Abstract

The purpose of this work was to investigate the efficacy and safety of novel dyes composed of lutein in association with brilliant blue (BB) for staining the vitreous and the internal limiting membrane (ILM) during vitreoretinal surgery.

The preclinical efficacy of lutein-based dyes (Retidyne™ and Retidyne™ Plus) was tested in human cadaveric eyes undergoing vitreoretinal surgery. These products were also tested in patients, that underwent pars plana vitrectomy. The preclinical study showed that contact between the lutein-based dyes and the retinal, lens, and vitreous surface resulted in orange staining of the vitreous and greenish blue staining of the ILM, which facilitated surgical steps in all eyes, with no histologic signs of toxicity.

In the clinical study we observed that both dyes were deposited on the posterior pole by gravity. Moreover, these dyes facilitated the ILM removal, and Retidyne Plus also stained the posterior hyaloid/vitreous. After the surgery, best corrected visual acuity improved in all eyes without clinical side effects toxicity signs on fundus images/visual fields.

Introduction

In ophthalmology, vital dyes have long been used as tools that enable surgeons to better visualize the transparent intraocular membranes and tissues, such as the ILM. Chromovitrectomy includes the use of vital dyes or crystals to improve visualization of the intraocular tissues during vitrectomy. Lutein and zeaxanthin are lipophilic pigments belonging to the group of carotenoids and are physiologically present in the macula lutea, an integral retinal structure in humans.

The current study evaluated the efficacy and safety of using novel lutein-based intraocular dyes, Retidyne™ (1% soluble lutein + 0.025% brilliant blue -BB) and Retidyne™ Plus (0.3% crystalline lutein + 0.025 BB) to improve the identification of the ILM, and both vitreous and ILM, respectively, during chromovitrectomy.

Methods

Preclinical efficacy studies

• The efficacy of dyes composed of lutein in combination with BB was tested in sixty human cadaveric eyes undergoing vitreoretinal surgery.
• The dye solutions were in contact with intraocular membranes for 1 minute.
• The intraocular membranes were removed by mechanical aspiration or membrane peeling initiated and completed with intraocular forceps.
• The specimens were examined by light and electron transmission microscopy.

Clinical studies

• Baseline ophthalmic examinations
• 18 patients were injected with Retidyne™
• 12 patients were injected with Retidyne™ Plus

Results

Preclinical studies

• Lutein alone was useful for vitreous identification.
• Lutein combined with BB had strong affinity for ILM and anterior capsule, resulting in a greenish blue staining.
• No dye solutions remained in the eyes after the membrane removal.

Clinical studies

• Intraoperative findings
  • The lutein-based dyes resulted in a green solution.
  • The green dyes were deposited on the posterior pole; vigorous dye flushing into the vitreous cavity was unnecessary.
  • Both dyes stained the ILM in a marked greenish-blue.
  • Retidyne™ Plus indirectly showed the posterior hyaloid and the vitreous base by deposition of the golden lutein crystals onto the vitreous.

Conclusions

• The new dyes were effective for the intraoperative identification and removal of the ILM and Retidyne™ Plus also stained the posterior hyaloid/vitreous base.
• The possibility of achieving selective posterior pole staining without the need for a fluid air exchange or vigorous dye injection also would improve the safety of chromovitrectomy.
• The possibility of performing procedures using only one dye for different structures could be very convenient.
• The absence of dye-related adverse events in the patients studied demonstrates the safety profile of Retidyne™ and Retidyne™ Plus.

References


Figure 1 – Study design: prospective, non-randomized, single-arm studies.

Figure 2 – Lutein crystals are deposit in the vitreous and induce a strong orange staining.

Figure 3 – Intraoperative view of the injection. A) Retidyne™ B) Retidyne™ Plus. The dye are deposited on the posterior pole due their high density.

Figure 4 – ILM peeling guided by the lutein-based dye (Retidyne™ Plus).