

Combined phacoemulsification and viscocanalostomy with Ologen implant versus combined phacoemulsification and viscocanalostomy

Document Date: 1/5/2013

Introduction

Surgical treatment of glaucoma is indicated in cases of failure of medical treatment. Trabeculectomy is considered the standard surgical treatment of glaucoma. Non-penetrating glaucoma surgeries, e.g. viscocanalostomy and deep sclerectomy, are becoming good alternatives. Viscocanalostomy has fewer complications than trabeculectomy, e.g. bleb leak, hypotony and bleb-related infections. ^[1-4]

Since the prevalence of both cataract and glaucoma increases with age, phakic patients who are scheduled for glaucoma surgery may also require cataract extraction, or patients scheduled for cataract surgery may be scheduled for combined surgery. Improvement of phacoemulsification techniques and stable anterior chamber depth with non-penetrating glaucoma procedures may favor combined viscocanalostomy and cataract surgery in patients with glaucoma and a coexisting cataract. ^[4]

A biodegradable porous collagen-glycosaminoglycan copolymer matrix implant (Ologen[®]) is a simple chemical analog of extracellular matrices and has been used as an adjuvant to increase the long-term success of trabeculectomy. The degradation time of this type of implant is around 180 days; this implant consists of porcine based, lyophilized, crosslinked type I atelocollagen ($\geq 90\%$) and glycosaminoglycans ($\leq 10\%$). During trabeculectomy surgery it is placed subconjunctivally and acts as a spacer to mechanically separate the subconjunctival and episcleral tissues to decrease subconjunctival fibrosis. ^[1,3]

Rationale

Primary open angle glaucoma is the second leading cause of blindness worldwide which needs effective attention otherwise it will lead to progressive optic nerve damage and eventual blindness.

The current surgical treatment of choice for medically uncontrolled glaucoma in association with cataract is combined phaco-trabeculectomy. However, this procedure is associated with both early and late postoperative complications.

Combined Non-penetrating glaucoma surgeries with phacoemulsification have been developed offering both surgeon and patient a safer, more convenient option.

With the use of Collagen implant with phaco-viscocanalostomy, it is expected to improve the pressure lowering effect of this procedure and increasing the success rate.

Research Question

Does phacoemulsification and viscocanalostomy with ologen implant have a better outcome, in patients with both cataract and primary open angle glaucoma, regarding postoperative IOP control and low complications rate, compared to phacoemulsification and viscocanalostomy alone?

Hypothesis

Our hypothesis is that using Ologen implant as a spacer in the subsclearal reservoir in phaco-viscocanalostomy reduces fibrosis and increase the success rate of this operation.

Aim of the Work

The Aim of this study is to evaluate the use of Ologen implant as an adjuvant in phaco-viscocanalostomy in patients with coexisting cataract and glaucoma.

Objectives

1. To estimate the number of patients with postoperative IOP \leq 21 mmHg after phaco-viscocalostomy with ologen implant compared to phaco-viscocalostomy alone 2 years after surgery.
2. To measure complete and qualified success rates after phaco-viscocalostomy with ologen implant compared to phaco-viscocalostomy alone 2 years after surgery.
3. To report and describe early and late postoperative complications after phaco-viscocalostomy with ologen implant compared to phaco-viscocalostomy alone 2 years after surgery.

Subjects and Methods

Before initiating this study, the protocol, the informed consent form and any other written information to be given to patients was reviewed and approved by the Ethics Committee of the Alpha vision center.

The investigator will explain to each patient the nature of the study, its purpose, the procedures involved, the expected duration, the potential risks, benefits involved, and any discomfort may be caused.

Each patient will be informed that participation is voluntary, that he or she may withdraw from the study at any time and without giving reasons. The withdrawal will not affect the subsequent medical or conservative treatment or relationship with the treating surgeon.

Technical Design

Center: Alpha vision center

Design: A prospective randomized controlled clinical trial.

Subjects: Patients will be collected from the outpatient clinic of Alpha vision center. The patient will be randomly assigned using simple randomization method to receive either Phacoemulsification and viscocanalostomy or Phacoemulsification and viscocanalostomy with Ologen implant.

Study sample: Based on previous studies by Shaarawy and Mermoud ^[5], the mean IOP at the first postoperative day was 6.4 (SD=3)mmHg for the DS-treated eyes, and 3.7 (SD=2)mmHg for the DSCI-treated eyes, the minimum total sample size of 32 will be sufficient to detect a power of 80% and a significance level of 5%. To allow for 25% losses, the sample was further increased to 81. Sample size estimation was performed by G power statistical package.

Inclusion criterion:

The inclusion criteria are the presence of significant cataract interfering with vision (visual acuity ≤ 0.5) in the presence POAG. Patients are included if cataract is associated with uncontrolled glaucoma, (IOP > 21 mmHg despite maximally tolerated medical therapy) or if the IOP is ≤ 21 mmHg with use of at least two antiglaucoma drugs with medication intolerance, poor patient compliance, patients cannot attend medical supervision or have visual field deterioration.

Exclusion criteria:

Patients will be excluded if they have closed-angle glaucoma, other types of open angle glaucoma (OAG), e.g. pigmentary glaucoma, inflammatory glaucoma or neovascular glaucoma, previous ocular trauma or surgery, lens subluxation or other eye diseases affecting the vision, e.g. anterior uveitis. Patients were also excluded if there is a large perforation of the Descemet's membrane with iris prolapse during surgery (cases with microperforation, which is defined as small perforation with no associated iris prolapse, occurring

during surgery will not be excluded) or if they have other intraoperative complications that might affect the IOP, e.g. vitreous loss.

Operational Design:

Patient histories will be taken including age, gender, previous ocular surgery, trauma or any previous ocular inflammation, e.g. keratitis, iridocyclitis, etc. Slit-lamp examination will be done for examination of anterior chamber angle, determination of the type of glaucoma and the degree of cataract, measuring IOP (using Goldmann applanation tonometer), assessment of optic nerve head and retinal examination, if possible. Visual acuity (VA) was expressed in decimal fraction.

Surgical procedures:

All operations will be carried out by one surgeon using peribulbar anesthesia.

After phacoemulsification, a traction suture in the cornea is made using 8-0 polyglactin 910 (Vicryl[®], Ethicon Inc, Bridgewater, NJ, USA).

A fornix based conjunctival flap is fashioned and no cautery is applied. Hemostasis is only achieved by using a microsponge soaked with 1/100,000 adrenaline. A superficial scleral flap of 5 x 5 mm is made and dissection is done 2 mm into the clear cornea. A smaller deeper flap of 4 x 4 mm is made until deroofting of Schlemm's canal is achieved. Decompression of the eye is done through one of the paracentesis incisions, then blunt dissection with a microsponge is done to create a descemetic window that extended over Descemet's membrane until 1 to 2 mm inside the clear cornea. Subsequently, the sides of the deep flap is freed from the adjacent sclera by Vannas scissors and the deep flap is cut by the same scissors.

The juxtacanalicular trabeculum is removed and then the two openings of Schlemm's canal are cannulated on both sides using a viscocanalostomy cannula (Eagle labs, Rancho

Cucamonga, CA, USA) and high-viscosity sodium hyaluronate (Healon GV; Abbott Medical Optic Inc., Santa Ana, CA, USA) is injected into the canal on both sides.

In the Phacovisco group, the superficial flap is closely sutured using four interrupted 10-0 nylon sutures, and then Healon GV is injected into the subscleral lake.

In the OloPhacovisco group, a 4 x 4 mm piece of Ologen® (Model: 862051 “12mm(D) x 1mm (H)”) (Aeon Astron Europe B.V., Leiden, The Netherlands) is fashioned to be nearly of the same size as the cut deep scleral flap to fit inside the subscleral reservoir (Fig 2). Then the superficial flap is sutured tightly over it using four interrupted 10-0 nylon sutures (Ethilon®, Ethicon Inc, Bridgewater, NJ, USA). Some air is injected from the paracentesis inside the eye. Then conjunctiva is closed using 8-0 polyglactin 910 sutures (Vicryl®, Ethicon Inc, Bridgewater, NJ, USA).

Postoperative management included topical administration of 0.5% moxifloxacin drops with a tapered schedule of 1% prednisolone acetate. Antiglaucoma medication is ceased after surgery in all cases.

Follow-up:

Postoperatively, follow-up examination will be done on days 1, 7, 14 and 30, then every 2 months for 2 years. The follow-up examination includes assessment of IOP, VA and slit-lamp examination. Postoperative complications will be recorded. Signs of inflammation, such as cell infiltration and flare, is recorded and graded from 0 to 4.

Nd:YAG laser goniopuncture is considered in all cases with elevated postoperative IOP above 21 mmHg after discontinuation of corticosteroid eye drops for at least 14 days. The Nd:YAG goniopuncture is performed using an Ellex Super Q YAG laser machine (Ellex Medical Lasers Ltd., Mawson Lakes, SA, Australia) and the gonioscopy mirror of Goldman three mirror universal laser lens (Ocular, Bellevue, Washington, USA) with a laser power

setting of about 3 to 6 mJ and using about 2 to 15 shots aiming at the opening of the trabeculo-Descemet window, the number of laser shots needed to open the Descemet's membrane was counted and recorded in each group. Antiglaucoma drugs will be prescribed if the IOP is elevated above 21 mmHg after considering Nd:YAG laser goniopuncture.

The main outcome measures are the IOP at the 2-year follow-up and the overall success, which included complete success when IOP is ≤ 21 mmHg without any antiglaucoma drugs, and qualified success if IOP is ≤ 21 mmHg with the use of a single antiglaucoma medication. Failure is considered if IOP ≤ 21 mmHg cannot be reached even with the use of a single antiglaucoma medication and after performing Nd:YAG laser goniopuncture, at any follow-up visit. The secondary outcome measures were surgical complications, the use and results of Nd:YAG laser goniopuncture and visual acuity results. The last data for failed cases were used for further statistical analysis.

RESULTS

Collected data will be presented in Tables and analyzed by computer software using appropriate statistical methods.

DISCUSSION

Discussion will be done on results compared to relevant literatures and scientific researches to explain the reasons for getting such results.

Conclusion and Recommendations

Conclusion and Recommendations will be derived from the findings of the study.

Statistical analysis plan:

The data will be analyzed using the software Statistical Package for Social Science (SPSS) version 16.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables will be expressed as mean \pm SD and compared using student t tests; two tailed test will be used to detect significance between the two groups and one tailed t test will be used to detect the significance before and after intervention in the same group. Mann-Whitney U test will be used for nonparametric analysis. Categorical variables will be expressed as percentages and will be analyzed using the chi square (χ^2) test. A value < 0.05 will be considered statistically significant.

References

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