# Extended Depth of Focus Intraocular Lenses in Cataract Surgery

### Katarakt Cerrahisinde Odak Derinliği Artırılmış Göz İçi Lensleri

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**ABS TRACT** Cataract surgery is becoming an increasingly common method for the treatment of presbyopia. In recent years, very successful visual results have been reported, especially with trifocal intraocular lenses (IOL). However, dysphotopsia and contrast sensitivity (CS) loss are the leading causes of dissatisfaction with these lenses. In addition, there are some absolute or relative contraindications for using these lenses in some comorbidities such as macular, corneal diseases and glaucoma. Recently, extended depth of focus (EDOF) lenses seem to be a promising solution against these problems. Unlike multifocal IOLs, EDOF lenses create a single, elongated focal point instead of multiple foci to enhance depth of focus (DoF). Since there will be no overlapping out-of-focus images, it can be considered that dysphotopsia problem are mostly avoided. Despite these advantages, EDOF lenses can also cause CS loss and insufficiency for near vision. In this article, the issues of EDOF classification, which have not yet been clarified, DoF enabling methods, especially spherical aberration (SA), differences between hybrid and pure EDOF lenses, mini-monovision (MMV) method applied with EDOF lenses to solve near vision and near spectacle dependence problems are discussed.

**Keywords:** Presbyopia correcting IOLs; EDOF IOLs; EDOF classification; non-diiffractive EDOF IOLs; spherical aberration; mini-mono vision; vision disorders; lenses

**ÖZET** Günümüzde katarakt cerrahisi presbiyopi tedavisinde giderek daha yaygın kullanılan bir yöntem haline gelmektedir. Son yıllarda özellikle trifokal göziçi lensleriyle (GİL) çok başarılı görsel sonuçlar bildirilmektedir. Buna karşın disfotopsi ve kontrast duyarlılık (KD) kaybı bu lenslerle görülen önde gelen tatminsizlik sebepleri olmaktadır. Ayrıca makula, kornea hastalıkları ve glokom gibi bazı eşlik eden durumlarda bu lenslerin kullanılmasının mutlak veya göreceli bazı kontrendikasyonları vardır. Son dönemde odak derinliği artırılmış (EDOF) lensler, bu sorunlar karşısında umut veren çözümler gibi görünmektedir. Çok odaklı lenslerden farklı olarak EDOF lensleri, çok sayıda odak yerine uzun tek bir odak yaratarak odak derinliğini (OD) artırmaktadırlar. Bu şekilde, üst üste gelen odak dışı imajlar olmayacağından, disfotopsi probleminden önemli oranda kurtulunabileceği düşünülebilir. Bu avantajlarına karşın EDOF lensleri de KD kaybına yol açabilmekte ve yakın görmede yetersizlik gösterebilmektedirler. Bu yazıda, henüz netleşmemiş olan EDOF klasifikasyonu, özellikle sferik aberasyon (SA) olmak üzere OD sağlayıcı yöntemler, hibrid ve pür EDOF lensler arası farklar, yakın görme ve yakındaki görme ve gözlük bağımsızlığı sorunları karşısında EDOF lensleri ile uygulanan mini-monovizyon (MMV) yöntemi konuları işlenmiştir.

**Anah tar Ke li me ler:** Presbiyopi düzeltici göz içi lensleri; EDOF lensleri; EDOF sınıflaması; non-difraktif EDOF lensleri; sferik aberrasyon; mini-mono vizyon; görme bozukluklari; lensler

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It is seen that the demand for presbyopia treatment is increasing with increased life<br>
tivities requiring near and intermediate vision such as using mobile phones and<br>
the produced to the produced by the produced by the pr expectancy and technological developments that led to the widespread daily accomputers, the need to see car panels while driving. For the presbyopia correction, monofocal lenses with monovision method, accommodative IOLs, bifocal and trifocal lenses with refractive and diffractive technologies have been used so far. All these designs, none of which is perfect, have advantages and disadvantages. Although the most widely used trifocal lenses provide high satisfaction to patients because they provide vision for all distances, their use can be problematic, especially in occupations where contrast sensitivity loss and photic phenomena are important as well as in the presence of concomitant eye diseases, mainly macular diseases.1,2 At this point, extended depth of focus (EDOF) lenses have emerged as a new option, especially against these limiting and unsatisfactory possibilities. At first glance, the definition of an EDOF lens seems simple and straightforward, such as increasing the length of the focus provided by a monofocal lens, but it varies greatly depending on how the focal length is increased, i.e., the physical mechanism used. For this reason, the classification of EDOF lenses can be confusing, with different nomenclature making them difficult to understand.

### UNDERSTANDINg EDOF AND CLASSIFICATION OF EDOF IOLs

One of the first classifications was based on EDOF formation mechanisms.3,4 1) Small Aperture, 2) Bioanalogical Design, 3) Diffractive Optics and 4) Non-Diffractive Optics (Spherical Aberration (SA) Based), but over time, this classification has become debatable whether the IOLs under the categories are true EDOFs or not. In 2017, the American Academy Ophthalmology Task Force published a consensus statement when a large number of lenses claiming to be EDOF appeared on the market in this way.5 According to the statement, the depth of focus (DoF) for an

EDOF IOLs should be at least 0.5 diopters greater than the DoF for a monofocal IOL at logMAR 0.2 (20/32). Additionally monocular distance corrected intermediate visual acuity (DCIVA) at 66 cm. should be superior to a monofocal lens and at least 0.2 logMAR and also best-corrected distance acuity should be non-inferior to monofocal control using a non-inferiority margin of 0.1 logMAR. To name a lens an EDOF IOL, the optical profile must be continuous, without a change in transition equally refractive or diffractive. Kanclerz et al.'s interpretation may be more revealing.6 According to this all the lenses that employ chromatic aberration (CA) or have a diffractive-hybrid profile, or an additional power to increase the near vision, with no pure continuous range of vision on the optical bench, are not pure EDOF IOLs. Thus, a pure EDOF concept emerged and hybrid EDOF concept was used for the first time by Kanclerz et al. Hybrid EDOFs are the combination with diffractive, refractive or both multifocal optical designs. Subsequently, the Alio group published a new classification, making the issue more detailed and more complicated (Table 1).<sup>7,8</sup>

Another nomenclature, before this, that creates confusion regarding terminology is "Enhanced monofocal". The same group is also referred to as "monofocal plus" or "mono-EDOF". This group is seen mostly in the last classification as type 5. According to the literature, this group broadly includes Tecnis Eyhance (Johnson & Johnson), IsoPure (Physiol), Xact (Santen), Zoe (Ophthalmo-Pro GmbH), RayOne EMV (Rayner), Lentis Quantum (Teleon Surgical), Evolux (Sifi), Vivinex Impress (Hoya), and Extend HP (Hanita Lenses).<sup>9</sup> Although this group of lenses was not previously considered EDOF because they did not meet one of the 4 elements of the ANSI criteria, they were



SA: Spherical Aberration, DoF: Depth of Focus, WF: Wavefront.

included as type 5 in Alio's classification and were accepted as an EDOF subgroup.<sup>10</sup> To my opinion, type 1, 2 and 5 subgroups can be referred as nondiffractive EDOF lenses.

According to another approach, non-diffractive IOLs separated as 1) Refractive EDOFs: [Mini-Well (SIFI), Vivity (Alcon), LuxSmart (Bausch&Lomb), Lentis Comfort (Teleon)] and 2) Refractive Enhanced Monofocals: [Eyhance ICB00 (Johnson & Johnson), IsoPure (Physiol), AE2UV/ZOE (Eyebright Medical), RayOne EMV (Rayner)].

As can be seen, the differences and diversity in lens manufacturing technologies do not make a clear distinction possible.

#### TRIFOCAL/EDOF IOLs COMPARISON

As it is known, the trifocal lenses are formed by at least 2 superimposing kinoforms, (which are diffractive optical elements) and the light is split in different orders by phase delay. Since some of the foci that occur very close to the eye, about 4%, cannot be seen by the human eye, which is called light loss. This ultimately affects the quality of vision and contrast sensitivity. In addition, these lenses have diffractive rings, and accordingly they cause night vision problems, which is known as dysphotopsia. In conclusion, we can say that dysphotopsia is the first and foremost problem of these lenses and the second major problem following dysphotopsia is the loss of contrast sensitivity (CS).

In contrast, EDOF lenses create a single, elongated focal point instead of multiple focal points, which increases the DoF. This is a continuous focus, they avoid secondary out-of-focus images, which are the main cause of haloglare type of dysphotopsia. Since the images of multiple overlapping foci will not be there, theoretically halo-glare type dysphotopsia problem can be expected to disappear or decrease significantly.

#### HOW IMPORTANT IS DYSPHOTOPSY AND CONTRAST SENSITIVITY LOSS?

Positive dysphotopsias (PD) are known as glare, light streaks, starbursts, light arcs, rings, haloes, or flashes of light. PDs are believed to be related directly to IOL material and design.11 Negative dysphotopsias (ND) are manifested like a temporal scotoma as an arc-shaped shadow. Although the incidence of PD and ND in the early period following MIOL surgery are reported to be 67% and 26%, these figures decrease to 2.2% and 0.13-3% after one-year respectively.12

Dysphotopsia or photic phenomena has been identified as the second most important cause of dissatisfaction with 38-42%, following blurred vision, after multifocal IOL (MIOL) surgery.13,14 Dysphotopsias have also been reported as the second cause of IOL exchange reason after contrast sensitivity loss with 34%.15 As can be seen, dysphotopsia is the main problem with MIOL or trifocal lenses today.

There are many publications in the literature confirming this problem. For example, a 2016 Cochrane database shows that while halo-glare occurs between 0-13% with monofocal lenses, the incidence increases to 12-76% with MIOLs.<sup>16</sup> It also reports that this is more pronounced in low light conditions. According to another meta-analysis of two hundred and three articles, night vision problems are significantly increased with MIOLs, and disabling halo and glare are reported in 0-10%.17 That different results have also been reported were seen with this meta-analysis on CS, while 1/3 of the publications finding no difference comparing with monofocal lenses, 2/3 studies reported a significant decrease with MIOLs, especially in the highest  $SFs$ <sup>17</sup>

#### HYBRID / PURE (NON-DIFFRACTIVE) EDOF IOL **COMPARISON**

According to the published American Academy Ophthalmology Task Force consensus, to say EDOF optical profile of the lenses must be continuous, without a change in transition equally refractive or diffractive.<sup>5</sup> However, it is seen that the first early group best-known accepted as EDOF IOLs are mostly hybrid designs containing diffractive rings, where DoF increase is also provided by SA contribution (Alio's classification type 4).<sup>7,8</sup> The best-known pioneer of these lenses was the Tecnis Symfony (J&J) IOL. Most of the published EDOF IOL comparisons with trifocal lenses have been made with this hybrid EDOF lens. For example, when we look at a published meta-analysis comparing Trifocal and EDOF IOLs, we interestingly see that trifocal IOLs such as Panoptix, ATLisa Tri and FineVision are only compared with Tecnis Symfony as EDOF lenses.<sup>18</sup> In summary, this comprehensive study by Guo et al. concluded that while there was no difference between the two groups in terms of distance vision, EDOF lenses provided better vision at intermediate distance and trifocals at near vision, and there was no significant difference in terms of CS, aberrations, and visual disturbances. In almost all studies subject to this meta-analysis, no difference was found between trifocal and Tecnis Symfony groups in terms of halo and glare. According to Webers et al. disabling glare

was seen 8% with trifocals, 7% with EDOF (Tecnis Symfony) lenses and disabling halo was found 39% and 21%, respectively.19 If we summarize the literature data above, Tecnis Symfony type hybrid EDOF lenses do not provide an advantage over trifocals for the main two problems, dysphotopsia and CS. In addition, they are even more disadvantageous for near vision. Perhaps the only advantage they offer over trifocals is slightly better vision at intermediate distances. Therefore, it would be more accurate to compare trifocal IOLs with the type 1, 2 and 5 groups (in Alio's classification) to understand whether nondiffractive or pure EDOF lenses provide an advantage or not.

Table 2 shows the general characteristics of the lenses belonging to these groups. The MiniWell IOL in Type 1 (although not FDA approved) and the Vivity (Alcon), Tecnis Eyhance (J&J) and RayOne EMV (Rayner) lenses in Type 5 are also FDA approved lenses that should be considered in comparisons.

The Type 2 group, considered pure EDOF, includes pinhole lenses. The most important example is the IC-8 (AcuFocus) lens. Although bilateral application was seen in studies, most of the applications were performed unilaterally in the non-dominant eye. In addition, the disadvantages of this group of lenses such as being inserted through a 3.5 mm corneal incision, creating visual disturbances such as halo in mesopic cases especially in patients with large pupils. Causing DoF decrease due to small optical diameter are also negatively important.20

In a multiple comparison study, AcrySof IQ Vivity (Non-diffractive EDOF/Refractive EDOF), AT LARA 829 (Multifocal), TECNIS Symfony ZXR00 (Hybrid EDOF) and AcrySof IQ SN60WF (Monofocal) IOL were compared.<sup>21</sup> While there was no statistical difference between the groups in terms of corrected and uncorrected visual acuity, halo, glare and starburst rates appeared very close to the monofocal group with non-diffractive EDOF Vivity IOL and caused significantly less visual disturbances than Hybrid EDOF lenses.

In a study by Hovenesian et al. consisting of Alcon Panoptix (Trifocal), Alcon Vivity (non-diffractive EDOF/Refractive EDOF), Blended technique with Alcon Restor 2.5 and 3 (Bifocal) and Monovision (MV) with Alcon Restor 2.5 (Bifocal) groups, no or very little response in halo-glare evaluation was the



lowest with 85% in Vivity, while Panoptix group reported 69%, Blended group 71% and MV group 75%.22 All differences were statistically significant ( $p<0.03$ ). In the same study, when looking at independence from spectacles issue, an opposite result was seen while the answer "I never wear glasses" was 83% in Panoptix group, this dropped to 33% in the Vivity group. The difference was very significant  $(p<0.0001)$ . When the patients in the Vivity group were asked in which situations they felt the need for glasses, 65% answered reading, 10% computer, 2% watching TV, 0% driving and sportive activities. The conclusion from this study is that non-refractive EDOF lenses seem to largely solve the halo-glare type dysphotopsia problems of trifocal lenses, but they are not as successful as trifocal IOLs for near vision. To solve this remaining problem, recently mini-monovision (MMV) approach has been recommended.

The amount of CS loss with non-diffractive EDOF lenses is also important. Table 3 shows that the CS loss is much less with pure EDOF lenses than with Trifocal and Hybrid EDOF lenses and even results are comparable with normal values. Especially at mostly affected high spatial frequencies, which corresponds to close up details and reading, it is seen that the differences in favor of pure EDOFs are becoming more prominent.

#### MINI-MONOVISION APPROACH WITH NON-DIFFRACTIVE EDOF IOLs

While non-diffractive EDOF lenses provide highly adequate visual results at far and intermediate distances, an important recent proposed solution for the limited response in near vision is the application of "mini-monovision" (MMV). Which aims to achieve emmetropia for the dominant eye and a myopic result around -0.25/-0.75 D. for the non-dominant eye.

The study by Park et al. shows a comparison of the Eyhance lens used for emmetropia in one group and MMV in the other.<sup>26</sup> The target for non-dominant eyes in the MMV group was -0.75 D. Postoperatively the emmetropia group had a mean postoperative SE of -0.18 D, whereas the MMV group had a mean postoperative SE of -0.19 D in the dominant eye and -0.95 D in the non-dominant eye. While there was no difference in visual acuity (VA) between the groups at distance and intermediate distance, binocular uncorrected near visual acuity (UCNVA) was found 0.33±0.13 in the near emmetropia group and 0.06±0.06 (logMAR) in the MMV group. Difference was significant ( $p<0.01$ ). This improvement in near vision is also seen significantly in the defocus curve from -1.50D. There was no difference between the groups in terms of CS and dysphotopsia was reflected in the subjective test results as halo 8%, glare and starburst 0% in both groups. Spectacle dependence was 0% at distance and 4% at intermediate distance in both groups, while at near distance it decreased from 80% in the emmetropia group to 20% in the MMV group. This study shows that when adequate myopic results are obtained in the non-dominant eye, the near vision deficiency problem of EDOF lenses is largely solved with the MMV approach.

Table 4 provides information about other studies using the MMV method.

In the study by Ganesh et al, that the targeted myopic result of -0.75 D. was achieved in non-dominant eyes was seen and we can see the positive effect of this especially in binocular near vision. However, due to the used hybrid EDOF (Tecnis Symfony) IOL, high dysphotopsia rates ae seen.

In the second study by van Amelsfort et al. MMV with a non-diffractive EDOF lens (Vivity), the result of the non-dominant eye was only -0.25 D.<sup>28</sup> Therefore, the improvement in near vision was limited and near spectacle independence was achieved only by 38%. However, with the use of a non-diffractive EDOF lens, dysphotopsia was almost negligible. An important lesson to be learned from





this study is that the addition of -0.25 D. to the non-dominant eye may be insufficient, and it can be recommended to perform MMV with the addition of at least -0.50 D. or - 0.75 D. to the non-dominant eye.

The third study is seen in Table 4, by Mastropasqua et al., was based on the MMV application enabled by lens design.29 Although emmetropia is planned in both eyes, the mini-well proxa lens with enhanced near effect is used in the non-dominant eye. With this application called Well-Fusion, it is seen that the problem of inadequacy in near vision is eliminated, but there is no numerical evaluation in the study, although positive information is given about how much spectacle independence is achieved and the rate of dysphotopsia.

The Alcon Vivity lens, which has recently been defined as a refractive EDOF, has also been reported to have a diffractive element due to its central shaping of 2.2 mm after invitro optical analyses (NIMO analysis).<sup>30</sup> Surprisingly, this new information necessitated a different placement for the Vivity lens in the classification. Therefore, comparison of Vivity with non-diffractive monofocal enhanced lenses becomes important to understand the clinical differences. A study comparing Vivity and RayOne EMV lenses with MMV approach was presented by the Findl group at the 41st ESCRS Congress in 2023.31 This study was carried out with 48 patients, as emmetropia for dominant eye and -0.50 D. for non-dominant eye targeted. While spherical equivalent (SE) values for non-dominant eyes were found as -0.37 D. in RayOne EMV group, -0.51 D. in Vivity group. There was no difference between the groups in terms of distance and intermediate vision, but a significant difference was reported in favor of Vivity in uncorrected binocular near vision. (0.30 and 0.20 logMAR, respectively, p=0.003). However, it was also noted that this may be due to the higher non-dominant eye myopic SE in the Vivity group. However, when looking at photopic and mesopic contrast sensitivity, much better results were seen with RayOne EMV. In the comparison made with the halometer, it was determined that the halo size was higher in the Vivity group. In conclusion, if MMV is performed with a slightly higher myopic addition to the nondominant eye, e.g. -0.70 D., better results can be obtained with Ray-One EMV.<sup>31</sup>

In my ongoing study I conducted with Ray-One EMV, in 24 eyes of 12 patients, at least mean 6 months follow-up, the mean UCNA was 0.0177 logMAR in dominant eyes and 0.0087 log-MAR in non-dominant eyes, with a target of emmetropia for the dominant eyes and -0.70 D. for the non-dominant eyes. Spectacle independence was 88.8% and reported dysphotopsia was zero. The NEI VFQ- 25 questionnaire yielded a score of 94.37±3.61 out of 100. Therefore, I found very satisfactory and successful first results of MMV approach with RayOne EMW.

#### WHICH SPHERICAL ABERRATION?

The most common method used to increase the DoF is to use spherical aberration (SA). As is well known, aberrations are also factors that reduce visual acuity and quality. In short, how much and which type should be used, positive SA or negative SA? The answer to the question is sought. It was reported in 2002 that higher order aberrations (HOA) help to increase DoF while at the same time decreasing the modulation transfer function (MTF) at high spatial frequencies.<sup>32</sup> In this regard, there have been many studies in the literature, especially on the determination of the widest DoF with various SA combinations created in front of the human eye with the help of adaptive optics, and on the other hand, finding the optimal values by determining the point from which people start to see unacceptably blurred (objectionable blur).<sup>33</sup> First of all, if we look at the increase in DoF with the addition of SA, the DoF increases by 30% with the addition of 0.3 μm primary SA (SA4) in the Zernike polynomial, while the increase is 45-62% when this value is increased to 0.6  $\mu$ m.<sup>34,35</sup> Later, the effect of primary (SA4) and secondary SA (SA6) combinations was investigated, and it was reported that this combination did not provide an increase when they were with the same sign, but significant increases in DoF were seen when they were combined with opposite signs.<sup>34,36,37</sup>

And that there is always some kind of trade-off between vision acuity and DoF is known. Yi et al., also reported that the mean DoF for objectionable blur in a human with normal HOAs was  $2.59\pm0.52$  D.<sup>36</sup> This was previously reported by Atchison as 1.77 D and 1.62 D and by Benard as 1.67 D.<sup>33,34</sup> When the total wavefront RMS was kept at a level less than 0.45 μm, the combined wavefront of Z04 and Z06 with opposite signs extended the DOF, on average, by 2.52 D/μm, compared to 3.31 D/μm reported y Benard et al.<sup>34</sup> While the combined wavefront of SA4 and SA6 reduced the VA at a rate of 0.40 logMAR/μm. For the loss of every 0.1 logMAR VA, there was an increase of 0.40 D in DOF, compared to 0.27 and 0.24 D/0.1 logMAR for SA4 and SA6 alone.

The focal center shifting with SA effect is also important, especially for presbyopia correction. With 0.6 μm SA4 (positive or negative) this change reaches up to 2.9 D/μm. with 0.6 μm SA6 it is about -3.5 D/μm. The combination of Sa4 and SA6 at different signatures increases this value even further.36

In the study of Bakaraju et al. it was reported that when SA between -0.20 and +0.20 μm were tested in model eyes, there was no difference found between negative and positive SA in terms of DoF increase.38 But since the focal center shift was in the myopic direction with -SA and in the hypermetropic direction with +SA, at medium and high spatial frequencies, which are typical of reading and near tasks, that -SA may give better results were said.

As for which SA is clinically better, the study by Schmidt et al. is very revealing.<sup>39</sup> Four lenses, defined as Type 5 in Alio's classification and enhanced monofocal in another nomenclature, were analyzed with the Shack-Hartmann sensor. Each lens was measured up to Zernike 10th Order. According to the data obtained, the SAs used and the root mean square (RMS) and peak to valley (PV) results are shown in the Table 5 below.

It is seen that SA 4-0 (=  $Z04$ ) and SA 6-0 (=  $Z06$ ) are used with different signs in all 4 lenses, thus maximizing the DoF increase in accordance with the previous information. RayOne EMV is the only IOL in this group that has positive SA predominantly. Since it does not have a problem to neutralize the corneal  $+$  SA, RayOne EMV is the one that uses smallest amount of SA and as a result, this decreases the total aberration of the IOL in other words total RMS value. Which means lower CS loss and better quality of vision. Whereas, if you create EDOF with negative SA, you must first add a negative SA large enough to neutralize the positive SA of the cornea and then add negative SA over it to extend DoF. It is seen that the total aberration value increases as the negative SA increases. Peak to valley (PV) is the measurement of the height difference between the highest point and the lowest point on the surface of the optic. Fitted PV value was also found smallest with RayOne EMV. In another study conducted by the same group with these 4 lenses, RayOne EMV was found to be the most resistant IOL among the 4 lenses to decentralization and tilt.40 According to the study, tilt and decentralization affect the Eyehance IOL the most. Despite all these, it is more reasonable to prefer negative SA lenses in oblate corneas that have undergone corneal myopic laser surgery.

#### **CONCLUSION**

EDOF lenses, except hybrid ones, have mainly four advantages over MIOLs. 1. Decreased photic phenomenon 2. Better uncorrected intermediate distance visual acuity 3. Less contrast sensitivity loss 4. Less susceptible to minor postoperative refractive errors. These advantages will make presbyopia corrective treatment possible for patients who have with absolute or relative contraindications to MIOLs including recalcitrant ocular surface diseases, high corneal astigmatism, irregular corneal astigmatism, other corneal diseases (Fuch's dystrophy), pseudoexfoliation, glaucoma, macular pathologies (epiretinal membranes) and age-related macular degeneration. Mild or moderate forms of these diseases seem to allow cataract surgery with EDOF lenses.

Our knowledge so far suggests that pure or non-diffractive EDOF lenses substantially solve the dysphotopsia problem seen with trifocal and hybrid EDOF lenses. However, in the face of the satisfactory near vision problem, the MMV is seen as the most valid solution method for today.



SA: Spherical Aberration, PV: Peak-to-Valley, RMS: Root Mean Square, Values more than 0.2 λ are highlighted.

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