Surgical procedure

Technical procedure

Instructions of surgical procedure.

- 30 minutes before surgery instill Pilocarpine 2% eye drop once only
- Topical anesthesia: instill Lidocaine 4% three times in 15 minutes
- Calibration test by means of power meter: 3mW/cm² ("POWER ON CHECK" displayed)
- Patient positioning under surgical mircroscope and blepharostate placement
- Mark the corneal area and carry out the disepithelisation of 9mm diameter using blunt spatula
- Instill 1 drop of Lidocaine 4% again
- Instill 4-6 drops of Ricrolin (Riboflavin solution 0.1%)
- Position optical head above the patient and align for accurate focusing
- Press pedal: from "POWER ON CHECK" to "STEP 0" (imbibition phase)
- After 10-15 minutes press pedal again to return to "WAIT" phase
- Width of UV-A light spot must be 8mm in diameter
- Instil 2 or more drops of Ricrolin at the beginning of each phase
- Press pedal to start "STEP 1" wich will last 5 minutes. The system will than pass automatically to the "WAIT" phase and then the next step
- Proceed to subsequent phases until completion of all phases
- After step 6 the system will automatically return to "POWER ON CHECK"
- Cleanse ocular surface with sterile saline solution, administer intrasurgery medication and position therapeutic contact lens (CL).

Intrasurgery medication

1 Tabl. Paracetamolo 500mg - Codeine 30mg (Co-Efferalgan BMS) or 1 Tabl. Ketorolac 10mg (Lixidol). Cleanse ocular surface and instill:

Ofloxacin collyrium 1-2 drops

Cyclopentolate 1-2 drops Flurbiprofen 1-2 drops

Postsurgery medication

The therapy begun in the surgical phase, to be repeated 4 times a day, continueing until removal of the contact lens (4-5th day). The CL to be removed on completion of the re-epithelialization. Topical medications after surgery should be continued for 15-20 days (according to medical advice) and consist of:

Ofloxacin collyrium 1-2 drops 4 times a day

Flurbiprofen 1-2 drops 4 times a day

Trium eye drops 1-2 drops 4 times a day for at least 3 months



Ophthalmic solution for parasurgical use



RICROLIN® is an ophthalmic solution containing Riboflavin 0.1%. This solution is instilled in the eye during irradiation of UV-A light as part of the parasurgical procedure of corneal collagen cross-linking. The principal objective of RICROLIN® is to provide a barrier against UV-A penetration beneath the corneal stroma, and thus protect the delicate internal structures of the eye (corneal endothelium, lens and retina) from damage that may be caused by radiation. RICROLIN® solution is in fact capable of reducing up to 95% of the UV energy that reaches the deep strata of the cornea.

In association with ophthalmic UV-A radiation, the solution is administered during conservative parasurgical procedures for keratoconus and other corneal estasia

In particular the treatment is indicated in the following conditions:

- Diagnosed Keratoconus and/or secondary ectasia on the basis of clinical, topographical and pachymetrical analyses - Clinically and instrumentally diagnosed Progressive Keratoconus

The administration of RICROLIN® in association with UV-A light retards the progression of Keratoconus

This treatment can prevent the necessity of corneal transplant. This treatment does not exclude the possible need of keratoplasty in the future.

Instructions for use

10-15 minutes prior to irradiation, instil 1 or 2 drops of the product using the appropriate dispenser provided and repeat treatment every 5 minutes. During treatment with UV-A light instil 1 or 2 drops of the solution every 5 minutes for

Composition

100ml of solution contains:

Riboflavin phosphate 0.127 g (equivalent to 0.1g of basic Riboflavin); Destrane

Excipients: Bihydrate sodium phosphate monobasic, Bihydrate sodium phosphate bibasic, Sodium chloride, Distilled water q.b. for 100g

Contraindications

There are no known contraindications associated with the ophthalmic solution. Use must be avoided in cases of hypersensitivity reactions to the components of the product or to other chemically-related substances

No systemic or eye structure related side-effects have been reported

- The product must be kept away from direct light
- Right up to the moment the product is to be utilised, it must be stored under refrigeration at a temperature between +4 and +8°C • Kept within its dispenser, the solution is maintained sterile
- Do not touch the eye surface or other objects with the cannula needle in order to avoid the risk of contamination to the solution
- Do not utilise the product after more than one hour from first use • Do not utilise the dispenser for more than one patient
- Do not utilise the product after the date indicated on the package
- Do not keep the product in temperature over 25°C
- The product is strictly indicated for external ophthalmic parasurgical use and
- is therefore utilised exclusively by registered Ophthalomologists.
- Do not utilise product if packaging is damaged

1 monodose sterile dispenser filled with 1 ml solution

1 sterile single-use cannula needle

Aldo Caporossi, Cosimo Mazzotta e Stefano Bajocchi:

Aldo Caporossi MD. FRCS. Cosimo Mazzotta MD. PhD. Stefano Baiocchi MD. PhD: Technological Innovations in Corneal Collagen Cross-Linking, Ophthalmology Times Europe,

Control pedal Fixation point

TECHNICAL CHARACTERISTICS

- Incorporated telecamera with focus controller
- Improved irradiation consistency thanks to the excellent UV illuminator, integrated with innovative optical system
- Adjustable diaphragm to vary the treatment area

• Timer and Monitor to observe all procedure steps

- Built on a stand with wheeled base
- Balanced operating arm

Characteristic of UVA source

Single LED for UV-A rays Maximum wavelength: 370nm

Width of ray: 8nm

Power density of irradiation 3mW/cm2 (nominal) Accuracy: ± 10%

Between 4 -11 mm (@ 54mm) Diameter of radiated area

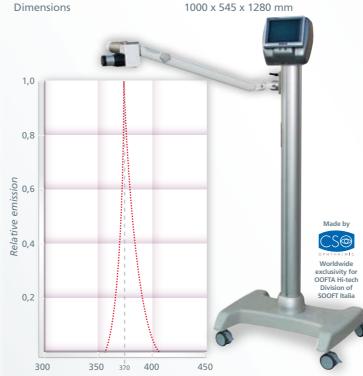
Couple of red LED Collimation system

Telecamera Integrated with optic head

Colour micro-telecamera Colour, 5.6 inch

Dimensions

Monitor



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RICROLIN®



