Evolving Standards of Care in Ocular Surface Disease: Expert Discussion & Clinical Protocols

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Introduction & Purpose

In January 2025, an expert roundtable was convened to discuss current thinking and evolving clinical protocols in the management of Ocular Surface Disease (OSD). The focus was on real-world, everyday cases and the use of Cryopreserved Amniotic Membrane (CAM) preparations to manage a variety of OSD presentations. This summary captures key takeaways from that discussion, highlighting the critical shift toward earlier intervention, particularly with CAM, to improve patient outcomes, prevent disease progression, and specifically address the often-overlooked condition of Neurotrophic Keratitis (NK). The intent of this document is also to provide practical pearls & principles for incorporating these evolving standards into daily practice.

WHY OCULAR SURFACE HEALTH MATTERS

OSD significantly impacts our patients' vision and quality of life.[1,2] If left untreated, it can compromise any effort at vision correction, including contact lenses & spectacles, cataract & refractive surgery outcomes, and even the success of glaucoma surgeries.[3,4]

Increasingly, Dry Eye Disease (DED) and other OSDs are recognized as being fueled by inflammatory processes and neurosensory abnormalities that can drive self-reinforcing cycles.[5,6] Crucially, this includes NK, a degenerative disease that often goes undiagnosed in its early stages, leading to progressive corneal damage, ulceration, and even perforation. Earlier detection & intervention are becoming the new standard for progressive conditions like DED and NK.[7,8]

Because OSDs are often multifactorial and may have overlapping causes, they frequently require a multimodal approach. As CAMs facilitate regenerative ocular surface healing through a range of mechanisms—modulating inflammation, promoting tissue repair & regeneration, and encouraging nerve regrowth—they have become essential tools for treating OSDs in our practices.[9,10]

CASE 1 DED

Case & Images Courtesy of Dr. Tracy Doll

A **65-year-old white female patient** presents with severe ocular redness & irritation that lasts throughout the day. She notes that symptoms began 6-weeks ago following upper eyelid blepharoplasty. She initially attempted self-treatment with various Over-The-Counter (OTC) eye drops, ointments, and washes, but these have been ineffective. She has not yet tried any prescription medications.

Ocular History
- LASIK OU in late 1990s
- Blepharoplasty 6-weeks prior to presentation

Medical History
Neurotoxin injections, dermal fillers, & facelift procedures

Examination (Figures 1–3)
- During conversation, the patient exhibits a substantially reduced blinking frequency, averaging approximately 1 blink per minute (vs. normal conversational rate of about 26 blinks per minute).[11] Examining the eyes in the resting position reveals a higher-than-expected upper eyelid position
- Korb-Blackie (KB) lid light test reveals moderate light escape at the lid seal
- Patient reports using a hard shield while sleeping for approximately 2-weeks following blepharoplasty, but has since discontinued its use
- Fluorescein staining shows poor tear film adherence, Punctate Epithelial Erosions (PEE), and streaking of dye across the lower cornea and conjunctiva
- Patient has tried various preservative-free artificial tears, which felt good but failed to "improve redness"
- She opted for OTC brimonidine tartrate 0.025% eye drops, but used every 2-hours, well in excess of label's recommendation (every 6 to 8-hours, no more than 4 times per day)

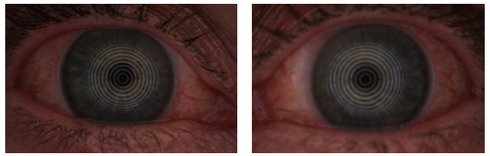


Figure 1. Image of patient OU in resting position. Note the location of the upper eyelid and that the patient does not have thyroid disease.

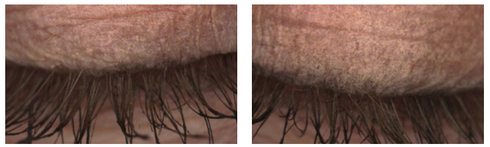


Figure 2. Upper eyelid and incomplete lid seal at presentation.

Diagnosis
- Chronic DED following blepharoplasty and exposure keratitis
- Suspected ocular surface toxicity due to overuse of OTC brimonidine tartrate drops

Treatment (Figure 4)
- To heal the ocular surface quickly, Prokera® Slim is placed for 3-days
- 1-week later, the corneal surface appears greatly improved
- Prescribed perfluorohexyloctane eye drops QID and topical cyclosporine 0.09% BID
- Patient is advised to use blink reminders throughout the day and eyelid shields at night (which she prefers to thick ointments or gels)
- Referred for a scleral contact lens evaluation but chooses to defer
- 6-months post blepharoplasty, eyelid position remains stable

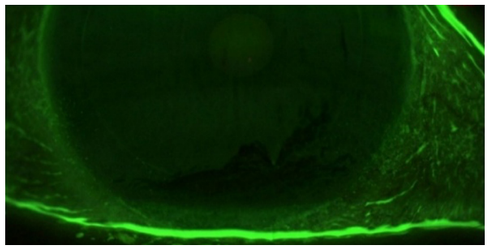


Figure 3. Corneal fluorescein staining OD.

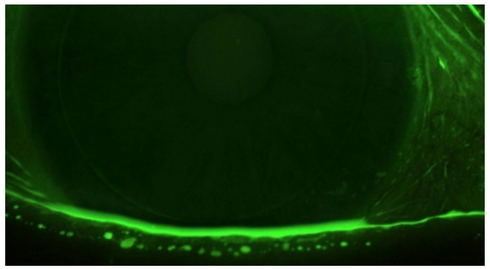


Figure 4. Corneal fluorescein staining shows a clear ocular surface 1-week post-Prokera Slim placement OD.

Follow up (Figure 5)
- 18-months later, the patient reports a lapse in adherence
- She takes a trip with friends to a dry & sunny location
- Expecting to be photographed, she wants "really white eyes" and reinitiates OTC brimonidine tartrate 0.025% BID for the duration of this trip (5-days)
- Upon her return, she presents with severe ocular redness potentially due to OTC brimonidine tartrate 0.025%
- Treatment includes first cleansing the ocular surface with a high-flow lid retraction-irrigation system, then placing Prokera Slim (OD, followed by OS) to speed healing
- With perfluorohexyloctane no longer covered under her new insurance, the patient now wishes to proceed with the scleral contact lens fitting process

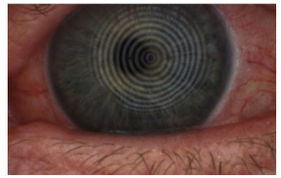


Figure 5. Severe ocular redness OS potentially due to an allergic reaction to OTC brimonidine tartrate 0.025%.

CASE 1 TAKEAWAYS

This case exemplifies a classic dry eye presentation and highlights key considerations for post-blepharoplasty management. Evaluating lid seal integrity and obtaining a detailed history of OTC eye drop use are essential steps, as both factors may contribute to ocular surface irritation. Treatment with Prokera® Slim containing CAM helped ocular surface healing, and ongoing use of perfluorohexyloctane, topical cyclosporine, blink reminders, and nightly stick-on eyelid shields helped manage contributors to her dry eye picture. However, the patient's repeated use of OTC brimonidine tartrate 0.025% eye drops led to a recurrence of hypersensitivity.

An allergy to brimonidine tartrate may manifest as hyperemia or follicular conjunctivitis,[12] while its preservative, benzalkonium chloride, is known to cause cytotoxic damage to conjunctival and corneal epithelial cells.[13] This damage can occur in as little as 7-days and is dose-dependent, with higher usage increasing the risk of adverse effects.

In cases of ocular surface toxicity and exposure keratitis like this, prompt intervention with CAM can help clear the corneal surface and facilitate rapid healing. CAM may be used to improve the ocular surface and reduce inflammation at any stage of DED, from mild to severe.[14,15]

Regenerative Healing

In the normal adult eye, corneal wound healing processes are triggered to address environmental or infectious insults through inflammatory pathways, which may include cell proliferation and migration, angiogenesis, and fibrosis. In contrast, fetal wound healing is described as "scarless" and characterized by a markedly diminished inflammatory response.[16]

The anti-inflammatory utility of CAM in wound healing is attributable to the complex of heavy chain hyaluronic acid pentraxin 3 (HC-HA/PTX3), which confers anti-angiogenic, anti-fibrotic, and anti-inflammatory benefits that facilitate restoration of tissue integrity and function.[16,17]

However, the method used for Amniotic Membrane (AM) preservation can affect the integrity of the membrane's extracellular matrix and its retention of HC-HA/PTX3, as demonstrated by histological and biochemical analyses. Cryopreservation has been demonstrated to maintain the extracellular matrix and the crucial biological components within AM, including HC-HA/PTX3, whereas dehydration via heat drying does not.[18]

Recent assays confirm that CAM preparations including AmnioGraft and CAM360 AG more effectively preserved HC-HA/PTX3 than their dehydrated counterparts (XcellerEyes and AmbioDisk).[19] While terminal sterilization, used for some dehydrated membranes and CAM360 AG to confer shelf stability, has been found to potentially degrade hyaluronic acid into a lower molecular weight and potentially proinflammatory form,[17,18] CAM360 AG has been found to largely retain HC-HA/PTX3 and its anti-inflammatory activity.[19]

NOTE: The FDA has not approved or recognized the precise method of action for HC-HA/PTX3. BioTissue is pursuing Biologic License Applications for its products.

Don't Wait to Intervene With CAM[14]

SELECT ACCORDING TO

Severity of disease
- Early placement of CAM in DED may help avoid progression
- Can be used for inflammation and ocular surface damage in DED at all levels of severity

Anticipated duration of therapy[9,15,20-24]
- CAM can provide meaningful benefit in as little as 5-days, making it an ideal option in the preoperative setting
- CAM's effects on signs & symptoms have been shown to last as long as 3-months after a single application

Patient receptivity & ability to tolerate
- Some patients may be more receptive to lower-profile Prokera Slim or CAM360 AG options

REPEAT AS NEEDED
(no postoperative global period for billing replacements)[25]

For patients with residual punctate keratitis, consider repeat CAMs as necessary to heal the ocular surface

CASE 2 DED & Stage 1 NK

Case Courtesy of Dr. Mark Milner

A **60-year-old white female patient** presents with complaints of blurred vision OD.

Ocular History
- DED
- Blepharitis
- Orbital meningioma removal from right side

Examination
Manifest refraction
20/60 OD and 20/20 OS

Lids
- OD: 2+ MGD, 2+ erythema
- OS: Trace to 1+ MGD and erythema

Cornea
- OD: 2-3+ Punctate Epithelial Keratitis (PEK) centrally; 4/4 corneal sensation centrally; TBUT 9-sec
- OS: no staining; 4/4 corneal sensation centrally; TBUT 5-sec

Plan
- Initiate cyclosporine BID
- Initiate erythromycin QHS until follow up
- Cenegermin-bkbj planned by previous provider but not started
- Warm compresses and artificial tears

Follow-up
2-weeks later
- PEK still 1-2+ OD
- Due to significant keratopathy and blurred vision, Prokera placed OD

2-days later
- Prokera removed
- Vision OD 20/25+1 with correction
- Staining improved to 1+ PEK
- Cenegermin initiated 1-month later

3-month follow-up
- Vision OD 20/20-2 with correction
- Corneal staining trace PEK

6-month follow-up
- Vision OD 20/20 with correction
- Cornea clear, no PEK

CASE 2 TAKEAWAYS

Recognizing this patient's marked asymmetry in staining prompted corneal sensitivity testing and led to the diagnosis of NK. In any patient with central staining, it is reasonable to suspect NK and perform corneal sensitivity testing.[7,26,27] Neurosurgery procedures, including orbital meningioma removal, can result in trigeminal nerve injury and consequent loss of corneal sensation.[28] As a progressive disease, NK can lead to worsening corneal damage and vision loss. Prokera offers the opportunity to restore corneal nerve health before significant tissue damage occurs.

In more advanced NK, we may initiate a prior authorization for cenegermin-bkbj while applying Prokera during the waiting period. A second Prokera may also be applied after cenegermin is initiated to manage inflammation. For later-stage NK, a Prokera Plus, with its double-layered design, may be preferable.

Dr. Doll's 3-step Process

PRE-CATARACT OPTIMIZATION

1 **Clean:** Treat the eyelids and periocular skin, managing blepharitis and any of its underlying causes, such as *Demodex* mites

2 **Calm:** Treat ocular surface inflammation using topical steroids, immunomodulators, and/or CAM—a remarkably safe & effective option

3 **Conserve:** Establish a daily regimen to prevent recurrence, including eyelid hygiene, lubrication, and ongoing DED therapy, as needed

What Makes CAM Different[9,10,18–20,24,29]

Unique Regenerative Properties
AM provides an excellent substrate for epithelial regrowth and low immunogenicity; CAM in particular retains its richness in HC-HA/PTX3 and confers anti-inflammatory, anti-angiogenic, and anti-fibrotic benefits

Supported by Scientific Evidence
Data shows that a single CAM can promote epithelialization and improve nerve regeneration and sensitivity as early as 1-month after administration, with benefits lasting up to 3-months

Objective & Subjective Benefits
Restoration of corneal integrity leads to noticeable symptom relief

In one study, CAM application improved ocular pain ratings in DED, from a 7 out of 10 at baseline to a 2 out of 10 at month-1[9]

Complementary Therapy
CAM is versatile & useful alongside a wide variety of other treatments

Remarkably Safe & Well Tolerated
CAMs, such as Prokera, have excellent safety profiles as reported in clinical studies, and CAM360 AG—the only shelf-stable, ringless CAM—offers a comfortable alternative to traditional self-retained CAM preparations

Durable Outcomes
Just a few days of treatment can confer long-lasting benefits

CASE 3 NK

Case & Images Courtesy of Dr. Robert Schultze

A **75-year-old white female patient** presents with blurry vision and reports that she has had a history of chronic foreign body sensation OD. She has undergone punctal occlusion of all four punctae and is unable to tolerate cyclosporine 0.05% eye drops. Her current treatment regimen includes lubricating eyedrops every 1 to 2-hours, varenicline nasal spray BID, prednisolone acetate 1% eye drops TID, loteprednol etabonate ointment applied to her lids QHS, and oral flaxseed oil. She is wearing scleral contact lenses for comfort.

Ocular History
- Ocular graft vs. host disease
- NK
- Filamentary keratitis

Examination
Corneal sensitivity
- OD: decreased in inferior, superior, and temporal quadrants
- OS: decreased in all 4 quadrants

Corneal staining
3+ PEE OD>OS

Diagnosis
Dry eye and Stage 1 NK

Treatment & Follow-up

Initial visit	CAM360 AG placed OD for 6-days
6-day follow-up	The patient reports that her right eye "feels better than it has in years"
2-months later	Patient undergoes blepharoplasty
1-month follow-up	Central cornea remains clear; patient continues topical steroids drops as needed

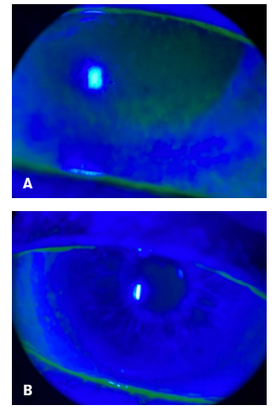


Figure 6. PEE visible via fluorescein staining OD before CAM360 AG **(A)** and resolved 3-months after CAM360 AG **(B)**.

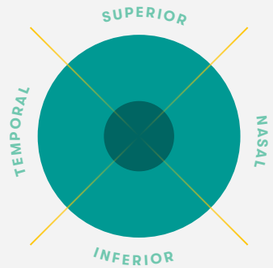
CASE 3 TAKEAWAYS

Many patients find that the CAM360 AG is comfortable, thanks to its ringless design and adhesive properties that allow it to stay in place under a Collagen Shield (CS) or Bandage Contact Lens (BCL). A single placement of CAM360 AG on this patient's right eye for 6-days improved the integrity and clarity of the central cornea within 1-week and maintained for at least 3-months, demonstrating its utility in the treatment of NK and DED. CAM360 AG rapidly and substantially reduced signs and symptoms while providing a shelf-stable, fully hydrated solution that supports corneal healing.

Corneal Sensitivity Testing

Corneal Sensitivity Testing should be considered when corneal staining appears incongruous with the level of patient symptoms ("stain without pain") or when DED signs & symptoms persist despite multiple treatments. Techniques for corneal sensitivity testing include the Cochet-Bonnet aesthesiometer, a cotton wisp, unwaxed dental floss (Dr. Milner's preferred method for its consistent texture), or a tapered tissue. Sensation can be assessed on a short scale (e.g., 0 to 3 or 4) and would ideally be performed in all corneal quadrants for a thorough evaluation.[27]

0	No sensation
1	Minimal sensation without response *(no blinking or movement)*
2-3	Partial sensation & varying response
4	Normal response *(strong reaction to touch)*



CASE 4 Pre-Cataract Optimization

Case & Images Courtesy of Dr. Tracy Doll

A **67-year-old white female patient** presents with a significant increase in irritation, redness, and watering OU (OD>OS). Her symptoms have been ongoing for a week at the time of presentation—5-days after Thanksgiving, which she enjoyed in the company of her young grandson, who had "pink eye." She characterizes the present irritation as different from what she's felt previously.

Ocular History

- Surgical-grade nuclear sclerotic cataracts OU, OD>OS
  - Surgical evaluation set for early December, less than a week away!
- Epiretinal membrane OU, with surgical peel/vitrectomy OD (1.5-years)
- Stage 1 NK
  - Successfully managed with CAM placement followed by chronic cyclosporine 0.09%
- Ocular rosacea (with *Demodex* blepharitis and MGD)
  - Successfully managed with IPL + thermal expression + okra lid hygiene
- Seasonal allergic conjunctivitis
  - Successfully managed with OTC mast cell/antihistamine drops

External Evaluation Findings → Viral Conjunctivitis

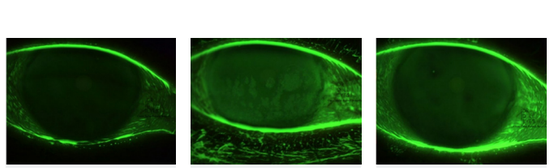
- PEE/Superficial Punctate Keratitis (SPK) Grade 4+ across entire cornea OD, Grade 1+ OS at lid seal
- Mixed papillary/follicular response on lower palpebral conjunctiva
- Serous/watery discharge

Assessment

- Cataract surgical evaluation and biometry is happening in 5-days
  - Concurrent infection rules out bandage contact lens or topical corticosteroids
  - Povidone iodine is likewise not a timely option, and perhaps insufficiently gentle for the patient's fragile corneas
  - Surgery cannot proceed until visually significant OSD is resolved
- CAM is the preferred choice
  - Opted for Prokera Slim containing CAM, based on prior patient response; placed OD for 2-days

Results Wednesday to Friday (post-CAM)

- Complete corneal clearance (Grade 4 → Grade 0 PEE)
- Patient had cataract surgery OD the day after Christmas
  - Results held through pre-op to 11-days later to 1-day post-op
- Patient requests repeat CAM 1-week before cataract surgery OS (scheduled early February 2025)



May 2024 Stable Ocular Surface | **Early December 2024** Viral Infection | **Mid-December 2024** Cornea Holding

Figure 7. Fluorescein staining shows the course of this patient's ocular surface before viral conjunctivitis, during the infection, and after CAM placement (just prior to cataract surgery).

CASE 4 TAKEAWAYS

CAM treatment safely healed this patient's corneal epithelium in just over 48-hours, even in the presence of a concurrent viral infection, effectively preparing the cornea for cataract surgery evaluation. This case highlights that CAM offers a fast, safe, and effective solution for restoring the ocular surface in the aftermath of viral infection and preserving the likelihood of accuracy in presurgical measurements.

If additional time had been available, povidone iodine could have been an option, and research suggests that ganciclovir gel, indicated for herpetic keratitis, may also help shorten the duration of viral conjunctivitis.[30-32]

Pre-Cataract Optimization has never been more critical. Precision in modern cataract & refractive surgery demands an uncompromised tear film & ocular surface. Even minor irregularities can threaten surgical precision, leading to inaccurate biometry, suboptimal intraocular lens performance, and postoperative dissatisfaction.[33-36] Attending to the health of the tear film & ocular surface is rewarded in patient outcomes & satisfaction.

CASE 5 Chronic DED & NK in Cataract Surgery Setting

Case & Images Courtesy of Dr. Walt Whitley

A **73-year-old white female patient** presents for a cataract surgery follow-up 1-month after OS surgery. She reports blurry vision and light sensitivity OU; she is using prednisolone TID OS and artificial tears TID OU

Ocular History

Monovision contact lens wear; DED treated prior to cataract surgery with corticosteroid drops, warm compresses, and preservative-free lipid-based artificial tears

Medical History

- Vertigo
- Basal cell carcinoma

Medications

- Calcium tablet
- Alendronate sodium
- Multivitamin

Allergies

- Penicillin

Examination

BCVA	OD 20/50-2 OS 20/30-2	**SLE**	2+ diffuse SPK OU

Diagnosis
Patient has chronic DED post-phaco w/monovision OU

Treatment Plan

- Stop prednisolone
- Rx lifitegrast BID OU, artificial tears BID OU
- Follow up in ~6-weeks to check tear osmolarity & meibography

6-Week Follow-up

BCVA	OD 20/70-2 OS 20/25	**SLE**	1+ mixed blepharitis/MGD 3+ diffuse SPK OU

Additional Testing (Figure 8)

- **Lid seal:** Because of inferior corneal staining, a Korb-Blackie light test was performed to check for exposure, which was ruled out
- **Corneal sensitivity:** OD reduced & OS absent

Diagnosis
Dry eye syndrome OU; MGD OU; Bilateral NK OS>OD

Treatment

1. Artificial tears BID, loteprednol BID, and punctal plugs
2. Heat mask, tea tree oil cleanser, discuss IPL R/B/A
3. Discuss Prokera containing CAM therapy R/B/A
4. Follow-up in 2 to 3-weeks for possible Prokera placement

Further Follow-up Visits

3-weeks later	Prokera OD "was very helpful to vision"
6-weeks later	Prokera OS
1-month later	NK follow up – 1+ SPK OU / TBUT 6-seconds Initiate cyclosporine BID OU / heat mask
12-weeks later	NK follow-up – stable symptoms & exam
10-weeks later	NK follow-up – symptoms improved / 2+ SPK OD, 1+ SPK OS

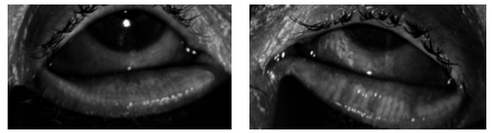


Figure 8. More than 50% of the meibomian glands in the patient's lower lids and approximately 40% in the upper lids are absent.

CASE 5 TAKEAWAYS

In a patient with chronic DED and worsening NK, placement of CAM turned out to be a key missing element needed to resolve corneal nerve & tissue damage. This patient experienced DED both before and after cataract surgery, with minimal improvement despite treatment with artificial tears, warm compresses, corticosteroids, and lifitegrast. Adding Prokera led to significant symptom relief and corneal healing, with effects lasting over 4-months post-treatment. Had CAM been used sooner, the patient may have experienced relief earlier with fewer adjunctive treatments.

As this case highlights, OSD is often multifactorial in origin and requires a multipronged & nuanced approach to treatment. To address this patient's symptoms, management of MGD, inflammatory DED, and NK was required; and the addition of CAM ultimately helped restore ocular surface integrity—pointing to the potential impact of earlier intervention. In mixed NK and DED presentations, we've found that topical prescription DED therapies as well as varenicline, a nasally administered cholinergic agonist indicated for DED, can be beneficial adjuncts to CAM.

Shifting the Paradigm in OSD Management

Early intervention is key
Proactive, comprehensive treatment can help prevent progression and improve outcomes

Suspect & test for NK
Perform corneal sensitivity testing in DED patients, especially those with central and/or incongruent staining

Tailor treatment
Use a multimodal, individualized approach to address underlying causes of OSD

Embrace regenerative healing with CAM
CAM offers rapid healing and long-lasting effects potentially due to its retained HC-HA/PTX3 complex

Choose the right CAM
Select the appropriate preparation based on indication, severity, and patient tolerability

Prioritize ocular surface optimization before surgery
CAM is ideal for rapid pre-surgical preparation

Repeat CAM as needed
Multiple applications may help achieve and maintain healing

Conclusion & Clinical Pearls

As demonstrated by these cases, CAM offers rapid, regenerative healing with an excellent safety profile, yet it remains an underutilized tool.

Both clinical studies and these real-world cases highlight its effectiveness, showing that even a short 2 to 5-day treatment can drive significant tissue healing and symptom relief, with benefits lasting up to 3-months.[9,15,22,24] Clinical evidence and our experience demonstrate that CAM has tremendous utility when administered earlier—treating Stage 1 NK and mild to moderate DED—as well as more advanced cases.[15,16,20]

The use of multiple serial CAM applications may have benefit, and CAM is available in multiple preparations, offering a versatile, long-lasting solution for both intraoperative and clinical applications, supporting surgical preparation & recovery.

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