Cationorm®
MORE THAN RELIEF

CLINICAL REVIEW

OPTIMISING OPHTHALMIC SURGERY OUTCOMES AND CONSIDERATION OF CATIONORM®

Key findings

- Management of Dry Eye Disease (DED) is important to optimising surgical outcomes and patient satisfaction
- Effective management of DED should ideally begin pre-operatively
- Formulation is a key consideration when choosing an artificial tear both pre and post-operatively
- Recent studies support the use of Cationorm® in the early post-operative healing phase after refractive surgery

Dry eye disease & surgical outcomes

Ophthalmic surgery, including refractive and cataract surgery, is well recognised as a cause of iatrogenic dry eye through transiently inducing or exacerbating dry eye disease (DED).[1]

The opportunity to optimise surgical outcomes and patient satisfaction by effectively managing DED ideally starts pre-operatively and continues post-operatively.[1-2] Pre-operative screening for DED and stabilisation of the tear film is particularly crucial prior to refractive surgery. Interestingly, most patients undergoing refractive surgery with pre-existing DED have obstructive Meibomian gland dysfunction and dry eye symptoms due to increased evaporation.[1]

One of the first-line treatment options for DED is the use of artificial tears (ATs).[3] While the efficacy of ATs in treating DED is well established, a more recently available artificial tear, Cationorm®, with its unique cationic nanoemulsion, may be a beneficial choice for DED both pre and post-surgery.[4-6]

Formulation matters - Cationorm®

Cationorm® is a preservative-free oil-in-water AT for DED that uses cationic emulsion (CE) technology. The unique formulation with its positive-charge is designed to be attracted to the negatively-charged ocular surface, optimising spreadability and residence time on the eye without compromising on viscosity (**Figure 1A**).[5]

Unlike many other ATs, Cationorm® targets all three levels of the tear film (**Figure 1B**)and is suitable for all types of dry eye disease including evaporative, mixed, and aqueous deficient.[5]

Figure 1A

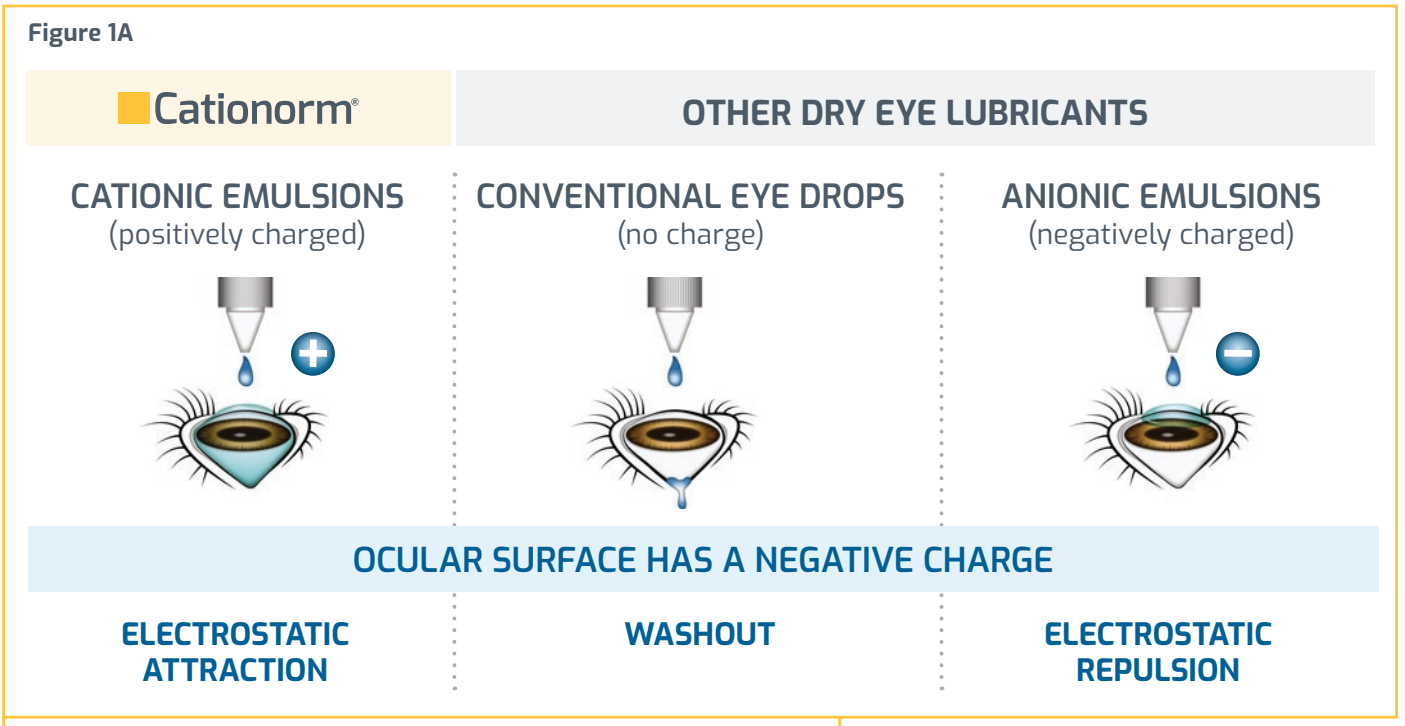


Figure 1B

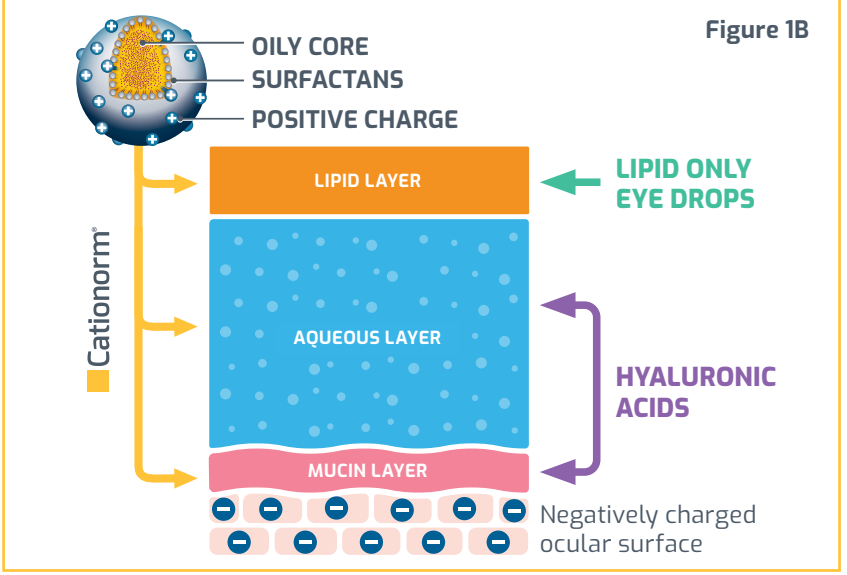


Figure 1 (A) The advanced positively-charged technology used in Cationorm® is designed to enhance attraction to the negatively-charged ocular surface. (**B**) The combination of an oily core, surfactants, positive charge and lubricants, enables Cationorm® to address all layers of the tear film, making it suitable for all types of dry eye.[5]

Cationorm® clinical data

The efficacy of Cationorm® for the treatment of DED has been demonstrated in several randomised, controlled, multicentre clinical trials.[5-8]

Two recent publications reporting the efficacy of Cationorm® specifically in the early postoperative healing phase after refractive surgery are summarised below.

Memona et al[9]

In a quasi-experimental study of 80 post-LASIK patients, Memona, et al. reported that Cationorm® was significantly more efficacious at improving qualitative and quantitative measurements than Systane Ultra® eye drops. Tear breakup time (TBUT) was performed on patients at baseline (pre-surgery), and at 2 days, 15 days and 1 month post-surgery, with a symptom questionnaire conducted at the 1 month mark. TBUT was not significantly different between the Systane Ultra® and Cationorm® groups at baseline or day 2. By day 15 however, mean TBUT in the Cationorm group was significantly improved vs Systane™ Ultra (12.3±1.713 and 8.93 ±2.485, respectively). This significance continued into day 30 (**Figure 2A**). The symptom questionnaire at 1 month post-surgery showed significant improvements in the Cationorm® group vs Systane for parameters including dryness, irritation and burning. (**Figure 2B**).

> **Cationorm® was significantly more efficacious at improving qualitative and quantitative measurements than Systane Ultra® eye drops.**

Figure 2A

Time post surgery	Product	Number of patients	Mean TBUT (±SD)	P value
15 days	Systane™ Ultra	40	8.93±2.485	<0.001
	Cationorm®	40	12.30±1.713	
30 days	Systane™ Ultra	40	9.05±2.4171	<0.001
	Cationorm®	40	12.93±1.745	

> **Significant improvements in the Cationorm® group vs Systane for parameters including dryness, irritation and burning.**

Figure 2B

Question	Product	Number of patients	Yes	No	P value
"Did you feel dry?"	Systane™ Ultra	39	27	12	<0.001
	Cationorm®	40	3	37	
"Did you feel irritation?"	Systane™ Ultra	39	18	21	<0.001
	Cationorm®	40	0	40	
"Did you feel watering?"	Systane™ Ultra	39	16	23	<0.001
	Cationorm®	40	0	40	
"Did you feel burning?"	Systane™ Ultra	39	19	20	<0.001
	Cationorm®	40	0	40	

Figure 2: (**A**) Quantitative (TBUT) and (**B**) Qualitative measurements (symptom based questionnaire) were significantly better in Cationorm®-treated patients post-LASIK surgery compared with Systane™ Ultra-treated patients (note: 100% of patients in both arms reported no for "Did you feel sore"). *Adapted from Memona et al.*

Jaworski et al[10]

Jaworski, et al. found that Cationorm® use resulted in significantly better Ocular Surface Disease Index (OSDI) scores compared with sodium hyaluronate (SH) 0.15%* for the treatment of DED after transepithelial photorefractive keratectomy (transPRK) or Epi-Bowman keratectomy (EBK). In this two-centre, prospective, randomised, double masked, parallel-group (1:1), comparative study, 255 eyes (129 patients) were randomised to receive either Cationorm® (n=128) or 0.15% SH* (n=127). OSDI and corrected (BCVA) and uncorrected visual acuity (UCVA) were tested before surgery, 1 week post- and 1 month post- surgery, with corneal epithelisation and subjective assessments of visual blurring and irritation assessed at 1 week post-surgery.

While there was no significant difference in UCVA between groups at any time points, OSDI scores were significantly lower at 1 week and 1 month post-surgery in the Cationorm® group (mean OSDI of 10.83 vs 16.92 in the Cationorm® and SH groups, respectively (p<0.001) (Figure 3B). Additionally, reports of blurred vision after AT installation was significantly lower in the Cationorm® group compared with SH, with 99 SH patients (78% of total group) and 112 Cationorm® patients (87.5% of total group) reporting no blurring (p=0.048) (Figure 3A).

*0.15% sodium hyaluronate (Biolan, Penta Arzneimittel, Stulln Germany. Not commercially available in Australia).

Figure 3A

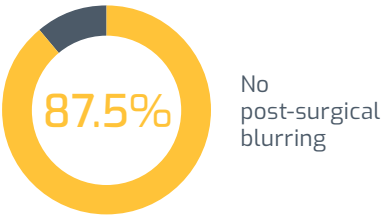


Figure 3B

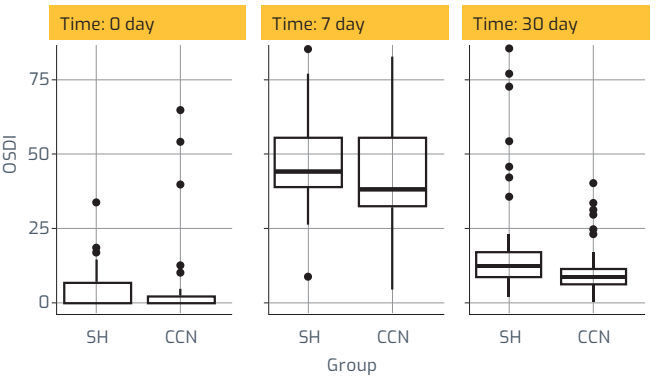


Figure 3: (A) 87.5% of post-surgery patients reported no blurring when using Cationorm®. **Figure 3:** (B) OSDI scores for Cationorm® patients were significantly better vs scores for SH (p=0.016 day 7, p<0.001 day 30). *Figure adapted from Jaworski et al.*

> **OSDI scores were significantly lower at 1 week and 1 month post-surgery in the Cationorm® group**

Conclusion

Management of DED as part of holistic approach to ophthalmic surgery is key to optimising surgical outcomes and patient satisfaction and should ideally begin pre-operatively. When recommending an artificial tear, formulation is an important consideration. Cationorm® with a unique positively-charged formulation targets all three levels of the tear film and is suitable for all types of dry eye disease including evaporative, mixed, and aqueous deficient.[5]

Cationorm® Product Summary

Formulation[4]	· mineral oils · glycerol · tyloxapol, poloxamer 188 · tris-hydrochloride, tromethamine · cetalkonium chloride (as cationic agent) · water for injection
Physiochemical properties[5,11,12]	· Low viscosity (1.1m²/s), close to viscosity of water for minimal blurring · pH 5.5-7.0 within physiological range of tears for comfort · Surface tension 41mL/m for tear film stability · Hypotonic 190mOsm/L to balance hyperosmolarity typical in dry eye · Unpreserved
TGA registered	Yes
PBS listed	· 10mL multidose bottle · PBS Authority – Streamlined. Code 6172 · Severe dry eye syndrome. Patient must be sensitive to preservatives in multi-dose eye drops
Dosage[4]	One drop up to four times a day to be applied to the affected eye(s)
Presentation[4]	Available as: · 10mL multidose bottle (shelf life of 3 months once opened) · 30 pack single dose vials

PBS Information: Cationorm Multi Dose (10mL) Authority required (STREAMLINED) 6172.
Refer to PBS Schedule for full authority information. Cationorm (30 x 0.4mL) is not listed on the PBS.

References:
1. Gomes JAP, et al. TFOS DEWS II iatrogenic report. Ocul Surf Jul;15(3):511-538. **2**. Schechter B, Mah F. Ophthalmol Ther 2022, 11:1001-1015. **3**. Jones L, et al. Ocul Surf. 2017 Jul;15(3):575-628. **4**. Cationorm Instructions for Use. Available at https://www.cslseqirus.com.au/products. **5**. Lyseng-Williamson KA. Drugs Ther Perspect. 2016; 32:317-322. **6**. Amrane M, et al. J Fr Ophtalmol. 2014;37(8):589–98. **7**. Aragona P, et al. (abstract no. 3125). Acta Ophthalmologica. 2011;89(Suppl s248). **8**. Robert PY, et al. Eur J Ophthalmol 2016; 26 (6): 546-555. **9**. Memona MAS, et al. Pak J Heal Sci 2022; 3(4):32-36. **10**. Jaworski D, et al. Euro J Ophthal 2023; 33(6):2178-2184. **11**. Daull P, et al. J Ocular Pharmacol and Therapeutics. 2020; 36: 355-365. **12**. Daull P et al. J Ocul Pharmacol Ther. 2016; 32(2):109-118.

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CSL Seqirus