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Dynamic stromal hydration during phacoemulsification: a comparative study with experimental data

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白内障超声乳化术中动态角膜基质水化实验数据的比较

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摘要

目的:报道一种不同的水化方法-动态角膜基质水化。白内障手术角膜基质水化时,常规水化技术虽然运用普遍,但需要对伤口密闭性进行标准化判断,而目前尚无精确地评价伤口边缘水化是否充分的标准。

方法:前瞻性随机对照研究。通过连续性灌注检测渗漏点。根据渗漏点进行基质水化,伤口边缘肉眼可见无渗漏时停止水化,应用 0.0125% 台盼蓝分别检测伤口位点的渗漏。术后 1d Seidel 试验评估伤口的密闭性。

结果:试验组共 120 眼,包含 360 个伤口位点(左侧 120 个,右侧 120 个,主要切口 120 个),对照组包含 120 眼。试验组中染色试验显示仅 22 眼中的 29 个伤口位点有房水外渗(8.0%),而对照组中有 30 眼中的 41 个伤口位点有渗漏(11.3%),差异有统计学意义($P=0.042$)。

结论:动态角膜基质水化是一项直接观测技术,可用作标准化常规基质水化。可通过简单的观察伤口动态评估基质水化时伤口的密闭性。

关键词:白内障手术;动态角膜基质水化;伤口渗漏

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Abstract

• AIM: To present a different approach called dynamic stromal hydration. Though common, conventional hydration technique should be standardized to ascertain wound integrity at the time of stromal hydration during cataract surgery. No explicit criteria exist to suggest that hydration of wound edges is adequate.

• METHODS: This study was designed as prospective, randomized, comparative study. Leakage sites were detected by continuous irrigation. At that point, stromal hydration was performed in consideration of the leakage points. The wound edges were hydrated until no further leakage could be visually detected. Trypan blue 0.0125% was applied over the wound sites, and each wound was individually observed for leakage. On the day after surgery, Seidel's test was performed to assess wound integrity.

• RESULTS: All 120 eyes in the experimental group were evaluated, including all 360 wound sites - 120 left side ports, 120 right side ports, and 120 main incisions - as were all 120 eyes in the control group. Though the dye test revealed leakage of aqueous humour from only 29 wound sites of 22 eyes (8.0% of 360 wounds) in the experimental group, leakage appeared in 41 wound sites of 30 eyes (11.3% of 360 wounds) in the control group. When groups were compared in terms of leakage, the difference was statistically different ($P=0.042$).

• CONCLUSION: Dynamic stromal hydration - meaning standardized conventional stromal hydration - is a direct observational technique that allows the easy evaluation of wound integrity at the time of stromal hydration by way of observing wound dynamics.

• KEYWORDS: cataract surgery; dynamic stromal hydration; wound leakage

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INTRODUCTION

The leakage of corneal incisions after phacoemulsification is a possible postoperative complication thatcan increase the risk of endophthalmitis. Before hydration, well-apposed edges of clear corneal incisions (CCIs) oppose the flow of aqueous humor from the edges themselves. The edges' apposition depends on many factors, however, including length, width, penetrating trajectory of the wound, distortion of the incision during surgery, instruments used, postoperative intraocular pressure (IOP), inflammatory response, and length of time since operation[1-5].

To augment the self-sealing wound dynamics of CCIs, stromal hydration is the technique most commonly performed, typically by hydrating the lateral walls and internal entry of incision. However, even if the size of the incision can be reduced from 3.2 to 1.4 mm, for example, other problems can remain. In response, various techniques involving dyes, stains, direct observation, and optical coherence tomography

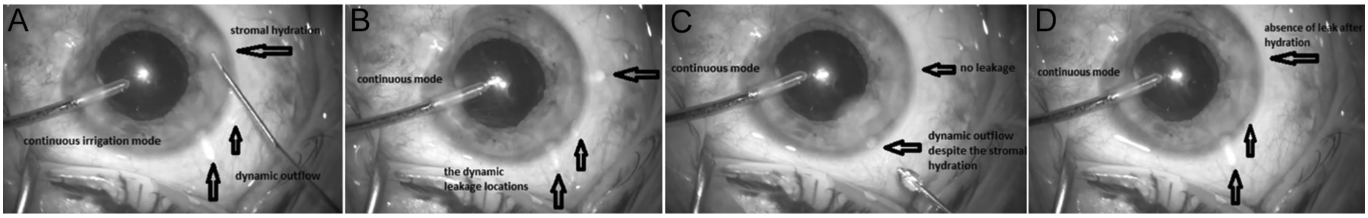

Figure 1　Description of dynamic stromal hydration　A: The irrigation cannula was maintained in the anterior chamber with continuous irrigation after the removal of the ophthalmic viscosurgical device. Dynamic outflow can be observed clearly at the main incision and side port. B: The hydration of the side port. C: Discontinuation of the outflow after the hydration of the side port. D: A pearl of the technique: the presence of leakage despite stromal hydration (more hydration is required in leakage point; if leakage persists, suturing should be considered).

(OCT) have been applied to better understand the integrity of wounds and their leakage[1-4].

Though common, conventional stromal hydration is not standardized, and no explicit criteria exist to suggest that hydration of wound edges is adequate. Added to the fact that the adequacy of wound integrity varies from surgeon to surgeon, the stages of the conventional hydration technique should be standardized to ascertain wound integrity at the time of stromal hydration. In response, we here present a novel technique called dynamic stromal hydration.

SUBJECTS AND METHODS

In this randomized, prospective study, an experimental group consisting of the 120 consecutive eyes of 106 patients and a control group consisting of the 120 consecutive eyes of 89 other patients, all scheduled for cataract surgery, formed the sample. The Lens Opacities Classification System (LOCS Ⅲ) was used for grading senile cataracts[6]. Only the grade 2 and 3 cataracts were included in the present study. Written informed consent was obtained from each patient. Local institutional review board approval was obtained and the study followed the tenets of the Declaration of Helsinki.

Surgical Technique　In each group, all surgeries were performed by the same surgeon. CCIs, each including (main incision and two side ports, were created as a single-plane tunnel incision, with a 2.2-mm knife for superior main incision and a 0.9-mm knife for the side ports (Alcon). The length of incisions was an average of 1.5 mm (1.3-1.7 mm), as measured by caliper. Microcoaxial phacoemulsification was performed with the Infiniti Vision system (Alcon) using torsional ultrasound. A 0.9-mm, mini-flared, 45° aspiration bypass system Kelman tip was used with an ultrasleeve (Alcon). The standard stages of CCI phacoemulsification were performed prior to intraocular lens insertion. Through the unenlarged incision, a one-piece acrylic intraocular lens was inserted via a system comprising a Royal injector and D-cartridge (Asico, USA).

In control group, after the removal of the ophthalmic viscosurgical device (OVD), the conventional hydration technique was performed by hydrating the lateral walls and internal entry of the incision. To determine whether stromal hydration was adequate, spontaneous leakage from wounds was observed and, if present, then so was the movement of the anterior chamber particles (*i.e.*, remaining OVD) in the direction of the leaking incision. The stabilization of anterior chamber formation and the apposition of wound edges were also assessed.

In experimental group, by contrast, to implement dynamic stromal hydration, after OVD removal the aspiration cannula was also removed from the anterior chamber, and the irrigation cannula was maintained there with continuous irrigation (bottle height 100 cm). The dynamic outflow created by continuous irrigation was clearly observed at the main incision and side port. A locked cannula-syringe system was used for stromal hydration. At that point, stromal hydration was performed in consideration of the leakage points, and balance salt solution (BSS) was injected via a 27-gauge cannula toward the anterolateral walls and internal roof of the incision until leakage ceased, at which point the continuous mode was stopped. To gauge the resistance of the wound edges, the continuous mode was then resumed before the irrigation probe was removed. The wound edges were hydrated until no further leakage could be visually detected (Figure 1A-1D), after which the irrigation cannula was removed from the anterior chamber. The other side port was hydrated by standard means. Lastly, to adjust the approximate IOP estimated physiologic pressure was applied to the cornea. Side port was used to release fluid to adjust pressure.

Dye Test　One or two drops of trypan blue 0.0125% (pH 7.39) were applied over the wound sites, and each wound was individually observed for leakage for at least 10 s. Aqueous humour flowing outward from the incision was observed as a stream of clear fluid washing away the trypan blue from the ocular surface. Wound leakage was graded as either small or large: small when egress of the aqueous humour was slow and in a narrow stream and large when the egress was rapid and in a broad stream (Figure 2A and 2B). All leakages were noted at the end of the dye test. The cases in which a leakage was detected was hydrated by considering the leakage points until the leakage ceased. After the observation period, the surface was irrigated with BSS in order to wash away the residual trypan blue on the ocular surface. Ultimately, intracameral cefuroxime was injected into the anterior chamber via right side port, and postoperatively, moxifloxacin 0.5% and prednisolone acetate 1.0% were prescribed.

On the day after surgery, routine postoperative control including intraocular pressure (IOP) measurements was performed. Seidel's test was performed to assess wound integrity. For the next 8wk, patients were observed for the development of

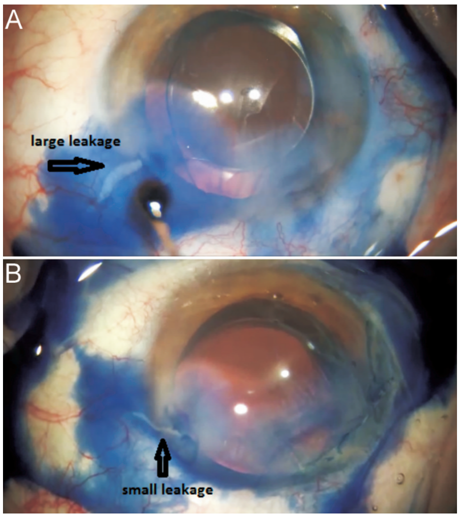

Figure 2 Intraoperative photographs of the clear fluid streaming into a pool of blue solution from A: Small leakage; B: Large leakage.

Table 1 Number of leakage sites in groups

Groups	L-port (*n*=120)	M-incision (*n*=120)	R-port (*n*=120)	Total wounds (*n*=360)
Experimental	15	8	6	29 (8.0%)[a]
Control	22	12	7	41 (11.3%)[a]

[a]P=0.042 (between groups).

postoperative endophthalmitis. The main outcome measure for the experimental group was the presence or absence of clearly observable wound leakage after stromal hydration; for the control group, the chief measure was spontaneous wound leakage at an estimated pressure. The groups were compared in terms of wound leakage, and an unpaired t-test and Chi-square test were used for statistical analysis.

RESULTS

The experimental group consisted of 54 females and 52 males aged an average of 68.2 ± 11.7 (55.0-88.0) y, whereas the control group consisted of 49 females and 40 males aged an average of 61.9 ± 16.6 (44.0-79.0) y. Compared by age and sex, the groups showed no statistical difference (respectively, P=0.09; P=0.12). The grade of cataract was 2.4±0.5 in experimental group, and 2.2±0.6 in control group (P=0.10)

All 120 eyes in the experimental group were evaluated, including all 360 wound sites-120 left side ports (L-port), 120 right side ports (R-port), and 120 main incisions (M-incisions)-as were all 120 eyes in the control group. Though the dye test revealed leakage of aqueous humour from only 29 wound sites of 22 eyes (8.0% of 360 wounds) in the experimental group, leakage appeared in 41 wound sites of 30 eyes (11.3% of 360 wounds) in the control group. When groups were compared in terms of leakage, the difference was statistically different (P = 0.042) (Table 1). In both groups, leakage of aqueous humour from R-ports was less than that from L-ports, at least according to the trypan blue method, and the difference was statistically significant (P = 0.038 in the experimental group, P = 0.015 in control group).

By types, 27 wounds (7.5% of 360 wound sites) showed small leakages and two (0.5% of 360) showed large ones in the experimental group, whereas 38 wounds (10.5% of 360) showed small leakages and three (0.8% of 360) showed large ones in the control group. Despite leakage, anterior chambers seemed stable in all eyes. No complication related with the syringe-cannula system was observed in either group, though suturing was required in two main incisions with large leakages-1 in experimental group and 1 in control group. In those eyes, no intraoperative or postoperative complications occurred, and according to the fluorescein test, wound leakage was not detected 1 d after surgery despite the transient mild intraocular pressure elevations in 19 eyes - 6 in experimental group, 13 in control group. In control group, only in 1 eye with IOP more than 30 mm Hg antiglaucomatous treatment was initiated.

DISCUSSION

Anterior chamber contamination may occur during cataract surgery at the time of wound closure. The type of indigenous flora, the extraocular fluid's entry into the anterior chamber, and the amount of fluid in the chamber, may influence its incidence. Postoperative endophthalmitis is a serious complication resulting from the entry of microorganisms into the eye. The isolation of microorganisms postoperatively could have been influenced by the surgical technique used, the surgical time, and the use of antibiotics. At that point, the integrity of CCIs becomes critical. In fact, most cases of endophthalmitis following cataract surgery are associated with wound defects, gaping, and leakage[7-9]. Moosajee *et al*[10] reported the safety of stromal hydration with cefuroxime in mouse corneas and claim that a reservoir of antibiotic at the wound can potentially act as a barrier of defense against microorganisms.

Many researchers and practitioners consider stromal hydration to be an important adjunct used to improve wound integrity in the early postoperative period, and both *in vitro* and *in vivo* studies have suggested the method's possible benefits. For one, well-apposed wound edges can reduce the risk of leakage, which is more likely to occur when the penetrating trajectory of the incision is perpendicular to the ocular wall. Two-stepped, three-stepped, and beveled incisions impede leakage, however, not only because they produce a bigger surface of apposition, but also because the compression *ab interno* or *ab externo* can act as a hydrostatic valve and close the trajectory. Since incision width diminishes the apposition of the edges of the wound if large, aqueous humour leakage can occur only minutes after surgery when wound closure is weak and IOP has exceeded immediate postoperative values. Nevertheless, leakage is highly exceptional 1d after surgery and requires a strong negative imbalance between IOP and wound closure forces[1,3-5].

The literature is divided over the effectiveness of stromal hydration[11]. One study of 80 patients found that stromal hydration was effective[12]. Another study reported a 66.7%

leak rate with stromally hydrated incisions[13]. It has been suggested that leaks may occur as the effect of stromal hydration wears off[14]. To this point, it is unclear how long the effects of stromal hydration last; various studies suggest anywhere from 1d[15] to 1wk[16]. The duration of stromal hydration may vary due to its presumed dependence on the endothelial pumping mechanism for a particular eye[14]. A new hydration technique focusing on hydrating the stromal pocket as opposed to the roof and walls of the incision was associated with significantly less leaking, but this newer technique may carry an additional risk of epithelial damage and/or increased astigmatism[17].

Fine *et al*[15] reported that an incision in the corneal plane with a chord length of at least 2.0 mm provides a beneficial architecture for adequate self-sealing. In that study, proper CCI construction resulted in an incision architecture with increased stability and safety, which precluded endophthalmitis for more than 10y in 9 000 cases in a single practice. Sykakis *et al*[18] furthermore assessed the use of hydrogel ocular bandages (HOB) on CCIs in phacoemulsification cataract surgery and determined that proper surgical wound construction without using an HOB could efficiently prevent the postoperative ingress of fluid through the primary corneal incision.

In another study involving a 2.75-mm, single-plane CCI, wound leakage was evaluated with povidone iodine 5% and showed an incidence of 16.5% in the 200 incisions made; leakage was small in all eyes except from one main incision and two side-port incisions[19]. At the same time, in evaluating wound integrity in 33 eyes subjected to 2.8-mm uniplanar CCI phacoemulsification and conventional stromal hydration, Mifflin *et al*[17] reported wound leakage in 28 of the 33 eyes, with direct firm pressure to the posterior edge of the incision and without spontaneous wound leakage in any eye.

Vasavada *et al*[20] later compared the incision integrity of two microcoaxial phacoemulsification systems-a 1.8-mm CCI system (Stellaris) and a 2.2-mm CCI system (Infiniti)-to find that incision enlargement and ingress of trypan blue into the anterior chamber were significantly greater and anterior segment-OCT wound gaping more frequent in the 1.8-mm CCI system. Currently, Das *et al*[21] emphasized the importance of microscope integrated intraoperative spectral domain optical coherence tomography for cataract surgery and reported that it was possible to assess wound morphology in clear corneal incisions, in terms of subclinical Descemet's detachments, tears in the inner or outer wound lips, wound gaping at the end of surgery and in identifying the adequacy of stromal hydration. However, the cost is major problem for this application.

In the present study, a single-plane incision with a roughly 1.5-mm tunnel was created in each eye. Although leakage occurred in 11.3% of 360 wounds subject to the conventional stromal hydration technique, it occurred in only 8.0% of 360 wounds subject to dynamic stromal hydration, for a difference that was significant. In both groups, leakage of aqueous humour from R-ports was less than that from L-ports, probably due to having used the phacoemulsification chopper through L-port during phacoemulsification, used the instrument to center the eye, and provided counter traction during injection. Endophthalmitis did not occur in any eyes during follow-up.

In practice, observing the level of the outward flow created by continuous irrigation can help to determine the apposition of wound edges before hydration. Planning stromal hydration with continuous irrigation in order to detect leakage sites and the discontinuation of the outflow through stromal hydration can also provide more visible, practical results for surgeons.

Dynamic stromal hydration is a standardized direct observational technique that provides visual hydration and makes determining sites of gaping wounds possible. With this technique, surgeons can directly observe the dynamic outflow, discontinuation of outflow, and leakage both during and after hydration. At times, the visible whitening of the anterior aspect of the corneal stroma may not indicate that leakage has ceased, and stromal hydration against the dynamic outflow may provide more efficient results. Moreover, stromal hydration allows anterior chamber formation by virtue of continuous irrigation.

This study poses some limitations. First, IOP measurements would be better set tonometrically instead of estimated by tactile means. Second, OCT would be more beneficial for detecting the efficacy of the technique and CCI measurements. Another aspect that may affect the leakage rate is the cannula used for irrigation/aspiration (I/A), for it is possible that removing the OVD through the main incision with a coaxial, sleeved I/A cannula is less likely to cause leakage, since the silicone sleeve tends to prevent the distortion of the incisional tissue. The latter is quite common with rigid round I/A hand pieces forced through corneal incisions. Also, the current study is limited to 8-week follow-up, longer follow-up data is required for more accurate results for the development of endophthalmitis.

In sum, dynamic stromal hydration-meaning standardized conventional stromal hydration-is a direct observational technique that allows the easy evaluation of wound integrity at the time of stromal hydration by way of observing wound dynamics.

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