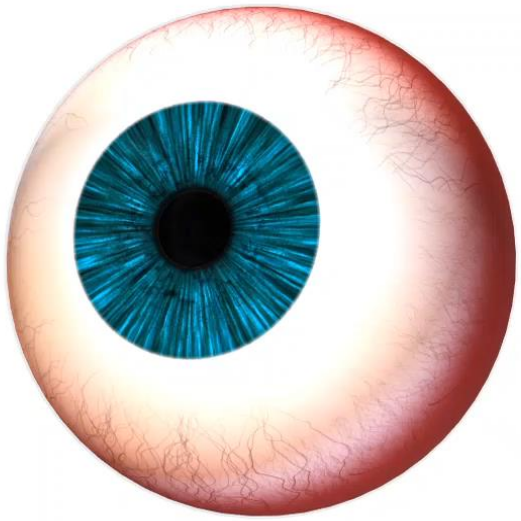
Corneal Biodynamic and Customized Surgery

from Italy, centuries of inspiration and innovation create custom vision

Corneal Biodynamic and Customized Surgery

The cornea, from a structural point of view behaves as a micro dome, subject to a uniform pressure, active from the inner side toward the outer side.



Overview

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The parameters necessary to study the corneal dynamics and to evaluate the entity of its deformations are:

- **Corneal diameter**
- **Corneal mean curvature**
- **Corneal thickness (pachimetry)**
- **Intra-ocular pressure**
- **Scleral indentation**
- **Corneal Elasto-plastic modulus**
- **Corneal Viscosity**

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Corneal dynamics, which depends by the above list of parameters and by their interactions, may be studied by mean of a finite element analysis.

More specifically, due to its subtractive nature, refractive surgery always induces a reduction of the structural strength of the cornea and an increase of its deformations.

Therefore, a refractive surgical procedure is well-conceived, from a dynamical point of view, when the deformations induced by the weakening of its structure are irrelevant versus the morphological modifications required by the surgery itself.

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The most relevant parameter which affects the corneal deformation is the limbus to limbus diameter. In fact, the corneal deformation can be approximately related to the **fourth** power of the total length. It is therefore necessary to know the corneal diameter from limbus to limbus to evaluate the stiffness of the corneal structure. Romans used to built their bridges where the river banks were closer!

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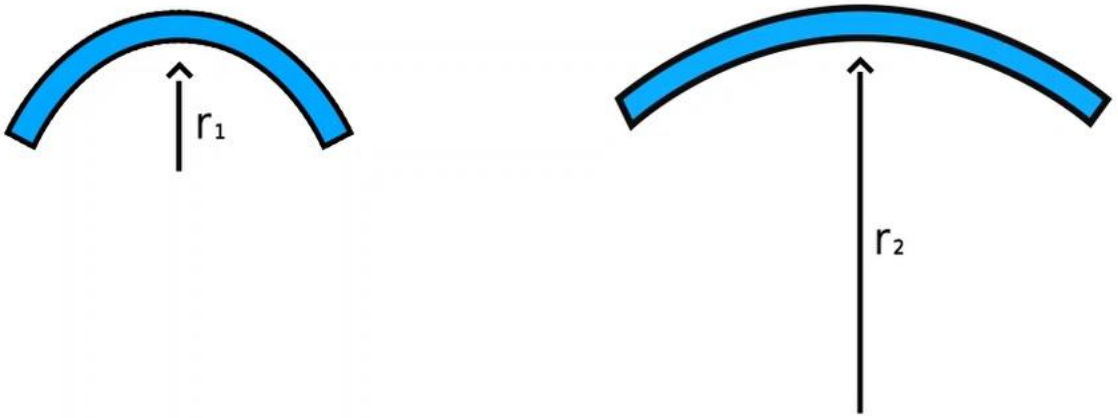
The average curvature of the cornea is also a very important parameter to evaluate the corneal dynamic. Therefore it's necessary to know the average corneal curvature from limbus to limbus.
It is easier to break the egg shell from its flatter side!



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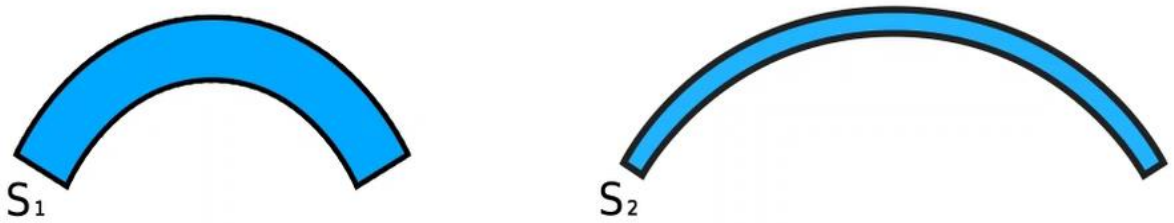
The thickness also plays an important role in corneal dynamic, even if less important than the corneal diameter and mean curvature. In fact, the deformation induced by the thickness are proportional to the **third** power of the thickness.



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Unfortunately the scleral indentation is a parameter which can not be taken in an adequate account in the stress-strain analysis, due to a lack of objective data. However it must be said that any possible scleral indentation defect can be considered as a dome based on weak foundations. So it's intuitive that a defect in the scleral indentation may cause a severe corneal deformation.

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The intra-ocular pressure provides a **linear** contribution to corneal deformation. Obviously, greater deformations correspond to greater pressure.

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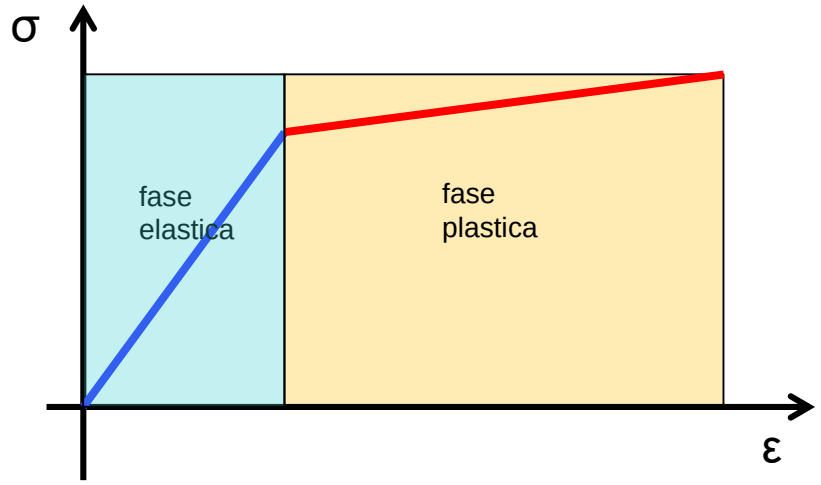
The Elastic modulus has a **linear** contribution to corneal deformation.

The cornea, like any material, when solicited by a mechanical stress, is deformed according to an elasto-plastic law, as per the following stress-strain diagram.

The **elastic** deformation recedes when the applied force are terminated, while the **plastic** deformation has a permanent nature. However, the cornea, due to its geometry, generally operates in the elastic range.



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The corneal structure is also subject to **viscous** deformations.
This deformation has a progressive nature and it progresses over time under the presence of a permanent stress, as the intraocular pressure.
A typical case of a progressive visco-elastic deformation is represented by the keratoconus pathology.

At early stages, a local area of weakness of the elastic modulus, may be identified, probably due to a local deficiency of the stromal collagen fibers crosslinking.
In following stages the stress induced by the intraocular pressure causes a viscous slipping of the stromal fibers which consequently causes a local reduction of the corneal thickness, thus inducing a further increase of the local stress and then, in a pathological close loop, a further local increase of deformation and decrease of thickness, until when, in the best possible scenario, the progression stops due to an increase of the elasticity module induced by a corneal crosslinking aging effect.

Elasto-Plastico Modulus

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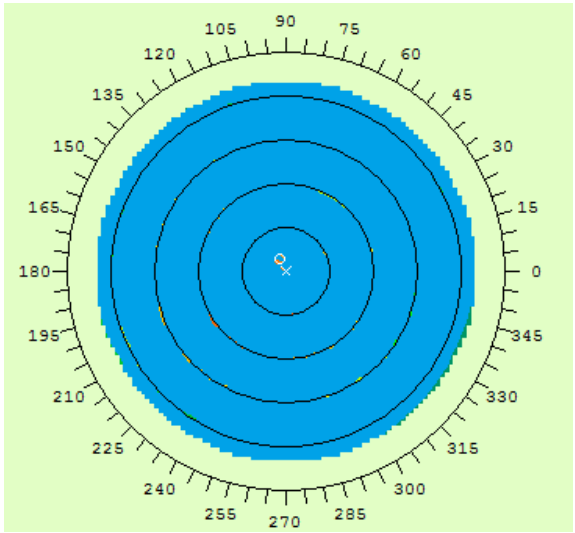
In order to identify, at a very early stage, the effective risk of a progressive degenerative pathology, it will be desirable to introduce innovative devices based on a technology, such as the Brillouin microscopy, able to provide in vivo accurate measures and maps of local values of the elasticity module.

These elasticity module maps will be useful to:

- evaluate corneal deformations and predict their evolution in case of corneal surgery;
- determinate customized crosslinking procedure in order to homogenize the elasticity module maps by increasing locally the corneal stiffness, as much as needed, to prevent any risk of ectasia.



Post-crosslinking elastic modulus map

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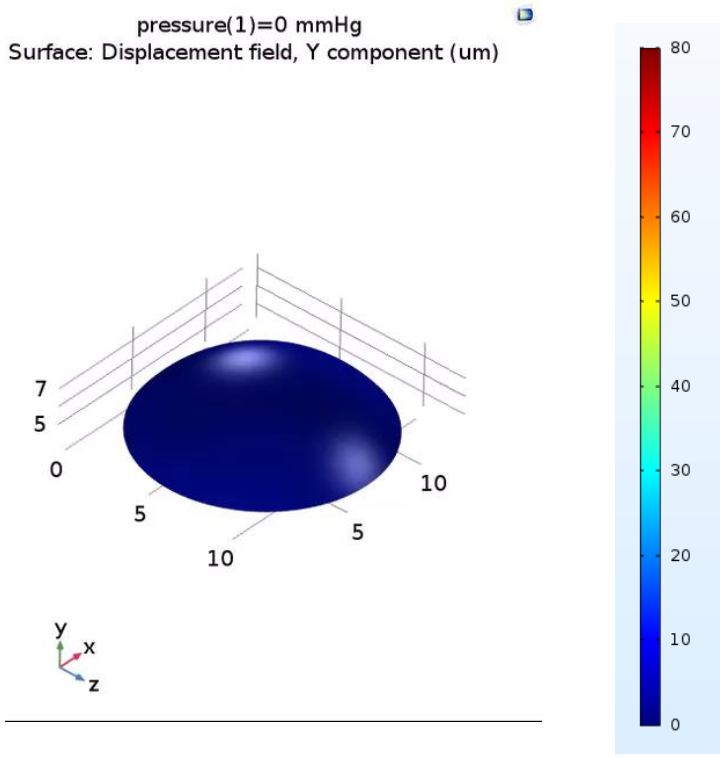
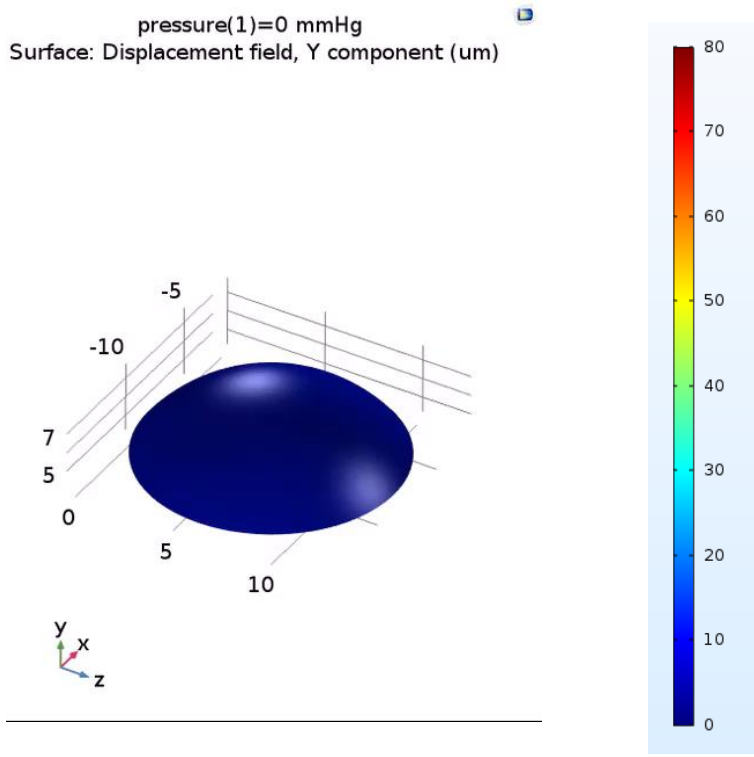
A stress-strain analysis, performed through a finite element approach, on a standard cornea model, shows that the intrastromal cut, in case of a femtolasik surgery, causes a weakening of the corneal rigidity of a factor included in the range between 2.1 and 2.3.



Superficial Ablation



Femtolasik

Femto-LASIK

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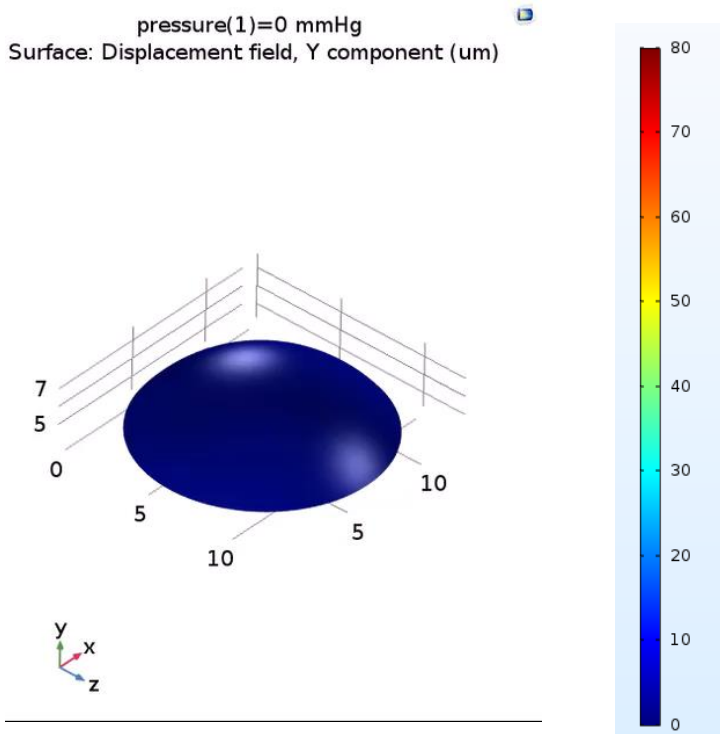
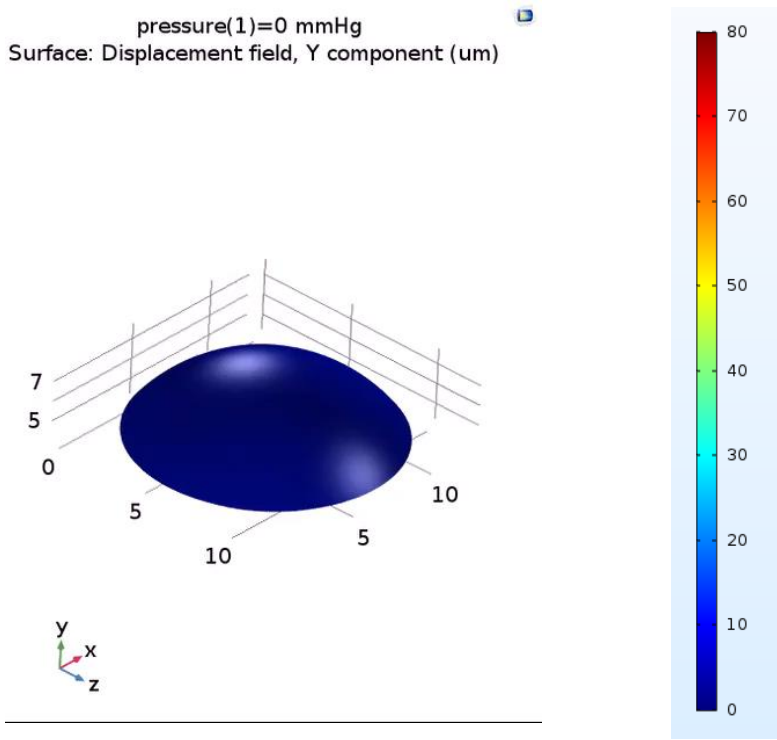
A stress-strain analysis, performed through a finite element approach, on a standard cornea model, shows that the intrastromal cuts, in case of a Smile surgery, cause a weakening of the corneal rigidity of a factor included in the range between 1.3 and 1.5.



Superficial Ablation



Smile

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A corneal surgery, for refractive or therapeutic purposes, should match the following requirements:

1) **customize the treatment to optimize quality of the vision;**

2) **minimize invasiveness of the treatment;**

3) **automate all surgical steps in a close loop.**

Custom treatment for quality of vision

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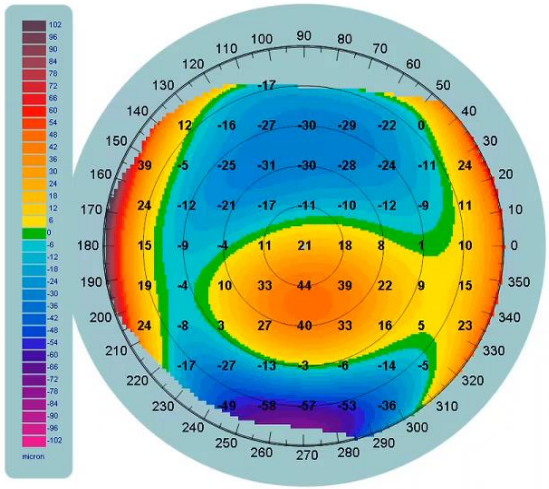
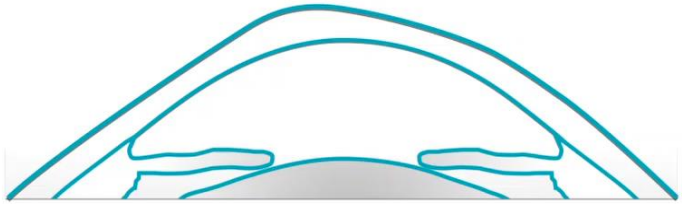
A corneal surgery should be customized, according to the patient needs, to achieve a smooth and regular post-operative surface, in order to take care of the nowadays well recognized concept to aim non exclusively at the "quantity" of the vision, 20/20 or better, but over all to achieve the best possible quality of the vision for the patient, thus trying to avoid any irregularity induced by the surgery which may cause glare, halos, starbursts and, more in general, a loose of contrast sensitivity.





ANTERIOR ELEVATION MAP

Custom treatment for quality of vision

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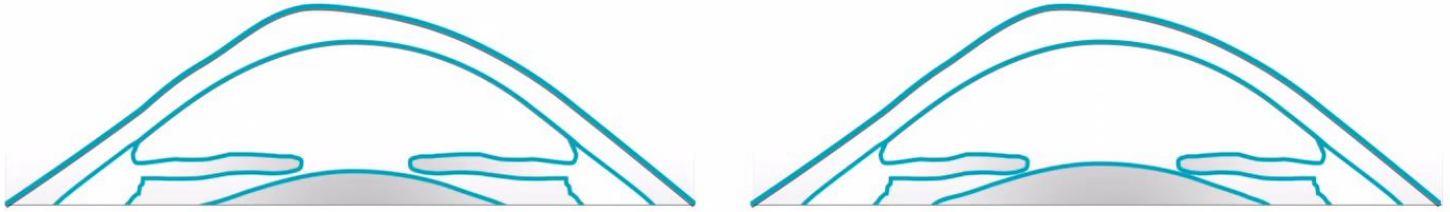
A reliable detection of corneal irregularities, by mean of a dedicated tomographer, is required to allow the laser to ablate them, thus implying the concept that the ablation should not be planned any more through a simple standard or wavefront analysis, but it must be defined as the **volume** of tissue which must be subtracted to bring the detected corneal shape at the ideal shape which is needed to optimize the quality of vision.



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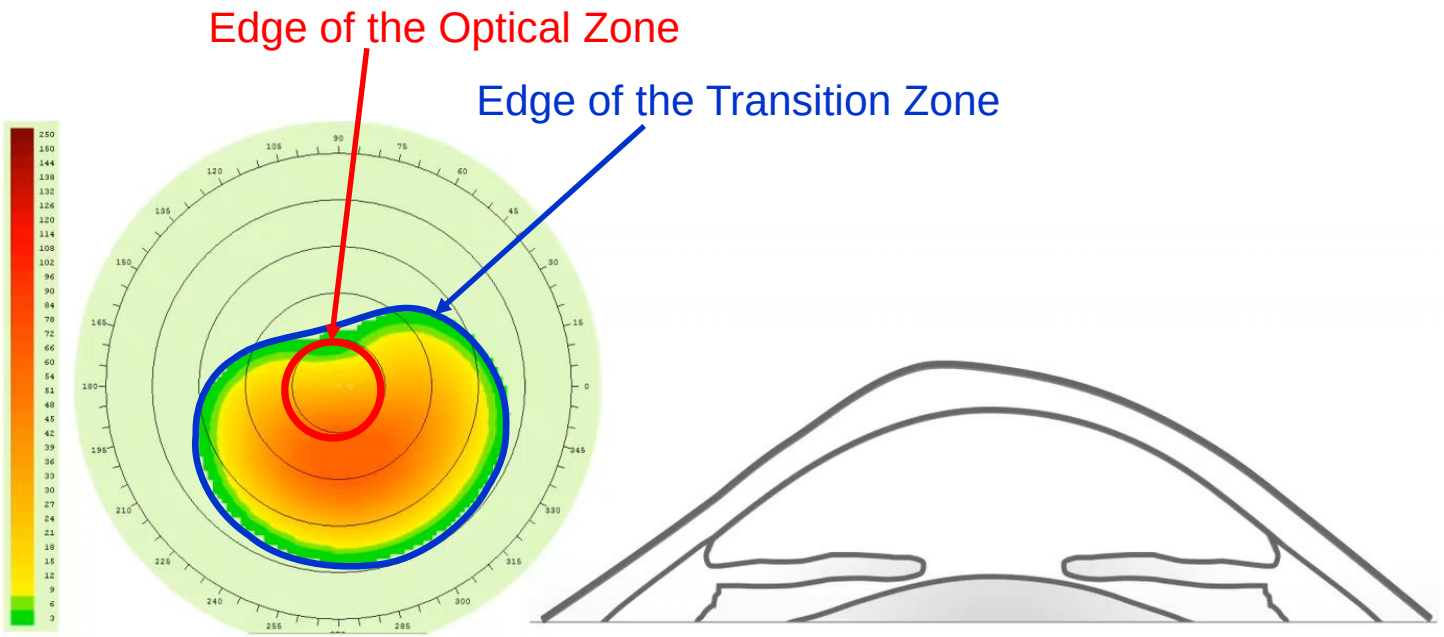
Moreover, a standard transition zone should not be planned anymore at the edge of the optical zone, but, on the contrary, a custom width zone, granting a radial constant average slope and the continuity of the curvature in the connecting zone, is required to avoid local irregularities.



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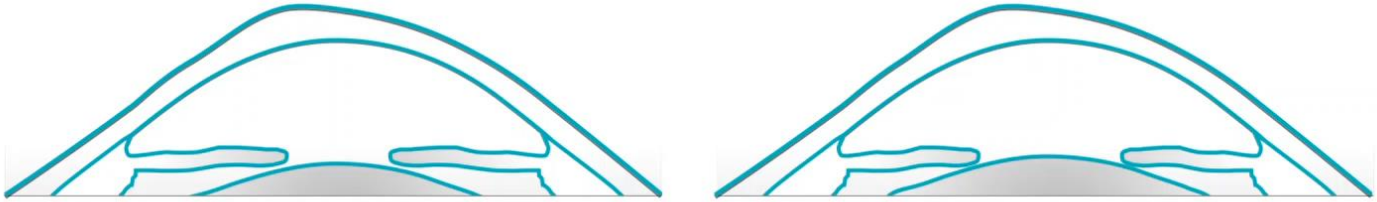
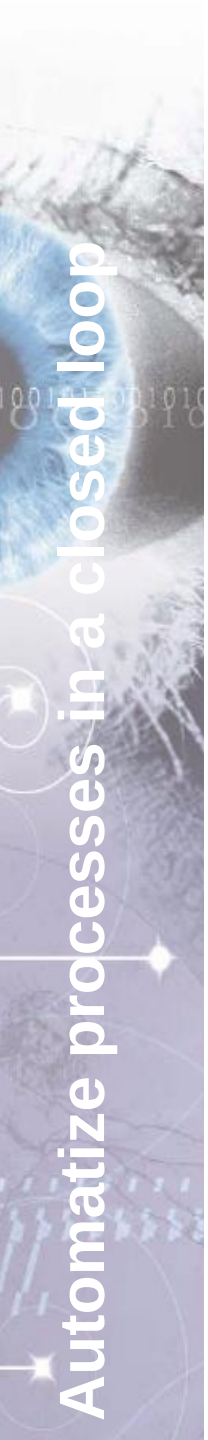
An evaluation of the pupil dynamics, related to the style of life of the patient, is needed to define, through a statistical analysis, the ideal **optical zone** for the patient, which should be as narrow as possible, to minimize the invasiveness of the treatment, being not necessary at all, thanks to the corneal regularization, to increase the optical zone up to 6.0 mm or more to avoid diffractive problems at the edge of the optical zone.



Minimize treatment invasiveness



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The execution of a customized corneal surgery requires a high degree of **automation** to grant the full process to be independent by the human being, to minimize pre-operative and/or intra-operative risk of errors, complications and unexpected outcomes. More specifically it should be required:

1) an objective process of validation of the acquired data, which are necessary to customize the surgical plan;
2) an automated process of execution of the surgery, giving the surgeon the strategical role to customize the surgical plan according to the patient needs;
3) a close loop control of the whole process to validate the surgical outcomes and to generate statistical analysis based on objective determinations.

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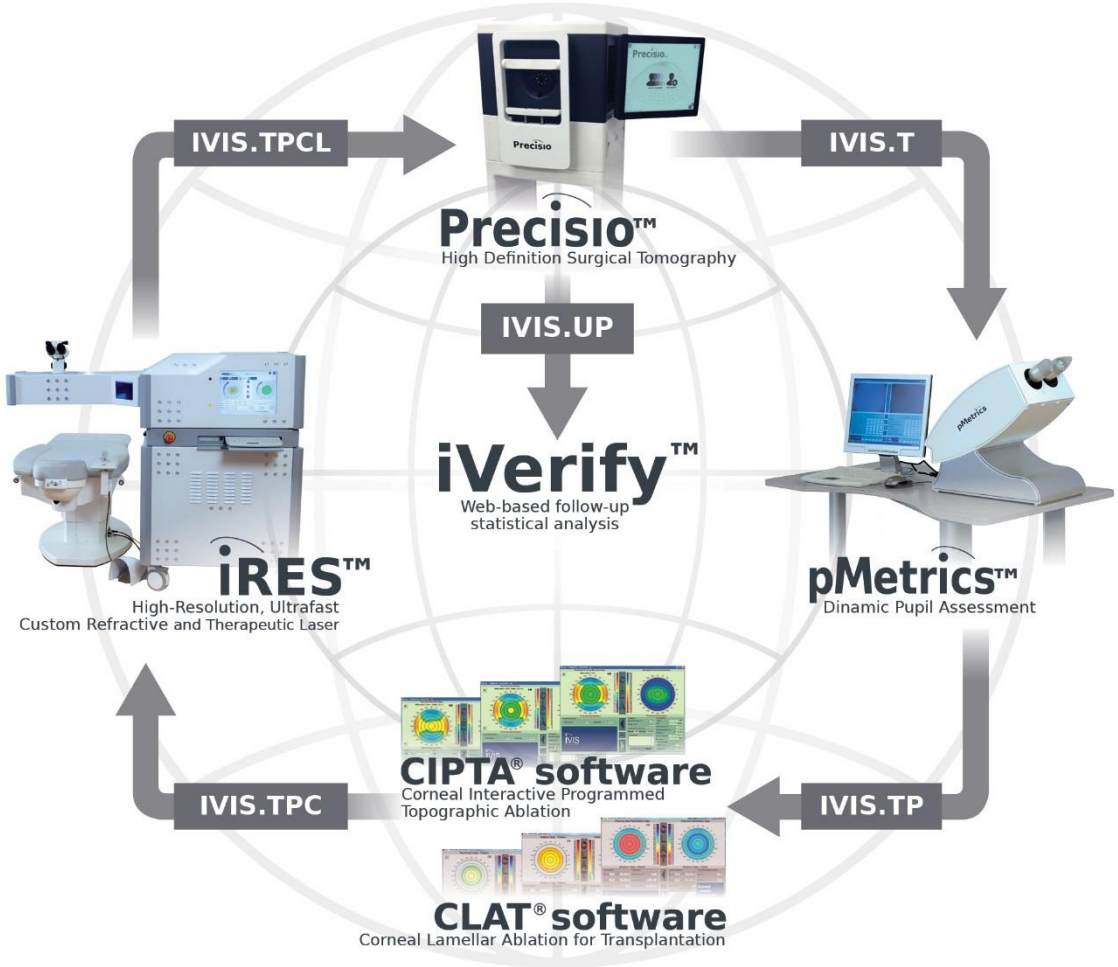
Automatize processes in a closed loop

Automate all surgical steps in a close loop

The 4D process



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Corneal Trans-epithelial surgery is the exclusive surgical procedure which allows:

1) True customized ablation for refractive and therapeutic surgery to optimize quality of vision and to minimize surgical invasiveness

2) A fully automated surgical process with a close loop control to grant an ideal match between planned ablation and achieved outcomes.

However Trans-epithelial surgery requires the epithelium to heal back again. Thus patients who undergo Trans-epithelial surgery, different than for LASIK, although not as much as for PRK, will be subject to undesirable collateral effects as to a sensation of discomfort or pain into the eye for a couple of days after surgery and vision fluctuation for almost one week until complete stabilization.

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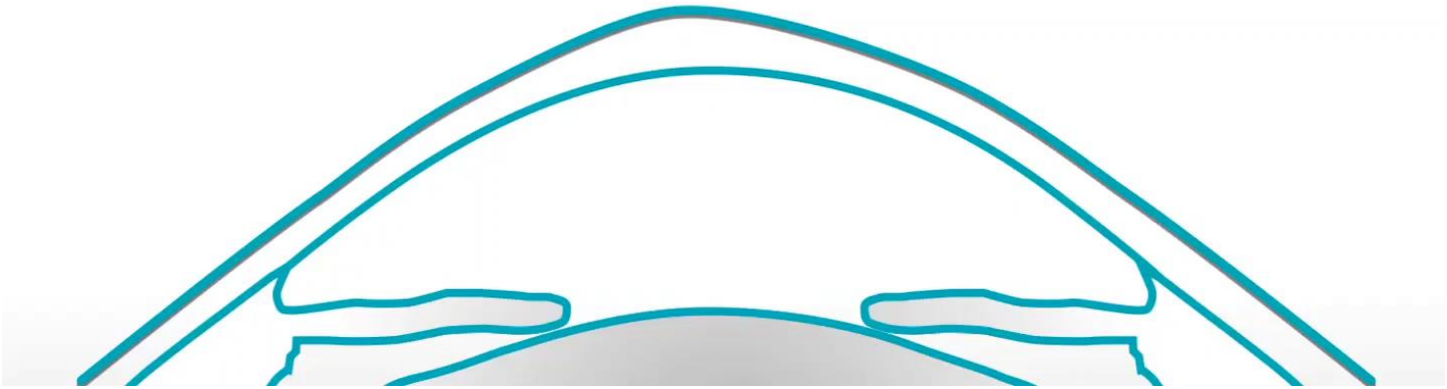
For this reason, the introduction of a **temporary substitute of the corneal epithelium** is highly desirable to eliminate post-operative pain in trans-epithelial surgery, to improve quality of vision in the immediate post-op and to control the healing process.

The temporary substitute of the epithelium must be a film of transparent, sterile and biocompatible self-adhesive hydrogel which must stick onto the debrided cornea, through appropriate means, to act as a barrier, to replace the epithelium, on a temporary basis, until complete corneal heling, after a corneal surgery.



iVIS TECHNOLOGIES

Innovative Solutions for Custom Refractive and Custom Therapeutic Surgeries

Thank you for your attention

from Italy, centuries of inspiration and innovation create custom vision