Comparison Between Clinical Outcomes of Two Different Designs of Toric Multifocal Intraocular Lenses

İki Farklı Tasarım Torik Multifokal Göz İçi Lensin Klinik Sonuçlarının Karşılaştırılması

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ABSTRACT

Purpose: To compare the clinical outcomes of plate haptic and open-loop haptic toric multifocal intraocular lenses (IOLs).

Materials and Methods: In this retrospective, comparative clinical trial, two different designs of multifocal toric IOL were implanted in 49 eyes of 38 cases with corneal astigmatism ≥ 0.75 Diopter (D). The cases that underwent AcrySof IQ restore multifocal toric IOL (Alcon, open-loop-haptic) implantation were assigned to Group1 (n=19) and the cases that underwent Acriva Reviol multifocal toric IOL (VSY, plate-haptic) implantation were assigned to Group 2 (n=30). After surgery, the groups were compared in terms of degree of IOL rotation, residual spherical refraction and astigmatism and uncorrected near and distance visual acuity.

Results: With regard to the results of postoperative 1st month, 3rd month, 6th month and 1st year, no difference was determined in terms of uncorrected distance visual acuity, spherical equivalent (SE), degree of astigmatism (CYL), degree of rotation, and uncorrected near visual acuity (p>0.05). Significant increase was determined in all postoperative follow-up periods in terms of the distance and near visual acuity as compared to preoperative values (p<0.05).There was no correlation between degree of rotation and age, axial length, SE and CYL (p>0.05).

Conclusion: Clinical outcomes of plate haptic Acriva Reviol multifocal toric IOL and open-loop haptic Acrysof IQ multifocal toric IOL are similar. Both types of IOL effectively reduce astigmatism and provide satisfactory uncorrected distance and near visual acuities.

Key Words: Open-loop haptic, Plate haptic, Toric multifocal intraocular lens.

ÖZ

Amaç: Bu çalışmada plate haptik ve openloop haptik torik multifokal göz içi lens (GİL)'lerin klinik sonuçlarını karşılaştırmak amaçlanmıştır.

Gereç ve Yöntem: Bu retrospektif, karşılaştırmalı klinik çalışmada, iki farklı tasarımdaki multifokal torik GİL, korneal astigmatizması ≥ 0.75 Diyoptri (D) olan 38 olgunun 49 gözüne implante edildi. AcrySof IQ restore multifokal torik GİL (Alcon, openloop haptik) İmplantasyonu uygulanan vakalar (n=19) Grup 1, Acriva Reviol multifokal torik GİL (VSY, platehaptik) implantasyonu uygulanan vakalar Grup 2 (n=30) olarak ayrıldı. Ameliyattan sonra gruplar GİL rotasyonunun derecesi, rezidüel sferik refraksiyon ve astigmatizma, düzeltilmemiş yakın ve uzak görme keskinliği açısından karşılaştırıldı.

Bulgular: Postoperatif 1.ay, 3.ay, 6.ay ve 1.yıl sonuçlarına dayanarak düzeltilmemiş uzak görme keskinliği, sferik eşdeğeri, astigmatizma derecesi, rotasyon derecesi ve düzeltilmemiş yakın görme keskinliği açısından fark tespit edilmedi (p> 0.05). Tüm postoperatif takiplerde, preoperatif değerlerle karşılaştırıldığında uzak ve yakın görme keskinliği açısından anlamlı artış saptandı (p<0.05). Rotasyon derecesi ile yaş, aksiyel uzunluk, sferik eşdeğer ve astigmatizma arasında korelasyon yoktu (p>0.05).

Sonuç: Plate haptik Acriva Reviol multifokal torik GİL ve openloop haptik Acrysof IQ multifokal torik GİL'in klinik sonuçları benzerdir. Her iki tip GİL de etkili bir şekilde astigmatizmayı azaltmakta ve tatmin edici düzeltilmemiş uzak ve yakın görme keskinliği sağlamaktadır.

Anahtar Kelimeler: Open-loop haptik, Plate haptik, Torik multifokal göziçi lensi

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Geliş Tarihi - Received: 20.08.2017
Kabul Tarihi - Accepted: 04.01.2018
Glo-Kat 2018; 13: 16-22

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INTRODUCTION

Increasing success of cataract surgery in the recent years has resulted in enhanced patient expectation concerning postoperative visual acuity. Beyond undergoing cataract surgery, particularly the patients with high socio-cultural level now expect their refractive defects to be corrected and do not want to wear either near and distance eyeglasses after cataract surgery. It has been more likely to meet such expectations along with the development of the methods that identify the power of intraocular lenses (IOLs) and accordingly this surgical method is called as refractive cataract surgery. Spherical refractive defects can be corrected with appropriate spherical IOL chosen based on accurate keratometry and calculation of axial length. However, approximately 20-30% of the patients undergoing cataract surgery has corneal astigmatism of 1,00 diopter (D) and over, whereas 10% has 2.0 D and over.[1-3] In cataract surgery, multifocal IOL implantation substantially solved the problem of near vision without eyeglasses and without impairing distance vision, which could not be achieved with classical monofocal IOLs.[4-6] However, it was reported that depth of focus reduces and problems such as blurred vision, photophobia, halo and glare are more prevalent in the patients that underwent multifocal IOL implantation and have uncorrected corneal astigmatism of 0.75 diopter and over.[7-9] In addition to correction of refractive defect and enabling near vision without the need for eyeglasses, also correction of astigmatism has been possible with multifocal toric IOL that has been manufactured recently. Accordingly, dependency on eyeglasses following surgery has become less prevalent. The manufacturers also concerned about the postoperative IOL rotation which constitutes the most important cause of postoperative failure, so they designed different types of multifocal toric lenses.

Therefore, the present study aimed to compare two different designs of multifocal toric IOLs implanted in the patients with cataract and corneal astigmatism in terms of postoperative residual astigmatism, degree of rotation of postoperative IOL, and uncorrected distance/near visual acuity.

MATERIALS AND METHODS

Multifocal toric IOL implantation was performed between May 2010 and August 2012 in 49 eyes of 38 patients with cataract and corneal astigmatism ≥ 0.75 D. Visual and refractive outcomes were retrospectively evaluated. Patients were assigned to two groups: Group 1 (n=19) underwent AcrySof IQ restore multifocal toric IOL (Alcon, open-loop-haptic); Group 2 (n=30) underwent Acriva reviol multifocal toric IOL (VSY, plate-haptic). Complete ophthalmologic examination including best corrected distance visual acuity (BCDVA), best corrected near visual acuity (BCNVA), autorefractometry, keratometry, topography, biomicroscopic examination, tonometry and dilated fundus examination was performed in all patients before surgical procedure. Patients with any corneal, retinal or macular disease that could affect visual and refractive outcomes were excluded. Axial length and keratometry readings were measured by IOLMaster (Carl Zeiss Meditec, Inc., Dublin, CA) Calculation of the power of IOL and determination of the axis that the lens will be placed were done by means of programs in the websites of the companies (www.acrysoftoriccalculator.com for AcrySof IQ restore multifocal toric IOL (Alcon) and http://easytoriccalculator.vsy.com.tr for Acriva reviol multifocal toric IOL).

Surgical Technique

Prior to the surgical procedure, reference points were marked on the limbus at horizontal 0-180 degree using corneal marker while patients were in the upright position. Afterwards, implantation axis was determined using these reference marks. Vertical axis of astigmatism did not taken into account while performing main corneal incision and temporal tunnel corneal incision was done by 2.5 mm keratome in all cases. It was targeted that capsulorhexis would be approximately 5.5 mm in diameter in order to cover the optic part of the lens. After extracting the cataract, the capsular bag was filled with viscoelastic material. The injector system of the same company with the owner of monoblock multifocal toric IOL was used and the lens was implanted into the capsular bag. After the viscoelastic substance in the anterior chamber and under the lens was adequately cleaned, the surgery was completed by providing the exact position of the lens making the corneal incision edematous using BSS.

Postoperatively, topical prednisolone acetate (Predforte1%, Allergan Inc., Irvine, CA) and moxifloxacin (Vigamox; Alcon) eyedrops were administered 5 times a day. Topical steroid was tapered weekly, while topical antibiotic was stopped at 10 days.

Patients were evaluated on the control visits performed on postoperative Days 1 and 7, as well as on the postoperative Months 1, 3, 6 and 12. Patients followed for less than 1 month were not included in the study. Binocular corrected and uncorrected distance visual acuities (CDVA and UDVA) were measured with Snellen Chart at 6 m under photopic conditions both before and after surgery. Binocular corrected and uncorrected near visual acuities (CNVA and UNVA) were measured at 14 inches (35.6 cm) from the patients' eye using a handheld Jaeger near reading chart under photopic conditions. Visual acuity values obtained by Snellen chart and Jaeger chart were converted to logMAR chart and were then analyzed. The amount of rotation of the lens was determined by exposing the eye to biomicroscopical coaxial slit light after providing complete dilation and the light was rotated until the axis marks of the lens were aligned with slit light.

Statistical methods

Descriptive statistics for categorical variables were presented as frequency and percentage, whereas descriptive statistics for continuous variables were presented as mean, standard deviation, median, minimum and maximum. Suitability of continuous variables with normal distribution was analyzed by the Shapiro Wilk test. Comparisons between groups for continuous variables were performed using an independent t-test or Mann–Whitney U test (abnormal distribution), and a Chi-square test was used for categorical variables. Comparison between preoperative and postoperative data of the cases in the study group was done using Two Related Samples test (Wilcoxon Signed Ranks test). Correlations between the continuous variables were determined with Spearman correlation analysis. Statistical significance was considered as a P value<0.05 and was performed using the Statistical Package for the Social Sciences software, version 16.0 (SPSS, Inc., Chicago, IL).

RESULTS

No difference was determined between the groups in terms of age and gender (p=0.611, p=0.263, respectively). Preoperative BCDVA values were 0.40 (0.20-1.30) logMAR in Group 1 and 0.40 (0.20-1.30) logMAR in Group 2 (p=0.482). Preoperative UNVA values were 0.60 (0.40-1.30) logMAR in Group 1 and 0.60 (0.30-1.40) logMAR in Group 2 (p=0.180). The mean baseline steepest keratometry (K_s), and flattest keratometry (K_f) in Group 1 were 42.91 D (38.09-47.20 D), and 42.51 D (39.80-44.76 D, respectively. On the contrary, the mean baseline K_s, and K_f in Group 2 were 45.21 D (41.72-49.27), and 43.95 D (41.56-45.55), respectively. Significant difference was determined between corneal refraction index (K_s) of the groups (p=0.011). No difference was determined between the groups in terms of axial length (Group 1=24.57 [22.50-27.13] mm) and Group 2= 23.33 [21.84-28.15] mm), p= 0.106). There was no difference in terms of preoperative spherical equivalent (SE) (Group 1= -7.00 D [-11.50 - +1.50], Group 2= -2.00 D [-10.50 - +2.25], p=0.099). Likewise, no difference was determined between the groups in terms of cylindrical refractive values (Group 1= -2.00 D [-3.25 - 0.75], Group 2= -2.25 [-5.75 - 0.75], p=0.132). Preoperative ophthalmic examination findings and comparison between the groups are summarized in Table 1.

There were no perioperative or postoperative complications occurred and multifocal toric IOLs were implanted into the capsular bag in all cases. Corneal suturing was not required in any of the cases. UDVA and UNVA values significantly increased and SE and cylindrical refractive errors significantly decreased in both groups in all postoperative control visits (Months 1, 3, 6 and 12) as compared to the preoperative values (Table 2).

In the 1st postoperative month data, no difference was determined between the two groups in terms of UDVA, UNVA, SE, CYL and degree of rotation (p=0.553, p=0.734, p=0.289, p=0.796 and p=0.099, respectively). Although the degree of rotation of the lenses was relatively higher in group 2, the difference was not considered statistically significant (p=0.099). In the postoperative 3rd month control, there were 17 cases in group 1 and 26 cases in group 2. Similarly, there was no difference between the groups in terms of UDVA, UNVA, SE, CYL, and degree of rotation of the lens (p=0.424, p=0.640, p=0.549, p=791, and p=0.096, respectively). In the 6th month visit, there were 17 cases in group

Table 1. *Comparison of preoperative demographic, systemic and ocular findings in two groups.*

	AcrySof IQ restore multifocal toric IOL (Group 1, n=19) Median (min-max)	Acriva reviol multifocal toric IOL (Group 2, n=30) Median (min-max)	P value
Age (year)	52 (25-80)	51 (20-76)	0.611*
Sex (male/female)	6/7	7/18	0.263#
BCDVA (logMAR)	0.40 (0.20-1.30)	0.40(0.20-1.30)	0.482*
UNVA (logMAR)	0.60 (0.40-1.30)	0.60 (0.30-1.40)	0.180*
K_f(D)	42.51 (39.80-44.76)	42.91 (38.09-47.20)	0.189*
K_s(D)	43.95 (41.56-45.55)	45.21 (41.72-49.27)	0.011*
Axial Length (mm)	24.57 (22.50-27.13)	23.33 (21.84-28.15)	0.106*
SE (D)	-7.00 (-11.50 - 1.50)	-2.00 (-10.50 - 2.25)	0.099*
CYL (D)	-2.00 (-3.25 - 0.75)	-2.25 (-5.75 - 0.75)	0.132*

BCDVA= Best Corrected Distance Visual Acuity; UNVA: Uncorrected Near Visual Acuitiy, K_f= Flat keratometry, K_s= Steep keratometry, SE: spherical equivalent; D = diopters; CYL: Degree of astigmatism.
*Mann- Whitney U Tests
Fisher Exact Chi-square tests.

Table 2. *Comparison of preoperative and postoperative visual acuity and refractive values in the groups.*

Pre-operative/post-operative Parameters	AcrySof IQ restore multifocal toric IOL (Gorup 1) P value	Acriva reviol multifocal toric IOL (Group 2) P value
1st-Month (Group 1; n=19, Group 2; n=30)		
Pre-BCDVA/ post-UDVA	<0.001	<0.001
Pre-SE/post-SE	0.038	0.012
Pre-CYL/post- CYL	0.028	0.006
Pre- UNVA/post-UNVA	<0.001	<0.001
3rd-Month(Group 1; n=17, Group 2; n=26)		
Pre-BCDVA/ post-UDVA	<0.001	0.001
Pre-SE/post-SE	0.036	0.026
Pre-CYL/post- CYL	0.032	0.017
Pre- UNVA/post-UNVA	<0.001	<0.001
6 th-Month (Group 1; n=17, Group 2; n=25)		
Pre-BCDVA/ post-UDVA	0.001	0.001
Pre-SE/post-SE	0.027	0.049
Pre-CYL/post- CYL	0.046	0.028
Pre- UNVA/post-UNVA	<0.001	<0.001
1st-year (Group 1; n=15, Group 2; n=23)		
Pre-BCDVA/ post-UDVA	0.027	0.001
Pre-SE/post-SE	0.041	0.035
Pre-CYL/post- CYL	0.047	0.012
Pre- UNVA/post-UNVA	0.001	0.001

*Two related samples tests (Wilcoxon Signed Ranks test).
Pre-BCDVA/ post-UDVA: Pre-operative Best Corrected Distance Visual Acuity/ Postoperative Uncorrected DistanceVisual Acuity. Pre-SE/ post-SE: Pre-operative spheric equivalent / post-operative spheric equivalent. Pre-CYL/post- CYL (D): pre-operative degree of astigmatism/post-operative degree of astigmatism. Pre-BCNVA/post-UNVA: Preoperative best corrected near visual acuity/postoperative uncorrected near visual acuity.

1 and 25 cases in group 2. Likewise, no difference was determined between the groups in terms of UDVA, UNVA, SE, CYL, and degree of rotation (p=0.360, 0.897, p=0.192, p=0.105, and p=0.159, respectively). In the first year visit, there were 15 cases in group 1 and 23 cases in group 2. Both groups were similar in terms of UDVA, UNVA, SE, CYL, and degree of rotation (p=0.382, p=0.712, p=0.174, p=0.062, and p=0.219, respectively). Results of postoperative comparison of the data of groups are summarized in Table 3. There was no correlation between degree of rotation and age, axial length, SE and CYL (p>0.05, Spearman's rank correlation). (Table 4).

DISCUSSION

Multifocal IOLs have been designed to provide near and intermediate distance after cataract surgery without impairing distance vision. However, problems such as glare and halo due to multifocal IOLs implanted in the patients with pre-existing corneal astigmatism have been frequently encountered in the studies.[7-9] Several methods, including changing the site of incision in phacoemulsification, astigmatic keratotomy or limbal relaxation incisions, have been tried during surgery to reduce astigmatism. However, these procedures have restrictions such as long-term mechanical instability and the limited degree of astigmatism that can be corrected. In addition, outcomes are influenced by many parameters including age, degree of astigmatism and number, depth and length of incisions leading to unpredictable correction depending on various degrees of wound healing.[10] Although correction of corneal astigmatism by laser procedures is an effective method, it requires additional surgical intervention.[11-13]

Today, toric lenses have been designed because such type of surgeries have been inadequate particularly in the cases with high-degree astigmatism and were proven to effectively cor-

Table 3. *Comparison of postoperative distance-near visual acuity, refractive error, and rotation degree of IOL in two groups.*

	AcrySof IQ restore multifocal toric IOL (Gorup 1) Median (min-max)	Acriva reviol multifocal toric IOL (Group 2) Median (min-max)	P value
1st-Month (Group 1; n=19, Group 2; n=30)			
UDVA (LogMAR)	0.10 (0.00-0.15)	0.10 (0.00-0.20)	0.553
UNVA (LogMAR)	0.22 (0.22-0.30)	0.22 (0.22-0.40)	0.734
SE (D)	0.00 (-2.25 – +0.50)	-0.25 (-2.25 - +1.75)	0.289
CYL (D)	-0.50 (-1.25 - +0.50)	-0.50 (-3.50 - +0.25)	0.796
Rotation degree(°)	1 (-4 - +5)	2 (-11 - +10)	0.099
3rd-Month(Group 1; n=17, Group 2; n=26)			
UDVA (logMAR)	0.10 (0.00-0.15)	0.05 (0.00-0.30)	0.424
UNVA (LogMAR)	0.22 (0.22-0.30)	0.22 (0.22-0.40)	0.640
SE	-0.25 (-2.00 – 0.00)	0.00 (-1.75 - +1.75)	0.549
CYL	-0.50 (-0.75 - 0.00)	0.00 (-3.25 - 0.00)	0.791
Rotation degree(°)	3 (-2 - +4)	2 (-11 - +10)	0.096
6th-Month (Group 1; n=17, Group 2; n=25)			
UDVA (log MAR)	0.05 (0.00-0.15)	0.10 (0.00-0.20)	0.360
UNVA (LogMAR)	0.22 (0.22-0.30)	0.22 (0.22-0.30)	0.897
SE	0.00 (-2.25 – + 0.50)	-0.50 (-2.25 - +1.50)	0.192
CYL	-0.50 (-1.25 - +0.50)	-0.50 (-3.00 - +0.25)	0.105
Rotation degree(°)	1 (-5 - +6)	3 (-12 - +10)	0.159
1st-year (Group 1; n=15, Group 2; n=23)			
UDVA (log MAR)	0.05 (0.00-0.15)	0.10 (0.00-0.15)	0.382
UNVA (LogMAR)	0.22 (0.22-0.30)	0.22 (0.22-0.30)	0.712
SE	0.00 (-1.75 – + 0.75)	-0.25 (-2.00 - +0.25)	0.174
CYL	-0.50 (-1.25 - -0.25)	-0.50 (-0.75 - 0.00)	0.062
Rotation degree(°)	1.5 (-6 - +5)	3 (-2 - +10)	0.219

UDVA: Uncorrected Distance Visual Acuity; UNVA: Uncorrected Near Visual Acuity; SE = spherical equivalent; CYL: Degree of astigmatism.

rect corneal astigmatism.[14-18] In addition to eyeglass-free near vision provided by multifocal toric intraocular lenses manufactured recently for cataract cases with corneal astigmatism, it has been also possible to correct corneal astigmatism. Postoperative successful outcomes depend on certain factors in multifocal toric IOL implantation same as toric IOL implantation. Multifocal-toric IOL implantation requires surgical experience; because it comprises both the problems specific to multifocal and to toric IOL implantation. Regular corneal astigmatisms benefit more from multifocal toric IOL implantation. Irregular corneal astigmatism is relatively contraindicated and toric IOL implantation should be considered only in mild-moderate cases that benefit from eyeglass.[19] The most important factor is the position of multifocal-toric IOL during surgery and its rotation after surgery.[20] Each degree of deviation from axis will result in residual astigmatism. It is estimated that each degree of rotation would cause 3.3% loss in cylindrical power of the lens. Cylindrical power is completely lost with 30-degree rotation of toric lens.[21] Hence, appropriate implantation of toric IOL during surgery and remaining stable in the postoperative period are of critical importance for surgical success. Rotational stability poses problem for silicone IOLs. This problem is less common for the acrylic lenses. [22] Prinz A et al. compared the rotational stability of plate-haptic acrylic multifocal IOL (Acri.Smart 46S) and 3-piece loop-haptic acrylic multifocal IOL (Acri.Lyc 53N), as well as development of posterior capsular opacification, and found no statistical difference in terms of degree of rotation but stated that rotation degree of plate haptic IOL is lower. [23] Xiao et al.

Table 4. *Correlation analyses (Spearman correlation test) between rotation degree and independent variables.*				
Rotation Degree	Age	Axial Length	SE	CYL
1st Month	r=-0.111, p=0.566	r=0.236, p=0.123	r=-0.062, p=0.238	r=-0.242, p=0.277
3rd Month	r=-0.362, p=0.273	r=-0.253, p=0.327	r=-0.290, p=0.388	r=-0.242, p=0.277
6th Month	r=-0.094, p=0.695	r=0.113, p=0.560	r=-0.031, p=0.924	r=-0.279, p=0.406
1st Year	r=-0.309, p=0.282	r=-0.031, p=0.892	r=-0.110, p=0.748	r=-0.330, p=0.321
SE = spherical equivalent; CYL: Degree of astigmatism.				

found no difference in postoperative rotational degrees between spherical (Acrysof Toric IOL (SN60TT)) and aspherical (Acrysof IQ Toric IOL (SN6AT) designed toric IOLs (3.84±1.68 degrees and 3.74±1.88 degrees, respectively). [24] Garzon et al. compared 3 different types of monofocal toric IOL (the Lentis LT [Oculentis, Berlin, Germany], enVista [Bausch & Lomb, Rochester, NY], and AcrySof IQ [Alcon Laboratories, Inc., Fort Worth, TX) with multifocal toric IOL (AcrySof IQ ReSTOR; Alcon Laboratories, Inc.) in terms of rotational stability and visual acuity. They found no difference and rotational instability was <5 degree in all 3 IOL groups.[25] Nakamura et al. evaluated near and distant visual acuity and rotational instability in tinted aspheric multifocal toric IOL (SND1T3, SND1T4, SND1T5, SND1T6 : Alcon) and rotational degree was 5.73 ± 4.36 degrees.[26]

In the present study, we evaluated open-loop-haptic AcrySof IQ restore multifocal toric IOL (Alcon) and plate-haptic Acriva reviol multifocal toric IOL (VSY) lenses in terms of postoperative rotational stability, residual astigmatism and uncorrected distance and near visual acuity. We found that rotational degree of plate haptic IOL was higher in the postoperative 1st and 3rd months, although it is not statistically significant. The rotational instability of Open-loop-haptic AcrySof IQ restore multifocal toric IOL was <6 degrees during the follow up whereas the rotational instability of plate-haptic Acriva reviol multifocal toric IOL (VSY) was <11 degrees. However, the difference between rotational degrees of two types of toric multifocal IOL was not significant enough to influence distance and near visual acuity and the degree of residual astigmatism in both study groups. .In their study evaluating Acrysof Toric IOL Zhu et al. found positive correlation between rotational instability and axial length and anterior capsular opacity.[27] In our study there was no correlation between rotational degree and axial length. Because of the retrospective nature of the study, contrast sensitivity and symptoms such as glare, haloe and photophobia could not be evaluated. This was the limitation of the study.

In conclusion, plate haptic Acriva reviol multifocal toric IOL and Alcon Acrysof Restor multifocal toric IOL implantations are safe and effective materials not only in obtaining best distance and near visual acuity but also correction of existing corneal astigmatism in accurately selected cases.

DISCLOSURES

The authors did not receive any financial support from any public or private sources.

The authors have no financial or proprietary interest in a product, method, or material described herein.

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