorrected astigmatism was equal to or less than 1.25 D Subjects with high refractive errors, ocular or systemic disease or a history of having ocular surgery were excluded. CCT measurements were obtained from only the right eye for each subject using Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer and Cirrus HD-OCT. The order of presentation of the instruments was randomized and all measurements for each subject were obtained at a single session. To assess the interexaminer reproducibility, two different examiners consecutively obtained CCT measurements in right eyes of 42 participants with Nidek AL-Scan, Galilei G4 Dual Scheimpflug Analyzer and Cirrus OCT, respectively. Examiners didn't know each others' measurement results.

Nidek AL-Scan

The Nidek AL-Scan uses light interference to measure CCT with a measurement area of 200-1200 µm. The AL-Scan incorporates threedimensional (3D) auto tracking and auto shot features to simplify use. For the Nidek AL-Scan instrument, participants were asked to fixate on the internal fixation light while the measurements were taken. The subjects were seated with their heads stabilized using a chin rest and brow bar. The instrument was aligned using the image of the eye on the computer monitor. Subjects were asked to blink just before measurements being taken. Blinking or loss of fixation was detected automatically by the instrument and the measurement was repeated.

Galilei G4 Dual Sheimpflug Analyzer

The dual Scheimpflug analyzer used in this study provides corneal thickness measurements for the central 9.0 mm. Data are automatically reported in concentric circles (with a diameter of 1.0 mm, 3.0 mm, and 4.0 mm), although corneal thickness can be measured at any point by manually placing the cursor at that point. A measurement was obtained for each subject's right eye using the Galilei Dual Sheimpflug Analyzer and the measurement was repeated by a different examiner. Images were captured with the subjects seated and their head stabilized with a chin rest and brow bar. The subjects were instructed to remain stationary, keeping both eyes open. The instrument was aligned with the subjects' pupil plane with the aid of the alignment screen. Immediately before the measurement, the room lights were switched off and the subjects were instructed to blink, and then to hold their eyes open. Images were captured automatically while subjects fixated on the internal fixation target. Loss of fixation or blinking was detected automatically by the software, and the measurement was repeated in this eventuality.

Cirrus HD-OCT

Scanning with the Cirrus HD-OCT (Cirrus Version 6.0) was performed using the anterior segment protocol. After the patient was seated and properly aligned, he or she was instructed to stare at an internal fixation target during image acquisition.

Three measurements were taken and subjects were realigned and asked to blink after each scan. Only images with signal strength equal to or higher than 6 were evaluated. Right eye of each subject was selected for CCT measurement. Mean of three measurements made by the same examiner was calculated. The CCT was measured manually with the caliper tool in the cross-line scan; the vertical distance between the two indicators of the caliper tool was considered the CCT.[16] The CCT measurements were always manually performed at the corneal apex.

Examinations were carried out from 10:00 AM to 2:00 PM to minimize the effect of diurnal variations of the corneal thickness.[18] Two different examiners (MSD and AT) obtained CCT measurements in 42 patients with Nidek AL-Scan, Galilei Dual Scheimpflug Analyzer and Cirrus HD-OCT to show interobserver repeatability.

Data Analysis

Repeated measures analysis of variance was used to compare CCT measurement results of three devices to find out whether they can be used interchangeably. The definitions of coefficient of reproducibility were based on those adopted by the International Organization for Standardization and a previous report.[19,20] Reproducibility of the data obtained was determined only when there was no statistically significant difference between measurements. Intraclass correlation coefficients (ICC) were used to show reproducibility of CCT measurements of three devices taken by two observers. Interobserver repeatability of measurements was evaluated by Bland-Altman analysis.[21] Limits of agreement (LoA) were defined as the mean difference ±1.96 SD of the differences.[21] This standard deviation represents the interobserver range of agreement (1.96 times), with lower values indicating higher repeatability and vice versa. If a difference between two observers measurements (as extreme as that described by the 95% limits of agreement) meaningfully affects the interpretation of the results,[22] then the range of agreement is clinically significant, interobserver repeatability not acceptable, and the method analyzed does not provide repeatable measurements.

Statistical analysis was performed using the SPSS for Windows Version 20.0 (SPPS Inc., Chicago, IL, USA). P values less than 0.05 were considered statistically significant.

RESULTS

The age of the participants ranged from 20 to 47 years (mean±SD: 29.6±7.23). There were 19 men (45.24%) and 23 women (54.76%) participants in the study. A sample size of 42 subjects gave a power of 0.9 to detect differences between the CCT measurements of three devices for p=0.05. Mean spherical equivalent refractive error ranged from -2.00 diopter (D) to +0.25 D (mean±SD: -0.53±0.59 D). The mean±SD values for CCT measured for the 42 subjects are shown in table 1. The measurements from the instruments agree with published literature values for the thickness of the cornea6 in the healthy human eye.

Comparing the three instruments using repeated measures analysis of variance, a statistically significant difference was not found between the measurements obtained for CCT (F=.015, p=0.985). Two observers' intraclass correlation coefficients (ICC) are shown at table 2. As ICC values closed to 1 are mentioned to be well correlated, measurements seemed to be well correlated between observers. Table 3 summarizes interobserver repeatability results for measuring CCT with Nidek AL-Scan, Galilei Dual Scheimpflug Analyzer and Cirrus HD-OCT. As stated above, the magnitude of the LoA determines whether or not two observers' measurement results can be used interchangeably.

Table 1: *Mean±SD Values for CCT Measures Obtained With the Three Instruments.*

	Nidek AL-Scan	Galilei Dual Scheimpflug Analyzer	Cirrus HD-OCT	p value
Parameter	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	
CCT (micrometer)	547.77 (30.36)	546.54 (31.52)	545.09 (33.09)	0.985

CCT; Central Corneal Thickness, SD; Standard Deviation.

Table 2: *ICC Values for CCT Measurements between two observers.*

	ICC	%95 CI
Nidek AL-Scan	0.997	(0.992, 0.999)
Galilei Dual Scheimpflug Analyzer	0.930	(0.842, 0.970)
Cirrus HD-OCT	0.985	(0.965, 0.994)

CCT; Central Corneal Thickness, ICC; Intraclass Correlation Coefficient, CI; Confidence Interval, HD-OCT; High Definition Optical Coherence Tomography.

Table 3: *Interobserver repeatability results for measuring CCT with Nidek AL-Scan, Galilei Dual Scheimpflufg Analyzer and Cirrus HD-OCT.*

	ROA	Mean Difference	LOA
Nidek AL-Scan	5.51	-0.22	-5.74-5.29
Galilei Dual Scheimpflug Analyzer	7.2	-1.61	-6.11-8.3
Cirrus HD-OCT	11.65	0.54	-11.11-12.20

CCT; Central Corneal Thickness, HD-OCT; High Definition Optical Coherence Tomography, ROA; Range of Agreement, LOA; Limits of Agreement.

There was agreement between the measurement results of two observers. Figure 1, 2 and 3 show the Bland and Altman plots for the three instruments' measurement comparisons by two observers.

Figure 4, 5 and 6 show the Bland and Altman plots between instruments. The values obtained are spread across the plots and are arguably a representative sample of the target population.

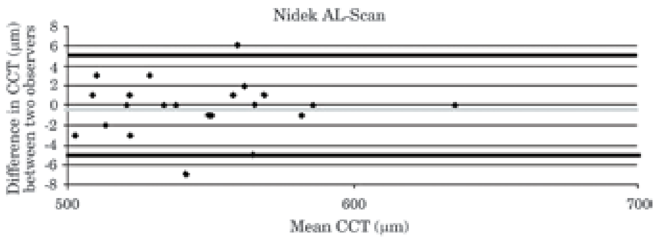

Figure 1: *Bland-Altman plot showing differences in CCT measurements with Nidek AL-Scan between the observer 1 and the observer 2 plotted against the mean value for both. The upper and teh the lower solid black lines represent the LoA, calculated as mean±1.96 SD (N=23 eyes) and gray line represents mean difference. There is a good spread of values across the plots. (CCT=Central corneal thickness).*

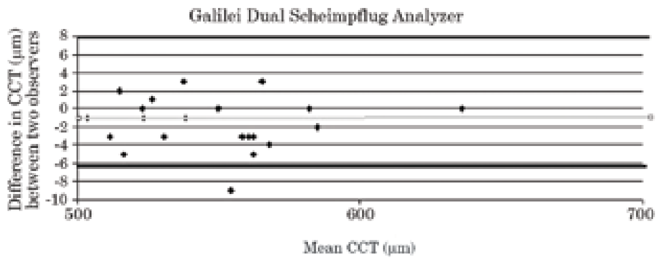

Figure 2: *Bland-Altman plot showing differences in CCT measurements with Galilei Dual Sheimpflug Analyzer between the observer 1 and the observer 2 plotted against the mean value for both. The upper and the lower solid black lines represent the LoA, calculated as mean±1.96 SD (N=23 eyes) and gray line represents mean difference. There is a good spread of values across the plots (CCT=Central corneal thickness).*

DISCUSSION

In our study, the CCT does not seem to be different among the three instruments. As a matter of fact, an ideal device measuring corneal thickness should measure in a thorough, accurate and fast manner and its measurement should also be repeatable and technically easy. The device should also scan all curvatures correctly and display a high level of device-patient compatibility. In present time, corneal measurements are important in diagnosing and follow-up of various corneal diseases[1,2] and in surgical procedures.[3-5] They are also increasingly used in diagnosing glaucoma and differential diagnosis.[6-11] Although there are some disadvantages including the contact with the cornea, the risk for epithelial damage or infection and patient discomfort, ultrasound pachimetry (USPM) has been the most commonly used method for measuring the CCT and is even considered as the "gold standard".[12] A wide range of devices are available for the measuring CCT such as conventional USPM, ultrasound biomicroscopy, confocal biomicroscopy, scanning laser topography, Scheimpflug imaging, partial coherence laser interferometry, optical low-coherence reflectometry (OLCR) and optical coherence tomography (OCT).[23-27] The effectiveness of various methods that are currently in use are also presented by comparing them with the USPM.[24,25] In some studies, three and even four of these devices are used together and the results of these studies are published by comparing them in terms of differences and compatibility.[24,27]

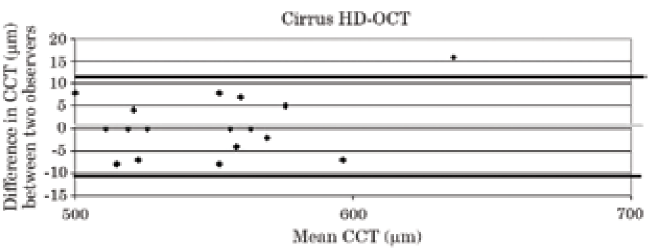

Figure 3: *Bland-Altman plot showing differences in CCT measurements with Cirrus HD-OCT between the observer 1 and the observer 2 plotted against the mean value for both. The upper and the lower solid black lines represent the LoA, calculated as mean±1.96 SD (N=23 eyes) and gray line represents mean difference. There is a good spread of values across the plots (CCT=Central corneal thickness).*

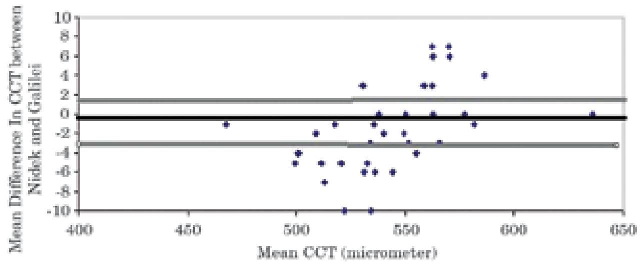

Figure 4: *Bland-Altman plot showing differences in CCT measurements between the Nidek AL-Scan and the Galilei G4 Dual Scheimpflug Analyzer plotted against the mean value for both. The upper and the lower solid black lines represent the LoA, calculated as mean±1.96 SD (N=23 eyes) and gray line represents mean difference. There is a good spread of values across the plots (CCT=Central corneal thickness).*

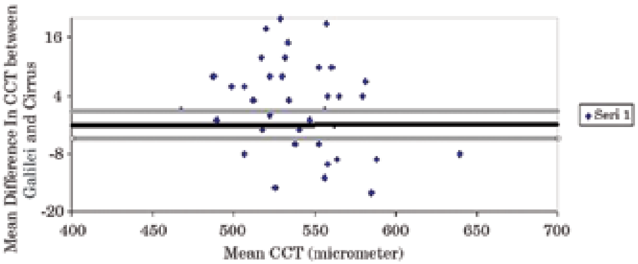

***Figure 5:** Bland-Altman plot showing differences in CCT measurements between the Galilei G4 Dual Scheimpflug Analyzer and the Cirrus HD-OCT plotted against the mean value for both. The upper and the lower solid black lines represent the LoA, calculated as mean±1.96 SD (N=23 eyes) and gray line represents mean difference. There is a good spread of values across the plots (CCT=Central corneal thickness).*

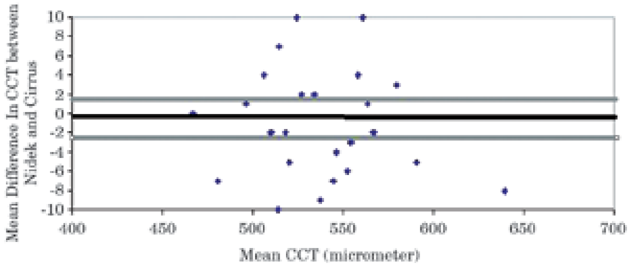

***Figure 6:** Bland-Altman plot showing differences in CCT measurements between the Nidek AL-Scan and the Cirrus HD-OCT plotted against the mean value for both. The upper and the lower solid black lines represent the LoA, calculated as mean±1.96 SD (N=23 eyes) and gray line represents mean difference. There is a good spread of values across the plots (CCT=Central corneal thickness).*

In our study, CCT was analyzed by using Nidek AL-Scan, Galilei Dual Scheimpflug Analyzer and Cirrus HD-OCT. The compatibility of these three devices with each other is examined. We were not able to find a study utilizing these three devices together in the literature but there were studies measuring CCT by using Galilei Dual Scheimpflug[17] and anterior segment OCT.[18,23] There were also studies that make comparisons with the Lenstar (LS) device that has a similar operation principle with Nidek AL-Scan.[28]

In their study that compares CCT measurements of Galilei Dual Scheimpflug Analyzer, Pentacam and USPM, Jahadi Hosseini et al demonstrated that Galilei Dual Scheimpflug Analyzer measured cornea thicker but they also indicated that their finding was not statistically significant.[29] By using Galilei, Pentacam, Orbscan ve USPM, Park et al,[30] compared their CCT measurements in healthy corneas with the CCT measurements after Laser In Situ Keratomileusis (LASİK). In healthy corneas, the CCT differences were insignificant. But Orbscan's CCT measurements were significantly thinner than other devices' measurements in corneas after LASIK. Kanellopoulos et al.,[31] reported that difference of the central CCT mesurements in healthy subjects with high resolution Scheimpflug, high frequency USPM and anterior segment OCT, was not statistically significant. Also, Lòpez-Miguel et al.,[32] measured CCT by using optical low-coherence reflectometry and spectral-domain optical coherence tomography devices and the difference between measurements was not statistically significant. Similarly, in an other study that compares the measurements of healthy corneas conducted with Scheimpfleug and anterior segment OCT, Huang et al.,[33] also were not able to find any statistical difference between the two methods, but at the same time they indicated that these two methods have high compatibility. Bayhan et al.,[34] who measured CCT with Optical Low Coherence Reflectometer and Combined Scheimpflug-Placido Disk Topographer reported that there is no statistically significant difference at measuring CCT between these two methods. Köktekir et al.,[35] state that they found no statistically significant difference in their study that measured CCT in healthy corneas by using Optical Low-Coherence Reflectometry and Ultrasound Pachymetry. The two methods' compatibility was compared through Bland Altman analysis, and these methods were found to have high compatibility.

The ability to obtain accurate measurements of the dimensions of the eye is becoming increasingly important in clinical practice and in research applications. There are several devices to measure CCT by different technical principles. It is obvious that instruments for clinical use need to have accuracy and reproducibility. Reproducibility describes the consistency between readings on the same instrument by different observers under the same conditions. The Galilei[22] and Cirrus[23] instruments' CCT measurements have previously been shown to have reproducibility but there is not such a report for Nidek AL-Scan. In our study, all these three devices seemed to have reproducibility. It is also important to find out if the CCT measurement data produced by Nidek AL-Scan, Galilei Dual Scheimpflug Analyzer and Cirrus HD-OCT are interchangeable. In our study, although there was a slight decrease through the CCT measurements of Galilei, Nidek and Cirrus respectively, it was not statistically significant. The results of our study confirm that these instruments can be used for measuring CCT interchangeably. The limitations of study were that the results were limited to the unoperated and healthy eyes and further studies in larger groups, including operated and glaucomatous eyes, are needed.

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