Efficacy and Safety of Phacoemulsification and Goniosynechialysis With or Without Kahook Dual Blade Goniotomy in Chronic Primary Angle-Closure Glaucoma: A 1-Year Randomized Controlled Trial

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Brief Summary Primary angle-closure glaucoma is a major cause of irreversible blindness. For patients with chronic primary angle-closure glaucoma and cataracts, the standard surgery is phacoemulsification and goniosynechialysis. This surgery deepens the anterior chamber and opens the angle. But it does not fix the damaged trabecular meshwork. Many patients still have high eye pressure after this standard surgery. The Kahook Dual Blade is a microinvasive device. It cuts and removes the diseased trabecular meshwork. This trial compares the 1-year results of standard surgery alone versus standard surgery with the Kahook Dual Blade. The study will measure eye pressure control, medication use, and safety.

Detailed Description Patients with chronic primary angle-closure glaucoma experience prolonged high intraocular pressure and long-term peripheral anterior synechiae. This chronic condition causes irreversible damage to the trabecular meshwork. Standard phacoemulsification and goniosynechialysis successfully separate the synechiae and open the angle. But the microscopic drainage filter remains blocked. Because the physiological resistance is not fixed, many patients have poor postoperative intraocular pressure control. They also face risks of delayed pressure spikes and synechiae recurrence.

The Kahook Dual Blade is designed to precisely cut a strip of diseased trabecular meshwork and the inner wall of Schlemm’s canal. Removing this blocked tissue allows aqueous humor to flow directly into the collector channels. We lack high-quality prospective randomized controlled trials to compare this combined procedure against the traditional approach.

This prospective, single-center, randomized controlled trial takes place at Peking University People’s Hospital. The study will randomly assign 68 patients to receive either standard surgery alone or standard surgery combined with the Kahook Dual Blade. The primary goal is to compare the 1-year efficacy and safety of the two treatments. The study also uses ultrasound biomicroscopy to group patients by specific angle-closure mechanisms. These mechanisms include pupillary block, plateau iris, and lens-induced types. The

researchers will evaluate how these different mechanisms affect the surgical outcomes.

Study Design

- **Study Type:** Interventional (Clinical Trial)
- **Allocation:** Randomized
- **Intervention Model:** Parallel Assignment
- **Masking:** Single Blind (Outcomes Assessor)
- **Primary Purpose:** Treatment

Arms and Interventions

- **Active Comparator: PEI-GSL Group**
  - **Intervention:** Procedure: Phacoemulsification with intraocular lens implantation combined with goniosynechialysis. A blunt instrument mechanically separates the peripheral anterior synechiae from the trabecular meshwork.
- **Experimental: PEI-GSL-KDB Group**
  - **Intervention:** Procedure: Phacoemulsification and goniosynechialysis combined with Kahook Dual Blade goniotomy. The Kahook Dual Blade excises approximately 4 clock hours (120°) of the diseased trabecular meshwork in the nasal quadrant.

Primary Outcome Measures

1. **Mean Intraocular Pressure (IOP)** [Time Frame: Baseline, Day 1, Week 1, Month 1, Month 3, Month 6, Month 12]
2. **Magnitude of IOP Reduction** [Time Frame: 12 months] (Absolute and percentage reduction from baseline).
3. **Cumulative Surgical Success Rate** [Time Frame: 12 months] (Defined as postoperative IOP $\leqslant$ 21 mmHg and IOP reduction $\geqslant$ 20% from baseline, without glaucoma reoperation).

Secondary Outcome Measures

1. **Change in Number of IOP-Lowering Medications** [Time Frame: Baseline to 12 months]
2. **Incidence of Adverse Events** [Time Frame: Up to 12 months] (Includes intraoperative posterior capsular rupture, postoperative hyphema, and transient IOP spikes).

3. **Extent of Peripheral Anterior Synechiae (PAS)** [Time Frame: Baseline, 6 months, 12 months] (Measured in clock hours using gonioscopy and anterior segment imaging).

Eligibility Criteria

- **Ages Eligible for Study:** 40 Years and older
- **Sexes Eligible for Study:** All
- **Inclusion Criteria:**
  - Confirmed diagnosis of chronic primary angle-closure glaucoma (PAS $\geqslant$ 180° on indentation gonioscopy, glaucomatous optic neuropathy, and visual field defects).
  - Visually significant cataract requiring phacoemulsification.
  - Inadequately controlled intraocular pressure (IOP > 21 mmHg despite maximum medications, or IOP $\leqslant$ 21 mmHg dependent on two or more topical medications).
- **Exclusion Criteria:**
  - Secondary angle-closure glaucoma (e.g., neovascular, uveitic, or lens-induced).
  - History of prior intraocular surgery or incisional glaucoma procedures (previous uncomplicated laser peripheral iridotomy is allowed).
  - Concurrent severe ocular pathologies limiting visual prognosis (e.g., severe diabetic retinopathy, advanced macular degeneration).
  - Central corneal endothelial cell density < 1500 cells/mm².
  - Severe systemic conditions preventing surgical tolerance or 1-year follow-up.