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MULTIFOCAL SCLERALS

Multifocal Scleral Lenses

A look at available lenses that can help our presbyopic patients.

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There are 1.7 billion people in the world today who have presbyopia. This number will continue to grow, and presbyopia will affect 2.1 billion people in the world by the year 2020 (Market Scope, 2012). Currently, in the United States, presbyopia affects 111 million people. These numbers will increase to 121 million people in the United States by the year 2020.

Presbyopia occurs normally in all patients around age 40. It is a progressive condition that tends to stabilize around age 60. Studies have indicated that multifocal contact lenses may satisfy about 90% of visual needs. According to Woods et al (2009), patients preferred visual acuity with multifocal over monovision contact lenses for most activities; multifocal contact lenses were preferred even if visual acuity was better with monovision than with multifocal lens correction.

Activities evaluated included both daytime and nighttime driving, watching television, and changing focus from distance to near. The advantages of multifocal contact lenses are numerous, including the ability to provide simultaneous vision.

Patients often want to maintain their youthful appearance and remain free of eyeglasses for as much of their lives as possible. In fact, 91% of contact lens wearers aged 35 to 55 desire to continue wearing contact lenses (Reindel and Edmunds, 2003). However, numerous studies have demonstrated that contact lens dropout ranges from 15% to more than 20% (Pritchard et al, 1999; Young et al, 2002; Richdale et al, 2007; Rumpakis, 2010; and others. Full list is available at www.clspectrum.com/references). Contact lens dropout increases around age 40 and significantly increases around age 42. Of interest in the soft contact lens population, 93% of patients were not wearing multifocal contact lenses at the time of dropout.

According to the Tear Film and Ocular Surface Society (TFOS), the reason for contact lens dropout is multifactorial (Nichols JJ et al, 2013). Contact lens discomfort, which eventually leads to contact lens dropout, may be due to contact lens or environmental factors. Contact lens considerations include material, design, fit and wear, and lens care. Environmental factors include inherent patient factors such as age and systemic disease, modifiable patient factors such as medications or compliance, and the ocular or external environment. In patients under the age of 45, comfort issues are the main reason for contact lens dropout. After age 45, vision and comfort are almost equally stated as the reason for contact lens dropout (Brujic and Miller, 2011).

The distinguishing factors of dry eye and contact lens dropout may blend. The prevalence of dry eye disease (DED) varies depending on how the disease is diagnosed, which population is surveyed, and the study citation. Prevalence rates of dry eye range from approximately 7% to 34% (Lin et al, 2003; McCarty et al, 1998). In the United States, an estimated 23 million people age 20 and older report DED of any severity (Market Scope, 2004).

Internationally, prevalence rates are even higher. For example, in Taiwan, the prevalence of DED is 33.7% in elderly patients (Lin et al, 2003). The prevalence of dry eye is 25% in Canada and 33% in Japan (Doughty et al, 1997; Shimmura et al, 1999).

Dry eye is one of the most common reasons why people visit their eyecare practitioner, and nearly 40% of people experience dry eye symptoms on a regular basis (Gallup, 2005). Studies have suggested that DED can have a considerable impact on quality of life (QOL) (Miljanović et al, 2007; Pflugfelder et al, 2008). Utility assessment scores to quantify the QOL of DED patients by Schiffman and colleagues (2003) demonstrated that moderate dry eye had a utility score of 0.78, which is in the same range reported for moderate angina (0.75). Perfect health has a utility score of 1.0, whereas death has a utility score of 0.

In clinical practice, we observe that patients who have signs and symptoms of DED are more likely to experience contact lens discomfort (Begley et al, 2001). With age, dry eye is more prevalent, which may exacerbate contact lens discomfort.

The Remedy

Scleral lenses are able to provide excellent vision and comfort as well as treat ocular surface disorders. The use of scleral lenses has become widespread across many ocular conditions, and the indications for scleral lenses continue to grow. Those indications include correction of irregular astigmatism from corneal ectasias, such as keratoconus and pellucid marginal degeneration, and from secondary corneal ectasias, such as post-corneal transplant, to treatment of ocular surface disease in severe dry eye due to Sjögren's or Stevens-Johnson syndrome.

At the time of publication, scleral lenses are also becoming more common for treatment of refractive error such as high myopia, high hyperopia, and presbyopia. The advantage of scleral lenses for patients who have high astigmatism is that lenses can rotate while retaining excellent vision. Patients who have residual refractive error post laser-assisted in situ keratomileusis (LASIK) surgery are particularly pleased with scleral lenses, as dry eye may be more prevalent in this population.

According to the "GP Annual Report 2015," published in *Contact Lens Spectrum*, of 130 total respondents, the majority reported fitting multifocal GP lenses (Bennett, 2015). Aspheric lenses were the most common design, with 83% of respondents fitting these lenses. Thirty-one percent of respondents fit scleral multifocal lenses. Thirty-three respondents fit scleral multifocal lenses less than or equal to 30% of the time, and eight fit scleral multifocal lenses more than 30% of the time.

Current Multifocal Scleral Lenses

AccuLens Inc. AccuLens has multifocal options in its Maxim, Comfort SL, and EasyFit designs. The Maxim Plus lens is for distorted corneas that also require presbyopia correction. Maxim scleral lenses are designed to fit a diverse range of corneal distortion, including advanced keratoconus, pellucid marginal degeneration, post-corneal surgery, and corneal trauma.

EasyFit Plus and Comfort SL Plus are multifocal lenses for non-distorted corneas. These lenses utilize a multi-curve/aspheric posterior surface to create proper corneal alignment. Both EasyFit and Comfort SL lenses are fabricated using patients' keratometry readings, spectacle prescription, and corneal diameter.

The multifocal may be center near or dual aspheric with center-distance progressive optics. The Dual Aspheric Multifocal with center-distance progressive optics is intended for emerging presbyopes and is available with up to +1.75D add.

For the center-near design, the optic zone is based on the pupil size in normal illumination. Also, with this design, a smaller optical zone is recommended in the dominant eye as compared to the nondominant eye. Add powers can be ordered in any power. In addition, adding +0.50D to the spectacle add power is beneficial.

Scleral lenses range in diameter from 15.7mm to 20.5mm for the Maxim Plus, 14.5mm to 15.0mm for the EasyFit Plus, and 15.7mm to 16.7mm for the Comfort SL Plus. Available powers for all lenses range from $\pm 20.00D$, and near add powers range from +1.00D to +3.50D. Toric options are available up to 6.00D. The lenses are manufactured in Boston XO₂ material (Bausch + Lomb [B+L]) with a 140 Dk.

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Custom fabrication of lenses is possible, including custom edge lift and optic zones. Optic zone adjustments are utilized to change the sagittal depth. A lens with a larger optical zone will have a deeper sagittal depth and will have better corneal coverage.

Both Maxim and Comfort SL can have up to eight posterior curves. There are four scleral curves, one limbal curve, and potentially three corneal curves, depending on the steepness of the base curve.

Art Optical Contact Lens, Inc. and Dakota Sciences LLC The So₂Clear Progressive corneal-scleral design (available from both companies) comes in a standard, aspheric cone and a progressive center-near design. The lens diameter ranges from 13.00mm to 15.00mm.

The So₂Clear Standard is indicated for astigmatism correction, difficult-to-fit single-vision patients, oval keratoconus, irregular corneas, pellucid marginal degeneration, and corneal ectasia. Base curves are available from 6.14mm to 9.50mm. Powers are available from $\pm 20.00D$ in 0.25D steps. Diameters range from 13.00mm to 15.00mm.

The So₂Clear Cone is indicated for moderate-to-advanced nipple and oval keratoconus. Base curves are available from 5.83mm to 9.00mm. Powers are available from $\pm 20.00D$ in 0.25D steps. Diameters range from 13.00mm to 15.00mm.

So₂Clear Progressive is ideal for standard design patients interested in a multifocal option. The standard So₂Clear fitting set can be used to fit the multifocal lens, and then the presbyopic version can be ordered based on the best-fit lens. It is a center-near multifocal design with a standard 2.0mm center-near zone that ranges from 0.05mm to 6.00mm in 0.05mm increments. Add powers range from +1.00D to +3.50D in 0.25D steps. Base curves are available from 6.60mm to 9.50mm. Powers are available from $\pm 20.00D$ in 0.25D steps. Diameters range from 13.00mm to 15.00mm. The lenses are manufactured in Boston XO₂ material. Fitting sets are available for both the So₂Clear Progressive and the Standard design.

Advanced Vision Technologies (AVT) The AVT Sag Sight Technology (SST) Scleral multifocal is a center-distance, back-aspheric lens with variable eccentricity zones for all ranges of distance, intermediate, and near visual demands. The AVT Scleral multifocal can be fit utilizing the standard AVT SST Scleral diagnostic fitting system; a special fitting set is not required. The best-fitting standard AVT SST Scleral diagnostic lens can be converted to the AVT multifocal scleral design.

This design is offered for normal or highly irregular corneas. Add powers are available from +0.50D to +3.50D. The diagnostic fitting system consists of three central base curves (40.00D, 45.00D, 50.00D), six diameters (15.6mm, 16.1mm, 16.6mm, 17.1mm, 17.6mm, and 18.1mm), and four tangent angle carriers. The tangent angle carrier is an adjustable peripheral landing zone of the lens. When fit properly, the tangent angle carrier can provide enhanced tear exchange throughout the day. These angles are described as low (2 steep angle), medium (1 steep angle), high (standard/average, which is the most common), extra high (1 flat angle), and extra extra high (2 flat angle).

The center thickness of all diagnostic lenses is 0.35mm (350 microns) to aid in determining the tear layer beneath the lens. Center thickness may be increased if lens flexure is present.

SST provides two identification marks at 12mm to aid in determining the horizontal visible iris diameter (HVID) and limbal clearance. Front-toric, multifocal front-toric, and toric-peripheral-curve lenses are available. There are no limitations in manufacturing outside of the availability of the material blank size.

Blanchard Contact Lens Inc. The Onefit 2.0 multifocal lens is a simultaneous vision, center-near aspheric multifocal system. A distance lens profile (D lens) is used for the dominant eye, and a near lens profile (N lens) is used for the nondominant eye. Both lenses work in tandem and complement each other. Both lenses have center-near designs with a standard add of +2.25D. The difference is that the near lens has more area in the center devoted to the add. On normal corneas, the Onefit 2.0 is fit on flat K; on ectatic corneas, it is fit 0.5mm to 0.6mm flatter than flat K. Base curves are available from 7.00mm to 9.00mm in 0.10mm increments. Powers are available from $\pm 20.00D$ in 0.25D increments. Diameters are available in 14.3mm, 14.6mm, 14.9mm (standard), and 15.2mm. The Onefit 2.0 series including the multifocal are available in an oblate design in which the central

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clearance can be reduced by 70, 110, or 150 microns without altering limbal clearance or scleral landing zone.

Essilor of America Inc. The Jupiter Plus lens is a pure center-distance lens with a proprietary design. It utilizes a combination of back and front curves to provide the maximum add available without any compromising of the distance vision, according to Essilor. The Jupiter Plus lens is optimal for computer and office work with a maximum add of +1.75D. The lens can be manufactured in Tyro-97 (Lagado), Boston XO (B+L), Boston XO₂, and Optimum Extra (Contamac).

Lens diameters are available in 15.0mm, 15.6mm, 16.6mm, 18.2mm, and custom diameters. Distance powers range from $\pm 20.00D$. Custom designs such as oblate geometry and toric peripheral curves are available in Jupiter Plus lenses. These lenses are able to fit both normal and irregular corneas.

According to Gary Richardson, consultant at Essilor, Jupiter Plus lenses may be used as an alternative to eyeglasses and progressive lenses to prevent myopia progression while protecting against some ultraviolet light and foreign objects. However, additional research is needed.

EyePrint Prosthetics, LLC EyePrint Prosthetics offers EyePrintPro multifocal lenses. EyePrint utilizes a unique rotationally stable scleral lens platform gleaned from obtaining an impression of the ocular surface. The EyePrintPro Multifocal design features a multi-zone back-surface design (**Figure 1**).

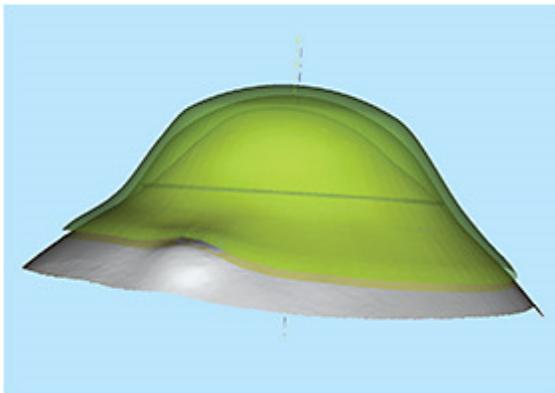


Figure 1. The EyePrintPro Multifocal side view of a virtual eye with the front and back surfaces. The design is a back-surface multifocal design.

Each zone is independent of the other and can be defined by either radius of curvature or eccentricity, negative or positive. The standard design is a back-surface center-distance design. An outer zone can be defined to allow for distance correction to be placed peripherally to accommodate improved nighttime distance vision as the pupil gets larger.

The EyePrintPro Multifocal option can be offered in a back-surface center-distance, variable zone or in a front-surface toric design. The proprietary EyePrint software enables practitioners to specify the visual axis when needed, offering a multifocal design for all types of irregular corneas.

Prism in any direction may be incorporated into the design to optimize the optics. The EyePrintPro offers spherical optics, toric optics, unlimited add powers, prism in any direction, decentered optics, and rotationally stable optics.

According to Keith Parker, president of AVT and co-founder of EyePrint Prosthetics, this multifocal platform in combination with the rotationally stable optics due to the Elevation Specific Technology (EST) can deliver optics targeting the peripheral retina to aid in control of myopia progression.

GP Specialists iSight scleral lenses utilize multiple aspheric conical curves to help achieve a more natural tangential fitting zone. This design has the ability to vault both the cornea and limbal zones while maintaining a minimal sagittal depth to help promote good tear exchange. Multifocal scleral lenses are available in both center-distance and center-near designs.

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The standard optical zone is 1.0mm and ranges from 0.5mm to 7.0mm. Base curves are available from 5.50mm to 9.50mm; powers are available from $\pm 20.00D$ in 0.25D steps. The standard diameter is 16.4mm. Available diameters range from 14.2mm to 24.00mm. The add power range is from +0.50D to +5.00D.

Lens Dynamics Inc. The Dyna Semi-Scleral and Scleral lens has a front-aspheric optic proprietary multifocal design. The back spherical surface is the same with or without the front multifocal; thus, the fit is the same for both modalities.

For the add, a front-aspheric radius is cut for the appropriate add up to +2.75D. The front optical zone in the center is spherical to help improve distance vision. Zones vary depending on the add (low add has 2.0mm, medium add has 1.5mm, and high add has 1.0mm zones).

Both Dyna Semi-Scleral and Dyna Scleral are available with a multifocal front design. For the Dyna Semi-Scleral lens, base curves range from 5.50mm to 8.50mm, powers are available from +10.00D to -20.00D, and diameters range from 13.0mm to 16.0mm. For the Dyna Scleral lens, base curves range from 7.00mm to 9.50mm, powers are available from +12.00D to -20.00D, and diameters range from 16.1mm to 19.0mm. Add power for both lenses is up to +2.75D. Lenses are available in Boston XO, Optimum Extra, Tyro-97, and Menicon Z materials. The edge can be modified from standard as needed with Quad Sym treatment (different edge lift in all four quadrants). Front-toric options are also available.

Metro Optics The InSight Scleral will be introduced and commercially available at the Global Specialty Lens Symposium (GSLs) in January 2016. Drs. Neil Hodur and Jennifer Harthan developed this lens design in collaboration with the research and development team at Metro Optics. InSight Scleral is a center distance design with the add power present in the midperipheral portion of the lens. Unlimited base curves and spherical powers are available. Cylindrical powers are available from -0.25D to -8.00D in 0.25D steps. Diameters range from 15.2mm to 15.6mm in the standard design and from 13.5mm to 20.0mm in the custom design. Available axes range from 1° to 180° in 5° steps. Peripheral curves are available in Standard, Flat1, Flat2, Flat3, Steep1, Steep2, Steep3. Toric peripheral curves are also available. Lenses are offered in Optimum materials from Contamac.

TABLE 1 Available Multifocal Scleral Lenses

Company	Brand	Multifocal Power (D)	Multifocal Style
AccuLens Inc.	EasyFit Plus Comfort SL Plus Maxim Plus	+1.00 to +3.50 Aspheric up to +1.75	Center near, Dual aspheric with center-distance progressive optics
Art Optical Contact Lens Inc.	So ₂ Clear Progressive	+1.00 to +3.50	Center near
Advanced Vision Technologies	AVT scleral	+0.50 to +3.50	Center distance, Back aspheric, Front toric
Blanchard Contact Lens Inc.	OneFit P&A	Up to +2.25 D lens and N lens	Center near
	OneFit 2.0	Up to +2.25 D lens and N lens	Center near
Dakota Sciences LLC	So ₂ Clear Progressive	+1.00 to +3.50	Center near
Essilor of America Inc.	Jupiter Plus	+1.75	Center distance
EyePrint Prosthetics LLC	EyePrint Pro	Unlimited add powers	Back-surface center distance variable zone, Front toric
GP Specialists	iSight	+0.50 to +5.00	Center distance, Center near
Lens Dynamics Inc.	Dyna Semi- Scleral	Up to +2.75	Multifocal aspheric front surface, Spherical front optic zone, Back spherical surface
	Dyna Scleral	Up to +2.75	Multifocal aspheric front surface, Spherical front optic zone, Back spherical surface
Metro Optics	InSight Scleral	+3.00	Center distance

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TruForm Optics Inc.	DigiForm 15 DigiForm 16.6	Up to +3.50	Center near
	DigiForm 18	Up to +3.50	Center near
Valley Contax, Inc.	Custom Stable	+1.50 to +3.50	Center near
	CSE Near 2.0 (clinical study name)	+1.25 to +3.25	Binocular distance and near system
Wave LLC	Multifocal	Up to +5.00	Center distance, Center near

TruForm Optics Inc. DigiForm 15.0mm, DigiForm 16.6mm, and DigiForm 18mm lens are all available in center-near front-surface multifocal options. DigiForm 18mm lenses are also available with front-surface center-distance multifocal options. Five different condition-specific designs are available.

The DigiForm 18 lens is an 18mm design with diagnostic etchings on the front surface of the lenses to aid in lens fitting. These lenses are indicated for post-refractive surgery, pellucid marginal degeneration, keratoglobus, Stevens-Johnson syndrome, post-trauma, ocular surface disease, or when corneal lenses don't center.

Available powers for all DigiForm lenses range from $\pm 30.00D$, and near add powers are available up to +3.50D. The add power and zone size may be specified with all DigiForm lenses. Add power may be specified in any 0.25D increment.

The standard zone size is 2mm center near. This may be adjusted depending on patient pupil size. This option is available with quadrant-specific, front-toric, and back-toric designs as well. Available lens materials are Optimum Extra, Menicon Z, Tyro-97, HDS100 (Paragon Vision Sciences), Boston XO, and Boston XO₂.

TruForm has fitting sets available with the add incorporated on the diagnostic lenses. George Mera, fitting consultant, TruForm Optics, recommends using the fitting set to establish the correct lens for each patient.

Valley Contax, Inc. The Custom Stable Near lens has a front-surface application containing a near zone that is derived from eye dominance and pupil size. This lens is designed for any patient who has struggled with the acuity of soft multifocal lenses and the comfort of corneal GP lenses. These lenses are designed to fit both normal and irregular corneas. The back surface of Stable Near lenses is designed like the single-vision versions; however, the near-center zone is designed to be one-half of the pupil size on the dominant eye and two-thirds of the pupil size on the nondominant eye. The near add is specified in the same way as with any conventional corneal GP lens.

Stable Near lens diameters range from 14.8mm to 17.8mm. These lenses are manufactured in Optimum Extra, Optimum Extreme (Contamac), Tyro-97, Menicon Z, Boston XO, and XO₂ materials. The lenses utilize various production techniques, including Digital Radial Edge Profile (DREP), which is an edging system designed to create a comfortable lens edge; plasma treatment; and analysis with the Nimo TR1504 (Lambda-X s.a.), which is advanced mapping and analysis to help ensure premium quality and an exact fit. Laser monogramming of the lenses is optional. Front toric and toric peripheral curves are also available.

Valley Contax is planning to launch a new multifocal scleral lens at the Global Specialty Lens Symposium in January 2016. The clinical study name of the lens is CSE Near 2.0. The lens design is a dynamic, binocular "D" and "N" system that incorporates near blending on the dominant eye and reverse near blending on the nondominant eye to provide simultaneous vision at all ranges. This lens is exclusively a front-surface add, and the design can be custom applied on all of the Custom Stable and Custom Stable Elite back-surface lenses. Sphere powers are available from +40.00D to -40.00D. Diameters range from 14.8mm to 17.8mm. Add powers range from +1.25D to +3.25D.

Wave LLC The Wave Multifocal is designed using software and is based on corneal topography. Both center-near and center-distance designs are available. Any base curve can be manufactured. For Wave Multifocal lenses, sphere and cylinder powers are available from +30.00D to -30.00D with toric and bitoric lenses. Diameters range from 12.5mm to

18.0mm. Add powers are up to +5.00D. Lenses may be manufactured in more than 20 different materials. The Wave multifocal optic zone can be adjusted in 0.1mm steps. The zone can be manufactured in an unlimited range. Asymmetric optic zones are also available.

According to Scott Lewis, president of Wave, the Wave Multifocal lenses are fit using the measured lens edge angle to guide the peripheral lens design. The lens edge angle is the angle between the edge and intermediate curve; the greater the angle, the closer it is to the cornea. Appropriate edge adjustments may be made to increase or decrease the angle.

The Future of Multifocal Scleral Lenses

Compared with two years ago, we now have a multitude of scleral lens options in a multifocal design. There is incredible new technology in a variety of designs to fit a variety of patients.

With an increase in dry eye in an aging population that wishes to continue wearing contact lenses, scleral lenses are a splendid option. Perhaps scleral lenses will be the tool to prevent contact lens dropout. **CLS**

For references, please visit www.clspectrum.com/references and click on document #241.



Dr. Barnett is the principal optometrist at the UC Davis Eye Center in Sacramento, CA. She is a Fellow of the American Academy of Optometry, a Diplomate of the American Board of Certification in Medical Optometry, and she serves on the Board of Women of Vision, Gas Permeable Lens Institute, Ocular Surface Society of Optometry, and The Scleral Lens Education Society (SLS). She is an advisor to AccuLens, Alcon, Alden Optical, Allergan, CooperVision, Bausch + Lomb, Novabay, Johnson & Johnson Vision Care, Zeiss, and the SLS, and she has received honoraria and/or travel expenses from Alcon, AccuLens, Alden Optical, Allergan, Johnson & Johnson Vision Care, and SLS.