Clinical Observation of Non-Staining Circular Capsulorhexis for Hypermature Cataract

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Abstract: Objective: To explore the circular capsulorhexis method and its clinical effect in phacoemulsification of hypermature cataract without staining. Methods: In this prospective randomized case-control study, 22 patients (22 eyes) with hypermature cataract were randomly divided into a staining agent group (10 cases, 10 eyes) and a non-staining agent group (12 cases, 12 eyes). Both groups underwent phacoemulsification with foldable intraocular lens implantation under topical anesthesia. In the staining agent group, 0.5% indocyanine green was used to stain the anterior lens capsule to assist in circular capsulorhexis; in the non-staining agent group, after puncturing the anterior lens capsule and aspirating the liquefied cortical material, the capsular bag was filled with viscoelastic agent to increase the contrast prior to circular capsulorhexis. The operability of the anterior capsule without staining in capsulorhexis was observed, and the effect of capsulorhexis, diameter of capsulorhexis opening, and operative time were compared and analyzed between the two groups. Results: Both groups successfully underwent circular capsulorhexis, with a success rate of 100%. The diameters of capsulorhexis opening in the staining agent group and non-staining agent group were 5.68 ± 0.15 mm and 5.54 ± 0.16 mm, respectively, without any statistical difference between the groups (P > 0.05); the operative time of the staining agent group (40.40 ± 5.42 s) was shorter than that of the non-staining agent group (50.92 ± 3.97 s), and the difference was statistically significant (P < 0.001). In both groups, phacoemulsification was successful, and intraocular lens were implanted into the capsular bags; their visual acuity showed significant improvement during the 1-month follow-up period after surgery, without any surgical complications. Conclusion: In hypermature cataract, injecting viscoelastic agent into the capsular bag for volume replacement, given a lack of capsule staining agent, can increase the contrast for capsulorhexis and reduce the risk of large capsular bag collapse on the zonular ligament. Thus, it is considered safe and effective. Circular capsulorhexis is conducive to a smooth phacoemulsification procedure.

Keywords: Hypermature cataract; Capsulorhexis; Phacoemulsification

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1. Introduction
With the improvement of people’s living standards and health awareness, many cataract cases in the early and mid-stages can be cured by surgery. However, hypermature cataract remains a problem in remote and underdeveloped areas. Hypermature cataracts can lead to a number of complications, including phacogenic uveitis [1], secondary glaucoma [2], and dislocation of the lens or lens nucleus [3,4]. Surgical extirpation is currently the only effective means of treating such cataracts. However, due to the liquefaction of fibers in the lens cortex and the fragility of suspensory ligaments in hypermature cataracts, it is often difficult to
perform circular capsulorhexis \([5-7]\), and the radial tear of the anterior capsule may extend to the equator part, which would increase the risk of dropped nucleus. Therefore, the surgery for hypermature cataract is a relatively complicated one. A successful continuous circular capsulorhexis and the treatment of exposed hard nuclei are the challenges in hypermature cataract surgery \([8,9]\). The use of stains (such as indocyanine green or trypan blue) for the anterior capsule can significantly improve the visibility of the anterior capsule under the operating microscope, which would help surgeons accurately determine the extent and effect of capsule tearing \([7-11]\). However, knowing how to increase the success rate of circular capsulorhexis and reduce the difficulty of surgery when there is a lack of staining agent or when the staining effect is poor has become an issue that perplexes grassroots ophthalmologists to carry out hypermature cataract surgery smoothly. In view of this, we introduce a non-staining circular capsulorhexis method in this study. We compared it clinically with the indocyanine green staining-assisted circular capsulorhexis method and determined its effect on the success rate and efficiency of hypermature cataract surgery in hope to provide reference for the clinical application of this method.

2. Data and methods

2.1. General information

Twenty-two patients (22 eyes) with hypermature cataract admitted to Xi’an Savaid Ophthalmic Hospital from January 2021 to January 2023 were included in this prospective randomized case-control study. Among the 22 patients, 8 were male and 14 were female, with an average age of 75.8 (68–92 years old). Table 1 shows the baseline data of the patients.

Inclusion criteria: hypermature cataract (cloudy-white lens, liquefied cortex, reddish and sinking nucleus, and absent red reflex). Exclusion criteria: (i) non-hypermature cataract; (ii) concurrent phacolytic glaucoma or lens-induced uveitis; (iii) concurrent corneal disease, glaucoma, fundus disease, and other eye diseases that affect vision; (iv) local and systemic contraindications to cataract surgery, such as severe hypertension, coronary heart disease, diabetic patients with poor blood sugar control, etc. This study was approved by the hospital ethics committee, informed consent was obtained from the patients, and all patients included in the study signed the informed consent form before the surgery.

Table 1. Comparison of preoperative baseline data of patients in the staining agent group and non-staining agent group

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of cases (eyes)</th>
<th>Age (number of cases)</th>
<th>Gender</th>
<th>Intraocular pressure (mmHg)</th>
<th>Visual acuity before surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staining agent group</td>
<td>12</td>
<td>77 ± 7.2</td>
<td>Male 6: Female 6</td>
<td>16.10 ± 2.18</td>
<td>Light perception/hand movement</td>
</tr>
<tr>
<td>Non-staining agent group</td>
<td>10</td>
<td>74 ± 3.3</td>
<td>Male 4: Female 6</td>
<td>16.75 ± 2.68</td>
<td>Light perception/hand movement</td>
</tr>
<tr>
<td>(P)</td>
<td>–</td>
<td>0.2502</td>
<td>–</td>
<td>0.7185</td>
<td>–</td>
</tr>
</tbody>
</table>

2.2. Surgical methods

All 22 patients received topical anesthesia (0.4% oxybuprocaine hydrochloride eye drops [Benuoxi, Japan Santen Pharmaceutical]) before surgery. A 2.4-mm dual plane limbal incision was made, and phacoemulsification was performed on the affected eye using a phacoemulsification device (Alcon, Centurion, USA). After capsulorhexis, the patients in both groups did not undergo hydrodissection, the cataracts were removed through the same operative steps, and foldable intraocular lens were implanted. All the surgeries were performed by the same physician.
2.2.1. Capsulorhexis in staining agent group
After injecting sterile air into the anterior chamber, 0.2 mL of 0.5% indocyanine green (Dandong Yichuang Pharmaceutical Co., Ltd.) was injected and left for 5–6 s. Circular capsulorhexis was completed by pulling the flap, during which viscoelastic agent was injected in the anterior chamber as appropriate to flatten the anterior capsule.

2.2.2. Capsulorhexis in non-staining agent group
An appropriate amount of viscoelastic agent (Alcon, USA) was injected into the anterior chamber. The anterior capsule of the central area was punctured with a 1-mL syringe needle, which was extended into the capsular bag to aspirate the liquefied cortex, and an appropriate amount of viscoelastic agent was injected into the capsular bag through the puncture port to maintain the shape of the capsular bag. The anterior capsule was flattened, and a capsulorhexis forcep was used to gently pick up the anterior capsule. Continuous circular capsulorhexis was then performed against the background of the transparent viscoelastic agent (Figure 1), during which the viscoelastic agent was supplemented as appropriate.

![Figure 1](image)

Figure 1. Capsulorhexis for hypermature cataract without staining. ① Hypermature cataract under the operating microscope (milky white and turbid lens, liquefied cortex, reddish and slightly sunken nucleus, and absent red reflex). ② Liquefied cortex overflows after anterior capsule puncture with a 1-mL syringe needle. ③ Aspiration of liquefied cortex in the capsular bag with a flat needle. ④ Appropriate amount of viscoelastic agent injected into the capsular bag to maintain the shape of the capsular bag. ⑤ Flap opened from the puncture port for capsulorhexis, and viscoelastic agent added to flatten the anterior capsule. ⑥ Complete circular capsulorhexis. ⑦ and ⑧ Phacoemulsification to remove the lens nucleus. ⑨ Lens nucleus cleaned, with presence of red reflex and complete anterior capsule ring.

2.3. Criteria for capsulorhexis success
The anterior capsule tearing diameter was controlled at 5–6 mm. Successful capsulorhexis: continuous capsulorhexis; round or slightly oval in shape; both ends are completely connected. Capsulorhexis failure: anterior capsulorhexis splits toward the equator during capsulorhexis; capsulorhexis opening is seriously off-centre; or capsulorhexis cannot be completed and converted into capsulotomy.
2.4. Observation indicators
The entire procedure was recorded on video. The success rate of circular capsulorhexis, capsulorhexis time (time record: three times of video playback, stopwatch record), and capsulorhexis diameter were compared between the two groups. Complications such as capsular tear (a tear at one site is counted as 1 site) and posterior capsular rupture (number of cases) were observed. The start time of capsulorhexis in the staining agent group was the injection of the staining agent into the anterior chamber; whereas the start time of capsulorhexis in the non-staining agent group was when the 1 mL syringe needle punctured the anterior capsule. Calculation of capsulorhexis diameter: after closing the corneal incision and the normalization of intraocular pressure, we took a screenshot of the orthotopic surgery video (Figure 2); the short axis of the annular capsulorhexis and the diameter of the optical zone of the intraocular lens implanted during the operation (6 mm) were taken as reference, along with the long-axis mean.

Visual acuity, intraocular pressure, and corneal edema were recorded on the first day and one month after surgery.

2.5. Statistical analysis
Measurement data were expressed as mean ± standard deviation (s), and SPSS 25.0 was used to perform paired t-test of independent samples for data analysis. \( P < 0.05 \) indicates statistically significant difference.

3. Results
3.1. Intraoperative circular capsulorhexis
Circular capsulorhexis was successfully completed in the two groups of patients, although the direction of capsulorhexis had to be adjusted several times during the surgery according to situations. No complications were observed, such as anterior capsular tear and posterior capsular rupture. One case (1 eye) in the staining agent group had a small capsulorhexis, and in order to prevent postoperative capsular bag shrinkage, the capsulorhexis was enlarged after implantation of the intraocular lens. In the non-staining agent group, under the background of the transparent viscoelastic agent, the edge of the torn anterior capsule was clearly visible, and viscoelastic was added 1 or 2 times during the surgery to flatten the anterior capsule as needed; the capsulorhexis went smoothly, with a success rate of 100%.

Capsulorhexis time: the capsulorhexis time in the staining agent group and non-staining agent group was 30–50 s and 47–58 s, respectively. The capsulorhexis time in the non-staining agent group was significantly longer than that in the staining agent group \( (P = 0.00002) \). The capsulorhexis diameter of the staining agent group and the non-staining agent group was 5.4–5.9 mm and 5.2–5.8 mm, respectively, and the difference was not statistically significant \( (P = 0.07528) \), as shown in Table 2.
### Table 2. Comparison of intraoperative data between the staining agent group and the non-staining agent group

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of eyes</th>
<th>Anterior capsule tear (site)</th>
<th>Posterior capsule rupture (example)</th>
<th>Capsulorhexis time (s)</th>
<th>Capsulorhexis diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staining agent group</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>40.40 ± 5.42</td>
<td>5.68 ± 0.15</td>
</tr>
<tr>
<td>Non-staining agent group</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>50.92 ± 3.97</td>
<td>5.54 ± 0.16</td>
</tr>
<tr>
<td>P</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.00002</td>
<td>0.07528</td>
</tr>
</tbody>
</table>

### 3.2. Postoperative effect

On day 1 after surgery, the uncorrected visual acuity of both groups improved significantly. The visual acuity and intraocular pressure of the staining agent group were 0.8–0.2, and 12.2–18.7 mmHg, respectively, while the visual acuity and intraocular pressure of the non-staining agent group were 0.7–0.2 and 11.4–19.8 mmHg, respectively; there was no significant difference in the postoperative visual acuity and intraocular pressure between the two groups ($P > 0.05$), as shown in Table 3. On postoperative day 1, 3 patients (3 eyes) had mild corneal edema in the central region of the cornea in each of the two groups. Local hypertonic agent was given, and it resolved in all 6 patients after 2 days.

At the re-examination 1 month after surgery, the visual acuity of the two groups was stable, with LogMAR 0.5–0.2 in the staining agent group and LogMAR 0.5–0.1 in the non-staining agent group; there was no significant difference in visual acuity and intraocular pressure between the two groups 1 month after surgery ($P > 0.05$), as shown in Table 4.

### Table 3. Visual acuity, intraocular pressure, and corneal edema in the staining agent group and non-staining agent group on postoperative day 1

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of cases</th>
<th>Visual acuity (LogMAR)</th>
<th>Intraocular pressure (mmHg)</th>
<th>Corneal edema (number of eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staining agent group</td>
<td>10</td>
<td>0.49 ± 0.20</td>
<td>15.30 ± 2.20</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>Non-staining agent group</td>
<td>12</td>
<td>0.45 ± 0.17</td>
<td>15.83 ± 3.46</td>
<td>3 (30%)</td>
</tr>
<tr>
<td>P</td>
<td>—</td>
<td>0.7247</td>
<td>0.8506</td>
<td>—</td>
</tr>
</tbody>
</table>

### Table 4. Visual acuity, intraocular pressure, and corneal edema in the staining agent group and non-staining agent group 1 month after surgery

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of cases</th>
<th>Visual acuity (LogMAR)</th>
<th>Intraocular pressure (mmHg)</th>
<th>Corneal edema (number of eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staining agent group</td>
<td>10</td>
<td>0.36 ± 0.11</td>
<td>15.70 ± 2.00</td>
<td>0</td>
</tr>
<tr>
<td>Non-staining agent group</td>
<td>12</td>
<td>0.36 ± 0.10</td>
<td>16.08 ± 2.41</td>
<td>0</td>
</tr>
<tr>
<td>P</td>
<td>—</td>
<td>0.6960</td>
<td>0.4893</td>
<td>—</td>
</tr>
</tbody>
</table>

### 4. Discussion

Cataract is one of the leading causes of blindness worldwide, and although drug reversal may become a potential treatment for cataract, surgery remains the only viable treatment at this stage [12]. With the continuous improvement of ophthalmic surgical instruments and techniques, hypermature cataract is no
longer a contraindication for phacoemulsification \cite{9,13-14}. Continuous circular capsulorhexis is the key to completing phacoemulsification for hypermature cataract \cite{10}. The main features of hypermature cataract include the liquefaction of lens cortex and hard and floating lens nucleus. In this case, even if femtosecond laser-assisted capsulorhexis is used, it is not easy. Furthermore, femtosecond laser, minimally invasive vitrectomy, electric capsulorhexis, etc., are not widely used in our country, especially in remote areas at present \cite{5-7,15}. Manual capsulorhexis has certain flexibility and is still the most basic capsulorhexis method in cataract surgery. When dealing with hypermature cataract, other than the poor contrast of the lens, the anterior capsule is often loose and inelastic, and the suspensory ligament is also fragile. Therefore, the edge of capsulorhexis is not easily controlled by conventional capsulorhexis flap, and the anterior capsule is prone to crack, thus increasing the risk of surgery \cite{15,16}.

The anterior capsule staining technique is often used to improve the success rate of circular capsulorhexis in hypermature cataracts. The common staining agents are 0.1% trypan blue and 0.5% indocyanine green \cite{7,11,16}. However, at times, there is a shortage of staining agents or poor staining of the anterior capsule. In addition, during capsulorhexis, the liquefied cortex may overflow, causing the field of view to be obscured. Therefore, during the surgery, the operator must use various capsulorhexis techniques flexibly based on the situation to complete circular capsulorhexis and subsequent lens nucleus processing. The non-staining method of “volume replacement” with viscoelastic filling of the capsular bag that was used in this study has the following characteristics: (i) aspiration of the liquefied cortex reduces pressure in the capsular bag; when the anterior capsule is punctured, it can be seen that the liquefied cortex overflows in the form of “smoking”, causing an instant decrease in tension of the capsular bag; further suctioning the anterior chamber and the liquefied cortex from the capsular bag can reduce the interference of the overflow on subsequent capsulorhexis; (ii) the filling restores capsular bag volume and increases anterior capsule contrast; injecting an appropriate amount of cohesive viscoelastic into the capsular bag through the puncture of the anterior capsule pushes the exposed lens nucleus and other interfering cortex away from the anterior capsule and restores the intracapsular volume (volume replacement); this step not only increases the contrast between the anterior capsule and the subcapsular material, but also helps reduce the interference of the excessive collapse of the capsular bag on the zonule; (iii) the filling maintains a certain tension in the anterior capsule; after injecting the viscoelastic agent into the capsular bag, adding a little cohesive viscoelastic agent on the surface of the anterior capsule further flattens the capsular membrane to avoid excessive pressure in the capsular bag and rupture the capsulorhexis opening; (iv) different types of viscoelastic agents; mixed viscoelastics can be used during surgery; both cohesive and diffuse types can be used together according to situations to form a “soft shell technology” \cite{9} to protect the corneal endothelium, stabilize the anterior capsule, and improve viscoelasticity; capsulorhexis can be well-achieved by shearing force, and the ideal shape of capsulorhexis can be maintained.

Among the patients in the present study, the success rate of circular capsulorhexis in the non-staining agent group was 100%, the capsulorhexis time was slightly longer than that in the staining agent group, and there was no significant difference in capsulorhexis diameter and postoperative vision recovery between the two groups. At the same time, when dealing with the nucleus, since the capsular bag is filled with viscoelastic agent, the phacoemulsification needle can enter the anterior chamber without perfusion and directly “pile” into the interior of the nucleus to complete the interception and chopping of the nucleus, which is beneficial to retaining the inside of the capsular bag. The viscoelastic agent stabilizes the posterior capsule and the exposed nucleus, prevents large-scale rotation or stabbing and scratching of the capsular bag, and improves the safety in surgery.

In non-staining circular capsulorhexis for hypermature cataract, viscoelastic agent is used to replace the volume in the capsular bag, which not only maintains the shape and tension of the anterior capsule as well as increases the contrast, but also forms a soft shell to stabilize the nucleus. This simple and practical
method increases the success rate of capsulorhexis and guarantees the completion of the surgery. The method we propose benefits patients with hypermature cataract for vision restoration surgery through phacoemulsification and also provides a choice of high-end intraocular lenses to meet the requirements for higher visual quality; thus, it is worthy of clinical application. However, this study has several limitations, including the small sample size. A multicenter clinical study with a larger sample size is needed to observe the possible surgical complications of non-staining circular capsulorhexis. Treatment with circular capsulorhexis for hypermature cataracts is still difficult, regardless of whether staining capsulorhexis or “volume displacement” capsulorhexis is used. We advise against its use in novices as much as possible.

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