

# New Therapy for Ocular Surface Disorders on the Horizon - Prosthetic Replacement of the Ocular Surface Ecosystem: A Review Article

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## Abstract

**Introduction:** Prosthetic replacement of the ocular surface ecosystem (PROSE) has been a major innovation in the management of ocular surface disorders. It is a prosthetic device almost similar to a contact lens, designed for the purpose of daily wear. It creates a transparent, smooth optical surface over the damaged cornea. Furthermore, it has an expanded artificial tear reservoir that provides constant lubrication while maintaining the necessary oxygen supply. It has been proposed as management for ocular surface disorders against invasive procedure like keratoplasty. Several clinical studies have come forward with promising results. Limitations of PROSE include high cost and reduced access.

**Key words:** Cornea, Keratopathy, Keratoplasty, Lubrication, Prosthesis

## INTRODUCTION

Prosthetic replacement of the ocular surface ecosystem (PROSE) is a novel treatment approach to ocular surface disease. It is a prosthetic device to replace and enhance the function of the ocular surface ecosystem, thereby improving vision, providing comfort and supporting ocular surface. PROSE was approved by the FDA in 1994 for daily wear in the treatment for irregular astigmatism and ocular surface disorders. Over the past 20 years, it has been referred as Boston scleral contact lens, Boston scleral lens, Boston scleral lens device, Boston scleral lens prosthetic device, and Boston ocular surface prosthesis (BOS-P).<sup>1</sup>

## DESIGN

The prosthetic devices created by Boston Foundation for sight are transparent domes, almost size of a

nickel. It is almost similar to a large hard contact lens and resembles in shape a margarita glass without the stem. PROSE devices fit under the eyelids, vaulting the damaged cornea, and resting on the sclera. Worn during waking hours, patients are trained in daily application, removal, and cleaning, as part of the treatment process (Figures 1 and 2).<sup>1,2</sup>

PROSE devices are made out of a highly gas-permeable hard plastic that allows oxygen to reach the cornea. They are designed to create a space between the prosthetic device and the eye that is filled with sterile saline. The liquid remains in the reservoir, providing constant lubrication by bathing the eye in a pool of artificial tears.<sup>2</sup>

Lack of corneal touch and positional stability excludes all sources of frictional micro trauma. The high oxygen permeability constant (Dk) of the material allows oxygen to diffuse readily through the lens matrix. PROSE treatment also overcomes the drawbacks of other modalities such as surgical risk and temporary effect of amniotic membrane grafting, the cosmetic and vision concerns of tarsorrhaphy, the contamination risk and the potential inconsistencies in preparation, and storage of autologous serum eye drops.<sup>3</sup>

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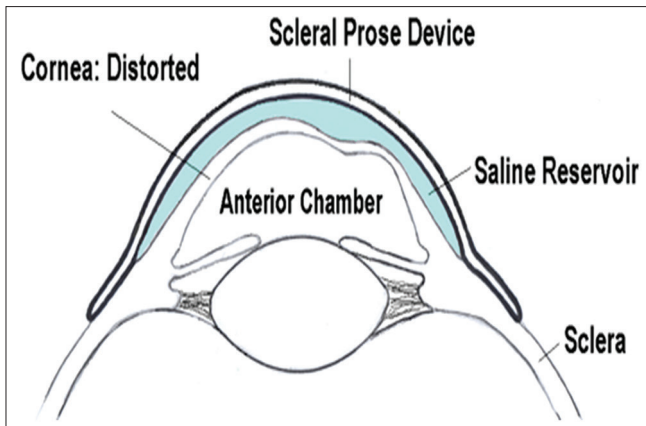


Figure 1: PROSE Device over a distorted cornea



Figure 2: PROSE device

Prosthetic devices are customized by specially trained PROSE doctors and made on-site at the Boston Foundation for sight PROSE Manufacturing Lab.

## PROSE CREATES

- A new clear, even optical surface over the irregular, damaged, or diseased cornea
- An artificial fluid reservoir that provides constant lubrication while maintaining the necessary oxygen supply.

## INDICATIONS

1. Corneal ectasia: Eyes with advanced corneal ectasia can be successfully fitted with the PROSE device, and the Visual Acuity outcome was better and faster compared to keratoplasty.<sup>4</sup>
2. The most popular indication is for an ocular surface disease like persistent epithelial defect (PED). The mechanism by which PROSE

supports re-epithelization in refractory persistent epithelial defect includes continuous lubrication, ocular surface protection, and maintenance of oxygenation.<sup>3,5,6</sup>

3. Steven Johnson Syndrome (SJS) and toxic epidermal necrolysis: with remarkable improvement in photophobia and surface breakdown, it also helps in healing of persistent epithelial defects associated with SJS when used on a daily wear basis.<sup>5,7,8</sup>
4. Limbal stem cell deficiency: Grover *et al.* report two patients with persistent epitheliopathy following treatment of conjunctival melanoma who were rehabilitated with PROSE. The authors finally concluded that “PROSE device can be a useful non-surgical option for these patients.”<sup>5,9</sup>
5. Neurotrophic keratopathy: Gumus *et al.* published a case report on the use of PROSE device in the management of persistent corneal epithelial defect from herpes zoster ophthalmicus. Along with other modalities of treatment such as oral doxycycline, autologous plasma, punctal plugs, multiple therapeutic lenses, and double layer amniotic membrane transplantation, he combined PROSE therapy. A remarkable change in the epithelial defect was seen within 3 weeks of daily use.<sup>5,10</sup>
6. Atopic keratoconjunctivitis - PROSE device can be considered in these patients with PED, who are poor candidates for contact lens use. It promotes rapid healing of PED.<sup>5</sup>
7. As a pharmaceutical reservoir - With PROSE, fluid turnover is low, allowing for prolonged availability of drugs in the reservoir. Epithelial toxicity could be enhanced by sustained contact. Hence, care is taken to use only preservative-free solutions.<sup>3</sup>

## TREATMENT PROVIDERS

PROSE treatment is provided by a group that is inclusive of an ophthalmologist (Cornea Specialist), optometrists who have completed the PROSE Fellowship and ophthalmic technicians.

Treatment takes almost 4-12 day long visits to complete, with periodic follow-up visits as needed during the first 6 months.

## CUSTOMIZATION PROCESS

PROSE doctors customize multiple trial prosthetic devices. Each step is followed by a trial session to make sure each patient achieves the best fit possible. The final device is unique to each patient’s eye condition.

## PATIENT TRAINING

Patients participate in three or more training sessions to learn application, removal, and care of their prosthetic devices. Family members and caregivers are also trained to assist patients.

## FOLLOW-UP WITH PRIMARY EYE CARE DOCTOR

Patients are asked to follow-up with their referring ophthalmologist within 2-3 weeks of finishing treatment. Meanwhile, ongoing care is provided by the primary eye care doctor in co-ordination with the PROSE treatment providers.

## ANNUAL EVALUATION

Patients are advised to come for Annual follow-up to their PROSE provider for a detailed evaluation of their PROSE

devices, make adjustments as required and address any related issues.

## ACCORDING TO THE BOSTON FOUNDATION FOR SIGHT

Following are the requirements for insertion:

- An application plunger
- A removal plunger
- Two alcohol wipes
- A small mirror
- Preservative-free saline (Figures 3 and 4).

## CARE AND HANDLING OF THE PROSE DEVICE

Following are the requirements:

- One PROSE disinfection case
- One unopened package of Clear Care™ (Figures 5 and 6).



Figure 3: Plunger



Figure 4: Method of insertion



Figure 5: Disinfection case



Figure 6: Prosthetic replacement of the ocular surface ecosystem cleaning solution

## CENTERS IN INDIA PROVIDING PROSE TREATMENT<sup>2</sup>

1. LV Prasad Eye Institute, Hyderabad
2. Sankara Nethralaya, Chennai
3. The eye super Specialities, Mumbai.

## LIMITATIONS

Limitations to the wider adoption of PROSE treatment include cost and availability at a limited number of tertiary eye care centers. An economic appraisal found that PROSE treatment is cost effective and cost beneficial in patients with severely compromised visual function attributable to the ocular surface disease. Others have also reported that epithelial defects that required PROSE for healing and typically recur following cessation of therapy. In comparison to earlier series of cases, the rate of microbial keratitis as a complication of treatment has been reduced by the use of a non-preserved topical fourth-generation fluoroquinolone in the device reservoir.<sup>3</sup>

## CONCLUSION

PROSE could be considered as a treatment option against an invasive procedure like keratoplasty for many ocular surface disorders. Numerous research articles are

supportive of the same. Many ongoing research works are also happening to prove the benefits of PROSE over keratoplasty.

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