Presbyopia is a multifactorial physiological aging mechanism that leads to a progressive functional loss of near vision. Scleral expansion surgery, cornea laser surgery with multifocal patterns or monovision approaches, conductive keratoplasty, clear lens extraction or cataract surgery using multifocal, accommodative IOLs or monovision monofocal lens are some of the techniques that have been used for the treatment of presbyopia.

Cornea laser surgery or CK are minimal invasive methods, but they provoke irreversible changes at cornea anatomy, whereas scleral surgery and clear lens extraction are more invasive techniques. The necessity to develop a minimal invasive, reversible, stable and safe surgical technique with an easy learning curve for patients between 45 and 60 years, who could be considered too old for presbyopia cornea laser surgery and too young for lens extraction, led to the development of a new approach based in the use of intracorneal inlays placed inside the stroma of the cornea.

The concept of intracorneal inlays for the correction of presbyopia takes origins in 1964, when Barraquer developed keratophakia, a lamellar refractive procedure in which an alloplastic lenticule was placed at the interface of the free corneal cap and the stromal bed. Because of the difficulty of the surgical procedure and the unpredictability of the refractive results was decreased the ophthalmologic community interesting for keratophakia. The development of right materials and studies for determining the appropriate size and depth of inlays have been challenging. Other intracorneal inlays have caused corneal necrosis, epithelial opacification, and problems related to decentration or inadequate corneal nutrition were some of the issues that influenced the efficacy of the procedure.

Recently, the necessity to develop a minimal invasive, reversible, stable and safe surgical technique with an easy learning curve for patients between 45 and 60 years, who could be considered too old for presbyopia cornea laser surgery and too young for lens extraction, led to the development of new tissue friendly corneal inlays placed under stromal flaps or inside stromal tunnel created using special mikrokeratomes or, more recently, femtosecond laser.

The more studied inlays for presbyopia during last years are Flexivue Micro-Lens (Presbia), ACI 7000 (Acufocus) and Presbylens (ReVision).

**FLEXIVUE MICRO-LENS (PRESBIA)**

Flexivue Micro-Lenses are made by hydrophilic polymer materials which have a central zone free of refractive power and a peripheral zone with a standard positive refractive power. The diameter is 3 mm and the thickness is less than 20 µm. At the centre of the inlay there is a central hole which allows nutritional flow through the corneal tissue. The lens is inserted inside a corneal stromal tunnel of the non dominant eye (fig. 1).

The lens offers at the operated eye (non-dominant eye) two different focal points, one for the far vision and a different for the near vision respectively.

During far vision the rays which pass through the central zone (neutral zone without refractive power) of the implant and through the free peripheral corneal tissue, are focused sharply on the retina, whereas the rays which pass through the refractive peripheral zone are focused in front of the retina.
During near vision the rays passing through the peripheral refractive zone will be focused on the retina. The rays which pass through the central zone of the inlay are out of focus behind the retina and the rays which pass through the peripheral clear cornea will be blocked by the pupil.

The differential of this corneal inlays respect other inlays or other monovision procedures like laser correction or cataract surgery is not just the procedure’s reversibility but also its dependence on pupil size. In fact, when wavefront refraction was used there was an inlay effect only when was analyzed the central 3 mm zone (corresponding to the inlay diameter). When was analyzed the central 6 mm zone, the effect decreased. Therefore, the maximal inlay effect occurred during near vision, when the pupil became smaller and decreased during far vision when the pupil is larger. This mechanism was called “smart monovision”.

Initially, the tunnel was created using a mechanical microkeratome composed by a central unit which controlled the suction pressure of the microkeratome, the velocity of cutting and the oscillation rate of the blade; a hand-piece; a suction ring which was applied on the cornea in order to stabilize the eye; and a cartridge blade system which created the tunnel.

Currently, the tunnel is created using femtosecond laser. The settings are those used for the creation of flap but with less energy and shorter spot separation in order to have a smooth surface where the inlay will apply without altering its shape. A special mask is used in order to limit the separation-cutting of the stroma in a pocket-shape zone. In the future special software will be developed for the femtosecond laser for the creation of customized pocket.

Once the tunnel is created, the inlay is implanted using a special inserter (fig. 2). The preferable position for the inlay is the centre of the cornea corresponding to the visual axes.

**ACI 7000 (ACUFOCUS)**

The design of this intracorneal inlay has evolved over the past 5 years, with a variety of styles, materials, and diameters that were tested in early phase research. The current standard design is a small ring made of polyvinylidene fluoride (PVDF) and carbon. The ACI-7000 contains nano particles of carbon in order to make it opaque. The inlay has a thickness of 10.0 mm, an outer diameter of 3.8 mm, and a central aperture or inner diameter of 1.6 mm (fig. 3). The small aperture increases depth of field of the eye, allowing for the surgical treatment of presbyopia. The surface of the ACI is perforated with 25.0 mm holes arranged in a random pattern to allow nutritional flow through the corneal tissue. The average light transmission of the PVDF inlays is 7.5% with a 1600 random-hole pattern (fig. 4).

Depth of field, defined as the distance in front of and beyond the object of regard that appears to be in focus,
is the optical principle used by the inlay. This principle is commonly used in photography and is controlled by the f-number (aperture stop). Increasing the f-number reduces the aperture diameter and increases the depth of field. Similarly, the pupil is the aperture stop of the eye’s optical system and as the pupil size is reduced, the depth of field increases. There is a limit, however, to how much the pupil size can be reduced. As the pupil size decreases, the amount of light transmitted is reduced and diffraction increases, which reduces visual acuity. Computer modeling has shown that an aperture of 1.6 mm provides sufficient depth of field while minimizing the impact of diffraction on visual acuity. The ACI-7000 intracorneal inlay is an opaque device that is centered over the pupil to create a fixed aperture setting of 1.6 mm, which increases depth of field to improve intermediate and near vision in presbyopic.

The inlay is implanted on the stromal bed of the nondominant eye after a superior-hinged lamellar flap created by using pendular mechanical microkeratome with a 170 mm cutting head. The procedure can be performed also in previously ametropic patients operated with LASIK by relifting the flap.

PRESBYLENS (REVISION)

Made from a proprietary micro-porous hydrogel material called Nutrapore®, the PresbyLens is composed of 78% water, with the same refractive index as the human cornea. It measures 10 microns thick at the edge and varies from 24 to 40 microns thick at the center. This inlay is used to change the anterior curvature of the cornea when placed under a superior-hinged lamellar LASIK corneal flap (fig. 5). Two millimetres in diameter, the PresbyLens is an intracorneal implant designed to provide a central zone for near vision and a paracentral zone for intermediate, which allows the remaining cornea to be used for distance vision. The lens is placed in the patient’s non-dominant eye. The candidates for the surgery must be natural emmetropes or emmetropes after LASIK surgery.

REFERENCES