"Blue period" - the new stylistic phase of ophthalmic surgeons?

A new development in the field of viscoelastic devices aims to make ophthalmological procedures faster, easier and safer

Figure 1 - "Blue period" - the new stylistic phase of ophthalmic surgeons? Picasso in conversation with an eye surgeon about "blue" as a color of reliability and safety

Ophthalmic Viscosurgical Devices (OVDs) are routinely used in cataract surgery to fulfill important functions in phacoemulsification and implantation of intraocular lenses (IOLs).

Product	Manufacturer	Composition	Classification
Pe-Ha-Blue® PLUS	GERMANY ALBOMED	% 1.7 NaHA, Trypan Blue (0.020 g/ml)	Cohesive
Pe-Ha-Luron® F		% 1.0 / 1.4 / 1.6 / 1.8 / 3.0 NaHA	Cohesive
Pe-Ha- Luron® RC		% 1.0 NaHA	Cohesive
Pe-Ha-Luron® PLUS (RC)		% 1.4 NaHA	Cohesive
Pe-Ha-Visco® (Easy Visc®)		% 2.0 HPMC	Dispersive
Pe-Ha-Visco® PLUS (Easy Visc® PLUS)		% 2.4 HPMC	Dispersive
Pe-Ha-Glide®		% 2.0 HPMC (Extra Ocular Use)	Dispersive
Pe-Ha-Guard®		% 2.0 HPMC (Extra Ocular Use)	Dispersive
Viscoat®	Alcon	% 3.0 NaHA 4% Chondroitin Sulfate	Dispersive
Provisc®		% 1.0 NaHA	Cohesive
DisCoVisc®		% 1.7 NaHA 4% Chondroitin Sulfate	Viscous-Dispersive
OcuCoat®	BAUSCH + LOMB	% 2.0 HPMC	Dispersive
Amvisc®		% 1.2 NaHA	Cohesive
Amvisc® Plus		% 1.6 NaHA	Viscous-Dispersive
Healon EndoCoat®	Johnson&Johnson VISION	% 3.0 NaHA	Dispersive
Healon® PRO		% 1.0 NaHA	Cohesive
Healon GV®		% 1.4 NaHA	Cohesive
Healon5® PRO		% 2.3 NaHA	Visco-Adaptive
Z-Hyalin	ZEISS CARL ZEISS MEDITEC	% 1.0 NaHA	Cohesive
Combvisc		% 1.5/3.0 NaHA	Cohesive-Dispersive
Visthesia 1,5% / 1,0%		% 1.5/1.0 NaHA , %1.0 Lidocain	Cohesive

Even experienced surgeons regard manual capsulorhexis as one of the most technically demanSding phases of cataract surgery. In specific preoperative situations, such as pseudoexfoliation syndrome (PEX) or mature cataracts, vital dyes are therefore frequently used to improve the visibility of the anterior capsule. Among the various vital dyes, trypan blue is considered to be one of the most effective in terms of staining degree and is also classified as safe for the human cornea and the cells of the trabecular meshwork.[1,2]

In order to limit the staining to the region of interest, methods have been described to mix dyes such as trypan blue or indocyanine green preoperatively with viscoelastic substances.[3,4] However, this method always involves the risk of contamination. A new development in the field of OVDs was recently presented by Albomed® (Albomed® GmbH, Schwarzenbruck, Germany). The blue-colored viscoelastic Pe-Ha-Blue® PLUS (**Fig. 2**) is a combination of bio-fermented sodium hyaluronate (1.7 %) and trypan blue (0.020 mg/ml) and is supplied sterile and premixed in a ready-to-use syringe. The CEapproved Pe-Ha-Blue® PLUS allows simultaneous injection of OVD and trypan blue in one single step, making ophthalmologic procedures safer, easier and faster.

Figure 2 - The new blue colored OVD Pe-Ha-Blue® PLUS

We conducted a prospective study in our clinic (Privatklinik der Kreuzschwestern, Graz, Austria) to evaluate this new OVD.[5] The objective of this case series was to investigate whether the use of PeHa-Blue® PLUS during cataract surgery in patients with PEX and narrow pupils (miosis) has advantages over the use of a clear standard OVD in combination with trypan blue. We included 52 cataract patients (52 eyes) with PEX in this comparative study. In all cases, a Malyugin ring (6.25 mm) was used intraoperatively to ensure sufficient pupil dilation. In group A (n = 26 patients) the blue colored Pe-Ha-Blue® PLUS was applied and in group B (n = 26 patients) a clear standard OVD (POLYHYL® 1.6 %; Polytech Domilens GmbH) together with trypan blue (VisionBlue®/Blue Color Caps®) was used (**Fig. 3**).

Figure 3 – Incident-light microscopic examination of the blue Pe-Ha-Blue®PLUS and the clear Polyhyl® 1.6 %; performed by A.F. Borkenstein at the Technical University of Graz (Austria)

The median age in both groups was 75 years. Postoperative examinations were performed 6 hours, 20 hours and 4 weeks after surgery. With Pe-Ha-Blue® PLUS, it is possible to fill the anterior chamber with OVD and trypan blue in one single step, which shortens the entire OR duration. The primary study endpoint was therefore the evaluation of the safety aspect and the operation time. Our results were unambiguous and showed a statistically significant lower OP duration in group A. Median surgery time for this first phase of surgery was 112 seconds in group A versus 165 seconds in group B ($p<0.001$).

This corresponds to a time saving of 53 seconds for the entire OR duration. By using Pe-Ha-Blue® PLUS, the total number of 9 necessary surgical steps in Group B (1: paracentesis 2: corneal incision 3: Suprarenin® injection 4: OVD injection 5: Malyugin ring insertion 6: OVD aspiration 7: trypan blue injection 8: trypan blue aspiration 9: re-injection of the OVD) could be reduced to only 5 steps because surgical steps 6 to 9 are not required. The shorter OR time increases the effectiveness of the surgical workflow and is therefore particularly interesting for high-volume clinics. In addition, the safety of the procedure is enhanced as a shortened operating time can reduce the incidence of complications such as endophthalmitis. In addition, less corneal edema and faster recovery are expected postoperatively due to the shorter contact time and less manipulation. In our opinion, this could be one reason why distance visual acuity on the first postoperative day was better in study group A (median UDVA: 0.15 logMAR) compared to group B (median UDVA: 0.22 logMAR). For the patient, a shorter OR time subjectively results in an additional "comfort factor", also with regard to local anesthesia.

In order to evaluate satisfaction with the surgical procedure and the OVD used in the study, the surgeon and the surgical nurse completed a short questionnaire immediately after the procedure. Our results showed a small advantage in favor of group A, which in retrospect also confirms our subjective impression. The overall satisfaction was rated "very good" or "good" in 89 % (group A) and 73 % (group B) of the cases.

After our clinical experience with Pe-Ha-Blue® PLUS in more than 100 challenging cases, we see further advantages of this new OVD besides time saving and the improvement of the surgical workflow. The blue viscoelastic is clearly visible to the surgeon, allowing full aspiration of all residues. This reduces the risk of postoperative IOP increase. In our study we demonstrated that the postoperative IOP was on average 1 mmHg lower in the Pe-Ha-Blue® PLUS group. Further evaluations with a larger number of cases are planned. In the case of toric IOLs, complete OVD removal between the lens and the posterior capsule also reduces the risk of postoperative IOL rotation. For IOLs with large optic diameters or lenses with plate haptic designs, any residual OVD can be visualized and completely removed. Thus, this OVD would also be an option in refractive procedures like clear lens extraction.

If an “Argentinian flag sign” occurs intraoperatively in cases of cataracta provecta/hypermatura during rhexis, the anterior chamber can be refilled again with Pe-Ha-Blue® PLUS. This creates endotheliumgently space and at the same time improves visualization without the risk of trypan blue entering the posterior chamber or the vitreous body. The same applies to intraoperative complications such as capsule tearing with vis-à-tergo. Furthermore, it was observed that pronounced synchisis scintillans and vitreous opacities are less disturbing for the surgeon intraoperatively, since the fundus reflex is reduced by the blue dye in the anterior chamber or in the capsular bag during the operation and thus the "moving shadows" are perceived less strongly. Disturbing air bubbles in the anterior chamber can also be identified more quickly during phacoemulsification and aspirated more easily. The resulting visco-free area, which appears as a bright spot surrounded by blue OVD, can then be quickly re-filled with new OVD without affecting the endothelium.

Of particular interest for educational purposes and trainees is the fact that Pe-Ha-Blue® PLUS and clear standard OVD can be used simultaneously to highlight structures in the eye and to achieve better stereoscopic vision. The fact that Pe-Ha-Blue® PLUS reduces the UV component of the microscope light also contributes to intraoperative protection of the macula, which seems to be particularly useful during long surgeries. If complications such as capsular defects or vitreous body loss occur, the blue OVD may also be useful to stain the posterior capsule without entering the vitreous and causing possible toxic side effects on the retina. In addition, the vitreous body becomes more visible in the anterior chamber and can be aspirated more easily (anterior vitrectomy).

It should be noted that Pe-Ha-Blue® PLUS stains the capsule less intensively than conventional trypan blue and that it cannot be used unrestrictedly during surgery for external applications, e.g. as protection or moisturization of the epithelium and conjunctiva, as this would impair the surgeon's view. In exceptional cases of a pronounced subcapsular cataract in high myopic eyes with fundus myopicus the visualization during the OR may be somewhat limited when using Pe-Ha-Blue® PLUS (reduced fundus reflex).

In order to achieve the maximum coloring effect of Pe-Ha-Blue® PLUS, it is very important to have a good proportion of blue light in the light source of the operating microscope. In general, Xenon or LED light sources offer a higher wavelength proportion corresponding to the blue color than tungsten or halogen light sources.

The study results as well as our clinical experience show that the new blue colored OVD can offer numerous advantages, such as more selective staining, improved visualization of anatomical structures in the eye and a reduction of the OR time in difficult cases. In addition to cataract surgery, we also see applications for Pe-Ha-Blue® PLUS in glaucoma (MIGS) and corneal surgery. In summary, a blue colored OVD can be a helpful alternative to clear standard OVD in challenging cases to improve the surgical workflow and make the entire procedure faster and safer.

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