TES™

Temporary Epithelium Substitute

from Italy, centuries of inspiration and innovation create custom vision

TES™

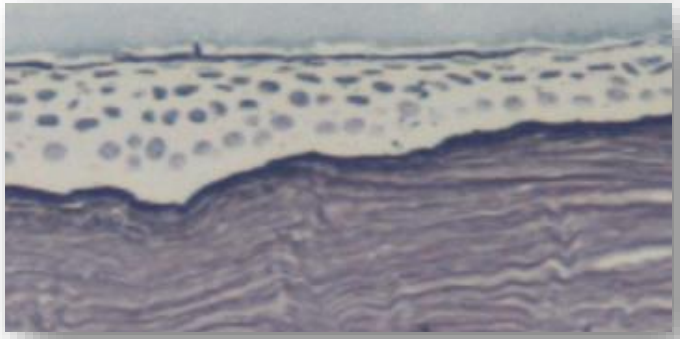
Corneal Trans-epithelial surgery is the exclusive surgical procedure which allows:

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

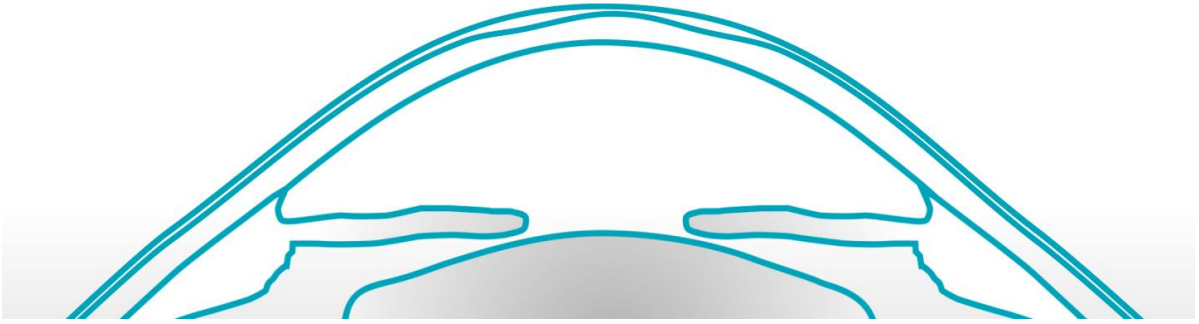
2) A fully automated surgical process with a close loop control to grant an ideal match between planned ablation and achieved outcomes.

TES™

To customize a complex case a PRK surgery can not be executed because both the detected morphological and refractive data are inclusive of the epithelial contribute.



Debriding the epithelium, as required by a PRK surgery, and executing the profile of ablation planned including the epithelium contribute will leave untouched the stromal irregularities, thus leading to a surgical failure.



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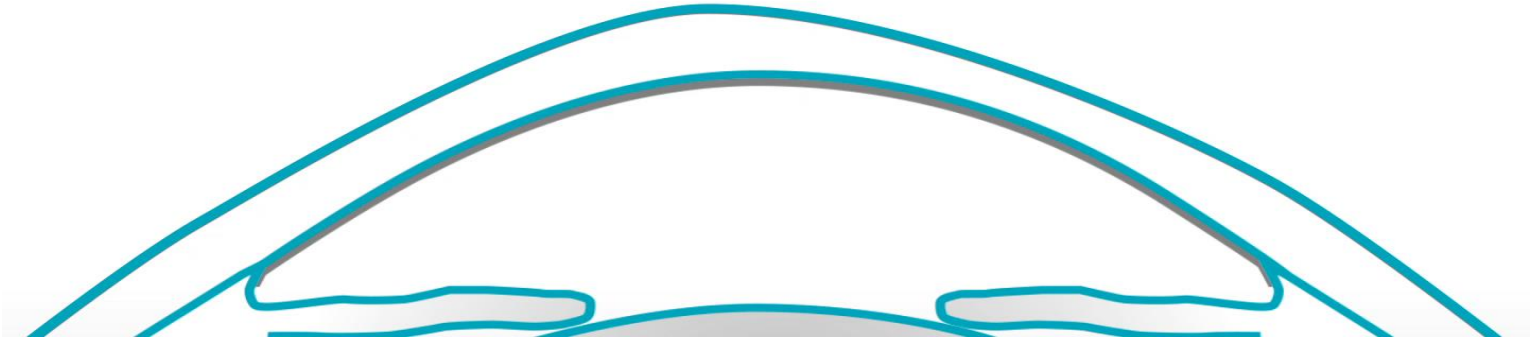
A femto-lasik or a smile surgery as well can not be executed to customize a complex case.

An intrastromal customized ablation should be delivered to regularize the peaks which are causing the high order of aberrations.

However, assuming that such peaks will be effectively removed by the laser ablation, once the flap will lay again over such modified intrastromal surface, being the peaks disappeared, there will be no further need for the epithelium to stay thinner is such locations, thus migrating, over time, in different locations and lastly compromising the desired surgical outcomes.



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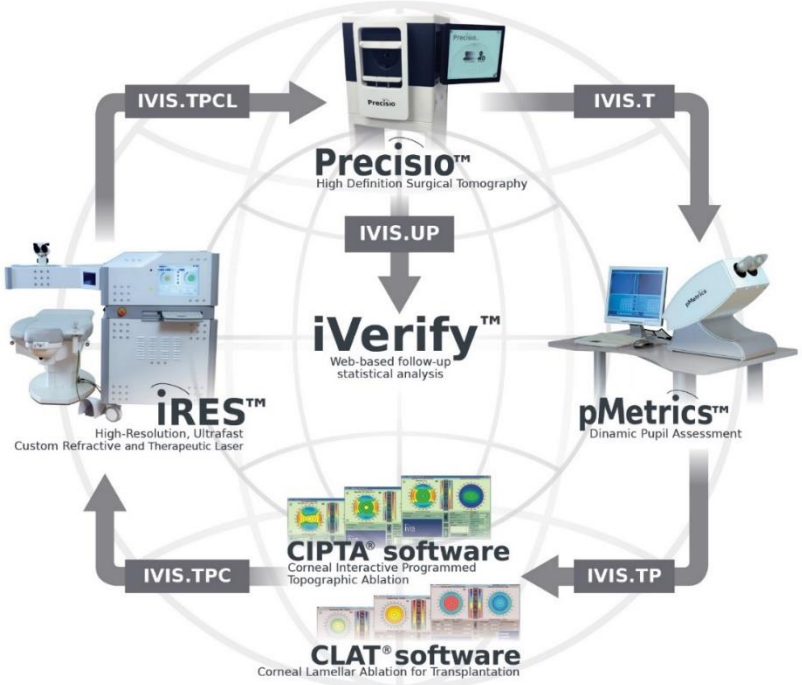
However Trans-epithelial surgery requires the epithelium to heal back again. Thus patients who undergo trans-epithelial surgery, different than for LASIK, although not as much as for PRK, will be subject to undesirable collateral effects as to a sensation of discomfort or pain into the eye for a couple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



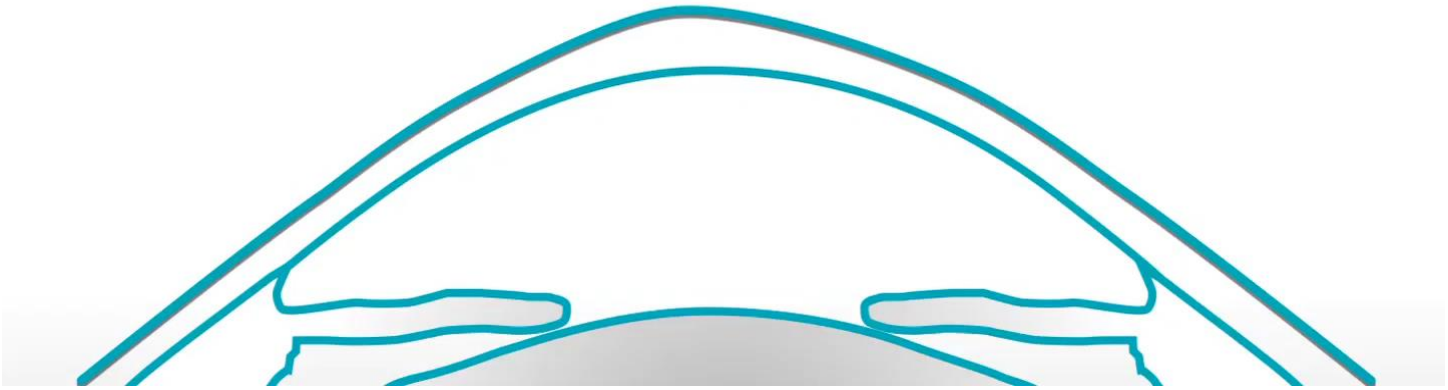
The iVis Technologies' strategy has always been oriented towards the research, development and production of an integrated platform to carry out customized no-touch refractive and therapeutic trans-epithelial corneal surgery by mean of a wireless protocol of communications and a closed loop control.

iVis Suite™

TES™

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.



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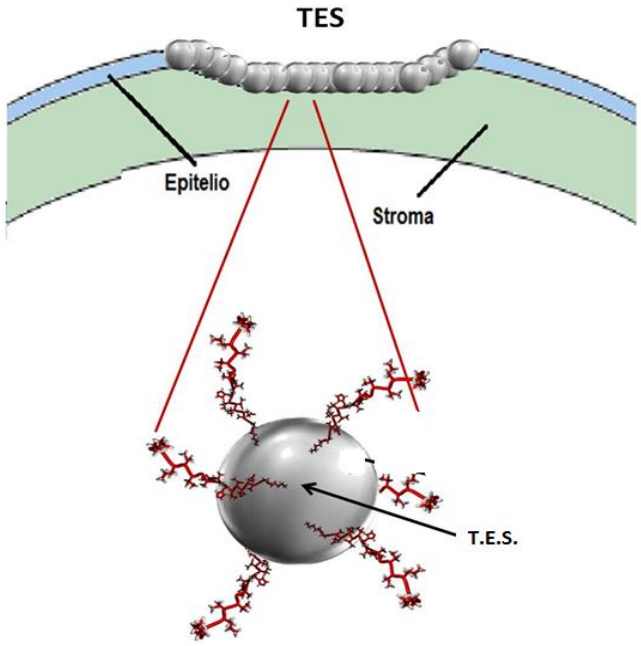
Therefore, in order to minimize the undesired collateral effects related to trans-epithelial surgery, the research and development of a Temporary Epithelial Substitute (TES™) was of strategic importance for iVis Technologies.
The idea behind TES™ is to fix a film of self adhesive hydrogel onto the debrided cornea, through appropriate means, to achieve a barrier, on a temporary basis, to replace the epithelium after a corneal surgery or a corneal injury.



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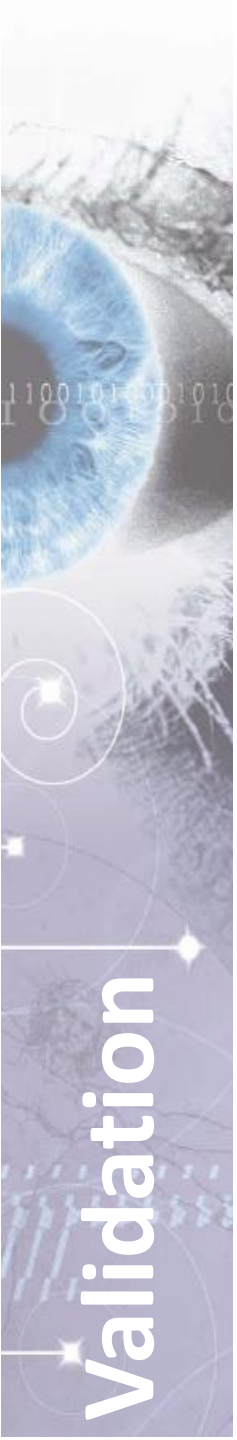
TES™ should match the following requirements:

- To be transparent, sterile, biocompatible and oxygen permeable;
- To have a good resistance to the mechanical stress of the eyelids;
- To reduce the post-op pain due to lack epithelium ;
- To help epithelium healing ;
- To reduce inflammatory process;
- To minimize side and adverse effects;
- To be easily removed by the re-growing epithelium.



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TES™ validation process was based on the following steps:

1) **Ex-vivo application on pig eye debrided by mean of an ophthalmic knife**

   Rational: To evaluate ex-vivo, in-situ TES™ modification, after crosslinking, from liquid state to hydrogel, on pig eye debrided by mean of an ophthalmic knife.

2) **In-vivo application on rabbit eye debrided by mean of an ophthalmic knife**

   Rational: To evaluate in-vivo, in-situ TES™ modification, after crosslinking, from liquid state to hydrogel, on rabbit eye debrided by mean of an ophthalmic knife.
   To determine the stromal cellular mortality after TES™ application;
   To evaluate quality and timing of the corneal re-epithalization process after TES™ application.
   To look for the eventual residual presence of TES™ onto the cornea after completion of the corneal epithelium healing.

3) **In-vivo application on rabbit eye debrided by mean of a trans-epithelial laser treatment**

   Rational: To evaluate in-vivo, in-situ TES™ modification, after crosslinking, from liquid state to hydrogel, on rabbit eye debrided by mean of a trans-epithelial laser treatment;
   To evaluate quality and timing of the corneal re-epithalization process after TES™ application.

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Ex-vivo TES™ application on a pig eye debrided by mean of an ophthalmic knife:

Rational:

- To evaluate ex-vivo, in-situ TES™ modification, after crosslinking, from liquid state to hydrogel on pig eye debrided by mean of an ophthalmic knife.

Validation

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In-vivo TES™ application on a rabbit eye debrided by mean of an ophthalmic knife:

Rational:

- To evaluate in-vivo, in-situ TES™ modification, after crosslinking, from liquid state to hydrogel on rabbit eye debrided by mean of an ophthalmic knife;
- To determine stromal cellular mortality after TES™ application;
- To evaluate quality and timing of the corneal re-epithalization process after TES™ application;
- To look for the eventual residual permanence of TES™ onto the cornea after completion of the corneal epithelium healing.

Validation

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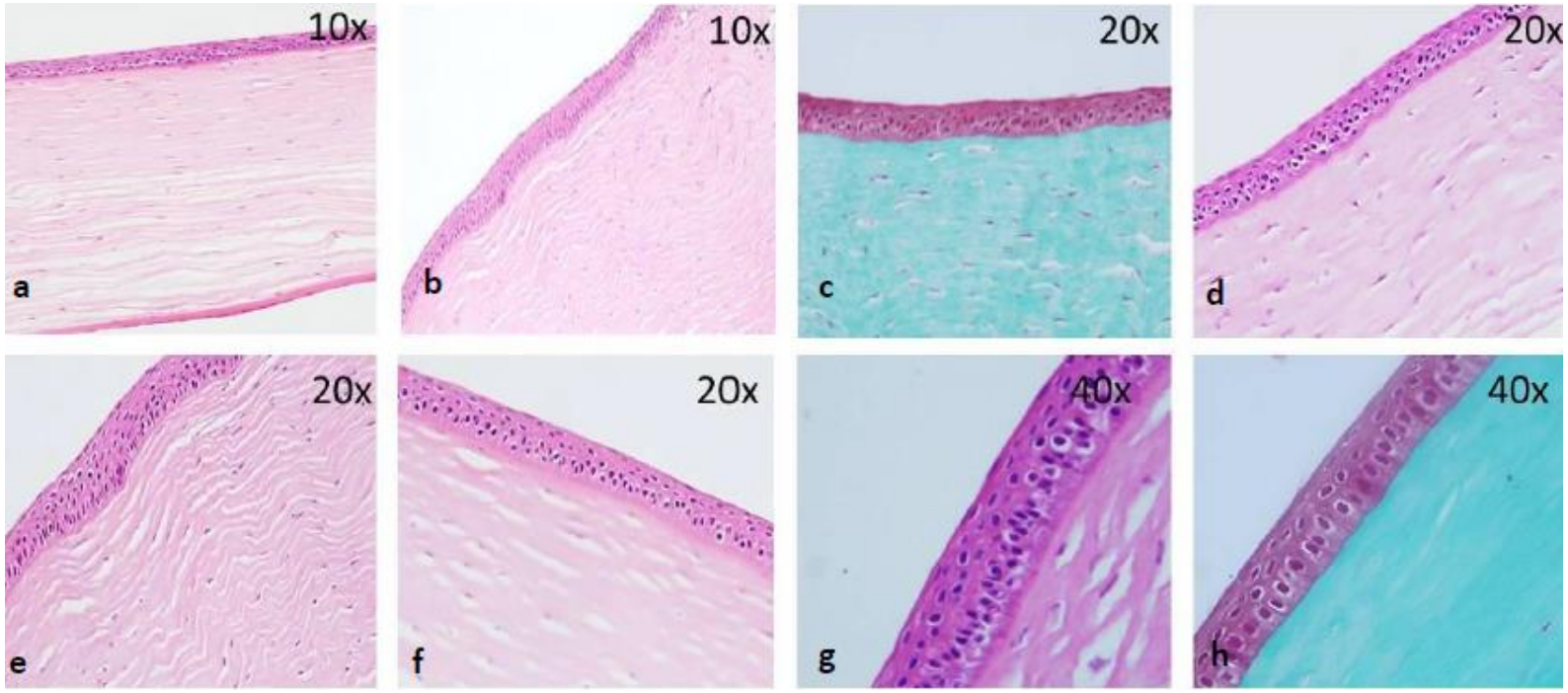
Histological analysis: no cytotoxicity

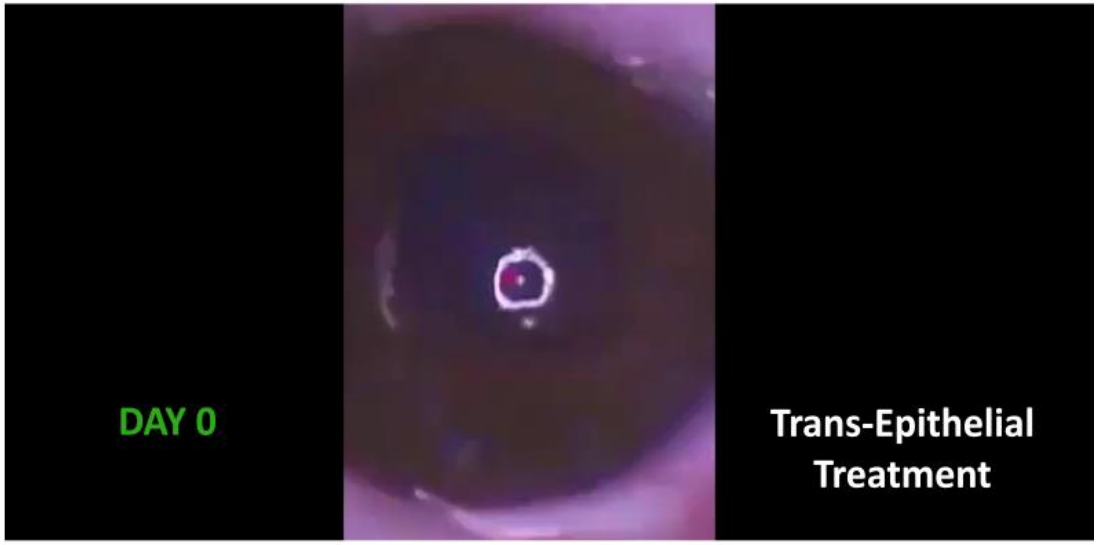


The lining epithelium appears to be in its physiological configuration, the cells are well organized among themselves.
TES™ has been completely removed from the site of deposition.

validation

TES™

In-vivo TES™ application on rabbit eye by mean of a trans-epithelial laser treatment



Rational:

- To evaluate in-vivo, in-situ TES™ modification, after crosslinking, from liquid state to hydrogel, on rabbit eye debrided by mean of a trans-epithelial laser treatment;
- To evaluate quality and timing of the corneal re-epithelization process after TES™ application;

Validation

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TES™ application onto the debrided eye is achieved by mean of a customized syringe which incorporates a prefilled volume of solution. The device is conceived to deliver an uniform and constant layer of TES™ on the whole corneal surface.

Delivery

Thank you for your attention

from Italy, centuries of inspiration and innovation create custom vision