

PROGRESSES IN MANAGEMENT IN OCULAR SURFACE AND CATARACT SURGERY

SUNDAY, SEPTEMBER 15th 2019

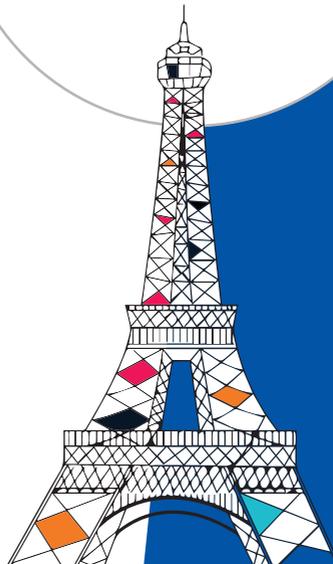
Chaired by Prof. **Christina GRUPCHEVA**

Laboratoires Théa Satellite Symposium

37TH CONGRESS OF THE ESCRS

PAVILLON 7, PARIS EXPO PORTE DE VERSAILLES
14 - 18 SEPTEMBER 2019

 **Théa**
let's open our eyes





PROGRESSES IN MANAGEMENT IN OCULAR SURFACE AND CATARACT SURGERY

Chaired by Prof. **Christina GRUPCHEVA**



CHAIRPERSON'S INTRODUCTION

Professor Christina GRUPCHEVA - Bulgaria



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CHAIRPERSON'S CONCLUSION

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● CHAIRPERSON'S INTRODUCTION

Professor Christina GRUPCHEVA - Bulgaria

Moderated Laboratoires Théa's Satellite Symposium PROGRESSES IN MANAGEMENT IN OCULAR SURFACE AND CATARACT SURGERY held on 15 September 2019 at the XXXVII Congress of the ESCRS in Paris, France.

● The first part of the symposium is as an overview on the concept of dry eye pathophysiology and treatment since the first tear substitute available in 1902. Over the last century, dry eye understanding has evolved profoundly. Advances in diagnosis and treatments of the ocular surface, for instance new bioprotective options such as trehalose and hyaluronic acid (Thealoz® Duo*, laboratoires Théa, France), will be discussed. Now it is clear that inflammation is among the most important mechanisms in the pathogenesis of Dry Eye Disease, triggering the vicious circle of Dry Eye. That's why **decoding inflammation in dry eye disease**

even without prominent evident clinical signs is essential. Reducing inflammation is an important target in dry eye disease treatment. This symposium is the opportunity to have an overview of the new advances in patient management with preservative free, low-dose hydrocortisone.

The second part of the symposium will concentrate on the use of the intracameral mydriatic and anaesthetic during cataract surgery. Mydrane®** is the first standardised ophthalmic combination of tropicamide 0.02%, phenylephrine 0.31% and lidocaine 1%, designed for single-use intracameral injection in cataract surgery.

*Thealoz® Duo, class IIb medical device: Trehalose 3% Sodium Hyaluronate 0.15%. Bioprotection, hydration and lubrication of the eye, for treatment of moderate to severe dry eye syndrome.

**Mydrane®: Solution for injection. Tropicamide 0.2 mg/mL, phenylephrine hydrochloride 3.1 mg/mL, lidocaine hydrochloride 10mg/mL. Indicated for cataract surgery to obtain mydriasis and intraocular anaesthesia during the surgical procedure in adults only. Mydrane® should only be used in patients who have already demonstrated, at pre-operative assessment, a satisfactory pupil dilation with a topical mydriatic therapy.

FROM ARTIFICIAL TEARS TO TARGETED EYE DROPS

Professor Christina . GRUPCHEVA - Bulgaria

Since the first tear substitute marketed in 1902, the concept of dry eye pathophysiology and treatment has evolved profoundly. Today, powerful topical treatments are needed for faster results, adapted to diurnal and overnight dynamics of the ocular surface, and allowing a personalized treatment for efficient and lasting results. Such targeted treatments are made possible by the large choice of eye drops, from aqueous supplementation to various viscosity-enhancing agents and anti-inflammatory topical drugs.

Targeted treatment starts with acute diagnosis of dry eye syndrome. It must be reminded that patients may have no symptoms, despite the presence of inflammation at microstructural level. Greater inflammation generates visible symptoms and signs visible at clinical level, such as red eye, and becomes therefore destructive to the delicate ocular surface.

Distinction must be done between evaporative dry eye and aqueous deficient dry eye. Then, the treatment is implemented by steps, which all include eye drops and particularly artificial tears.

Step 1	Step 2	Step 3	Step 4
Education regarding the condition, its management, treatment and prognosis Modification of local environment Education regarding potential dietary modifications (including oral essential fatty acid supplementation) Identification and potential modification/elimination of offending systemic and topical medications Ocular lubricants of various types Lid hygiene and warm compresses of various types	If above options are inadequate consider: Non-preserved ocular lubricants to minimize preservative-induced toxicity Tea tree oil treatment for Demodex (if present) • Tear conservation • Punctal occlusion Moisture chamber spectacles/goggles Overnight treatments (such as ointment or moisture chamber devices) In-office, physical heating and expression of the meibomian glands (including device-assisted therapies, such as LipiFlow) In-office intense pulsed light therapy for MGD Prescription drugs to manage DED • Topical antibiotic or antibiotic/steroid combination applied to the lid margins for anterior blepharitis (if present) • Topical corticosteroid (limited-duration) • Topical secretagogues • Topical non-glucocorticoid immunomodulatory drugs (such as cyclosporine) • Topical LFA-1 antagonist drugs (such as lifitegrast) • Oral macrolide or tetracycline antibiotics	If above options are inadequate consider: Oral secretagogues Autologous/allogeneic serum eye drops Therapeutic contact lens options • Soft bandage lenses • Rigid scleral lenses	If above options are inadequate consider: Topical corticosteroid for longer duration Amniotic membrane grafts Surgical punctal occlusion Other surgical approaches (eg tarsor-rhaphy, salivary gland transplantation)

[Jones L. et al. TFOS DEWS II Management and Therapy Report. The Ocular Surface [2017] 6:15]

FOCUS ON ARTIFICIAL TEARS IMPROVEMENT

Artificial tears may be preserved or preservative free. It is nowadays well known and documented that chronic exposure of the ocular surface to preservatives induces toxicity and adverse changes to the ocular surface.

Available preservative free tear substitutes include: hyaluronic acid (HA), hydroxypropyl methylcellulose (HPMC) and carboxy methylcellulose (CMC). HA is statistically superior to CMC on subjective symptom and on objective measurements, especially on the long term^{1,2}.

Ocular residence time is a crucial parameter of efficacy. Indeed, even during sleep, there are rapid eye movements under close eyelids, and the ocular surface needs to be lubricated. Ocular residence time not only depends on viscosity, but on several parameters: mucoadhesion, pH, surface tension, tonicity.

Normal tears viscosity ranges between 1.05 and 5.97 mPa.s. Further increases simply result in reflex tearing and blinking in order to restore the original viscosity of tears (homeostasis). Increased viscosity in a product might feel cooler and can be preferred by some patients, especially before going to sleep.

Well known from food industry, trehalose is a natural bioprotectant/osmoprotectant, and was recently developed as an additive to tear substitutes in dry eye treatment. Among several properties, such as osmoprotection, protein protection, membranes stabilization, autophagy induction, the reduction of apoptosis is particularly interesting as apop-

tosis is one of the triggering mechanisms in inflammatory ocular surface damage.

PERSONALIZED TREATMENT STEP BY STEP: FOCUS ON TOPICAL DRUGS

- **Treatment step 1** involves a lot of patient's education, including lifestyle modifications (humidity, fresh air, nutrition ...) and different elements of eyelids hygiene.
- **Step 2 adds topical drugs** to step 1.

Mild topical corticosteroids are very effective in reducing inflammation by stopping the inflammatory cascade at different points. They have been demonstrated to ameliorate the signs and symptoms associated with DED and to prevent DED exacerbation³. All steroids are not the same especially in terms of complications and short term steroids may be beneficial in dry eye. There is good evidence, both from clinical and in vitro studies reviewed, that preservative-free formulations are better tolerated and should be preferred for long-term treatments.

Cyclosporine A is a fungal-derived peptide that inhibits T-cell activation and inflammatory cytokine production. Cyclosporine A inhibits apoptosis by blocking the opening of the mitochondrial permeability transition pore and by increasing the density of conjunctival goblet cells. It is the first agent focused on the pathogenesis of this disease and can be used for long term without significant adverse effects, and it may be used on longer periods of time than steroids.

Lifitegrast is a novel integrin antagonist, which competitively antagonizes the LFA-1 binding to ICAM-1, thus inhibiting T-cell activation, cytokine release, formation of immunological synapse, and subsequently

1) Groß D et al. Comparative study of 0.1% hyaluronic acid versus 0.5% carboxymethylcellulose in patients with dry eye associated with moderate keratitis or keratoconjunctivitis. Clin Ophthalmol. 2018;12:1081-8.
 2) Prabhawati P et al. Performance profile of sodium hyaluronate in patients with lipid tear deficiency: randomised, double blind, controlled, exploratory study Br J Ophthalmol 2007; 91(1): 47-50.
 3) Cutolo CA et al. The Use of Topical Corticosteroids for Treatment of Dry Eye Syndrome. Ocul Immunol Inflamm. 2017; 14:1-10.

decreasing the ocular inflammatory cycle. Lifitegrast was found to be a highly potent drug in various clinical trials as it alleviates both the signs and symptoms of DED. It protects the corneal surfaces and is well tolerated locally as well as systemically⁴.

Personalization of step 2 involves more attention to the eyelids and especially Demodex, with topical treatments such as tea tree oil and relevant terpinen-4-ol products. This step also include moisture chambers, and systemic treatment including tetracyclines.

- **Step 3** adds several possibilities to the previous steps, including **serum drops:** autologous serum (AS), adult allogeneic serum, umbilical cord serum or platelet preparations. The use of AS is based on the assumption that AS contains biochemical components that may allow to mimic natural tears more closely than artificial tears. But a recent Cochrane review⁵ reported inconsistency in possible benefits of AS for improving

participant-reported symptoms and other objective clinical measures. Thus, there might be some benefit in the short-term, but there is no evidence of an effect after two weeks of treatment.

- In **step 4**, the **long term use of steroids** is proposed, as well as various **surgical approaches**. Amniotic membranes may provide very good results in some patients.

Patients must understand from our explanations that the diagnosis and treatment of dry eye is a process taking time and requiring a gradual implementation following standardized steps and repeated evaluation. Subjective symptoms assessment may be more comparable if supported by standardized questionnaires such as OSDI. Signs are evaluated by a variety of non-invasive objective tests, likely to quantify the improvement. T-BUT, staining and osmolarity measurement are probably the most useful among them.

CONCLUSIONS

Publication numbers on dry eye are growing exponentially since the eighties. The more is known about dry eye pathophysiology, the more personalization of treatment is feasible. Personalized treatments are complex but they are crucial for the management of the patients.

DECODING INFLAMMATION IN DRY EYE DISEASE: NEW ADVANCES IN PATIENT MANAGEMENT

Professor Gerhard GARHÖFER – Austria

Inflammation is among the most important mechanisms in the pathogenesis of Dry Eye Disease, triggering the vicious circle of Dry Eye. As such pro-inflammatory cytokines and other inflammatory markers can be found on the ocular surface of patients with Dry Eye Disease, even without prominent evident clinical signs⁶.

From a pathophysiological point of view, inflammation induces two major consequences: tissue destruction and inflammatory cytokines released, which in turn fires up inflammation. The neurosecretory block leads to a reduction of corneal sensitivity and reflex tear secretion, with a final consequence of a compromised tear film^{7,8}.

known to reduced inflammation by limiting the mechanics stress to the ocular surface. As such, it has been shown that a 30 days treatment with a lubricant eye drop solution reduces ocular symptoms and signs altogether with the inflammation marker HLA-DR⁹.

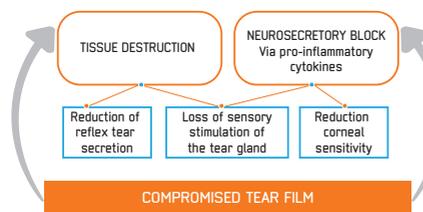
If treatment with lubricants is not sufficient, international guidelines recommend the use of anti-inflammatory eye drops such as topical steroids or cyclosporine.

Cyclosporin A is a powerful anti-inflammatory agent, with proved efficacy in dry eye. However, the benefit of cyclosporine A is rather slow to establish, with a full effect achieved after 3-6 months of treatment¹⁰.

Corticosteroids block the whole inflammatory cascade of arachidonic acid¹¹. Their effects in dry eye have been well documented for decades, on symptoms as well as on inflammatory markers, and are achieved on a rather short time.

The downside of corticosteroids is the occurrence of adverse effects after long-term use, mainly cataract, with a considerably increased risk compared to people not using steroids¹². A further risk of topical therapy with corticosteroids is ocular hypertension, which increases with the relative anti-in-

INFLAMMATION AND ITS TWO MAIN CONSEQUENCES



Thus, reducing inflammation is an important target in dry eye disease treatment. This can be achieved by different treatment modalities. As a first step, topical lubricants are

4) Semba CP, Gadek TR. Development of lifitegrast: a novel T-cell inhibitor for the treatment of dry eye disease. Clin Ophthalmol. 2016;10:1083-94
 5) Pan Q et al. Autologous serum eye drops for dry eye. Cochrane Database Syst Rev. 2017;2:CD009327.
 6) Baudouin C et al. Clinical impact of inflammation in dry eye disease: proceedings of the ODISEY group meeting. Acta Ophthalmol. 2018;96(2):111-9.
 7) Bron AJ et al. Predicted phenotypes of dry eye: proposed consequences of its natural history. Ocul Surf. 2009;7:78-92.
 8) Lambiase et al. Alterations of tear neuromediators in dry eye disease. Arch Ophthalmol. 2011;129:981-6.
 9) Fernandez KB et al. Modulation of HLA-DR in dry eye patients following 30 days of treatment with a lubricant eyedrop solution. Clin Ophthalmol. 2015;9:1137-45.
 10) Sall et al. Two multicenter, randomized studies of the efficacy and safety of cyclosporine ophthalmic emulsion in moderate to severe dry eye disease. CsA Phase 3 Study Group. Ophthalmology 2000;107(4):631-9.
 11) Kim SJ et al. Nonsteroidal anti-inflammatory drugs in ophthalmology. Surv Ophthalmol. 2010; 55:108-33
 12) Wang JJ et al. Ophthalmology. Use of inhaled and oral corticosteroids and the long-term risk of cataract. 2009;116(4):652-7.
 13) Tripathi RC et al. Corticosteroids and glaucoma risk. Drugs Aging. 1999;15(6):439-50.
 14) Becker B. Intraocular pressure response to topical corticosteroids. Invest Ophthalmol. 1965;4:198-205.

flammatory potency of the drug^{13,14}. Although the reason for the IOP increase is not fully clarified, there is evidence that it is related to dysfunction of trabecular meshwork cells.

Trabecular Meshwork cells have glucocorticoid receptors. Their binding induces changes in TM cell gene- and protein- expression, inhibit TM cell function (proliferation, migration, phagozytosis) and increases extracellular-matrix deposits (increased synthesis and decreased removal).

Hydrocortison (HC) was originally developed in 1938. HC combines a strong anti-inflammatory effect with limited penetration through the cornea and into the anterior chamber and thus little effect on intraocular pressure.

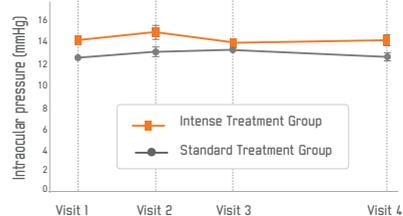
A new formulation of low concentration hydrocortison 0.335% (Treatment of mild non-infectious allergic or inflammatory conjunctival diseases Eyedrops) preservative-free with reduced penetration through the cornea may further reduce the incidence of IOP rise. To assess this hypothesis, a randomized, active-controlled, investigator-blinded, parallel group study has been

conducted in 60 patients aged 51±14 years, with moderate to severe dry eye (DED)¹⁵.

The main inclusion criteria were a history of DED for at least 3 months, currently treated with topical lubricants for at least 3 months and having yet an OSDI score ≥ 22 points and conjunctival hyperemia ≥ Grade 3 on the Efron Scale.

After inclusion, patients were randomized between a standard treatment scheme (8 days 3 times daily followed by 3 days twice daily) and an intensive treatment scheme (12 days 4 times daily followed by 2 days twice daily). A follow up was performed during 28 days after inclusion.

The decrease in hyperhemia and OSDI score was significant in both groups. No change in IOP has been observed in either group.



CONCLUSIONS

Inflammation is one of the key triggers of ocular surface diseases. Treatment with preservative-free, low-dose hydrocortison reduced ocular redness and decreased OSDI in both study groups with no change in IOP. Because of its good safety profile, preservative free, low dose hydrocortison may be an interesting alternative to standard corticosteroid treatment of ocular surface inflammation in dry eye.

TO STREAMLINE THE FLOW OF YOUR CATARACT SURGERY LIST

Professor Rudy NUIJTS - The Netherlands

Most cataract surgeons nowadays strive towards cataract surgery that is fast, efficient, and comfortable to the patient. Optimal mydriasis and anesthesia are crucial in improving efficiency of cataract surgery and preventing intraoperative complications: sufficient mydriasis is necessary for visualization of the capsulorhexis, lens implantation, and poor mydriasis during cataract surgery increases the risk of intraoperative complications.

With regards to anesthesia, we have already seen a shift from retrobulbar techniques to topical anesthesia in the Netherlands, which is more efficient and more comfortable to the patient.

A survey amongst 480 european cataract surgeons has shown that, when asked what they found most important about mydriasis, the stability and size of the mydriasis were valued highest (European Observatory of Cataract Surgery, 2015).

Topical mydriasis is still the most common method used. However, this method has several disadvantages. Firstly, it takes time to achieve proper mydriasis after instillation of the eye drops, which requires the patient to be present at the hospital well in advance of the surgery. Furthermore, multiple administrations are necessary, which is done by a nurse, to whom wages need to be paid. Topical mydriatics can

have multiple systemic side effects, such as tachycardia and cardiac arrhythmia. Finally, they may reduce the integrity of the ocular surface, which may impair visualisation during cataract surgery.

Mydrane® is a solution for intracameral injection which contains phenylephrine and tropicamide, as well as lidocaine for additional anesthesia. It is designed for patients undergoing cataract surgery who have demonstrated sufficient pupil dilation following topical mydriatic administration during the preoperative visit.

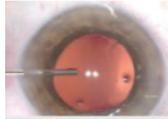
The purpose of the current study was to compare the effectiveness and costs of Mydrane® to two alternatives: topical mydriatics and Mydriaser®*. The study was a single center study in the Zuyderland Medical Centre, Heerlen, the Netherlands, non-randomized and comparative with three study groups recruited consecutively. The main inclusion criterion was patients undergoing cataract surgery under topical anaesthesia. The main exclusion criteria were the presence of ophthalmic disorders affecting visual acuity or potentially interfering with surgery, and patients with known incomplete mydriasis as determined during the preoperative visit.

The main outcome parameter of the study is incremental costs of the surgery.

15) Kallab et al., Topical Low Dose Preservative-Free Hydrocortison Reduces Signs and Symptoms in Patients with Chronic Dry Eye: A Randomized Clinical Trial. Adv Ther. 2019 Nov 18. doi: 10.1007/s12325-019-01137-8

* Mydriaser®: ophthalmic insert. Tropicamide 0.28 mg/mL, phenylephrine hydrochloride 5.4 mg/mL. Indicated to obtain pre-operative mydriasis, or for diagnostic purposes when monotherapy is known to be insufficient.

TESTED MYDRIATICS

Intracameral injection	Ocular insert	Topical eye drops
		
Contains: - Lidocaine 1% - Phenylephrine 0.31% - Tropicamide 0.02% Administration mode: Intracamerally, during surgery	Contains: - Phenylephrine 5.4 mg - Tropicamide 0.28 mg Administration mode: placed in inferior fornix, preoperatively, by nurse	Contains: - Phenylephrine 2.5% - Tropicamide 0.5% - Cyclopentolate 1.0% Administration mode: 3 X preoperatively, every 10 minutes, by nurse

Secondary outcomes were set as, pupil diameter, determined by the ratio between white-to-white distance and pupil diameter at various critical time points, just before the main incision, just before OVD injection, just before CCC, just before IOL insertion, and just before cefuroxime injection at the end of surgery. And satisfaction of the cataract surgeons with mydriasis and visualisation during the case. Patients evaluation by the CatQuest questionnaire preoperatively and 4 weeks postoperatively, and by VAS pain scale, ranging from 0 to 10, directly postoperatively.

In the current study performed in Netherlands, Mydrane® is more costly than Mydriaser® and topical mydriatics, which is largely related to the higher purchase price and the longer surgery duration.

However, it is important to realize that a cost analysis is specific to the healthcare system in which it was performed, and its results cannot be directly translated to other countries, for instance, due to differences in costs.

A retrospective study by Labetoulle et al. (ESCRS winter meeting 2019) has reported significant delay reduction with intracameral mydriatics : mean surgery time reduced by 3.19 min, mean room occupancy time by 4.7 min and mean rotation time between consecutive patients by 6.29 min.

Davey et al. performed a model-based budget impact analysis in UK, evaluating the costs for one hospital over 1 year (3000 cataract operations). The direct costs of Mydrane® was £18 000, compared to £3.300 for the other mydriatics. But the topical group had higher nurse costs (£19.400 vs £0), resulting in slightly higher total costs for topical group : £114 500 vs £108 300¹⁶.

The current study was designed for the conditions in the Dutch - health system. In Netherlands, Mydrane® has a higher purchase price than topical mydriatics. But *the price difference may be higher or lower depending on the country, and the extra cost may be compensated or not by savings on other costs components, especially if the intracameral injection is nurse time saving.* Indeed, as the global patient flow remained the same during the study it has been difficult to assess this criteria.

An other important limitation of the current study was that the quality of the ocular surface was not investigated. *Mydrane® being injected in the anterior chamber may preserve the ocular surface integrity, which may improve visualization during surgery and patient satisfaction as well as post-surgery ocular surface diseases, as shown in other studies.*

KEEP OCULAR SURFACE HEALTHY IN CATARACT SURGERY

Professor Jose GÜELL – Spain

Dr Spyridoula SOUKI, MD, FEBO – Spain

Cataract surgery is one of the most common surgical procedures performed worldwide. It may induce or aggravate dry eye disease, and a proper management of ocular surface pre/postoperatively can increase patient satisfaction.

Pupillary dilatation is commonly achieved by repeated topical administration of mydriatic/cycloplegic agents before CS that can impact integrity of ocular surface. Intracameral (IC) route of mydriatics delivers direct to the anterior chamber the right dose of drugs to achieve pupillary dilatation and may minimize adverse effects. Furthermore, IC administration reduces the need of preoperative eye drops, mitigating corneal toxicity and ocular surface damage.

The EFOS study (EFfects of Mydrane® and standard topical mydriatics and anaesthetics protocol on Ocular Surface after cataract surgery) was designed to assess Mydrane® compared to standard mydriatic eye-drops protocol in terms of effects on ocular surface.

EFOS is a phase IV, open-label, randomized clinical trial conducted in the Instituto de Microcirugía Ocular (IMO), Barcelona, Spain. All surgeries were performed by one experienced surgeon; Prof. José Luis Güell.

50 patients, aged 40 to 88 years, undergoing cataract surgery in both eyes were included in the study. Inclusion criteria requested healthy eyes with pupil size ≥ 7mm and cataract hardness < 3 (LOCS III).

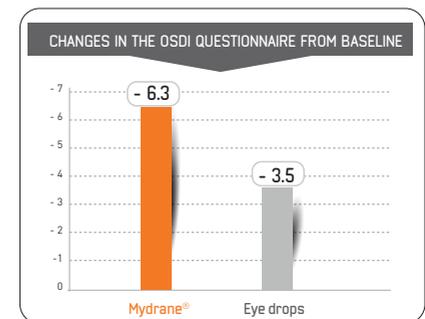
Subjects received Mydrane® (plus oxybuprocain chlorhydrate 0.4%+ tetracaine chlorhydrate 0.1% as topical anaesthetics) in one

eye and the standard eye-drops (oxybuprocain chlorhydrate 0.4% + tetracaine chlorhydrate 0.1% plus phenylephrine 10% and tropicamide 1% as mydriatics) in the fellow eye.

Subjects were randomized (1:1) to receive the Mydrane® or standard eye drops for their first surgeries. Surgery of the fellow eye was performed within 7 days after the first surgery. Patients were evaluated before, immediately after, 1 day and 7 days after each surgery.

The mean OSI obtained from the double-pass point-spread function image (HD Analyzer) indicated no significant lower intraocular scattering in Mydrane®, but practical implication of *better optical quality*.

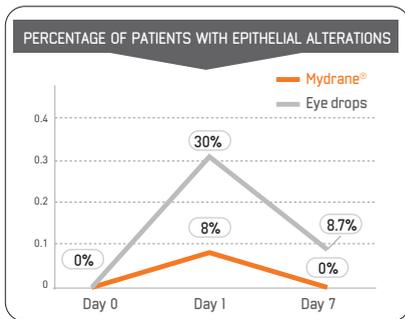
The parameters of vBUT, obtained from the HD Analyzer, indicated no significant differences between eyes. *The eyes operated with Mydrane® had lower OSDI values* than standard eye drops group. The difference was not statistically significant but was clinically meaningful.



¹⁶ Davey K et al. Budget impact model of Mydrane®, a new intracameral injectable used for intra-operative mydriasis, from a UK hospital perspective. BMC Ophthalmol. 2018;18(1):104

Fewer epithelial alterations were detected in the eyes operated with Mydrane®.

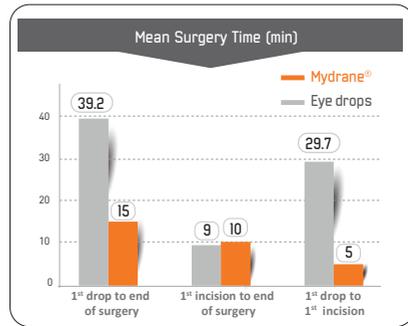
30% of the eyes operated with eye drops had epithelial alterations meanwhile only 8% with Mydrane® group. There were fewer epithelial alterations detected in eyes that received Mydrane® 24h after surgery and no epithelial alterations 7 days after surgery. Corneal epithelial alterations persisted further than 7 days in some cases with standard eye-drops.



Conjunctival staining scores increased just after the surgery in both groups. But it decreases faster in the eyes operated with Mydrane®. Hyperaemia assessment scores were clinically decreased faster in the Mydrane® group.

The percentage of the patients and surgeon who evaluated the *surgery as very satisfactory* were significantly higher in Mydrane® group than eye drops.

Mean surgery times were shorter in Mydrane® group, first drop to first incision and first eye drops to end of surgery times.



Conjunctival inflammation decreased faster in eyes that received Mydrane® than those with standard eye-drops.

Subjective ocular complaints scored with OSDI questionnaire were fewer in Mydrane® cases

Patient preparation time/waiting time for surgery was reduced in the Mydrane® cases and was less stressful for the patient.

20% of standard eye-drops patients expressed feeling discomfort during surgery and experienced ocular symptoms in the immediate postoperative time.

Both surgeon and patients felt more comfortable and satisfied during eye surgery with Mydrane®.

CHAIRPERSON'S CONCLUSION

Professor Christina GRUPCHEVA - Bulgaria

Moderated Laboratoires Théa's Satellite Symposium PROGRESSES IN MANAGEMENT IN OCULAR SURFACE AND CATARACT SURGERY held on 15 September 2019 at the XXXVII Congress of the ESCRS in PARIS, France.

The understanding on dry eye is growing exponentially since the eighties. The more is known about dry eye pathophysiology, the more personalization of treatment is complex but also crucial. *Treatment of Dry Eye is not just about lubricants. We need also combine strategy with lid hygiene, lubricants and preservative free anti-inflammatory therapy.* Inflammation is recognized as having a prominent role in the development and progression of the pathogenesis of DED. Inflammation is both a cause and effect of DED. Although artificial tears, even those supplemented with osmoprotectants (e.g.trehalose), have been shown to decrease hyperosmolarity and ocular surface inflammation, they might be not enough to address

the underlying disease process. Anti-inflammatory eye drops like the new preservative free, low-dose hydrocortisone are thus a therapeutic option for breaking the vicious inflammatory cycle.

Mydrane® is a solution for intracameral injection which contains phenylephrine and tropicamide, as well as lidocaine for additional anesthesia. Mydrane® is effective and safe for initiating and maintaining large and *stable mydriasis and analgesia* during cataract surgery. Mydrane® will allow surgeons to *save time* and can help to *optimise organisation of the fast track process* through its efficacy. Mydrane® *reduces the risk of systemic and local side effects* seen with the topical drugs.

CONCLUSIONS

Mydrane® usage in routine cataract surgery reduces corneal epithelial toxicity and ocular surface damage. Faster recovery of ocular surface integrity is achieved with less intraocular scattering and better optical quality. Patient comfort and satisfaction is increased before, during and after surgery.

Indicated for cataract surgery to obtain mydriasis and intraocular anaesthesia during the surgical procedure in adults only. Mydrane® should only be used in patients who have already demonstrated, at pre-operative assessment, a satisfactory pupil dilation with a topical mydriatic therapy.

mydrane

Solution for injection Tropicamide 0.2 mg/mL, phenylephrine hydrochloride 3.1 mg/mL, lidocaine hydrochloride 10mg/mL



A **clear**
difference

RAPID PUPIL DILATION DIRECTLY IN THEATRE PROVIDING:

- ✓ Stable mydriasis
- ✓ Improved comfort for you and your patients
- ✓ Anaesthetic effect
- ✓ More flexibility in the management of the surgical list
- ✓ Reduction of nurse workload in pre-op allowing them to be more available for patients



WCORRES2019-BA

MYDRANE® 0.2 mg/ml + 3.1 mg/ml + 10 mg/ml solution for injection.

COMPOSITION: 1 ml of solution for injection contains 0.2 mg of tropicamide, 3.1 mg of phenylephrine hydrochloride and 10 mg of lidocaine hydrochloride. One dose of 0.2 ml solution contains 0.04 mg of tropicamide, 0.62 mg of phenylephrine hydrochloride and 2 mg of lidocaine hydrochloride. Excipient with a known effect: sodium (0.59 mg per dose). Excipients. **Indications:** MYDRANE® is indicated for cataract surgery to obtain mydriasis and intraocular anaesthesia during the surgical procedure. MYDRANE® is indicated in adults only. **Posology:** MYDRANE® should only be used in patients who have already demonstrated, at pre-operative assessment, a satisfactory pupil dilation with topical mydriatic therapy. **Adults:** Slowly inject, by intracameral route, 0.2 ml of MYDRANE® in only one injection, at the start of the surgical procedure. **Contraindications:** Hypersensitivity to the active substances (tropicamide, phenylephrine hydrochloride and lidocaine hydrochloride) or to any of the excipients. Known hypersensitivity to anaesthetics of the amide type. Known hypersensitivity to atropine derivatives. **Pregnancy:** MYDRANE® should not be used during pregnancy. **Breastfeeding:** MYDRANE® should not be used during breast feeding. **Undesirable effects:** Nervous system disorders (uncommon): Headache. Eye disorders (uncommon): Keratitis, Cystoid macular oedema, Intraocular pressure increased, Posterior capsule rupture, Ocular hyperaemia. Vascular disorders (uncommon): Hypertension. **Nature and contents of container:** One paper/PVC blister containing 1 ml sterile brown glass (type I) ampoule filled with 0.6 ml of solution for injection. Separated 5-micron sterile filter needles packed in individual blisters are provided. Box of 1, 20 and 100 sterile ampoules together with respectively 1, 20 and 100 5-micron sterile filter needles. Kit of one paper/PVC blister containing one 1 ml sterile brown glass (type I) ampoule filled with 0.6 ml of solution for injection and one 5-micron sterile filter needle. Box of 1, 20 and 100 kits (i.e. blister containing a sterile ampoule and a sterile filter needle). Not all pack sizes may be marketed **MARKETING AUTHORISATION HOLDER:** Laboratoires THEA - 12, Rue Louis Blériot - 63017 Clermont-Ferrand Cedex 2 - France **MARKETING AUTHORISATION NUMBER(S):** To be completed nationally. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:** To be completed nationally. **DATE OF REVISION OF THE TEXT:** 13 June 2019