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# **RPIA Project: OPTOMED Innovative Technologies in Ophthalmology**



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# Summary

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**The OPTOMED Project aimed at the development and transfer of innovative instrumentation and methodologies used in Ophthalmic surgery to enterprises of Tuscany operating in the field of Opto-electronics and in hospital care in the most important university clinics and hospitals.**

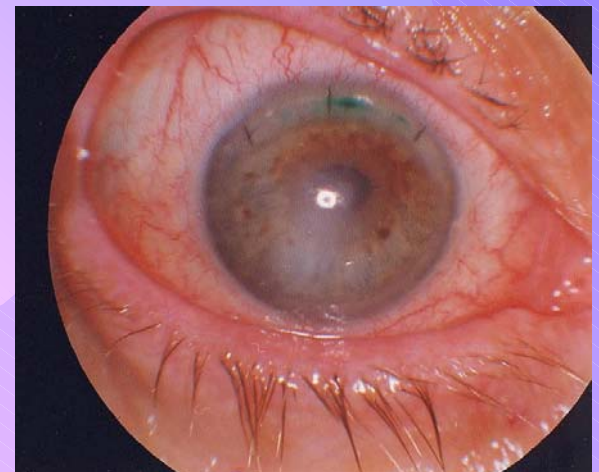
**Specifically, the OPTOMED project has set up prototypes of new surgical diode lasers, instruments for ophthalmic diagnostics, and new pharmaceutical formulations of photosensitisers .**

# Introduction:

## Laser corneal welding ①



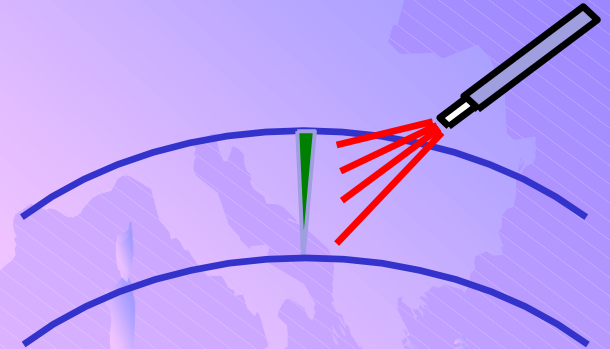
- Laser-induced welding (soldering) of corneal tissue is an original proposal made by two Italian scientists (R. Pini and L. Menabuoni), which received the approval of the Italian Health Ministry for pre-clinical and clinical trials.
- The technique is based on laser-induced activation of the endogenous collagen, which behaves like a thermally activated glue
- It is proposed for use in the transplant of the cornea, in substitution of the conventional continue suture, as well as in cataract and post-traumatic corneal surgery.



# Laser corneal welding ②



- The laser welding technique is based on the application of a biocompatible photosensitizer (i.e. a dye solution) in the corneal cut, which is then irradiated by a diode laser emitting at 810 nm. The role of the photosensitizer is to enhance the local absorption of laser light, in order to activate corneal collagen and produce tissue fusion.
- The repaired cut is immediately water-tight, with good mechanical strength and no adverse side-effects (such as heat damage).





# Advantages of diode-laser corneal suturing



**Expected improvements of laser-assisted suturing in corneal surgery (especially in corneal transplant):**

- **Simplification of the surgical procedure and reduction of the intervention time (3-5 min. vs. 30-45 min.)**
- **Reduction of suture material and, consequently, of post-operative inflammation (foreign body reaction)**
- **Reduction of post-operative astigmatism**
- **Better and faster healing process (3-6 months as compared with 12-18 months of conventional surgery)**

# Objectives of the OPTOMED Project



- Development of **new demonstrative prototypes** (lasers, photosensitizers, and instruments for ophthalmic diagnostics)
- **Pre-clinical experimentation** of the developed technologies and related surgical methodologies
- Definition of **clinical protocols** in view of the clinical use
- Evaluation of **economical and social impact** of the new technologies and surgical procedures
- **Diffusion, dissemination and training** through meetings, conferences, exhibitions, and university specialization courses.

# Partnership: 6 Public Organizations



## 2 PUBLIC RESERCH CENTERS:



- **Consorzio CEO - Unità CLAM (Centro Laser Applicazioni Mediche), Firenze – Group leader, project managing**



- **Istituto di Fisica Applicata “Nello Carrara” - CNR, Firenze – Technology transfer, preclinical researches, diffusion and dissemination**

## 4 OPHTHALMIC CLINICS – Evaluation of preclinical tests, recommendation for clinical protocols :



- **Clinica Oculistica II, Dip. Scienze Chirurgiche Oto-Neuro-Oftalmologiche, Univ. Firenze c/o P.Careggi**



- **Dip. Scienze Oftalmologiche e Neurochirurgiche, Univ. Siena**



- **U.O. Oculistica, ASL 4 Prato**



- **U.O. Oculistica, ASL 10 Firenze**

# Partnership: 8 Private enterprises



**ACTIS**



- **ACTIS srl, Firenze – Development of diode lasers**
- **Molteni Farmaceutici spa, Scandicci (FI) – Development of the chromophore**
- **ITAL TBS spa, Pisa – Analysis on clinical costs of the new procedures**
- **CSO- Strumenti Oftalmici srl, Scandicci (FI) – Development of corneal topographs and aberrometers**
- **Gestione SILO srl, Scandicci (FI) – Optical components and systems**
- **EUREL srl, Scandicci (FI) – Electronic components**
- **Loto d.i., Firenze – Fiber systems for diode lasers**
- **EL.EN. spa, Calenzano (FI) – Production and commercialization of diode lasers**



## Results ①:

# The diode laser for cornea suturing

**ACTIS**  
ACTIVE SENSORS

**LOTO**  
Scientific Instruments

**EL EN**  
El. En. Group

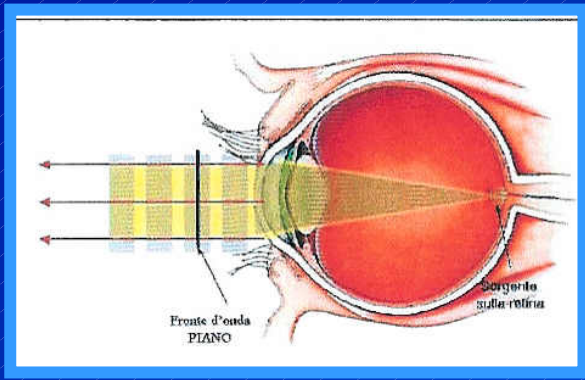
- AlGaAs diode laser @ 810 nm
- Fiber optic delivery system with fibers of 200/300  $\mu\text{m}$  core diam.
- Hand piece to be used under surgical microscope



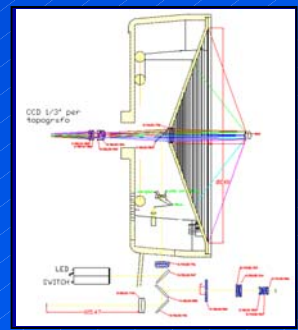
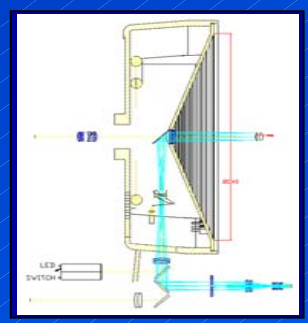
Emission wavelength	810 $\pm$ 10 nm
Output power	0.5-10 W *
Type of emission	CW and pulsed
Repetition rate (pulsed)	0.5-500 Hz
Power emission stability	$\pm$ 20 %
Aiming beam	635 nm, 1 mW
User interface	Touch screen LCD
Size	24x18x36 cm

\* 50-1000 mW with the 1/10 optical attenuator accessory

# Results ②: Corneal topograph+eye aberrometer



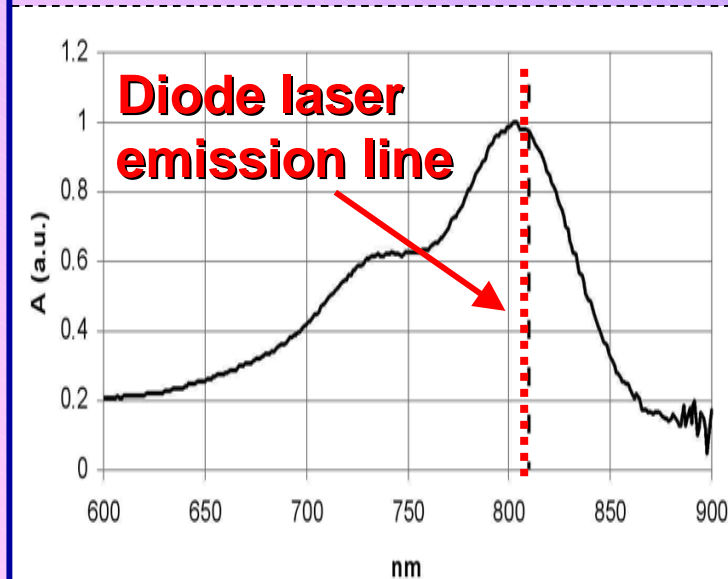
**Total aberrometry:** it measures the total modification of the light front wave propagating in the eye, including the astigmatism induced by the cornea



# Results ③: the Photosensitizer

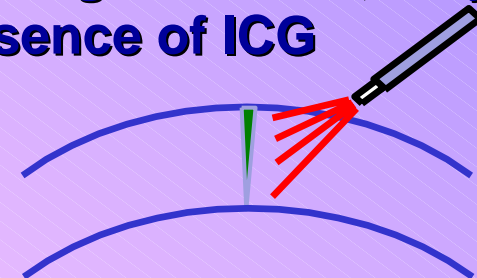
**Diode laser radiation at 810 nm is used in association with an exogenous dye (photosensitizer), i.e. a solution of Indocyanine Green characterized by high optical absorption of the diode laser light.**

**Absorption spectrum  
of ICG in corneal tissue**



**Advantages in comparison with other laser approaches:**

- **Very low laser power (< 100 mW, 5-10 W/cm<sup>2</sup>)**
- **Selective and localized welding in the cut, only in presence of ICG**





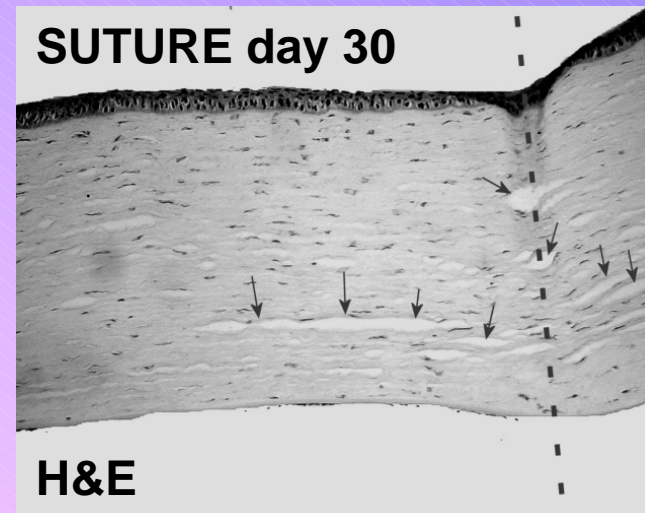
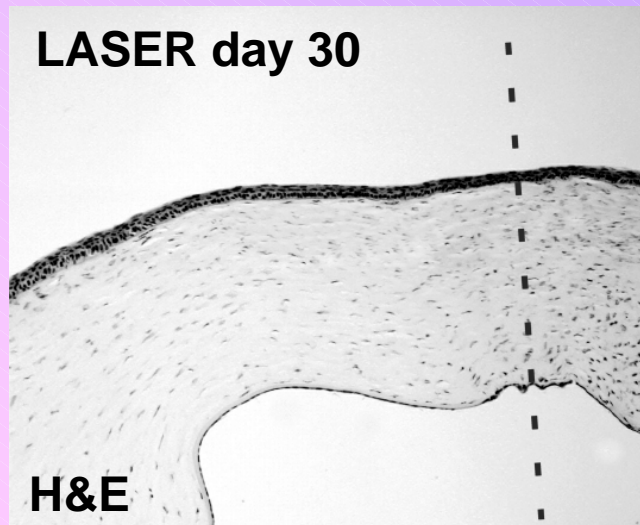
# Results ④:

## Preclinical studies on the healing process

*IFAC-CNR*

### Results of histology exam. in a follow up study up to 90 days :

- the healing process was found to develop in a shorter time and with less inflammatory and foreign-body reactions
- the architecture of the cornea regained an almost physiological aspect with continuity of epithelium and endothelium and regularly organized collagen fibers in the stroma .





# Promotions of the OPTOMED Project



The project was promoted and publicised by means of:

- A brochure (in Italian and English) printed in 2000 copies, which was used in all the public occasions of diffusion.
- Participation to 5 meetings and exhibitions
- 5 scientific articles
- Several communications to national and international scientific conferences
- About 20 Press reports, articles in Italian newspapers, interviews



# Beneficiaries of OPTOMED results ①



The project has developed a network of public and private partners which enabled it to attain innovation transfer in various application fields. Beneficiaries could be identified as follows:

**1) The industrial sector:**

a group of enterprises working in the fields of laser technology, optics and electronics components, ophthalmic instruments, pharmaceutical products, economic consulting and planning for the Health System. All of them have the capacity to engineer, mass produce and market such products and instruments.

**2) The medical field:**

Instruments, pharmaceutical products, and innovative procedures were created and tested in four important university clinics and hospitals in Tuscany, thus involving the final target consumers during the actual development phase.

# Beneficiaries of OPTOMED results ②



3) The public health system, in terms of both economic and social advantages.

## 3.1) Economic advantages:

- a reduction in length of average hospital stays;
- smaller expenses due to the lower number of checkups necessary during the healing process
- lower relapse rate
- reduced expenditure for eyeglasses and vision correction

3.2) Social advantages referred to health benefits for patients and to improvement in their quality of life. Specifically:

- technical/surgical advancements in corneal transplants and in the suturing of corneal wounds
- more efficient healing with less astigmatism



# Positive aspects of multidisciplinary



- **OPTOMED's managing was carried out by research centers, well experienced in co-ordinating quite large and multidisciplinary research projects.**
- **Beside researchers and industrial engineers, the working groups included also the end users, i.e. ophthalmic surgeons, which provided an immediate validation of the new technologies. This helped to shortening the time-to-market of the products.**
- **The management had strong interactions with the Regional steering committee by means of the group of experts nominated by the Tuscany Board. This also helped a transversal coordination with other projects carried out in the same program frame.**



# Obstacles in terms of design and implementations



- **MANAGING PROBLEMS:** Small enterprises and hospital clinics, which had no previous experiences in co-ordinated projects, encountered big problems in facing bureaucratic and administrative managing of the project. A simplification of administrative procedures would help in the future to improve this figure.
- **TECHNOLOGY PROBLEMS:** During the development of the project we realized that only innovations that were almost mature for the industrial development had the major possibilities of success. Sometimes the innovation appeared “too innovative” for the industrial process, especially when research centers proposed the whole design of new devices.

# Optomed: *present* developments



- **Production of a pre-series of diode lasers for clinical use**
- **Clinical phase: routine use in corneal transplants (20)**
- **Related patents: 2 Italian + 2 International (PCT)**
- **New related Projects and Networks:**



**Clinical Project on laser-assisted “lens refilling” (2004-2007)**



**Network for Optoelectronics in Tuscany (2005-2006)**



**Pilot Project (Virtual Enterprise)  
on minimally-invasive  
ophthalmic surgery (2007-2008)**

# Thank you for your time!

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