

**The TECNIS® Multifocal 1-Piece IOLs,  
Models ZKB00, ZLB00 and ZMB00  
Patient Information Brochure**

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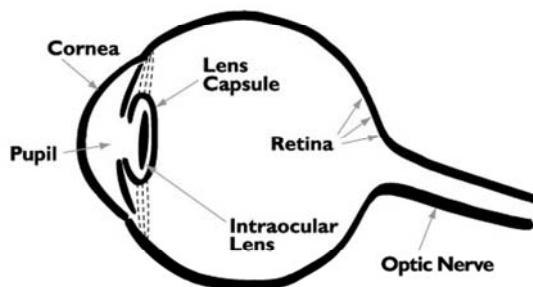
## Introduction

If you have a cataract, don't worry. You're not alone. Every year, nearly 2,500,000 Americans have cataract surgery. It is one of today's safest and most successful procedures. This brochure is designed to help you and your eye doctor decide on the best type of treatment choice for you. If you have questions about cataract surgery or any of the information in this brochure, please ask your eye doctor.

## What is a cataract?

Inside your eye is a natural lens that helps focus light. The lens creates images in the back of your eye (called the retina) like a camera focuses images on film (**Figure 1**). As people age, the lens can become less clear, even cloudy. This cloudiness in the lens is called a cataract. Just as a dirty camera lens can spoil a picture, a cataract can prevent light from focusing clearly inside the eye. Typical signs of cataracts are blurred vision and sensitivity to light. For example, you may have trouble reading, or driving at night or at dusk. Colors may seem less vivid and it may be difficult to thread a needle, shave or put on makeup.

**Figure 1: Diagram of eye with intraocular lens implant**



## What to expect before cataract surgery

The most common treatment today is to remove the clouded natural lens and replace it with an artificial lens. The artificial lens is called an ***intraocular lens***, or "IOL". **Figure 2** compares the size of a TECNIS® Multifocal 1-Piece IOL to a U.S. penny.

**Figure 2: Size comparison of TECNIS® Multifocal 1-Piece IOLs and U.S. penny**



When you and your eye doctor agree to proceed with your cataract surgery, you will have an evaluation before surgery. This includes checking for any eye diseases and

measuring your eye to select the correct lens power. Be sure to tell your eye doctor if you have any health conditions that may affect your surgery or vision and provide an updated list of medications to your doctor.

### **What to expect during cataract surgery**

Cataract surgery is usually done as an outpatient procedure. You will be given anesthesia in the form of eye drops to numb your eye. Typically, you will be fully awake during the surgery but you will be comfortable and should feel little or no discomfort. To remove the cataract, your surgeon will first make a tiny incision in your eye. Then, a very small probe will be inserted so the cataract can be broken into little pieces. Next, the probe will be used to vacuum out the cataract pieces. Now there will be room for the intraocular lens (IOL) to be placed in your eye. The surgeon will insert the IOL through the same tiny incision. When the surgery is complete, your eye doctor may place a protective patch or shield over your eye. Right after surgery, you should remain in the recovery area for a short time. You should make plans to have someone else drive you home.

### **What to expect after cataract surgery**

After your operation, your eye doctor should give you an identification card to keep in your wallet. This card shows the type of implant in your eye. You should present this card to any eye doctor who examines your eyes after your surgery.

You will be given a date and time for a follow-up appointment with your eye doctor. Typically, your eye doctor will examine you the following day. Your doctor will examine you several more times following your surgery. Many patients may begin to see better within 1 to 2 days, more are stable at 10 to 14 days. Some may take 4 to 6 weeks to recover from surgery. Improvements in vision are different for each individual.

Your doctor may prescribe eye drops and/or medicines after surgery. Take all prescribed medicines and apply antibiotic eye drops as instructed by your eye doctor. Be sure to speak with your eye doctor if you have any questions or concerns as a result of your cataract surgery.

### **Choosing the implant best for your vision**

Your eye doctor has a choice of IOLs that may be used to improve your vision. You may want to discuss with your eye doctor whether a monofocal IOL, multifocal IOL, or other IOL is best for you. There are also alternatives for restoring useful vision after the operation, including glasses with thick lenses and contact lenses. You should discuss the potential risks and benefits of your treatment options with your eye doctor.

#### **Monofocal IOLs from Abbott Medical Optics Inc. (AMO)**

AMO's monofocal IOLs are designed to restore far vision. This type of IOL can give you excellent vision at one distance, usually far. This means that you should see well when you go to a ball game or read distant signs; but you will probably need glasses for tasks requiring near vision, like reading a book or doing crafts.

#### **The TECNIS® Multifocal 1-Piece IOLs**

The TECNIS® Multifocal 1-Piece IOLs are made of the same materials and overall design as the TECNIS® monofocal IOLs. The TECNIS® Multifocal 1-Piece IOLs will give you good far vision. They can also give you good near and intermediate vision (at

approximately 2-5 feet). For example, if you play golf, you may be able to see where your drive lands, sink your putt, and write down the score – without wearing glasses. Or when shopping, you may be able to read the aisle signs and the package labels, and count your change, all without glasses. Overall, you may not need to wear your glasses for daily tasks.

There are currently three different TECNIS® Multifocal 1-Piece IOLs available, Models ZKB00, ZLB00 and ZMB00. All three models are designed to provide better near vision and similar far vision to that of a standard monofocal IOL. However, each model has a different reading power. This can be explained in terms of store-bought reading glasses (“readers”) that are usually designated by power, such as +2.00 or +2.50. Model ZKB00 is designed to provide near vision like that with a pair of +2.00 readers, Model ZLB00 is designed to provide near vision like that with a pair of +2.50 readers and Model ZMB00 is designed to provide near vision like that with a pair of +3.00 readers. The three models give you an option in choosing a multifocal IOL depending on your lifestyle. Talk to your eye doctor to determine which IOL option is right for you.

The table below compares expected differences between the three TECNIS® Multifocal 1-Piece IOL Models, ZKB00, ZLB00 and ZMB00 and includes a comparison to familiar readers.

**Table 1:**  
**Comparison of Expected Near Vision Differences between the Three TECNIS®**  
**Multifocal 1-Piece IOL Models**

| Lens Model                              | Approximate Reading Distance | “Readers” Comparison |
|---|------------------------------|----------------------|
| Monofocal IOLs                          | None                         | None                 |
| TECNIS Multifocal Model ZKB00 (+2.75 D) | 50 cm (20 inches)            | +2.00                |
| TECNIS Multifocal Model ZLB00 (+3.25 D) | 42 cm (16 inches)            | +2.50                |
| TECNIS Multifocal Model ZMB00 (+4.00 D) | 33 cm (13 inches)            | +3.00                |

## Risks

No matter what lens you choose, there are risks or problems that can happen with cataract surgery. The problems could be minor, temporary, or affect your vision permanently. Complications are rare and may include the worsening of your vision, bleeding, or infection. There are also tradeoffs with receiving a multifocal lens. Whereas your use of glasses may decrease, it may come at the cost of some sharpness of your vision. Even with glasses, this loss of sharpness may become worse under poor visibility conditions such as dim light or fog. You may also notice more halos (rings of light around a light source) or glare (scattered light effect around a light source), which are more common with multifocal IOLs than monofocal IOLs. Call your eye doctor right away if you

experience any itching, pain, flashing lights, “floaters”, redness, severe headache, nausea/vomiting, light sensitivity, or watery eyes after surgery.

## **Warnings**

1. A very small number of patients (less than 1% in U.S. clinical studies) may be dissatisfied and request removal of their multifocal IOL.
2. Under poor visibility conditions, your vision may be reduced more than it would be with a monofocal IOL. Under these conditions, you may have more difficulty recognizing some traffic signs and hard-to-see objects in the road. Therefore, you may need to take extra care when driving, especially in poor light conditions.
3. In rare instances, multifocal IOLs may make some types of retinal surgery more difficult.
4. You should not receive this device if you have had previous trauma to your eye.
5. Children under the age of 2 should not receive this device.

## **Precautions**

1. If your eye is not healthy (including glaucoma), your vision may not be good even after your cataract is removed. In this case, you may not get the full benefit of the multifocal IOL. Before surgery, your eye doctor will check to see if you have any eye diseases.
2. There is a chance that your vision with a multifocal IOL may not be good enough to perform very near or detailed “up-close” work without glasses. Depending on the type of TECNIS® Multifocal 1-Piece IOL you choose, the lens is designed for near vision from 13 to 20 inches
3. Take all prescribed medicines and apply eye drops as instructed.
4. You should avoid any activity that could harm your eye while you are recovering from surgery. Your eye doctor will tell you what activities you should avoid.
5. If you wear contact lenses, your eye doctor may ask you to stop wearing them before being tested for the multifocal IOL.

## **Making the right choice**

AMO’s monofocal IOLs and TECNIS® Multifocal 1-Piece IOLs have been well-studied. Both are used to replace the natural lens of the eye. AMO’s monofocal IOLs are primarily intended to provide far vision and you will most likely require glasses for near vision. The TECNIS® Multifocal 1-Piece IOLs are designed to provide far and near vision at the same time so that the need for glasses is minimized.

**Table 2** will help you compare the Monofocal IOL and the TECNIS® Multifocal 1-Piece IOLs.

**Table 2:**  
**Expected IOL Performance for Patients**

|  | <b>TECNIS® MULTIFOCAL IOL,<br/>MODELS ZKB00, ZLB00 AND ZMB00</b>  | <b>MONOFOCAL IOL</b>   |
|--|---|--|
| <b>Far Vision</b>                                    | The clinical studies proved the TECNIS® Multifocal 1-Piece IOLs provided far vision comparable to the monofocal IOL.  | A monofocal IOL is designed to provide far vision  |
| <b>Near Vision</b>                                   | The TECNIS® Multifocal 1-Piece IOLs are designed to provide near vision at different near working distances.  | A monofocal IOL is not designed to provide near vision.  |
| <b>Visual Effects (i.e. halos, starburst, glare)</b> | <p>Visual effects may occur especially under nighttime or low-light conditions. Such visual effects are likely to be less for the TECNIS® Multifocal 1-Piece IOLs with lower near reading powers.</p> <p>These visual effects may affect your ability to drive a car under certain environmental conditions, such as driving at night or in poor visibility conditions.</p> | These visual effects may also occur with monofocal lenses as well; however, the reported incidence of these visual effects is lower with monofocal IOLs. |
| <b>Use of Glasses</b>                                | <p>You may be better able to function without glasses or contact lenses for many daily tasks.</p> <p>The clinical studies proved that patients were able to wear glasses less often for near vision if they received the multifocal lens.</p>   | You will likely need prescription glasses, contact lenses, or reading glasses for many near vision tasks.  |
| <b>Low Contrast Vision (driving) 4-6 months</b>      | You may have more difficulty distinguishing road signs and hazards as quickly under low-light conditions (see Table 4).   | Under poor visibility conditions, your vision may not be as sharp as in good light.  |

**Table 3** presents some of the clinical study results for the TECNIS® Multifocal 1-Piece IOL Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D) 6 months after surgery. At 6 months, there were 143 patients who had received the TECNIS® Multifocal 1-Piece IOL Model ZKB00, 150 patients who had received the Model ZLB00. There were also 146 patients who had received the monofocal IOL.

**Table 3:**  
**U.S. Clinical Study Results for the TECNIS® Multifocal 1-Piece IOL, Models ZKB00, ZLB00 and the Monofocal Comparison IOL 6 Months after Surgery (Binocular Results)**

|  | <b>TECNIS® MULTIFOCAL IOL, MODEL ZKB00 (+2.75 D) (143 patients)</b> | <b>TECNIS® MULTIFOCAL IOL, MODEL ZLB00 (+3.25 D) (150 patients)</b> | <b>MONOFOCAL IOL (146 patients)</b>                 |
|--|---|---|---|
| <b>Far Vision: 20/40 or better without glasses</b> | 99% of patients had good far vision without glasses                 | 99% of patients had good far vision without glasses                 | 99% of patients had good far vision without glasses |

|  | <b>TECNIS® MULTIFOCAL IOL, MODEL ZKB00 (+2.75 D) (143 patients)</b>  | <b>TECNIS® MULTIFOCAL IOL, MODEL ZLB00 (+3.25 D) (150 patients)</b>  | <b>MONOFOCAL IOL (146 patients)</b>  |
|--|--|--|--|
| <b>Far Vision:<br/>20/40 or better with glasses</b>                          | 100% of patients had good far vision with glasses  | 100% of patients had good far vision with glasses  | 100% of patients had good far vision with glasses.   |
| <b>Near Vision:<br/>20/40 or better without glasses</b>                      | 95% of patients had good near vision without glasses   | 99% of patients had good near vision without glasses   | 34% had good near vision without glasses   |
| <b>Near Vision:<br/>20/40 or better with glasses designed for far vision</b> | 97% of patients had good near vision when wearing glasses designed for far vision  | 97% of patients had good near vision when wearing glasses designed for far vision  | 23% of patients had good near vision when wearing glasses designed for far vision  |
| <b>Combined far and near vision: 20/32 or better without glasses</b>         | 76% of patients had good far and near vision without glasses   | 90% of patients had good far and near vision without glasses   | 7% of patients had good far and near vision without glasses  |
| <b>Use of glasses</b>  | Percentage of patients reported using glasses:<br>Always 1%<br>Sometimes 38%<br>Never 61%  | Percentage of patients reported using glasses:<br>Always 1%<br>Sometimes 24%<br>Never 75%  | Percentage of patients reported using glasses:<br>Always 11%<br>Sometimes 87%<br>Never 2%  |
| <b>Use of glasses for far vision</b>   | Percentage of patients reported using glasses to see far:<br>None of the time 98%<br>Part of the time 1%<br>All of the time 1%       | Percentage of patients reported using glasses to see far:<br>None of the time 98%<br>Part of the time 1%<br>All of the time 1%       | Percentage of patients reported using glasses to see far:<br>None of the time 90%<br>Part of the time 4%<br>All of the time 6%       |
| <b>Use of glasses for near vision</b>  | Percentage of patients reported using glasses for near vision:<br>None of the time 62%<br>Part of the time 34%<br>All of the time 4% | Percentage of patients reported using glasses for near vision:<br>None of the time 77%<br>Part of the time 19%<br>All of the time 4% | Percentage of patients reported using glasses for near vision:<br>None of the time 3%<br>Part of the time 63%<br>All of the time 34% |

|  | <b>TECNIS® MULTIFOCAL IOL, MODEL ZKB00 (+2.75 D) (143 patients)</b>                                   | <b>TECNIS® MULTIFOCAL IOL, MODEL ZLB00 (+3.25 D) (150 patients)</b>                                   | <b>MONOFOCAL IOL (146 patients)</b>   |
|--|---|---|---|
| <b>Ability to function at near distances without glasses</b>   | 81% of patients said they were able to function comfortably at near distances without glasses         | 86% of patients said they were able to function comfortably at near distances without glasses         | 33% of patients said they were able to function comfortably at near distances without glasses         |
| <b>Ability to function at intermediate distance (2-5 feet) without glasses</b>   | 98% of patients said they were able to function comfortably at intermediate distances without glasses | 97% of patients said they were able to function comfortably at intermediate distances without glasses | 94% of patients said they were able to function comfortably at intermediate distances without glasses |
| <b>Quality of overall vision (ability to function at distance and near) without glasses, according to a patient survey</b> | 9.1<br>(On a scale of 0-10 with 10 being the best)  | 9.0<br>(On a scale of 0-10 with 10 being the best)  | 8.3<br>(On a scale of 0-10 with 10 being the best)  |
| <b>Quality of near vision indoors with dim lighting</b>  | 64% of patients said they had good near vision indoors with dim lighting                              | 63% of patients said they had good near vision indoors with dim lighting                              | 75% of patients said they had good near vision indoors with dim lighting                              |

|                       | <b>TECNIS® MULTIFOCAL IOL, MODEL ZKB00 (+2.75 D) (143 patients)</b>  | <b>TECNIS® MULTIFOCAL IOL, MODEL ZLB00 (+3.25 D) (150 patients)</b>  | <b>MONOFOCAL IOL (146 patients)</b>   |
|-----------------------|--|--|---|
| <b>Visual effects</b> | <p>More difficulty with night vision, halos and glare are expected with the multifocal IOL than with a monofocal IOL. At 6 months, most cases were “mild” to “moderate”; however, some were “severe” for halos (1%). In a survey where patients were asked specifically about visual symptoms, patients reported severe difficulty with halos (6%), glare (1%), and night vision (1%) at 6 months.</p> <p>77% of patients said they had little to no trouble with glare while driving toward the sun.</p> <p>74% of patients said they had little to no trouble with glare while driving toward oncoming headlights.</p> <p>Some patients also reported to their doctors that they experienced blurred vision or had difficulty with vision; mostly at near distances (12%).</p> | <p>More difficulty with night vision, halos and glare are expected with the multifocal IOL than with a monofocal IOL. At 6 months, most cases were “mild” to “moderate”; however, some were “severe” for halos (4%), night glare (2%), and starbursts (1%). In a survey where patients were asked specifically about visual symptoms, patients reported severe difficulty with halos (11%), glare (5%), and night vision (3%) at 6 months. In one case (&lt;1%), a patient requested to have the multifocal lens removed due to difficulty with halos/ glare.</p> <p>76% of patients said they had little to no trouble with glare while driving toward the sun.</p> <p>71% of patients said they had little to no trouble with glare while driving toward oncoming headlights.</p> <p>Some patients also reported to their doctors that they experienced blurred vision or had difficulty with vision; mostly at near distances (9%).</p> | <p>At 6 months, some patients reported to their doctors that they experienced halos and glare particularly at nighttime; however, most cases were “mild” to “moderate” with none (0%) being “severe.” In a survey, some patients reported difficulty with severe halos (2%), glare (7%), and night vision (4%) at 6 months.</p> <p>77% of patients said they had little to no trouble with glare while driving toward the sun.</p> <p>81% of patients said they had little to no trouble with glare while driving toward oncoming headlights.</p> <p>Some patients also reported to their doctors that they experienced blurred vision or difficulty with vision mostly at near distances when not using reading glasses (23%).</p> |

|   | <b>TECNIS® MULTIFOCAL IOL, MODEL ZKB00 (+2.75 D) (143 patients)</b>  | <b>TECNIS® MULTIFOCAL IOL, MODEL ZLB00 (+3.25 D) (150 patients)</b>  | <b>MONOFOCAL IOL (146 patients)</b>  |
|---|--|--|--|
| <b>Patient satisfaction with the lens</b> | In a survey, patients were asked if they would choose to have the same lens implanted, if they were given a choice. At 6 months, most patients (97%) said they would choose this multifocal again. | In a survey, patients were asked if they would choose to have the same lens implanted, if they were given a choice. At 6 months, most patients (94%) said they would choose this multifocal again. | In a survey, patients were asked if they would choose to have the same lens implanted, if they were given a choice. At 6 months, most patients (88%) said they would choose this monofocal lens again. |

**Table 4** presents some of the clinical study results for the TECNIS® Multifocal IOL (currently marketed as ZMB00) one year after surgery. At one year, there were 331 patients who had received the TECNIS® Multifocal IOL with a +4.00 D reading power. There were also 116 patients who had received the Monofocal IOL.

**Table 4:  
U.S. Clinical Study Results for the TECNIS® Multifocal 1-Piece IOL, and the Monofocal Comparison IOL 1 Year after Surgery (Binocular Results)**

|  | <b>TECNIS® MULTIFOCAL IOL (+4.00 D) (331 patients)</b>  | <b>MONOFOCAL IOL (116 patients)</b>   |
|--|---|---|
| <b>Far Vision:<br/>20/40 or better without glasses</b>                       | 99% of patients had good far vision without glasses   | 99% of patients had good far vision without glasses   |
| <b>Far Vision:<br/>20/40 or better with glasses</b>                          | 100% of patients had good far vision with glasses   | 100% of patients had good far vision with glasses.  |
| <b>Near Vision:<br/>20/40 or better without glasses</b>                      | 99% of patients had good near vision without glasses  | 39% had good near vision without glasses  |
| <b>Near Vision:<br/>20/40 or better with glasses designed for far vision</b> | 98% of patients had good near vision when wearing glasses designed for far vision             | 19% of patients had good near vision when wearing glasses designed for far vision             |
| <b>Combined far and near vision:<br/>20/40 or better without glasses</b>     | 98% of patients had good far and near vision without glasses                                  | 21% of patients had good far and near vision without glasses                                  |
| <b>Use of glasses</b>  | Percentage of patients reported using glasses:<br><br>Always 1%<br>Sometimes 13%<br>Never 86% | Percentage of patients reported using glasses:<br><br>Always 11%<br>Sometimes 84%<br>Never 5% |

|  | <b>TECNIS® MULTIFOCAL IOL<br/>(+4.00 D) (331 patients)</b>  | <b>MONOFOCAL IOL<br/>(116 patients)</b>   |
|--|---|---|
| <b>Use of glasses for far vision</b>   | Percentage of patients reported using glasses to see far:<br><br>None of the time 94%<br>Part of the time 5%<br>All of the time 1%  | Percentage of patients reported using glasses to see far:<br><br>None of the time 83%<br>Part of the time 8%<br>All of the time 9%  |
| <b>Use of glasses for near vision</b>  | Percentage of patients reported using glasses for near vision:<br><br>None of the time 94%<br>Part of the time 5%<br>All of the time 1%   | Percentage of patients reported using glasses for near vision:<br><br>None of the time 5%<br>Part of the time 64%<br>All of the time 31%  |
| <b>Ability to function at intermediate distance (2-5 feet) without glasses</b>   | 90% of patients said they were able to function comfortably at intermediate distances without glasses   | 84% of patients said they were able to function comfortably at intermediate distances without glasses   |
| <b>Quality of overall vision without glasses (according to a patient survey)</b> | 8.9<br>(On a scale of 0-10 with 10 being the best)  | 7.9<br>(On a scale of 0-10 with 10 being the best)  |
| <b>Visual effects</b>  | More difficulty with night vision, halos and glare are expected with the multifocal IOL than with a monofocal IOL. Some patients got used to these effects over the first year while others continued to notice them. At one year, most cases were "mild" to "moderate"; however, some were "severe" for halos (5%), night glare (2%), and starbursts (2%). In total, severe halos, night glare, or starbursts were reported by 7% of patients at one year. Few patients (1.5%) reported difficulty with their night vision. In a survey where patients were asked specifically about visual symptoms, patients reported severe difficulty with halos (18%), glare (17%), and night vision (7%) at one year. Some patients (18%) also experienced blurred vision or had difficulty with vision; mostly at intermediate distances (8%). In a few cases (1%), patients requested to have the multifocal lens removed due to difficulty with halos/ glare or image quality (blurry/hazy vision). | Some patients reported to their doctors that they experienced halos and glare particularly at nighttime; however, most cases were "mild" to "moderate" with none (0%) being "severe." Some patients also experienced blurred vision or difficulty with vision mostly at near distances (9%). In a survey, some patients (4%) reported difficulty with severe halos at one year. |

|   | <b>TECNIS® MULTIFOCAL IOL<br/>(+4.00 D) (331 patients)</b>   | <b>MONOFOCAL IOL<br/>(116 patients)</b>  |
|---|--|--|
| <b>Patient satisfaction with the lens</b>           | In a survey, patients were asked if they would choose to have the same lens implanted, if they were given a choice. At one year, almost all patients (92%) said they would choose this multifocal lens again.  | In a survey, patients were asked if they would choose to have the same lens implanted, if they were given a choice. At 4–6 months, most patients (85%) said they would choose this monofocal lens again. At one year, even more patients (90%) said they would choose this lens again. |
| <b>Low contrast vision (driving)<br/>4–6 months</b> | 30 multifocal and 30 monofocal IOL patients participated in a night-driving simulation substudy. Results indicated that those with multifocal IOLs may have more difficulty distinguishing road signs and hazards as quickly under low-light conditions compared to patients with monofocal IOLs. The low contrast vision (driving) study results are also relevant to Models ZKB00 (+2.75 D) and ZLB00 (+3.25 D). | In general, under poor visibility conditions, vision with a monofocal IOL may not be as sharp as in good light.  |

### What this means to you

To choose an IOL that is best for you, you should evaluate the comparison factors in **Tables 1, 2 and 3** as they relate to your quality of life. We recommend that you ask your eye doctor to assist in this evaluation.

If you do a lot of night driving in your job or lifestyle, then a TECNIS® Multifocal 1-Piece IOL may not be for you, and if you wish to minimize halos, then you may be happier with a monofocal IOL.

If being able to see well at near, intermediate, and far and being less dependent on glasses would make your life better, then one of the TECNIS® Multifocal 1-Piece IOLs may be the right choice for you. However, you should weigh the possible advantages and disadvantages before deciding. Whichever IOL you choose, we hope that you are satisfied and have great pleasure in your improved vision.

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