

Study of the Safety and Effectiveness between ologen™ Collagen Matrix Implant and Mitomycin-C in Standard Glaucoma Filtration Surgery



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Purpose:

To evaluate the efficacy and safety of collagen matrix implant in trabeculectomy comparing with patients undergoing trabeculectomy with Mitomycin-C. The primary end points are to prove effective control of Intra Ocular pressure (IOP) morphology of diffuse blebs, and normal depth of anterior chambers. The secondary end point is to prove the safety regarding complications or side effects.

Methods:

In this non-randomized, parallel clinical trial 22 eyes were categorized into two groups, each comprising 11 eyes. Group A comprised patients that received trabeculectomy with Collagen Matrix implant (ologen™) Mean age was 53 years (range 23-70). Group-B comprised patients allocated for trabeculectomy with Mitomycin-C. Mean age was 61.25 years (42-70 years) Complete success was defined as patients with IOP ≤ 21 mmHg with well-formed Anterior Chamber and filtration bleb. All patients were operated by the same surgeons (SA, NB). Patients were evaluated for IOP, visual acuity, bleb morphology and complications at 1st, 7th, 30th, 60th, 90th and 180th post-op days.

Results:

Mean pre-operative IOP was 35.33mmHg (21 -55mmHg) in Group A versus 34.6mmHg (21 - 45mmHg) in Group B. On day 30th the mean IOP in Group A was 11.5mmHg (5-30mmHg) vs. 13.37mmHg (2-40mmHg) in Group B.

In Group A, 5 patients developed Grade-I shallow anterior chamber that resolved by day 7th, and 2 patients developed choroidal detachments that resolved by 30th post-op day. The rest of the patients developed thin walled diffuse blebs. In Group B, 07 patients develop Grade-I shallow anterior chamber and polycystic blebs.

Conclusions:

Implantation of Collagen Matrix implant (Ologen™) effectively brings IOP under control through the formation of a loosely structured filtering bleb. This device may represent a safe, simple and effective therapeutic approach for treating refractory glaucoma without determined complications seen using adjunctive therapy.



Fig 1: Creation of Partial Thickness Scleral Flap

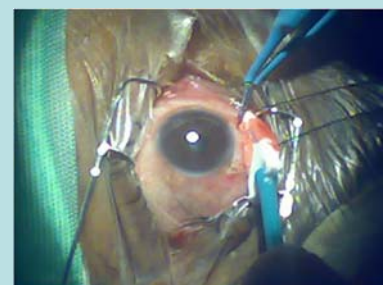


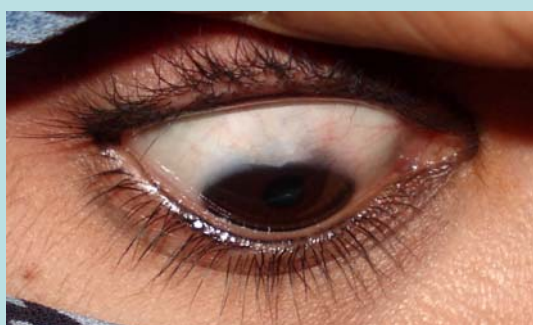
Fig 2: Vessel Cauterization



Fig 3: Partial Thickness Scleral Flap



Fig 4: Ologen Implant In place



Rt. Trabeculectomy with Ologen Implant 06 months Post-Op Showing diffuse thin walled filtering bleb.



Lt. Trabeculectomy with Mitomycin-C in the same patient showing Polycystic Over hanging bleb.