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FULL LENGTH ARTICLE: CATARACT

Prospective Randomized Clinical Trial Evaluating Efficacy and Safety of A New Ophthalmic Viscosurgical Device In Patients Undergoing Cataract Surgery

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Abstract

Purpose:

To evaluate the efficacy and safety of Bio-Hyalur LVD compared to Viscoat® ophthalmic viscosurgical device (OVD) in patients undergoing routine cataract surgery.

Setting:

Two tertiary eye care hospitals in Italy

Design:

Prospective randomized clinical trial

Methods:

This study compared the outcomes of Bio-Hyalur LVD versus Viscoat® ophthalmic viscosurgical device in patients undergoing standard cataract surgery with phacoemulsification and intraocular lens implantation from January 2021 to April 2022. The primary outcome was mean change in IOP at 6 hours. Secondary outcomes included 1-, 7-, 30- and 90-day mean intraocular pressure (IOP), 7-, 30- and 90-day best corrected visual acuity, endothelial cell density (ECD), change in central corneal thickness (CCT) and complications including intraocular inflammation.

Results:

A total of 84 eyes of 84 patients (n = 41 in the Bio-Hyalur LVD group and n = 43 in the Viscoat group) were screened, enrolled, randomized, and included in the analysis. Mean change in IOP was significantly higher in the Viscoat group than in the Bio-Hyalur LVD group 6 hours ($p = 0.034$), 7 days ($p < 0.001$), 30 days ($p < 0.001$) and 90 days ($p = 0.003$) postoperatively. Mean change in UDVA and CDVA was significantly higher in the Bio-Hyalur LVD group 30 and 90 after surgery. No significant differences in ECD, CCT and complication rates were observed between groups at any time point.

Conclusion:

Bio-Hyalur LVD OVD is safe and effective for use in patients undergoing routine cataract surgery. Bio-Hyalur LVD OVD did not confer a higher risk of postoperative increase in IOP.