ROSE BENGAL PHOTODYNAMIC ANTIMICROBIAL THERAPY (RB-PDAT)

The molecule that **reveals** disease also **eliminates** it.

- Developed by the Ophthalmic Biophysics Center at Bascom Palmer Eye Institute
- RB: 100+ years of ophthalmic use | PDAT: 10+ years of ophthalmic research & clinical validation

VisiRose

THE PROBLEM

Corneal infection is winning. Drugs are losing.

5-10M

Cases annually; leading infectious cause of corneal blindness worldwide

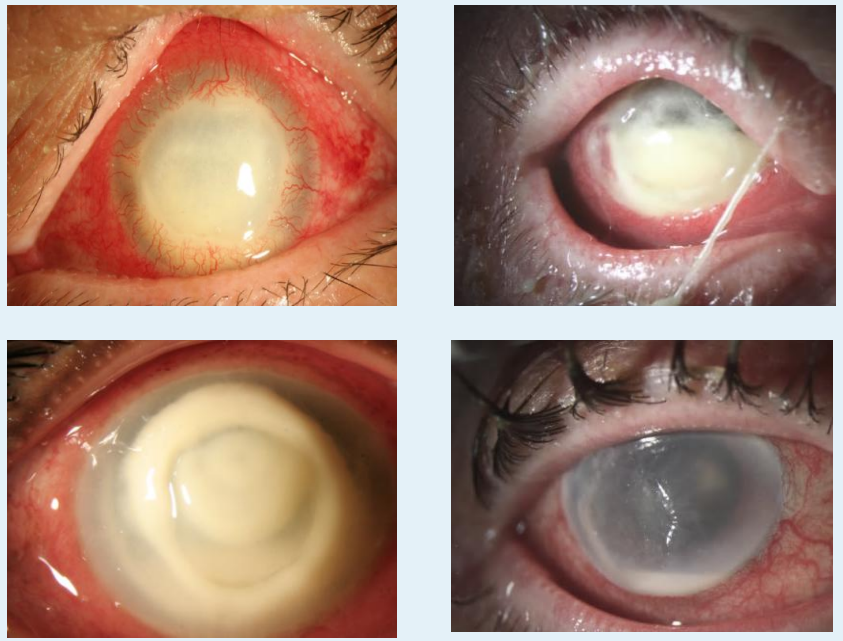
Bacterial	Fungal
P. aeruginosa, *S. aureus*, MDR strains	*Fusarium*, *Aspergillus*, *Candida*

Parasitic	Viral
Acanthamoeba	*HSV*

UNMET NEED IN INFECTIOUS KERATITIS

When antimicrobials fail, the fallback is surgery.

Therapeutic keratoplasty (corneal transplant) is a major ophthalmic surgical intervention for a condition that should be treated in the clinic. Rising pathogen resistance is eroding the drugs that stand between the patient and the operating room. Antimicrobial resistance is a declared European health priority. Infectious keratitis is among its most visible and most preventable ophthalmic consequences.



THE SOLUTION & MECHANISM

One mechanism. Indifferent to the pathogen. Hard to resist.

Rose Bengal (RB), a fixture in ophthalmology for 100+ years

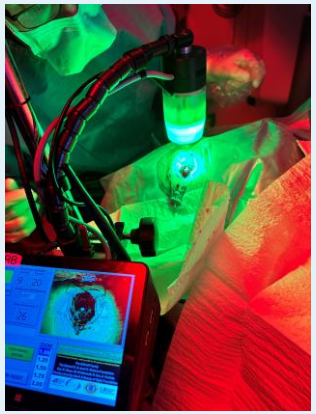
In 1914, Römer, Cobb, and Löhlein reported RB combating ocular pneumococcal infections. In 1919, Kleefeld established its use for corneal staining. In 1933, Sjögren introduced RB to detect keratoconjunctivitis sicca. Its application in diagnosing ocular surface disease, dry eye, and corneal ulcers continued in various formulations. This history was largely forgotten until the Ophthalmic Biophysics Center at Bascom Palmer Eye Institute developed RB-PDAT as a solution for severe progressive infectious keratitis in the 2010s.

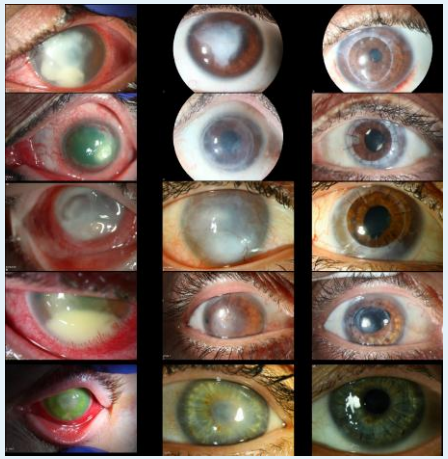
Rose Bengal Photodynamic Antimicrobial Therapy (RB-PDAT)

Bascom Palmer Eye Institute
UNIVERSITY OF MIAMI HEALTH SYSTEM

Ophthalmic Biophysics Center

1. **RB Applied**
   RB preferentially perturbs infected tissue.
2. **Light Activation**
   Green light excites RB to singlet excited state.
3. **ROS Generation**
   ROS is produced: superoxide, singlet oxygen.
4. **Pathogen Destruction**
   ROS destroys pathogens.
5. **Immune Modulation**
   Antimicrobial peptide induction, pro- and anti-inflammatory signaling.





THE EVIDENCE

RB-PDAT: 10+ years of independent signals.

Broad-Spectrum Efficacy

Active against multiple types and strains of pathogens, reducing or eliminating the likelihood of resistance

Non-Invasive Treatment

Easy to administer; avoids the need for surgery

Rapid Resolution

Faster, better treatment outcomes compared to traditional therapies

Cost Effectiveness

Lower direct and indirect treatment costs (e.g., operative and non-operative services, loss of wages)

RB-PDAT Peer-Reviewed Clinical Data

>280	Patients treated with RB-PDAT
3	Pathogen categories covered
7	Pathogen species treated clinically
>10	Years of clinical use
4	Countries with clinical use
6	Institutions treating patients
36	Peer-reviewed clinical publications

REAGIR Phase 3 RCT (NCT05110001)

- 330-patient double-masked sham-controlled RCT; adjunctive RB-PDAT vs. standard antimicrobials; single RB-PDAT treatment
- 91% of patients had fungal keratitis; ~70% Fusarium; bacterial keratitis excluded by design
- Primary endpoint (BSCVA at 6 and 12 months) not met in the overall population
- Fusarium subgroup (n=210): 0.17 lines better vision with RB-PDAT; directionally favorable (p=0.1); largest, most powered subgroup
- **First positive signal versus natamycin standard of care in nearly 50 years**
- Acanthamoeba subgroup (n=10): 2.5 lines better vision, smaller scar; directionally favorable, underpowered
- Clinical publications showing strong resolution rates used multicycle protocols

Independent Validation; Global Reach & Impact

Stanford MEDICINE

ARAVIND EYE CARE SYSTEM

LVPEI So that all may see. LV Prasad Eye Institute

Instituto de Oftalmología F.A.P. Conde de Valenciana, I.A.P.

UCSF University of California San Francisco

UNIFESP Universidade Federal de São Paulo

THE OPPORTUNITY

Global Reach. Expanding Indications. Built for Access.

THE MARKET

$20B+

Global ophthalmic market for RB-based therapies

AMR-Concern Markets

US & Europe

High-Incidence Markets

Asia, Latin America, and Africa

INDICATION EXPANSION

LEAD

Infectious Keratitis

CLINICAL DATA

Infectious Scleritis

NON-CLINICAL DATA

Corneal Ectasia

NON-CLINICAL DATA

Keratoconus

NON-CLINICAL DATA

Floppy Eyelid Syndrome

AFFORDABILITY & ACCESSS

No Surgery Required

Topical application + green light eliminates operative costs and associated risk

Lower Total Cost

Fewer treatment days vs. prolonged antimicrobial courses; avoids keratoplasty costs

Clinically Validated Across Medical Centers

BPEI (USA), Aravind (India), LV Prasad (India), UNIFESP (Brazil), Instituto de Oftalmología (Mexico)

No Known Resistance

Eliminates cost and complexity of resistance testing and drug cycling

Scalable Delivery Model

Compact PDAT device; suitable for academic and community ophthalmology settings globally

RB-PDAT is a platform with the potential to redefine the standard of care for corneal infection globally.