

RegenSight
The Theranostic Eye Care Health Company

ESCRS iNovation ESCRS ESCRS iNovation® Day
Friday 6th September 2024
Fira Gran Via, Barcelona, Spain

Unveiling *incision-free* theranostic technology for the correction of visual disorders

OUR VISION

Founding and Mission
Regensight, founded in July 2019, aims to revolutionize ophthalmic care through *incision-free theranostics* technology.

Targeted Visual Disorders
Focus on **keratoconus**, **low-grade myopia** and **presbyopia**, addressing the needs of half of the global population.

Market Potential
Meeting the growing market demand by providing **precision**, **personalized** and **predictive** treatments for visual disorders.


RegenSight
REGENERATE. IMPROVE

THE SHIFT

Hushering a Paradigm Shift in Eye Care

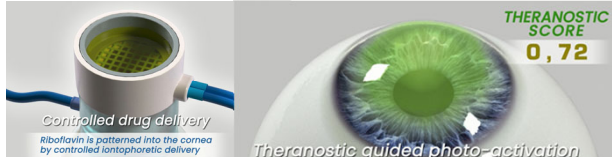
Visual disorders are the most frequent causes of visual disability at all ages

CURRENT SURGERY IS PAINFUL, INVASIVE AND HAS RISK OF VISION LOSS




Laser vision correction and intracorneal implants surgeries bend incident light via **changing thickness** WITH TISSUE REMOVAL OR INCISIONS

REGENSIGHT IS INCISION-FREE AND FREE OF RISKS



Regensight improves vision through **theranostic-guided** UV-A light photo-polymerization of stromal proteins within a **patterned distribution of riboflavin** in the cornea WITHOUT TISSUE REMOVAL

THERANOSTIC SCORE
0,72



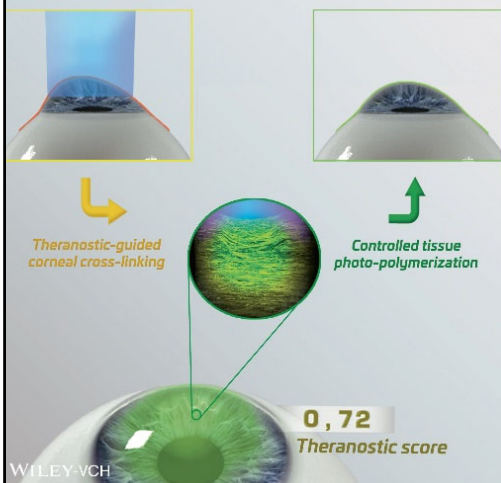
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JOURNAL OF BIOPHOTONICS

12/2022

www.biophotonics-journal.org

Theranostic-guided corneal cross-linking: Practical evidence on a new treatment paradigm for keratoconus. Giuseppe Lombardo, Giuseppe Massimo Demaro, Sebastiano Seno, Marco Lombardo



WILEY-VCH

Theranostics Technology - Overview


Transformative Paradigm
Theranostics combines **therapy** and molecular **diagnostics**, offering an *incision-free* solution for addressing visual disorders

Patterned molecular drug delivery
Precise, fast, patterned delivery of **riboflavin** in the cornea

Simultaneous measurement and treatment
Utilizes UV-A light to **monitor riboflavin** delivery in the cornea and to **photo-polymerize stromal proteins** in **targeted corneal regions**.

Scientifically & Clinically Validated*
Currently validated for precise and predictive treatment of keratoconus with **high accuracy** (91%) and **precision** (95%)

*CLINICAL TRIAL [NCT05457647](https://clinicaltrials.gov/ct2/show/study/NCT05457647)
Ophthalmology 2024; in press



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DEVELOPMENTS

Enhancing Human Vision

01

Current Focus

Introducing the **new gold standard of care for keratoconus** in the short term, enhancing RegenSight market presence and patient impact.

02


Medium-Term Plans

Development of **new treatment options for low-grade myopia and presbyopia**, expanding the product line and market reach.

03

Long-Term Vision

Establishing RegenSight as a **leader in incision-free ophthalmic care**, tackling visual disorders of significant societal impact by harnessing theranostics and precision & personalized treatment strategies.



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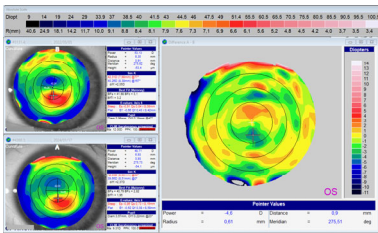
THERANOSTICS

Advantages



Precise and Predictive

Offering a **transformative technology** for visual disorders, redefining the treatment approach while mitigating the risks linked with conventional surgical techniques.



Incision-free Solution

Theranostics provides an advanced **incision-free** approach to treating visual disorders, **enhancing patient compliance** and visual outcomes.



Data-Driven Approach

Leveraging **machine learning (Artificial Intelligence)** to enhance the accurate assessment of targeted therapy, ensuring tailored and effective eyecare solutions.

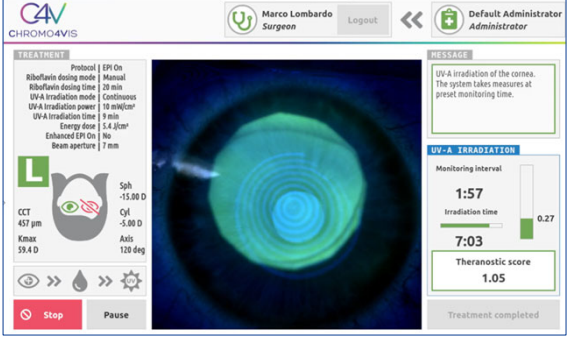


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OUR SCIENCE

Scientifically & Clinically Validated




Clinical Validation of Theranostics

Clinically validated for precise treatment of keratoconus with **predictive personalization of the therapeutic outcome**, achieving **significant improvements** in visual acuity and corneal shape.



Scientific Publications

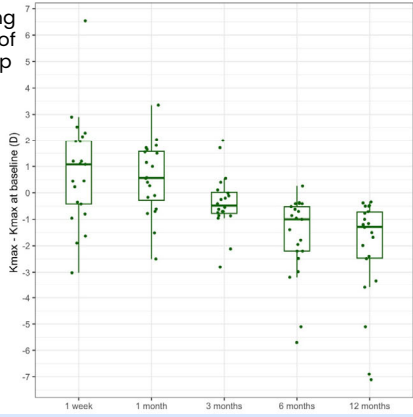
Numerous scientific publications showcasing the efficacy and impact of theranostics in treating visual disorders.



OUR EVIDENCE

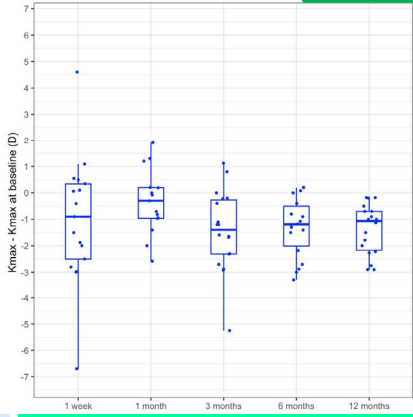
CLINICAL TRIAL NCT05457647: True Positives

epi-off Thera CXL $-2.1 \pm 1.9 D$
 $P < 0.001$



State-of-the-Art epi-off CXL K_{max} change:¹⁻⁵
 $-1.3 \pm 1.4 D$

epi-on Thera CXL $-1.3 \pm 0.9 D$
 $P < 0.001$



State-of-the-Art epi-on CXL K_{max} change:¹⁻⁵
 $-0.3 \pm 1.5 D$

We redefined treatment approach for keratoconus: the paradigm of THERANOSTICS is REAL EFFICACY in REAL TIME

- 1. Sykasis E et al. Cochrane Database Syst Rev. 2015;2015(3):CD010621
- 2. Ng SM et al. Cochrane Database Syst Rev 2021;3(3):CD013512
- 3. Serrao S et al. Int Ophthalmol 2022; 42(1): 337-348
- 4. Chunyu T et al. Sci Report 2014; 4: 5652
- 5. Li J et al. Plos ONE 2015;10(5):e0127079.

CLINICAL CASE (1) 16 years old patient (keratoconus)

Epi-off CXL using Thera-CXL platform

Pointer Values	Sim K
Power = 43.32 D	43.98D (7.67mm) @145°
Radius = 6.84 mm	43.79D (7.71mm) @55°
Distance = 1.68 mm	diff = -19D
Meridian = 262.37 deg	Best Fit (Maloney)
Height = -186.8 µm	BFs = 43.88 BFc = 0.43
Pupil: Diam 6.43mm, Off 0.15mm @245°	
E-values: Axis 6	
CLMI (keratoconus screening) Ma: 2.86D PPK: 40.0%	Deep: Es: 0.43 Cs: -0.19
	Flat: Et: -0.51 Cfo: 0.25 r: 7.7 mm

Pointer Values	Sim K
Power = 47.45 D	43.94D (7.68mm) @131°
Radius = 7.11 mm	43.62D (7.74mm) @41°
Distance = 1.68 mm	diff = -32D
Meridian = 259.21 deg	Best Fit (Maloney)
Height = -187.9 µm	BFs = 43.98 BFc = 0.21
Pupil: Diam 3.74mm, Off 0.21mm @166°	
E-values: Axis 6	
CLMI (keratoconus screening) Ma: 2.36D PPK: 18.0%	Deep: Es: 0.50 Cs: -0.25
	Flat: Et: 0.21 Cfo: -0.05 r: 7.7 mm

Pointer Values	Sim K
Power = 45.4 D	42.52D (7.86mm) @129°
Radius = 7.43 mm	42.9D (7.87mm) @39°
Distance = 1.71 mm	diff = -01D
Meridian = 251.81 deg	Best Fit (Maloney)
Height = -188.8 µm	BFs = 42.78 BFc = 0.74
Pupil: Diam 3.18mm, Off 0.12mm @169°	
E-values: Axis 6	
CLMI (keratoconus screening) Ma: 1.47D PPK: 2.9%	Deep: Es: 0.19 Cs: -0.04
	Flat: Et: -0.39 Cfo: 0.15 r: 7.90mm

Visual Acuity
Preop: 10/10 -1.50 sf
Postop: 10/10 uncorrected

K_{max} change at 1-year:
-3.9 D
 (SoA epi-off CXL: -1.3 D)

riboflavin score = 1.71 & theranostic score = 0.85

CLINICAL CASE (2) 25 years old patient (keratoconus)

Epi-on CXL using Thera-CXL platform

Pointer Values	Sim K
Power = 51.25 D	47.97D (7.24mm) @137°
Radius = 46.16D (7.31mm) @130°	diff = 1.82D
Distance = 0.97 mm	Best Fit (Maloney)
Meridian = 256.75 deg	BFs = 47.97 BFc = 3.7
Height = -24.3 µm	BFTI = 1.35
Pupil: Diam 3.37mm, Off 0.41mm @355°	
E-values: Axis 6	
CLMI (keratoconus screening) Ma: 3.43D PPK: 70.7%	Deep: Es: 0.43 Cs: -0.19
	Flat: Et: -0.51 Cfo: 0.25 r: 7.7 mm

Pointer Values	Sim K
Power = 48.15 D	45.44D (7.43mm) @149°
Radius = 43.86D (7.72mm) @139°	diff = 1.75D
Distance = 0.65 mm	Best Fit (Maloney)
Meridian = 248.18 deg	BFs = 45.35 BFc = 2.53
Height = -29.8 µm	BFTI = 1.29
Pupil: Diam 3.20mm, Off 0.30mm @352°	
E-values: Axis 6	
CLMI (keratoconus screening) Ma: 3.25D PPK: 61.5%	Deep: Es: 0.50 Cs: -0.25
	Flat: Et: 0.21 Cfo: -0.05 r: 7.7 mm

Pointer Values	Sim K
Power = -3.81 D	Distance = 0.43 mm
Radius = 0.53 mm	Meridian = 256.4 deg

Visual Acuity
Preop: 20/25 -0.50 = -2.00 cyl 120°
Postop: 20/20 -1.75 cyl 135°

K_{max} change at 1 year: -3.0 D
 (SoA epi-on CXL = -0.3 D)

riboflavin score = 0.80 & theranostic score = 1.05

DISCOVER MORE AT
www.regensight.com