

SOFT italia

TRANSEPIHELIAL CORNEAL  
CROSS-LINKING  
BY IONTOPHORESIS

FOR THE PATIENT

## WHAT IS TRANSEPITHELIAL CORNEAL CROSS-LINKING (TE-CXL)?

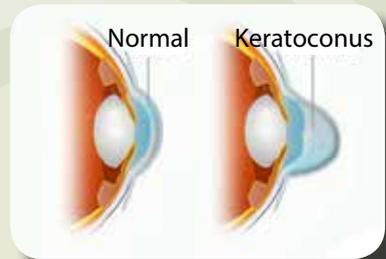
Transepithelial Corneal Cross-Linking (TE-CXL) is an innovative technique to treat keratoconus and corneal ectasia (wear of the corneal profile that induces the occurrence of vision defects): in these disorders, the cornea is “weakened” and therefore tends to be progressively deformed under pressure within the eye.

TE-CXL treatment makes use of a harmless substance, riboflavin or Vitamin B2, to create a chemical reaction within the stroma (the “skeleton” of the cornea), triggered by ultraviolet light emitted by a lamp specially designed for this purpose.

The chemical reaction leads to multiplying of the links between collagen fibres (the protein that makes up over 70% of the stroma) which are diminished in patients with keratoconus, thus allowing for an increase in the cornea’s mechanical resistance with the subsequent reduction of wear to the same.

The transepithelial technique is performed without removal of the corneal epithelium (the thin layer covering the cornea), as is the case with other techniques because the formula used includes specific molecules which allow the riboflavin to be transported to the inside of the cornea where it can perform its action.

Since this treatment is not invasive, it is very well tolerated, because it involves less eye discomfort and guarantees quicker vision recovery compared to the techniques that require the removal of the epithelium.



## WHAT IS CORNEAL IONTOPHORESIS?

Recent scientific research aimed at greater optimisation of the cross-linking procedure that may combine efficacy and safety with greater ease and speed of treatment. This is now possible thanks to a new technique called IONTOPHORESIS, able to ensure a more rapid transfer and greater uniformity and distribution of riboflavin within the cornea. Iontophoresis (from *iontos* = ion and *phoresis* = transport, transport of ions) consists of the transfer of molecules, with an ionic charge (among which riboflavin), throughout the tissues to be treated, by means of a low intensity electric field. It is a harmless technique for ocular tissue (it works at very low intensity charges), and it provides access to more homogeneous concentrations of riboflavin, compared to passive permeation, and with much faster overall treatment periods. In fact, corneal iontophoresis allows for the corneal cross-linking procedure to be reduced to only a total of 14 minutes (absorption and UV-A irradiation) from the 60 minutes required for the standard transepithelial technique (with passive absorption): the cornea riboflavin absorption phase through iontophoresis requires 5 minutes and the UV-A irradiation at 10 mW/cm<sup>2</sup> requires 9 minutes.



TE-CXL WITHOUT IONTOPHORESIS - DURATION 1 hr

TE-CXL WITH IONTOPHORESIS - DURATION 14 minutes

The combined IONTOPHORESIS-UV-A treatment ensures greater biomechanical resistance within the treated corneas, as shown in the recent scientific literature.

## HOW IS THE PROCEDURE PERFORMED?

On the day of the treatment, eye drops are used to temporarily restrict the pupil (**Fig. 1**). The eye and the area around it are cleansed with an antiseptic solution (**Fig. 2**), anaesthetic eye drops are used to further reduce even the slightest feeling of discomfort.

After applying a tool to maintain the eye open (called a blepharostat, **Fig. 3**), the Ophthalmologist places an appropriate ring on the cornea of the patient, which is filled with riboflavin (RICROLIN®+) (**Fig. 4**).

A low intensity charge, absolutely imperceptible to the patient, allows the riboflavin to enter the cornea in only 5 minutes rather than the 30 minutes that would be required for passive absorption (or with riboflavin that is dropped into the eye).

After 5 minutes of iontophoresis, the ring is removed and the treatment with low intensity ultraviolet rays is performed (**Fig. 5**) (these rays are not damaging to the eye). This phase lasts 9 minutes.

At the end, the eye is rinsed with saline solution and medicated with specific eye drops (**Fig. 6**).

After the procedure, the Ophthalmologist will place a contact lens to protect the eye, which will be removed after 3-4 days.

Immediately after the treatment, the Ophthalmologist will perform some simple checks of the eye to ensure that the procedure went well.

1



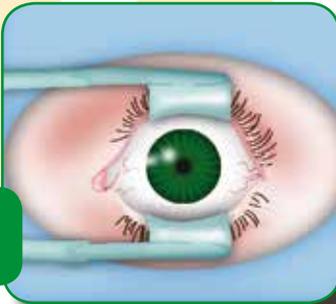
Instillation of miotic eye drops (to temporarily restrict the pupil).

2



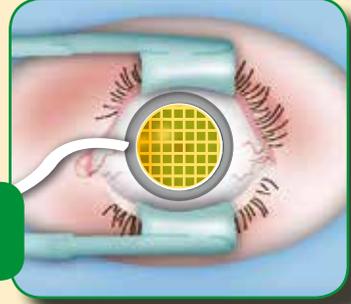
Cleansing of the area around the eye.

3



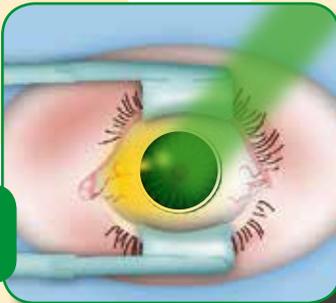
Application of the blepharostat.

4



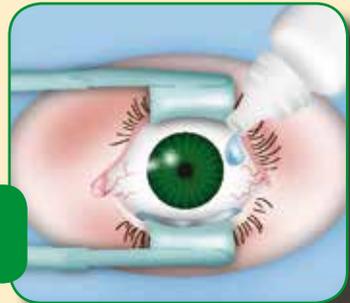
Application of the ring for iontophoresis, which allows for the absorption of riboflavin (RICROLIN®+) inside the stroma within 5 minutes.

5



Irradiation with low intensity ultraviolet rays for 9 minutes.

6



Rinsing of the eye with saline solution. Medicating with specific eye drops.

## IS TE-CXL TREATMENT WITH IONTOPHORESIS PAINFUL?

The TE-CXL treatment by Iontophoresis is generally well tolerated. The postoperative course does not cause any particular inconvenience; however, within the initial 48 hours after the procedure, moderate secretion of tears and photophobia (increased sensitivity to light) may occur.

In addition, a mild sensation of a foreign body may be felt as well as moderate conjunctival hyperaemia (the white part of the eye may appear reddened). These phenomena, the sensation of a foreign body and/or a slightly reddened eye, are usually resolved within a few hours.

After the intervention, some patients may experience temporary eye pain, attenuated by the contact lens. In some cases it may be useful to take NSAIDs (non-steroidal anti-inflammatory drugs) orally.

Quality of vision after the procedure will be the same as before the procedure, without blurring phenomena; as recommended by the Ophthalmologist, this may allow for work or school activities to be resumed rather quickly.

## WHAT NEEDS TO BE DONE AFTER TREATMENT?

The Ophthalmologist will prescribe several eye drops, which must be administered to the treated eye four times a day for the recommended period. The Ophthalmologist will apply a protective contact lens that must be worn for a few days. Several supplements may be recommended to encourage faster recovery of function. In addition, Ophthalmologist check-ups will be scheduled on a pre-determined basis, which are very important to regularly attend.

## WHAT CAN BE EXPECTED FROM THE TREATMENT?

Will eyesight improve?

TE-CXL with iontophoresis is a technique that aims to slow down and in some cases, stop the progression of keratoconus, avoiding a worsening of the quality of vision.

TE-CXL with iontophoresis is not a “refractive” technique, and it does not have the objective of correcting defective vision, even if some patients, after a few months, report “improved” vision.

This is an event that occurs often, although not in all cases.



The logo for SOOFT italia, featuring the word "SOOFT" in a large, white, serif font with a red dot above the second 'O', and "italia" in a smaller, white, sans-serif font to its right.

SOOFT italia

042 MI - S14

The logo for SOOFT italia, featuring the word "SOOFT" in a large, white, serif font with a red dot above the second 'O', and "italia" in a smaller, white, sans-serif font to its right.

SOOFT italia

SOOFT italia S.p.A.  
C.da Molino, 17 - 63025 Montegiorgio (FM) [www.sooft.it](http://www.sooft.it)

The logo for OOgroup, featuring two interlocking white circles with a red dot in the center of the intersection, followed by the word "group" in a red, sans-serif font.

OOgroup  
[www.oogroup.it](http://www.oogroup.it)

TRANSEPIHELIAL CORNEAL  
CROSS-LINKING  
BY IONTOPHORESIS

FOR THE PATIENT