Influence of optic quality on contrast sensitivity and visual acuity in eyes with a rigid or flexible phakic intraocular lens

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PURPOSE: To determine whether the difference in optic quality between 2 types of phakic intraocular lenses (pIOLs) affects visual quality.

SETTING: Fundación Oftalmológica del Mediterráneo, Valencia, Spain.

METHODS: Before implantation of a pIOL for myopia, all eyes had an examination including corrected (CDVA) and uncorrected (UDVA) distance visual acuity testing, corneal endothelial cell count (ECC), and intraocular pressure (IOP) measurement. The postoperative outcomes, determined at least 1 year after surgery, were CDVA; UDVA; contrast sensitivity function under photopic, mesopic, and mesopic with glare conditions; ECC; IOP; keratometry (Scheimpflug photography); and total ocular aberration (Hartmann-Shack aberrometry).

RESULTS: Twelve eyes had implantation of an Artisan pIOL (rigid pIOL group) and 18 eyes, of an Artiflex pIOL (flexible pIOL group). The mean preoperative CDVA was 0.04 logMAR $\pm$ 0.01 (SD) in both groups (P>.5). The mean postoperative CDVA was 0.01 $\pm$ 0.02 logMAR in the rigid IOL group and 0.01 $\pm$ 0.06 logMAR in the flexible IOL group (P>.9). The photopic contrast sensitivity function was better with the rigid pIOL, and the mesopic contrast sensitivity function was slightly better with the flexible pIOL; however, neither difference was statistically significant.

CONCLUSIONS: Optic quality, measured by modulation transfer function and evaluated by average modulation, was approximately 13% better with the rigid pIOL than with the flexible pIOL. However, the difference was not enough to affect visual quality. At 1 year, the 2 groups had similar CDVA and contrast sensitivity function values, indicating that other optical or neural factors compensate for differences in optic quality.

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Today, the main techniques for correcting mild to high ametropia are corneal ablation (eg, laser in situ keratomileusis, photorefractive keratectomy)[1] and phakic intraocular lens (pIOL) implantation in the anterior chamber[2–5]; posterior chamber pIOLs are also used in some of these cases. Both techniques may achieve similar performance in the correction of refraction (especially myopia or hyperopia). However, laser treatments often result in increased higher-order aberrations (HOAs) that can significantly decrease visual performance for certain tasks. This includes daily tasks such as driving, face recognition, and others that require good contrast sensitivity; thus, the absence of significant halos or aberration can affect the retinal image.[6–9] Moreover, laser techniques are limited to low to mild ametropia because the ablation decreases corneal thickness. Other possible postoperative complications include corneal ectasia, keratoconus, and dry eye.[10–13]

Complications have also been reported after pIOL implantation. These include IOL displacement, corneal opacification due to endothelium cell loss, lens epithelial growth, and nuclear sclerosis related to pIOL–crystalline lens contact.[14–18] Nonetheless, long-term follow-up studies[19,20] found that pIOL implantation is reversible with immediate onset of refractive effect, is stable, does not directly alter the corneal epithelium or stroma, results in little postoperative pain, and is low cost and safe in most cases. Compared with laser procedures, pIOL implantation causes little or no increase in HOAs[3] and provides better visual quality based on an increase in visual acuity. Other studies[21,22] have evaluated contrast sensitivity function after pIOL implantation.

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Several types of pIOLs have been developed in recent years, including Artisan (model 204) and Artiflex (model 401) IOLs for myopia (both Ophtec). The main difference between the 2 IOLs is the optic material. The Artisan optic is rigid and made of ultraviolet–absorbing poly(methyl methacrylate) (PMMA). The Artiflex optic is made of polysiloxane, which is a flexible silicone-based organic polymer. The materials of both IOL models have fair uveal and capsular biocompatibility, although the flexible silicone IOL is not the best choice for patients with certain pathology.[23–26] Implantation of the rigid IOL requires an incision of at least 6.2 mm. The flexible IOL can be implanted through a 3.2 mm main corneal incision. A smaller incision decreases trauma to the cornea, leading to less surgically induced aberration (mainly astigmatism).

Clinical studies report that the larger the corneal incision, the greater the surgically induced astigmatism (SIA). In a short-term study, Coullet et al.[4] concluded that the Artiflex IOL provides faster visual recovery and better uncorrected distance visual acuity (UDVA) than the Artisan IOL based on UDVA results 1 year after surgery. However, long-term studies[27–29] found that statistically, SIA resulting from a large incision eventually decreases to the same levels as SIA after pIOL implantation through a small incision.

On the other hand, the modulation transfer function (MTF) of these 2 pIOLs has been measured using an artificial eye model (ie, a lens inside a cavity that simulates optics conditions in the eye). The MTF is an objective measure that fully describes the behavior of an imaging system when the phase component is not captured by the sensor, as in the human eye.[30] Artigas et al.[31] measured the MTF and found that the Artisan IOL performed better than the Artiflex at all frequencies, indicating that the former yields better retinal image quality. They also found that the injection effect of the foldable IOL on MTF disappeared after 2 hours. However, the difference in image quality could also be the result of differences in visual performance between patients.

We therefore performed a comparative clinical study of the visual performance in patients who had implantation of an Artisan or Artiflex pIOL. We analyzed the possible influence of the optic quality of the pIOLs on the outcomes.

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PATIENTS AND METHODS

Patients who had an Artisan pIOL (rigid pIOL group) or an Artiflex pIOL (flexible pIOL group) in at least 1 eye were selected at random. Some patients had a rigid pIOL in 1 eye and a flexible pIOL in the other eye, some had the same pIOL in both eyes, and some had a pIOL in 1 eye only.

Inclusion criteria were no surgical complications, no other eye disease or surgery, an adequate ECC, age from 20 to 45 years, HOA levels (all Zernike coefficients <1.5 μm), no unexplained decrease in corrected distance visual acuity (CDVA) (CDVA >0.8) postoperatively, and no significant variation in pIOL position. In addition, the eye had to met the safety index requirement (ie, postoperative CDVA $>$ preoperative CDVA).

Preoperative clinical measurements were CDVA, UDVA, endothelial cell count (ECC), and intraocular pressure (IOP). The postoperative measurements were the same as preoperatively with the addition of contrast sensitivity function under photopic, mesopic, and mesopic with glare conditions; keratometry by Scheimpflug imaging (Pentacam, Oculus); and total ocular aberration using a Hartmann-Shack aberrometer. The postoperative examinations were performed at 12 to 24 months to allow vision to stabilize, especially in the rigid pIOL group based on the assumption that SIA would decrease postoperatively.[27–29] The long-term follow-up also allowed time for postoperative complications (eg, induced nuclear sclerosis, corneal opacity) to manifest.

Phakic Intraocular Lenses

Both pIOL models used in the study are 3 piece and iris-claw fixated. They have an overall diameter of 8.5 mm, a 6.0 mm concave–convex optical zone, and poly(methyl methacrylate) (PMMA) haptics. The rigid pIOL is available in powers from −1.00 diopter (D) to −15.50 D and the flexible pIOL, from −2.00 to −14.50 D; the powers are in 0.50 D steps for both pIOLs.

Surgical Technique

The same surgeon (C.P.) performed all pIOL implantations. Thus, other than the size of the main incision, the technique was expected to have a similar effect in all eyes.

Before surgery, the pupil was constricted with pilocarpine 2%. All surgeries were performed using peribulbar anesthesia (4 cc equal amounts of mepivacaine 2.00% and bupivacaine 0.75%). A Honan balloon (30 mm Hg) was applied for at least 7 minutes before surgery.

In the rigid pIOL group, 2 vertical paracenteses were created at 2 o'clock and 10 o'clock, directed toward the enclavation area. A 6.5 mm main incision was created at 12 o'clock. After an intracameral injection of acetylcholine, the anterior chamber was filled with an ophthalmic viscosurgical device (OVD). The pIOL was introduced with a Kelman-like forceps and rotated 90 degrees inside the eye until it

was horizontally positioned (3 o'clock and 9 o'clock); care was taken to avoid contact between the crystalline lens and the pIOL during this maneuver. Under a closed system, the pIOL optic was fixated with a forceps (Ophtec BV) at 12 o'clock. The iris was held at the 9 o'clock meridian (through 1 paracentesis) to enclave it in the claws of the pIOL using an enclavation needle; care was taken to ensure an appropriate amount of tissues was grasped. The other claw was enclavated in the same way at the 3 o'clock meridian through the second paracentesis. Centration of the pIOL over the pupil was checked. Next, a slit iridotomy was performed at 12 o'clock and the OVD was aspirated. Five interrupted 10-0 nylon sutures were used to close the wound. Suture tension was checked with a standard qualitative Maloney keratoscope.

In the flexible pIOL group, a small incision was centered at 12 o'clock, as in the rigid pIOL group. The pIOL was implanted through a 3.2 mm corneal tunnel incision and was inserted using a purpose-designed disposable spatula that allows the surgeon to fold the pIOL and pass it through a 3.2 mm incision. The top of the spatula and the IOL were covered with a drop of OVD before they were introduced into the eye. After the anterior chamber was refilled with an OVD, the pIOL was introduced into the anterior chamber. The incision began at the vascular margin of the limbus; the paracenteses were made at the 10 o'clock and 2 o'clock positions, oriented toward the enclavation side and parallel between them. After the spatula was withdrawn, additional OVD was used to push the pIOL toward the iris. The pIOL was then rotated into a horizontal position using the manipulator that comes with the pIOL. The enclavation needle was introduced into the anterior chamber through a paracentesis at 2 o'clock. With the surgeon grasping the PMMA haptic only, the pIOL was fixated using a curved forceps. The same enclavation method was applied to the opposite side to complete the implantation. In most cases, the incision was watertight and suturing was not necessary.

In both groups, 20 mg of gentamicin with 2 mg of betamethasone were applied subconjunctivally immediately after surgery. After the first postoperative day, homatropine 10% was applied topically every 12 hours and dexamethasone 1% and gentamicin 3% every 6 hours. The drugs were tapered after 3 days and stopped after approximately 30 days.

Main Outcome Measures

The main outcome measures were contrast sensitivity function under photopic and mesopic conditions and CDVA. Total and ocular corneal aberration data were excluded from the analysis for reasons outlined in the Discussion.

Visual Acuity Visual acuity was measured with an AZ8 phoropter (Topcon). Letters were high contrast with photopic luminance.

Contrast Sensitivity Contrast sensitivity function was assessed to determine whether differences in the MTF between the pIOLs affected quality of vision. This subjective measure is proportional to the global MTF of the optics of the eye (contrast sensitivity function = MTF of the eye × neural contrast sensitivity function).[32] Assuming eyes in both groups followed the neural contrast sensitivity function distribution of normal eyes[33] and the difference between groups was significant, the pIOL with the better MTF value would result in better vision. Conversely, the flexible pIOL might perform better because of better recovery of the eye after surgery.

Contrast sensitivity function measurements were performed using a CSV-1000E chart (VectorVision). The chart has 4 rows corresponding to spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd) at a viewing distance of 2.5 m. Each row has several sinusoidal gratings for different contrasts. The chart provides numerical values for normal subjects (aged 20 to 55 years) under photopic and mesopic conditions. Photopic contrast sensitivity function was measured with a luminance of 85 candelas [cd]/m^2 and mesopic contrast sensitivity function, with a luminance of 3 cd/m^2. All measurements were performed with the best monocular distance correction to eliminate the effects of postoperative residual refraction and SIA. Contrast sensitivity function was also measured after 5 seconds of disability glare at each frequency under mesopic conditions.

Statistical Analysis

To assess contrast sensitivity function, the Student *t* test and Hotelling test for multivariate Gaussian distribution of contrast sensitivity function measures were used. In addition, contrast sensitivity function results were calculated as standard scores to obtain a single coefficient to better determine whether contrast sensitivity function was better in 1 pIOL group or the other. The standard scores were calculated as the difference in each contrast sensitivity function value at a certain frequency and the corresponding mean of the normal population, divided by the standard deviation. The scores for each frequency were averaged. Values are reported as means ± SD. A *P* value less than 0.05 was considered statistically significant.

RESULTS

Twelve eyes in the rigid pIOL group and 18 eyes in the flexible pIOL group met the inclusion requirements. The mean age of patients was 30 ± 5 years and 33 ± 6 years, respectively ($P > .05$). The mean preoperative spherical equivalent was 9.2 ± 2.6 D in the rigid IOL group and −9.6 ± 2.6 D in the flexible IOL group and the residual astigmatism, −0.4 ± −0.3 D and −0.4 ± −0.2 D, respectively ($P > .7$). The preoperative ECC was 2617 ± 352 cells/mm^2 in the rigid pIOL group and 2347 ± 409 cells/mm^2 in the flexible pIOL group; postoperatively, the values decreased slightly, but not significantly. The mean postoperative IOP in all eyes was 12.5 ± 2.9 mm Hg.

Table 1 shows the preoperative and postoperative CDVA as well as the difference between the 2 time points. There was no statistically significant difference in CDVA between the rigid pIOL group and flexible pIOL group preoperatively ($P > .5$) or postoperatively ($P > .9$). The CDVA was similar between the groups and was within the normal range.

Figure 1 shows the mean contrast sensitivity function measurements under photopic conditions and Figure 2, under mesopic conditions. Table 2 shows

Table 1. Corrected distance visual acuity.

Exam	Mean CDVA ± SD		*P* Value
	Rigid pIOL	Flexible pIOL	
Preop	0.04 ± 0.10	0.04 ± 0.10	.59
Postop	0.01 ± 0.02	0.01 ± 0.06	.98
Postop − preop	−0.02 ± 0.04	−0.03 ± 0.08	.56

CDVA = corrected distance visual acuity; pIOL = phakic intraocular lens

Table 2. Mean of the 4 frequencies of the contrast sensitivity function standard scores.

Condition	Mean Standard Score ± SD	
	Rigid pIOL	Flexible pIOL
Photopic	−1.20 ± 0.50	−0.80 ± 0.90
Mesopic	0.20 ± 0.04	0.40 ± 0.06

pIOL = phakic intraocular lens

the mean standard contrast sensitivity function scores under the 2 illuminations. The standard scores suggest that both groups had poorer contrast sensitivity function under photopic conditions than the normal range provided by the chart used to measure the function but slightly better performance under mesopic conditions. However, performance with the rigid pIOL was slightly better than with the flexible pIOL under photopic conditions but worse under mesopic conditions; neither difference was statistically significant. All *P* values were significantly greater than 0.05 (Table 3); therefore, the null hypothesis could not be rejected. The same was true for the Hotelling test.

DISCUSSION

This study evaluated whether differences in optic quality between rigid pIOLs and flexible pIOLs results in differences in postoperative visual performance. In a previous study,[31] we showed in experimental determinations of MTF values that the optic quality (given by the mean modulation value) of the rigid pIOL was approximately 5% less than the average modulation of a monofocal IOL with all pupil sizes; the exception was the 4.0 mm pupil, for which the reduction was 10%. Similarly, foldable pIOLs reduce the monofocal average modulation by approximately 16% with all pupil sizes, with the reduction increasing to 24% with 4.0 mm pupils. The absolute difference in average

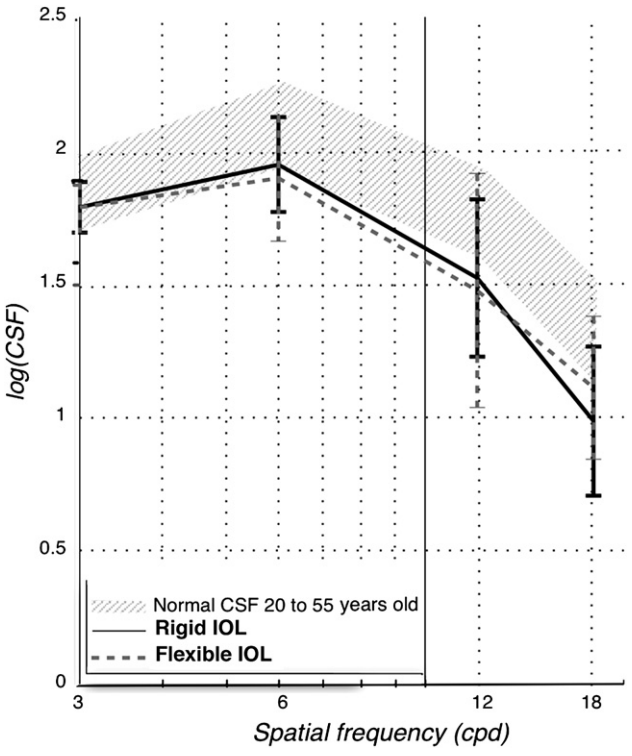

Figure 1. Mean logCS ± SD (with spectacle correction) under photopic conditions (85 cd/m^2).

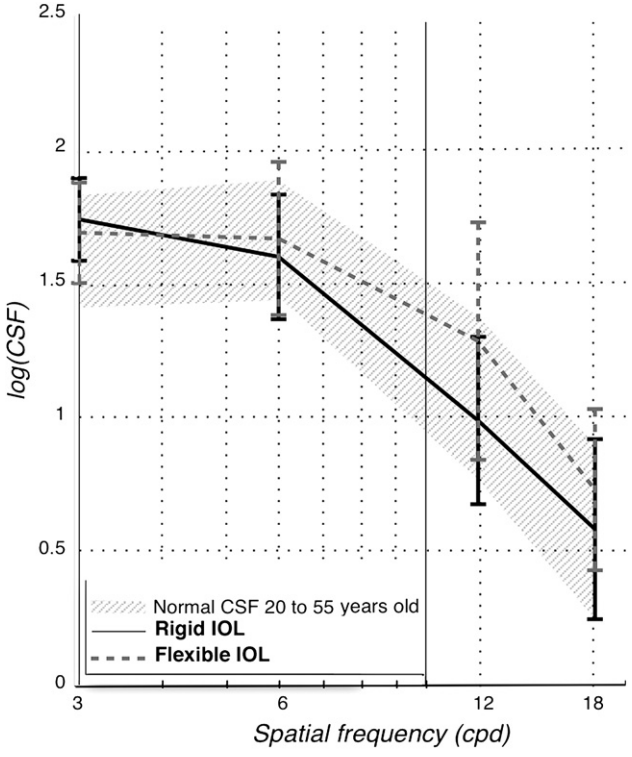

Figure 2. Mean logCS ± SD (with spectacle correction) under mesopic conditions (3 cd/m^2).

Table 3. Results of Student *t* test for each frequency and Hotteling test for multivariate Gaussian distribution of contrast sensitivity function measures.

	Rigid pIOL Versus Flexible pIOL: Null Hypothesis				
	P Value (*t* Test)				
Condition	CSF (3 cpd)	CSF (6 cpd)	CSF (12 cpd)	CSF (18 cpd)	Hotteling (Global CSF)
Photopic	0.78	0.19	0.74	0.33	0.76
Mesopic	0.58	0.84	0.54	0.42	0.74

cpd = cycles per degree; CSF = contrast sensitivity function

modulation between the rigid pIOL and the foldable pIOL was similar with all pupil sizes (approximately 13%). However, the difference in the optic quality of these IOLs might not be sufficient to yield differences in visual skills. This is because in addition to the optic quality of the IOL, several other ocular and neural factors have a significant influence on visual performance.

In our study, CDVA measured 1 year or more postoperatively was approximately the same (0.0 logMAR) in eyes with a rigid pIOL and eyes with a flexible pIOL; the CDVA was in the normal range for the age of the patients. Our results agree with those reported by Coullet et al.,[4] who found no statistically significant difference in the percentage of eyes with a UDVA better than 20/25 (0.1 logMAR) at 1 year between the Artisan pIOL and Artiflex pIOL groups. In our study, the CDVA was not statistically significantly different between groups. However, in the study by Coullet et al., eyes with the flexible pIOL recovered sooner than eyes with the rigid pIOL; that is, they had better visual acuity 1 month and 3 months postoperatively. Therefore, the difference in optic quality between the 2 pIOLs is not great enough to affect the final CDVA. In our study, the postoperative examinations were performed from 12 to 24 months after surgery, by which time the eyes had stabilized. Thus, SIA, which would likely be greater with the rigid IOL because of the large incision, should not have affected the postoperative measurements.

Contrast sensitivity function has a direct relationship to MTF. Therefore, the optic quality of IOLs (MTF) might be expected to influence the patient's visual quality (contrast sensitivity function). In our study, the contrast sensitivity function with the rigid pIOL was slightly better than that with the foldable IOL under photopic conditions (85 cd/m^2) except at the highest spatial frequency (18 cpd); however, the difference between the 2 pIOLs was not statistically significant. In addition, at higher frequencies, the contrast sensitivity function was slightly lower with the 2 pIOL models than the normal range of the test chart used in our study.

The mesopic (3 cd/m^2) contrast sensitivity function curves were within the normal range with both pIOLs. However, the mesopic contrast sensitivity function was better with the flexible pIOL than with the rigid pIOL except at the lowest frequency (3 cpd), although the difference was not statistically significant.

Regarding statistical analysis in our study, the mean and standard deviation were calculated for the preoperative CDVA, postoperative CDVA, and the difference between the 2 values. The mean preoperative CDVA was similar between the 2 pIOL groups. Although the mean postoperative CDVA may indicate which of the 2 groups had better visual acuity, the mean difference between the preoperative CDVA and postoperative CDVA in each group might give more precise information due to the high level of interpatient variability. We used the logMAR unit to record CDVA because increments of logMAR are thought to be more linearly related to the difficulty of the VA task and more independent of the absolute values, allowing comparison between them.

On the other hand, contrast sensitivity function frequencies were fitted to a multivariate Gaussian distribution. The advantage of this approach over fitting 1 Gaussian per frequency is that the nondiagonal elements in the covariance matrix give additional information. These coefficients show the linear relationship between different frequencies. Two groups with different pIOLs might have equal means and standard deviations but different values for other terms in the covariance matrix. A statistical test that accounts for the former magnitudes only will determine that the groups are not different. With the more complete information, the differences might be more visible. Thus, we used the Hotelling T-square distribution, which is a generalization of the Student *t* statistic adapted to the covariance matrix. Furthermore, an expectation-maximization algorithm was used for fitting to the distribution; this approach adapts better when some values are missing.

We also test contrast sensitivity function after 5 seconds of disability glare at each frequency under mesopic conditions. However, there is no proposed standard for how glare measurements should be performed with the contrast sensitivity test we used in the study. Our results show high variability, and no conclusion was reached. The reaction time, the time required to see the highest score after the glare was introduced, and the maximum score varied greatly between patients. In some cases, contrast sensitivity function scores were higher at some frequencies after glare than under stable mesopic conditions.

Finally, the contrast sensitivity function results were summarized using standard scores. Such scores are commonly used to compare different normal distributions. Using this approach, the different scores at each frequency are more comparable and can be averaged.

Regarding preoperative and postoperative measurements, although the total and corneal aberration coefficients were used in the exclusion process, they were not included as outcome parameters because HOAs are well correlated between eyes of the same patient but not between individuals.[34] Thus, the coefficients would not be valid parameters in an evaluation in which the eyes were not paired, as in our study.

Optic quality is also affected by the geometry of the optic surfaces as well as by scattering and diffraction processes along the path of light. Coefficient expansion of the wavefront aberration requires an infinite number of aberration coefficients to describe real behavior, and aberrometers are limited in this regard. Furthermore, pIOL implantation yields no or a slight increase in HOA in normal eyes who have not had laser treatment. The flexible pIOL we used in our study is reported to induce less HOA than the rigid model.[35,36] However, the values of these coefficients may differ between eyes of patients because of factors other than HOAs.

The exclusion criteria ensured that the eyes in our study had vision that was within the range for normal young eyes so that, on average, the HOA aberrometry results would be similar between the 2 pIOL groups.

There is no good measurement unit to describe the level of HOA. The RMS of the wavefront at the entrance pupil is often used. In general, the higher the RMS value, the greater the loss of quality of vision. However, Applegate et al.[37] point out that different subjects with the same RMS may have very different visual acuity. We sought to determine whether there is a connection between visual acuity, contrast sensitivity function, and RMS but found no relationship between RMS and the subjective measures.

In conclusion, a difference in optic quality (average modulation) of approximately 13% between the rigid pIOL and flexible pIOL was not sufficient to affect the patients' visual quality. Other optical and neural factors likely compensated for the difference, yielding similar visual acuity and contrast sensitivity values in the 2 groups 1 year after surgery.

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