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LETTER TO THE EDITOR

# First experience with Oasis Collagen SOFT SHIELD® for epithelial defect after corneal cross-linking

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**Abstract**

*Background* To investigate response of dissolving collagen contact lenses as an alternative for bandage contact lenses, for the post-interventional care of epithelial defects after corneal cross-linking (CXL) treatment for keratoconus.

*Patients and methods* Follow-up visits were performed at day 1, 4 and 1 month after the intervention. We reviewed notes for re-epithelialization, comfort/pain and any untoward effects of Collagen SOFT SHIELD®. Assessment included visual acuity (VA), refraction (SE); corneal haze, epithelial erosion and pain status were assessed subjectively on a 4-point scale, from 0 (none) to 3 (severe).

*Results* Thirty consecutive CXL patients with collagen shield application after CXL were included. Mean age was 28 years (range from 16 to 51 years old). Pre-CXL VA was 0.7 logMAR IQR 0.4–1.0; post-CXL VA at day 4 and month 1 was 0.6 logMAR IQR 0.4–0.9. Post-operative mean SE was 5.5D ± 4.1D. In all patients, the Collagen SOFT SHIELD® was completely dissolved at the 4-day follow-up visit. In most cases, epithelial defect was closed at day 4, on average 0.8 ± 0.5 days post-intervention; all epithelial defects were closed by month 1. Haze was minimal (mean haze score 1.4 ± 0.7 at day 4 and 1.0 ± 0.6 at 1 month). No adverse effects such as infection were observed.

*Conclusions* This study indicates that Oasis Collagen SOFT SHIELD® is valuable and safe alternative to standard bandage contact lens for the treatment of epithelial defects. This outcome may be of particular interest in patients where the contact lens removal is likely to be problematic.

**Keywords** Collagen soft shield · Corneal epithelial defect · Bandage contact lens · Corneal re-epithelialization · Corneal collagen cross-linking

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Collagen corneal shields were developed as a corneal bandage lens and are currently indicated for ocular surface protection following surgery and in traumatic and non-traumatic corneal conditions [1]. Collagen shields are manufactured from porcine or bovine collagen, and three different collagen shields are

currently available with dissolution times of 12, 24 and 72 h. The theoretical, experimental and clinical evidence supports a role for collagen corneal shields as a drug delivery device and in the promotion of epithelial and stromal healing [2, 3]. We conducted a study to evaluate a collagen contact lens for corneal erosion after corneal cross-linking (CXL) for keratoconus. The study was reviewed by the Queen Victoria Hospital, NHS Foundation Trust, East Grinstead UK internal ethical committee, audit number 1731. We affirm that the study was performed in accordance with the guidelines of the declaration of Helsinki. Thirty consecutive CXL patients with collagen shield application after CXL were included. Follow-up visits were performed at day 1, 4 and 1 month after the intervention. Baseline characteristics and data on re-epithelialization, comfort/pain and any untoward effects of Collagen SOFT SHIELD® (OASIS Medical, Inc. San Dimas, California, USA) (Fig. 1) were recorded. Assessment included visual acuity (VA), refraction (SE); both corneal haze and epithelial erosion status were assessed subjectively on a 4-point scale, from 0 (none) to 3 (severe) at day 4 and at month 1. Pain was assessed on a 4-point scale from 0 (none), 1 (small), 2 (considerable) and 3 (severe). The re-absorption of the lens was also assessed. The collagen soft shield is purified bovine collagen, which has been engineered to provide a protective barrier over the cornea prior to re-absorption. This collagen lens is understood to disintegrate after 72 h in situ, and as such it does not need to be removed by the doctor unlike a standard bandage contact lens. Briefly, cross-linking is a procedure including removal of corneal epithelium (in our cohort by a hockey knife), application of riboflavin eye drops and irradiation with UV light. Corneal cross-linking is performed in patients with progressive keratoconus (which is an ectatic corneal disease) to halt progression. The standard post-operative regimen previously included the application of a bandage contact lens and antibiotic eye drops (ofloxacin eye drops qid) [4]. This was changed to the application of a collagen shield (Fig. 2).

In our study, the patients mean age was 28 years (range from 16 to 51). Median pre-CXL VA was 0.7 LogMAR with an inter-quartile range (IQR) 0.4–1.0; median post-CXL VA at day 4 and month 1 was 0.6 LogMAR (IQR 0.4–0.9) and 0.6 LogMAR (IQR 0.4–0.9), respectively. Post-operative mean SE ($\pm$ SD) was 5.5D $\pm$ 4.1D. In all patients, the collagen shield was completely dissolved at the 4-day follow-up visit. In most cases, the epithelial defect was closed at day 4 (mean defect score 0.8 $\pm$ 0.5); all epithelial defects were closed by month 1. Haze was minimal; patients had a mean haze score of 1.4 $\pm$ 0.7 at day 4 and 1.0 $\pm$ 0.6 at 1 month. No adverse side effects such as infection were observed. Patients who had low pain at day 4 (mean pain score 1.3 $\pm$ 0.6) reported no pain or discomfort at month 1.

Like the standard bandage contact lens, the soft shield allows ocular healing to take place by providing a protective barrier over the surface of the eye, but

**Fig. 1** The Collagen SOFT SHIELD® is a clear, pliable, thin film of purified bovine collagen that has been lightly cross-linked to provide the desired degradation time on the eye (72 h). It has a nominal diameter of 14 mm and a compound base curve which approximates 9 mm when hydrated

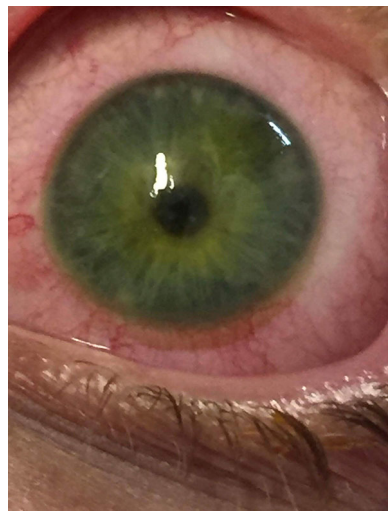

**Fig. 2** SOFT SHIELD® on the patient's eye after performed corneal cross-linking

unlike the bandage lens it is reabsorbed. As the shield gradually degrades, a thin layer of collagen is released which helps lubricate the eye and which may have additional benefits. To our knowledge, the present study is the first report ever published on this device as a treatment after CXL. Collagen cross-linking with riboflavin–UVA is a minimally invasive method but traditionally requires epithelial removal and contact lens placement, which could be a predisposing factor to infectious keratitis along with the instillation of topical nonsteroidal anti-inflammatory drugs, anaesthetic agents and the possible role of apoptosis [5]. Furthermore, there have been cases of Acanthamoeba keratitis after CXL reported in the literature [6]. A self-resorbing contact lens might be of particular interest in patients where the removal is problematic. A considerable impediment of clinical care in these young patients is compliance, since the time that a bandage contact lens remains in situ is proportional to rate of infection; this is an important consideration. Therefore, the use of reabsorbing contact lens assures that the risk of infection is limited. Additionally, reabsorbing lenses simplify clinical care in children and mentally impaired patients where contact lens manipulation can be challenging. Possible disadvantages could be that the bovine material is leading to inflammation, potential integration of collagen shield material in the anterior stroma with additional inductions of opacities and possible corneal infection. However, in this patient population no advert incidents were observed. Another limitation is the price, which is substantially higher than a normal bandage contact lens. We are aware of the limitations of our study; however, this could be considered as a clear-cut pilot study for further investigation. The present work was performed as a part of a clinical performance audit of patient care after CXL at the Queen Victoria Hospital, East Grinstead, UK. As a result of this audit, the post-CXL treatment regimen was modified from standard bandage contact lens to collagen soft shield. However, as this is the first report in the literature on this device after CXL, further studies are needed to confirm our experience.

In conclusion, this study demonstrates that Oasis Collagen SOFT SHIELD® is a good alternative to a standard bandage contact lens for the treatment of epithelial defects after CXL. Like the standard bandage contact lens, the soft shield allows ocular healing to take place by providing a protective barrier over the surface of the eye, but unlike the bandage lens it is reabsorbed and needs no removal.

#### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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