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Advances in Refractive Surgery

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In recent years, refractive surgery has undergone significant technological advances that have led to enhanced safety, predictability, and patient satisfaction. In the past, the goal was to achieve an uncorrected visual acuity that was similar to the best-corrected acuity with contact lenses or glasses. Today, there is the potential for improving best-corrected acuity, as well as overall quality of vision. Over a 20-year period, excimer laser surgery of the cornea has evolved from a series of experiments in animals to >5 million clinical procedures. Advancements in laser vision correction and the evolution of other procedures (eg, phakic implants and refractive lens exchange) allow most patients the potential to be free of optical aids for distance vision and innovations are also being developed to help with near vision.

Refractive surgery patients are different from typical patients coming into the office. They are healthy, active, working people who don't have the time or inclination to sit in a waiting room. Because laser vision correction, phakic intraocular lenses (IOLs), and refractive lens exchange are elective procedures, these patients are selective about where to go for them. Respecting their time and any anxieties about refractive procedures are vital to the success of an eye-care professional. How well the office manages the patient's experience – from the first phone call to the last follow-up visit – will determine how rewarding refractive surgery will be for the patient and for the practice. This issue of *Ophthalmology Rounds* explores innovations in refractive surgery, patient selection, counseling, and postoperative care.

Indications

Patients selected for refractive surgery should be ≥18 years old with a stable refractive error. There is one exception to this rule: if the patient desires refractive surgery to qualify for an occupation (eg, a firefighter or a police officer), it doesn't matter if the refraction changes slightly from year to year. He/she will not be removed from an occupation just because, several years after qualifying, they refract at -1.00 diopters (D). The refractive indications for laser in situ keratomileusis (LASIK), advanced surface ablation (ASA), collagen shrinkage procedures, phakic IOLs, and refractive lens exchange are listed in Tables 1 and 2.

Laser vision correction

Although each refractive surgeon has his/her own upper and lower limits, the range of correction for LASIK and ASA is approximately +5.00 D to -10.00 D. Astigmatism between - 0.25 D and - 6.00 D may also be laser-corrected. Options in laser vision correction for both LASIK and ASA include either a standard or custom ablation (Figure 1). The best quality of vision and best-corrected visual acuity is achieved with a custom ablation that may be accomplished by an aspheric ablation, a wavefront-guided ablation, or a topographically-linked ablation.

An aspheric ablation uses keratometry readings to adjust the energy delivered to the mid-peripheral cornea so that a more prolate corneal curvature is achieved.[1] This curvature resembles the normal cornea, which is steeper in the centre and flatter on the periphery. This reduces the induction of spherical aberration and improves the quality of night vision.

A wavefront-guided ablation attempts to reduce higher-order aberrations such as coma, trefoil, and spherical aberrations that can affect quality of vision.[2] In general, patients with a low incidence of higher-order aberrations do well with an aspheric ablation,[3] while those with a high incidence of higher-order aberrations do better with a wavefront-guided ablation.

A topographically-linked ablation corrects irregular corneas with resultant improvement in best-corrected spectacle acuity.[4] Unlike wavefront-imaging that measures 150 to 250 refractive points of the eye, a topographic system can measure over 22,000 points on the cornea. Linking this data to the laser has the capability of improving best-corrected spectacle acuity in patients with keratoconus, forme-fruste keratoconus, and other forms of irregular astigmatism.

Recent improvements in outcomes after ASA (Figure 2) have been achieved with the development of flying spot lasers that produce a smoother ablation, larger optical and transition zones that fool the corneal healing response, cooling techniques (eg, ice) that decrease inflammation,[5] and

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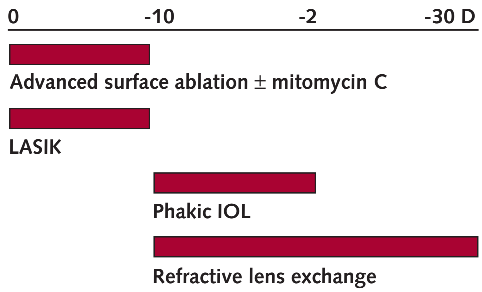
Table 1: **Refractive indications for myopic refractive surgery**



adjunctive medications (eg, topical Mitomycin C[6] and oral Vitamin C[7]) that decrease corneal haze.

An epi-LASIK technique is being developed that uses a microkeratome with a blunted blade to create an epithelial flap.[8] The flap is lifted, the laser ablation performed, and the flap repositioned. This technique avoids the potential flap complications of LASIK (eg, button-holes, incomplete flaps, and diffuse lamellar keratitis). Early clinical results have demonstrated that visual recovery is more rapid when compared to ASA.

Improvements in microkeratome technology for LASIK have resulted in enhanced safety and predictability of flap thickness. The femtosecond laser is now an option for cutting a flap.[9] Although clinical results with the laser have improved, there are conflicting reports about which technology is superior: mechanical microkeratome or laser keratome.[9,10] The laser is capable of cutting thin flaps in thin corneas with enhanced safety. The question is whether this offers better results than performing ASA.

Phakic IOL and refractive lens exchange

For higher degrees of myopia (greater than -10 D) or hyperopia (greater than +5 D), an intraocular procedure should be considered (eg, phakic IOL or refractive lens exchange).[11] The phakic IOL is inserted in the anterior chamber and attached to the iris (eg, Verisyse lens, Figure 3) or behind the iris and in front of the crystalline lens (eg, Implantable Contact Lens [ICL], Figure 4).[12] The advantages of a phakic IOL are reversibility and retention of accommodation. Contraindications are large pupils >7 mm and an anterior chamber depth <3.2 mm.[13] Many high hyperopes do not qualify for a phakic IOL because of a shallow anterior chamber. The surgeon orders the phakic implant (spherical power, astigmatism, axis, and diameter) based on refraction, anterior chamber depth, and the horizontal corneal diameter.

Table 2: **Refractive indications for hyperopic refractive surgery**

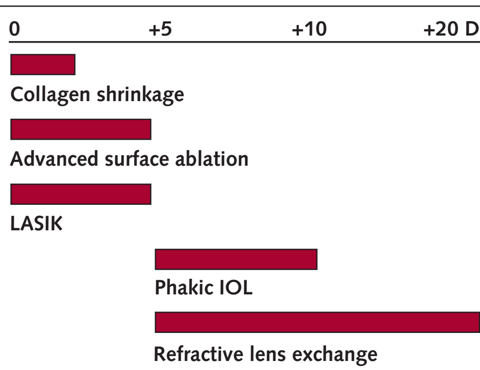


Figure 1: **Laser vision correction provides patients the option of decreasing their dependence on glasses or contact lenses**

A refractive lens exchange is simply a lens extraction and the insertion of an IOL. The procedure is typically performed under topical anesthesia with a clear corneal incision. Neither sutures, nor a patch are required. Astigmatism can be treated by inserting a toric implant and/or limbal relaxing incisions. In addition to correcting high myopia or hyperopia, another case to consider is the patient >60-years-old who has lost most accommodative ability. If there are signs of early cataract, it is best for the patient to have a lens extraction and an implant, instead of laser vision correction. Wavefront-imaging is being developed that will differentiate between higher-order aberrations of the cornea and those of the lens. If the aberrations are high and primarily from the lens, a refractive lens exchange is the preferred procedure.

Innovations in intraocular implants provide more options for refractive lens exchange patients. Pseudo-accommodative or multifocal implants are now available.The lens that has been on the market for the longest is the Array implant with a series of zonal rings (Advanced Medical Optics). It is capable of providing distance and near vision. Although halos around lights are a common postoperative complaint, they generally diminish with time.[14] The Restor lens (Alcon) utilizes a different principle that incorporates both a refractive and diffractive optic (Figure 5).[15] The central 3.6 mm of the optic is the diffractive portion; it consists of a series of rings whose step heights decrease peripherally by 1.3 microns to 0.4 microns. At night, when the pupils are large, most of the light energy goes for distance focus and, therefore, the incidence of glare and halos is low (approximately 15%) and generally mild in severity. Patient selection and expectations are critical to the acceptance of multifocal lenses. In addition, exact biometric

Figure 2: **Rotary brush used in advanced surface ablation to remove the corneal epithelium**

Figure 3: **Verisyse phakic IOL attached to the midperipheral iris**

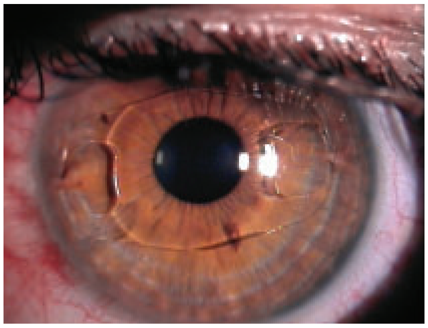
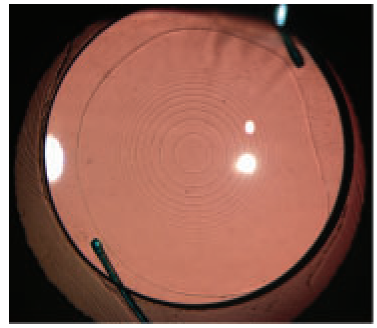


Figure 5: **The Restor lens which has a central diffractive optic and a peripheral refractive optic**



readings and precise placement centrally and in the bag are critical for success. Low postoperative astigmatism is important for satisfactory uncorrected acuity.

An ideal intraocular implant provides excellent vision at all focal distances. There is a great deal of research into the development of an accommodating lens. The first lens approved in the United States was the CrystaLens,[16] which is a plate design with hinges that are capable of flexing. The proposed mechanism of action is that ciliary muscle contraction results in increased vitreous pressure that pushes the lens forward with resultant improvement in near vision. The optic of the lens is small at 4.5 mm. A YAG capsulotomy does not diminish the effectiveness of the lens. Another accommodating implant in clinical trials is the Visiogen Dual Optic Lens (two optics joined by spring haptics).[17]

Intraocular procedures are typically associated with a minimal healing response and a rapid return of vision. The main risk is infection or endophthalmitis, which are extremely rare, occurring in <1 in 10,000 eyes. Patients with high myopia are at increased risk of retinal detachment with an intraocular procedure;[18,19] however, the risk appears lower with a phakic implant than with a refractive lens exchange. Preoperative and postoperative dilated fundus examinations are critical to detect any retinal tears that can be treated.

The quality of vision is generally excellent with a phakic IOL or a refractive lens exchange. If there is a residual refractive error, laser vision correction can optimize uncorrected visual acuity (UCVA). This is usually performed at least 2-4 months following the intraocular procedure. The combination of procedures is termed bioptics.

Thermal collagen shrinkage procedure

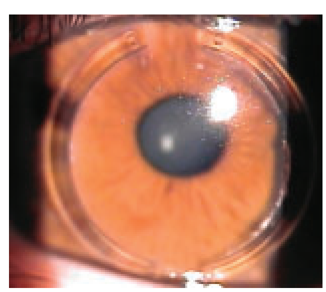
Thermal collagen shrinkage procedures of the cornea were developed to steepen the central cornea to correct hyperopia. The holmium laser was used to create multiple superficial burns to the peripheral cornea; however, there was a high incidence of regression over a period of 1-2 years and this laser is rarely used today. New technology, developed by Refractec, known as "conductive keratoplasty," delivers radiofrequency energy into the midperipheral stroma to create multiple deep burns at 80% depth. When a series of 8 to 32 treatment spots are placed in up to 3 rings in the corneal periphery (6, 7, and 8 mm optical zones), striae form between the spots to create a band of tightening. This causes the central cornea to steepen and corrects hyperopia. Clinical data have demonstrated improved outcomes that are generally limited to up to 2 D of hyperopia.[20] The advantage of the procedure is that no incisions are made in the central cornea; however, predictability and stability are not as accurate as with laser vision correction. There has been renewed interest in the procedure for correction of presbyopia by inducing a myopic shift to allow for reading.

Figure 4: **The Implantable Contact Lens**

Intracorneal rings

This procedure was initially developed to correct low degrees of myopia by insertion of polymethylmethacrylate (PMMA) rings in the midperipheral cornea (Figure 6). A small vertical incision is made superiorly that is approximately two-thirds of the corneal depth. A suction device is then placed on the sclera to increase pressure in the eye to make the cornea firm. Using a circular metal dissector, a channel is created on either side of the initial incision. The ring segments (available in different thicknesses) are then inserted into the cornea. By increasing the thickness of the midperipheral cornea, the centre of the cornea is flattened. The new curvature of the cornea overlying the pupil allows low levels of myopia to be corrected. Although the procedure was appealing because of its potential reversibility, refractive outcomes have not been as accurate as with laser vision correction and

Figure 6: **Intracorneal ring segments to correct myopia**



it was not able to correct astigmatism or hyperopia. The procedure is rarely performed today for myopia correction, but it has a role in the treatment of keratoconus and corneal ectasia. The ring segments can flatten the cornea and delay the need for a penetrating keratoplasty.[21]

Patient selection

Serious complications of refractive surgery are, fortunately, extremely rare. "Disappointment" is much more common and may cause more problems for the refractive surgeon than serious vision loss. Disappointment can be minimized by careful patient selection (to weed-out inappropriate personality types) and the presentation of facts, so that nothing that is said or done will impart unrealistic expectations. Any mention of 20/15 or "perfect vision" can lead to an expectation of that outcome. Avoid making promises, instead, comments like "greatly improved vision" or "reduced dependence on glasses and contact lenses" foster realistic expectations. Marketing materials and staff interactions must also follow this pattern of refusing to over-promise.

Patient selection is more than a matter of meeting objective criteria. Perfectionists, individuals unable to tolerate small disappointments, and others who are likely to be grossly upset if they don't achieve 20/20 or better vision from their surgery should be excluded. However, with limited exposure to the patient, it is hard for the refractive surgeon to spot these personality traits. Working with a co-managing doctor who has known the patient for years and, therefore, has a greater insight into the patient's personality, is a great advantage.

The best candidates for refractive surgery are those who are strongly motivated to get rid of corrective lenses (Table 3), but who recognize that their postoperative uncorrected vision may not be quite what it was with correction prior to surgery. Good candidates are relatively easygoing and able to tolerate mild disappointments. Table 4 lists some of the attitudes and ocular conditions that make a patient a poor candidate. Recognizing these factors is essential to decrease potential postoperative problems.

For patients having ASA, one should not understate the possibility of some postoperative discomfort and delay in achieving optimum acuity. It is better to overstate the possibility than for the patient to be surprised by it. This is much less an issue with LASIK, where patients tend to be comfortable postoperatively and experience an early return of best-corrected visual acuity. However, in many situations, a patient may be a candidate for ASA, but not for LASIK. ASA is the procedure of choice for patients with:

• epithelial basement membrane dystrophy (EBMD) as there is an increased risk of epithelial ingrowth with LASIK

• relatively thin central corneas, so that <250 microns of tissue would be left in the bed after ablation (there is the risk of corneal ectasia with LASIK)

• narrow palpebral fissures and/or deep-set eyes (which make work with the microkeratome difficult)

• keratoconus or form-fruste keratoconus (risk of corneal ectasia with LASIK)

• extremely flat corneas (<39 D, that would result in a small diameter flap with LASIK), or steep corneas (>48 D, leading to increased risk of a button-hole flap with LASIK or ectasia if forme-fruste keratoconus)

Table 3: Good candidates for refractive surgery

- Very unhappy with their dependence on corrective lenses
- Think they are poor candidates for contact lenses
- Believe wearing corrective lenses restricts them in sports and similar activities
- Think they look better without glasses
- Worry about what would happen to them if they lost/broke their glasses or contact lenses
- Would prefer merely functional vision without correction to excellent vision with corrective lenses
- Would be happy if their uncorrected vision could be much improved, even if corrective lenses were still necessary
- Adjust well to change
- Are easygoing; can tolerate disappointment
- Are not perfectionists

Table 4: Poor candidates for refractive surgery

- Under 18 years old
- Unstable refraction/progressive myopia
- Irregular astigmatism with loss of BCVA
- Dry eyes, with punctate keratopathy or filaments
- Cataract
- Herpes simplex
- Vision threatening macular disease (eg, diabetic retinopathy)
- Pregnancy
- Unrealistic expectations
- Unwilling to commit to follow-up

Prior to the surgery

• Contact lens wearers must stop wearing their lenses for a period long enough to allow the corneas to stabilize (as shown by refraction and topography). For rigid gas-permeable contact lens wearers, this may be for a month or longer (Figures 7A and 7B). The corneas of soft lens wearers stabilize very quickly, sometimes within hours; however, 1 week is necessary to be certain that the cornea is stable

• Pupil size should be checked, preferably with infrared light (eg, Colvard pupillometry). An estimation of pupil size can be made with a narrow slit-beam with the room lights off and the patient fixating on a point in the distance. Glare and halos are uncommon today with laser vision correction using large optical and transition zones. In general, there are no contraindications to advanced laser eye surgery based on pupil size. However, with phakic implants, the pupil size should be <7 mm.

• Significant dry eye with punctate keratopathy should be aggressively treated with lubricating drops, gels, ointments, oral omega-fatty acids (eg, BioTears capsules, EyeV Inc), and/or silicone plugs prior to surgery. If symptoms or corneal findings cannot be resolved, the patient is a poor candidate for laser vision correction.

• Rule-out glaucoma. Patients with glaucoma are more susceptible to elevated pressures when topical steroids are used. In addition, a baseline disc evaluation and, if indicated, a visual field can be of value since postoperative intraocular pressures may be artificially low

Figure 7A: Irregular astigmatism seen after an RGP lens has been removed. History of lens wear for over 20 years.

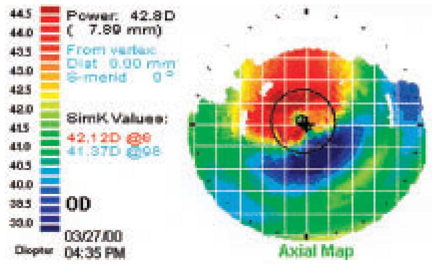
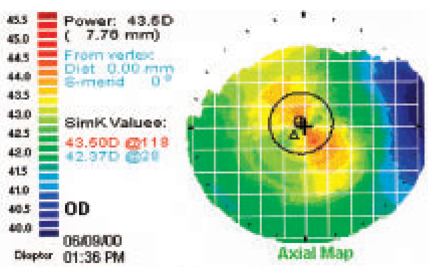


Figure 7B: Irregular astigmatism has resolved after discontinuing contact lens wear for 3 months. The patient is a satisfactory candidate for laser vision correction



following myopic laser vision correction, secondary to corneal thinning.

- Look for any vision-threatening retinal disorders (eg, myopic macular degeneration, age-related macular degeneration, diabetic retinopathy, etc). These patients are at risk for vision loss in the future and are not considered good candidates for refractive surgery.
- Rule-out peripheral retinal disease (increases likelihood of retinal tear and detachment).
- The quality of vision can deteriorate with a postoperative cornea that is either too steep (>50 D) or too flat (<36 D). The postoperative curvature should be predicted. If it is outside an acceptable range, recommend a phakic IOL or refractive lens exchange.

Medico-legal issues

Some patient situations are problematic for medicolegal reasons. For example, if a patient with an underlying disease (eg, diabetic retinopathy, myopic macular degeneration, age-related macular degeneration) suffers vision loss 1-2 years after refractive surgery, he may hold the surgery accountable rather than the disease. One should exercise extreme caution here. Since a patient's vision is almost always correctable with spectacles or contact lenses, avoiding surgery may be wise in these circumstances. Pregnancy can affect refraction and wound healing and any untoward event during pregnancy may be blamed on the procedure or related medications. Hence, it is wise to postpone refractive surgery during pregnancy.

Postoperative care

Postoperative examinations allow the doctor to listen to and counsel the patient. It also permits the evaluation of uncorrected visual acuity (UCVA), best-corrected visual acuity (BCVA) with a manifest refraction, and detection of any complications. If there is a loss of BCVA, the cause must be identified.

Table 5: Causes of loss of best-corrected visual acuity in laser vision correction

	LASIK	ASA
Infection	+	+
Decentered ablation	+	+
Irregular ablation	+	+
Central island	+	+
Corneal haze	+	+
Superficial keratitis	+	+
Diffuse lamellar keratitis	+	-
Flap striae	+	-
Flap button-hole	+	-
Epithelial ingrowth	+	-

After laser vision correction

Loss of acuity (Table 5) may be secondary to irregular astigmatism from an ablation problem (decentered or irregular ablation, central island), flap complication (eg, striae or button-hole), diffuse lamellar keratitis, superficial keratitis, corneal haze, or an intraocular problem. In the absence of slit lamp evidence of corneal abnormalities or intraocular problems, a computerized videokeratography can rule-out an ablation problem as the cause. Additional laser treatment may be needed if BCVA does not improve or symptoms do not resolve.

BCVA and refractive stability occur earlier with LASIK than with ASA. In the LASIK patient, BCVA is typically achieved in 24 hours and refractive stability occurs between 1 and 3 months. The lower the refractive error, the earlier the refractive stability. With ASA, best-corrected acuity is usually achieved by 1 month and refractive stability in 4-6 months. Fluctuation in vision is uncommon after 3 months with LASIK, and after 6 months with ASA. Most of the early fluctuations in vision are secondary to an induced dry eye condition. If so, lubricating drops, gels, ointments, oral omega-fatty acids, or punctal plugs may be helpful.

For patients with an under- or overcorrection, an enhancement procedure can be considered, but this should wait until at least 4 months following LASIK or 6 months following ASA. These delays are only approximate; the key is to wait until refraction is stable, with <0.5 D change from the previous month's examination. If a patient has residual or consecutive myopia and is presbyopic or early prepresbyopic, a trial should be considered to determine the acceptability of monovision before undertaking surgical enhancement.

A patient who is surgically treated to intentionally create monovision and experiences difficulty, especially with night driving, can be given a prescription for glasses that correct distance vision in both eyes. If there are problems with binocular vision and sporting activities, try fitting a contact lens to the reading eye to improve distance vision. If a patient complains of glare, halos, monocular diplopia, or poor quality of vision that does not resolve after a few months, it is important to identify the cause. Any residual uncorrected refractive error can result in significant visual complaints. Computerized videokeratography can identify an abnormal ablation pattern. If no abnormality is found on topography, consider wavefront analysis to determine if any significant higher-order aberrations have been induced. If so, a customized or wavefront-guided ablation can be performed, with the goal of resolving the patient's symptoms and improving the overall quality of vision.

After refractive lens exchange

Complications are uncommon, with risks that are similar to a cataract operation with insertion of an intraocular implant. The most serious complication is endophthalmitis; fortunately, the incidence is <1 in 10,000 eyes. Other complications include corneal edema (transient or permanent), subluxation of implant, cystoid macular edema, toxic keratopathy from eye drops, capsular opacification, and retinal detachment. Detecting these complications is critical for early rehabilitation. A residual refractive error can be treated by either a secondary implant in the sulcus to correct hyperopia or myopia, limbal relaxing incision to reduce astigmatism, or laser vision correction.

After phakic IOL

As with all intraocular procedures, there is a small risk of endophthalmitis. A more common complication with a posterior chamber phakic IOL is pupillary-block glaucoma. The patient presents with pain, elevated intraocular pressure, and a shallow anterior chamber. The previous laser iridotomies may be closed, requiring emergency retreatment. In general, the complications vary, depending on the phakic IOL and include subluxation of the implant (Verisyse > ICL); transient corneal edema (Verisyse > ICL); cataract (Verisyse < ICL); pigmentary glaucoma (Verisyse < ICL); and pupillary-block glaucoma (Verisyse < ICL). A residual refractive error can be treated with laser vision correction.

The bottom line

Refractive surgery patients require a high level of attention from the eyecare team, from the first phone call to the last follow-up visit. Determining a patient's suitability for refractive surgery is based on both objective criteria and an evaluation of their motivation and personality. Patients who cannot tolerate less than a 20/15 result, are pregnant, or have vision-threatening retinal disease, should be discouraged. Candidates for refractive surgery should undergo external eye, slit lamp, and fundus examinations, manifest and cycloplegic refractions, determination of pupil size, computerized videokeratography, pachymetry, and wavefront-imaging. The patient's general health and sensitivity to medications are important parts of the history. Monovision should be discussed with all presbyopic and early prepresbyopic patients. The surgeon must help patients to make informed decisions about the best procedure for them, be it laser vision correction, refractive lens exchange, or phakic IOL, and should take care not to promote unrealistic expectations. Clear guidelines and an efficient protocol will make refractive surgery rewarding for the refractive surgeon, the eyecare team, and the patient.

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