Wound integrity of modified anterior stromal hydration Vs. conventional hydration after clear corneal incision phacoemulsification

Isha Lohmror, Pankaj Sharma, Sonal Kalia

Purpose: To compare the self-sealing ability of temporal clear corneal incisions for phacoemulsification using conventional stromal hydration (CH) with two modified methods: the anterior stromal pocket hydration (ASPH) and the modified stromal pocket hydration (MASH). Methods: Patients undergoing routine phacoemulsification surgeries were randomized to receive the CH, ASPH, and MASH (n = 30 eyes in each group). In the ASPH, an anterior stromal pocket was created superficial and parallel while in the MASH; it was superficial and perpendicular to the plane of the main incision. The primary outcome measure was wound leakage assessed after applying firm downward pressure on the posterior lip of the main corneal incision, simulating eye rubbing. Results: On application of pressure to the posterior lip, leakage was seen from 19 eyes (63%) in the CH group, while this was seen in only two eyes (7%) each in the ASPH and MASH groups (P < 0.001). The likelihood of wound leak after applying pressure to the posterior lip reduced by 86% in the ASPH and MASH groups compared to CH (Odds ratio = 0.14, 95% CI = 0.05 – 0.35, P < 0.001). The mean surgically induced astigmatism was 0.18 ± 0.14D and there were no differences in SIA across the three groups (P = 0.42). More eyes in the ASPH required conversion to CH (n = 4, 13%) due to difficulty in localizing the pocket compared to MASH (n = 0, P = 0.03) Conclusion: Both, the ASPH and MASH techniques reduce the risk of wound leakage and do not induce astigmatism. The MASH technique makes it easier to consistently localize the pocket.

Key words: Phacoemulsification, wound hydration, stromal pocket, clear corneal incision

The integrity of the clear corneal wound is extremely important to achieve excellent outcomes during and after phacoemulsification cataract surgery. A secure wound prevents any egress of anterior chamber contents outside the eye thereby preventing hypotony. It also prevents accidental seepage of ocular surface contents inside the anterior chamber, thereby reducing the risk of endophthalmitis to a large extent. In view of these benefits, every surgeon aims for a watertight wound closure at the end of surgery.

The self-sealing ability of the wound depends upon its configuration; biplanar, square wounds <3 mm with adequate length into the stroma doing better than larger rectangular wounds.[1] In addition to the wound, other factors such as type of blade used and technique of phacoemulsification may also influence wound integrity. Stromal hydration of corneal incisions have been shown to enhance wound integrity and has been adopted universally due to these benefits,[2] despite certain claims about hydration causing changes in the incision length and leading to high intraocular pressure (IOP) in the early postoperative period.[3] However, stromal hydration is not effective in all cases even with excellent wound configuration, and may require reinforcement with sutures. Additionally, it has been shown using simulations that eye rubbing can lead to wound leak from clear corneal incisions in a large proportion of patients.[4] Although stromal hydration or wound suturing represent traditional approaches, there exists a lot of literature on the use of adhesives to improve wound closure,[5] suggesting that achieving watertight closure is not always possible.

In addition to conventional stromal hydration techniques, modified methods of hydration have been described to improve wound-sealing rates. Mifflin et al. have described an anterior stromal pocket constructed above and parallel to the plane of the main wound, and they showed that hydrating this pocket alone, without hydrating the main wound, significantly reduced leakage rates. In our experience with this technique, we found it difficult to localize the anterior stromal pocket at the end of surgery and hence had to perform conventional wound hydration frequently. To overcome this difficulty with localization, we modified the way the anterior stromal pocket was created. In this study, we compare wound leakage rates across conventional wound hydration, anterior stromal pocket hydration described previously and the modified stromal pocket hydration technique we have devised.

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: WKHLRPMedknow_reprints@wolterskluwer.com

Cite this article as: Lohmror I, Sharma P, Kalia S. Wound integrity of modified anterior stromal hydration Vs. conventional hydration after clear corneal incision phacoemulsification. Indian J Ophthalmol 2021;69:1769-74.
Methods

This was a randomized study performed at a tertiary care government hospital in North India between December 2012 and March 2013. The study was approved by the institutional ethics committee and was conducted as per the tenets of the declaration of Helsinki. All participants signed an informed written consent before enrolment.

Participants

All consecutive patients >40 years of age presenting to our hospital with uncomplicated senile cataract and willing for surgery were invited to participate in the study. Consenting patients willing to come for 1 follow-up visit were enrolled for the study. Only one eye was enrolled from one patient. Eyes with coexistent ocular pathologies affecting the cornea, anterior chamber angles and retina were excluded. Similarly eyes with coexistent or past uveitis, glaucoma, mydriasis ≤ 5 mm, pseudoxefoliation, subluxated cataracts, etc., that could predispose to surgical complications were excluded from the study. Eyes experiencing vitreous loss were to be excluded since all these eyes were to receive sutures precluding our ability to assess leakage. All participants underwent a comprehensive opthalmic evaluation at time of enrolment including best-corrected visual acuity (BCVA), dilated slit lamp and fundus evaluation and ocular biometry.

Randomization and masking

Participants were randomized into three groups: conventional stromal hydration (CH), anterior stromal pocket hydration (ASPH) and modified anterior stromal pocket hydration (MASH) in a 1:1:1 ratio using random number allocation codes. Patients were masked to the technique used while the operating surgeon was informed immediately before the surgery about the technique to be used. An investigator, masked to the technique used, evaluated patients on day 1, day 7 and 1-month follow-up.

Surgical technique

All surgeries were performed by a single surgeon (PS). A uniplanar, square-shaped, clear corneal incision using a 2.2 mm stainless steel bevel – down keratome was fashioned temporally and standard phacoemulsification was completed using the Sovereign Compact phacoemulsification system (White Star, AMO, USA) and chopping maneuvers. Then, a foldable acrylic intraocular lens (Aurofold, Aurolabs, Madurai, India) was implanted in the bag followed by restoration of the anterior chamber volume via the side port incision. Management of the main surgical wound was as per the technique allocated randomly.

In the CH group, we followed the technique of conventional stromal hydration. In summary, a 27G hydration canula was used to hydrate the lateral edges and internal roof of the main clear corneal tunnel, until stromal whitening was seen and the intraocular pressure (IOP) was deemed adequate by the operating surgeon at the end of surgery. In the ASPH group, an anterior stromal pocket was fashioned at the start of surgery, immediately after the main incision was constructed, using a technique similar to the one described by Mifflin et al.9 The pocket was created using the same keratome used to make the main incision; however, the keratome was advanced only till the triangular bevel entered the stroma with its tip facing the center of the pupil, at a more superficial plane parallel to the plane of the main incision [Fig. 1]. In the MASH group, a similar pocket was created using the same keratome, superficial to the main incision, but the keratome was initiated 1 clock hour supero-temporal and advanced perpendicular to the plane of the main incision such that its tip faced towards the infero-temporal limbus as opposed to the centre of the pupil in the ASPH group (Video 1). In the ASPH and MASH groups, the main wound was not hydrated at the end of surgery; instead the respective pockets were hydrated alone. [Fig. 2]

In case the surgeon found it difficult to find the stromal pockets in these groups or hypotony persisted after pocket hydration, he was permitted to convert to conventional hydration, but any such conversion was noted by an independent observer present inside the operating room and reported separately. Wound leakage and patching were recorded after all attempts at hydration were completed.

Assessment of wound leakage

In all the three groups, after forming the anterior chamber via the side port to establish adequate IOP, the main surgical wound was dried using a week cell sponge or cotton tipped applicator and wound leak was assessed at three time points by the operating surgeon and the independent observer viewing surgery on a monitor: first before stromal hydration, second after stromal hydration and third, after applying firm downward pressure on the posterior lip of the main corneal incision using a 27G cannula. [Fig. 3] The amount of pressure applied was to simulate eye rubbing. In case a wound leak was detected at this stage, minimal hydration was performed again and the eye was patched for 4 hours. All surgeries were recorded to corroborate wound leakage.

Postoperative evaluation

The Pentacam (Oculus, Germany) was used to image the corneal incision 24 hours after the surgery and at 1 week follow-up [Fig. 4] to document wound apposition and localized descemet’s membrane detachment [Fig. 5]. A Siedel’s test was performed by a masked observer on postoperative day 1 to determine any wound leakage. At 1 follow-up, corneal astigmatism measured using a manual keratometer (Bausch & Lomb, USA) and surgically induced astigmatism (SIA) was measured by comparing corneal astigmatism values preoperatively vs. postoperatively. All measurements were done by a single masked observer at all time points.

Statistical analysis

All continuous variables were expressed as mean with standard deviation or median with interquartile range while categorical variables were expressed as proportions (n, %). Visual acuity was converted to the logarithm of the minimal angle of resolution (logMAR) for analysis and comparisons before and after surgery were done using the paired t test. The Shapiro-Wilk test was used to determine the normality of distribution of continuous variables. When normally distributed, group differences in continuous variables were determined using the analysis of variance (ANOVA) or the Kruskall–Wallis test when there were non-parametric distributions. Group differences in categorical variables were analyzed using the Chi-square or the Fischer’s exact test. The likelihood of experiencing wound leakage after ASPH or MASH as compared to conventional hydration was assessed using logistic regression analysis
and outcomes were expressed as odds ratios (OR) with 95% confidence intervals (CI).

All data were entered using Microsoft Excel and analysis was performed using STATA 12.1 I/c (Stata Corp, Fort Worth, Texas, USA). All P values < 0.05 were considered statistically significant.

**Results**

We enrolled 90 eyes of 90 eligible patients in the study, of which 30 each were in the CH, ASPH, and MASH groups. The mean age of participants was 62.8 ± 8.6 years and 50% (n = 45) were men. All patients (100%) visited at 1 follow-up. Of the 90 eyes, 71 (79%) had immature cataract while 19 had mature cataracts, the mean BCVA at baseline was 1.1 ± 0.62 logMAR and mean axial length was 23.2 ± 1.1 mm. Table 1 shows a comparison of demographics and baseline clinical characteristics between eyes that underwent CH, ASPH, and MASH. Patients in the ASPH group were significantly older compared to the remaining groups [Table 1]. There were no other differences between the three groups in terms of preoperative features.

Majority of the eyes showed leakage from the main surgical wound prior to stromal hydration [Table 2]. However, only 1 eye showed leakage after adequate stromal hydration, belonging to the ASPH group. On application of pressure to the posterior lip of the corneal incision that simulated eye rubbing, leakage was seen from two-third of the eyes (n = 19) in the CH group, while this was seen in very few eyes in the ASPH (n = 2, 7%) and MASH (n = 2, 7%) groups (P < 0.001). A logistic regression showed that the likelihood of wound leak after applying pressure to the posterior lip reduced by 86% in the ASPH and MASH groups compared to CH (OR = 0.14, 95% CI = 0.05 – 0.35, P < 0.001). Similarly, a significantly higher number of eyes were patched in CH group [Table 2]. The operating surgeon found it more difficult to locate the stromal puncture in the ASPH group (n = 4 eyes, 13%) compared to the MASH group (P = 0.03) leading to converting to conventional hydration in these eyes [Table 2]. Descemet’s membrane detachment localized to the surgical wound was seen more commonly in the CH group, but this difference was not statistically significant across groups. A Siedel test performed on postoperative day 1 was negative in all the eyes. Wounds appeared well apposed on Pentacam imaging in all eyes.
Table 1: Comparison between demographic and baseline clinical factors between eyes with conventional hydration, ASPH and MASH

| Variable                  | Conventional hydration (n=30) | ASPH (n=30)     | MASH (n=30)    | P     |
|---------------------------|-------------------------------|-----------------|--------------|-------|
| Age (years)               | 62.2±7.1                      | 66.9±8.2        | 59.5±9.2     | 0.01  |
| Gender (% men)            | 17 (57%)                      | 14 (47%)        | 14 (47%)     | 0.67  |
| Cataract grade: Immature  | 20 (67%)                      | 27 (90%)        | 24 (80%)     | 0.10  |
| Mature cataract           | 10 (33%)                      | 3 (10%)         | 6 (20%)      |       |
| Axial length (mm)         | 22.94±0.8                     | 23.12±0.7       | 23.47±1.5    | 0.90  |
| K reading (vertical)      | 44.34±1.82                    | 44.31±1.72      | 43.72±1.65   | 0.29  |
| K reading (horizontal)    | 44.56±1.88                    | 44.35±1.70      | 43.97±1.48   | 0.39  |
| BCVA (logMAR)             | 1.34±0.79                     | 0.99±0.51       | 1.02±0.47    | 0.18  |

Figure 3: Diagram depicting assessment of wound leakage: Step 1: Prehydration: Main incision dried with sponge and BSS injected from sideport and leakage noted from main incision. Step 2: Posthydration-spontaneous: After hydration check for any spontaneous leak. Step 3: Posthydration-on firm pressure: Pressure applied on posterior lip of main incision with a blunt tip applicator and leakage of fluid noted

At one postop follow-up; the mean BCVA was to 0.03 ± 0.07 logMAR, a significant improvement compared to baseline (P < 0.001). The mean SIA was 0.18 ± 0.14D and there were no differences in SIA across the three groups [Table 2]. None of the eyes experienced any intraoperative complication and none require sutures at the end of surgery. There were no cases of endophthalmitis or any other postoperative complication in any of the groups.
Table 2: Comparison between intraoperative and postoperative factors between eyes with conventional hydration, ASPH and MASH

| Variable                                      | Conventional hydration (n=30) | ASPH (n=30)  | MASH (n=30) | P  |
|-----------------------------------------------|-------------------------------|--------------|------------|----|
| Leakage prior to wound hydration             | 27 (90%)                     | 24 (80%)     | 23 (77%)   | 0.37|
| Leakage after hydration**                    | 0                             | 1 (3.3%)     | 0          | 0.99|
| Leakage due to pressure on posterior lip of wound | 19 (63%)                 | 2 (6.7%)     | 2 (6.7%)   | <0.001|
| Difficulty in finding additional pocket       | ---                           | 4 (13%)      | 0          | 0.03|
| Conversion to conventional hydration          | 0                             | 4 (13%)      | 0          | 0.03|
| Patch eye after surgery                       | 19 (63%)                     | 6 (20%)      | 3 (10%)    | <0.001|
| Descemet’s detachment                        | 3 (10%)                      | 0            | 0          | 0.32|
| K reading (vertical)                         | 44.38±1.83                   | 44.35±1.73   | 43.72±1.66 | 0.25|
| K reading (horizontal)                       | 44.44±1.87                   | 44.23±1.68   | 43.79±1.46 | 0.32|
| BCVA (logMAR)                                | 0.04±0.07                    | 0.04±0.07    | 0.03±0.06  | 0.68|
| SIA (Diopters)                               | 0.16±0.14                    | 0.16±0.12    | 0.22±0.17  | 0.42|

** All hydration attempts

Discussion

In this randomized study, we found that the wound leakage was significantly higher in eyes that received conventional stromal hydration compared to the anterior and modified anterior stromal hydration techniques we describe here. The ASPH and MASH techniques had very similar outcomes except that it was difficult to accurately locate the anterior stromal pocket in more than 10% cases prompting the surgeon to perform conventional hydration. However, this was not seen in any of the eyes in the MASH group suggesting that pocket localization is much easier with this technique. Neither of these techniques resulted in higher astigmatism compared to the conventional group.

Achieving a watertight incision after clear corneal phacoemulsification is one of the main goals of cataract surgeons. To ensure this, most resort to stromal hydration of the main and side port incisions and rarely use a single suture to secure the wound. This risk of a leaky wound including endophthalmitis, corneal edema, hypotony and lens displacement far outweigh problems associated with stromal hydration such as localized descemet’s detachment and incision elongation. Even though the wound appears well sealed at the end of surgery, and there is no apparent hypotony in the immediate postoperative period, patient manipulations such as inadvertent rubbing have been shown to raise IOP and cause leakage in 67% of eyes. The higher rate of endophthalmitis after widespread adoption of temporal clear corneal incisions also lend credence to this theory that transient wound leakage occurs in more eyes than we estimate. Hence it is prudent to consider better ways of securing wounds than existing techniques. Corneal adhesives have shown excellent results in achieving this.

In this study, we describe two techniques of stromal hydration that appear to be more effective than conventional hydration and reduce risk of leakage by 86%, even when pressure is applied to the posterior lip of the clear corneal incision, as happens with eye rubbing. Similar results were reported by Mifflin et al., in their study comparing ASPH and conventional hydration groups. Wound leakage rates were similar in both these techniques; however, we continued to find it difficult to clearly localize the anterior stromal pocket when made parallel to the main wound (i.e. ASPH) while it is much easier to find when made at a perpendicular plane (i.e. MASH). We believe that the stromal edema that occurs in the main wound during various phacoemulsification maneuvers may extend superficially and involve the additional pocket created immediately on its roof, thereby making it difficult to isolate it with a 27G cannula. On the other hand, the modified pocket is created adjacent to the wound instead of immediately above it and does not get hydrated as much during surgical steps and hence is easier to localize. Another modification that may make wound localization easier is the use of trypan blue dye during making the tunnels.

It is important to create the stromal pockets immediately after making the main incision and before introducing the phacoemulsification probe and sleeve inside the eye. Creating a pocket at the end, when there is hyptony, is exceedingly difficult and almost impossible to maintain a superficial plane as desired. Based on our results, both ASPH and MASH can be adopted by surgeons to reduce wound leakage rates, however, we recommend the MASH due to its better discoverability at the end of the surgery and equal ease of construction. An additional benefit is that none of these techniques lead to greater astigmatism in the postoperative period.

The drawbacks of the study are the relatively small sample size and lack of use of a standardized pressure gauge to apply force to the posterior lip of the corneal incision. The surgeon could not be masked and hence may have applied variable force on the posterior lip of the incision, thereby influencing results. The advantages of this study are the randomized trial design, assessment of wound leakage with video evidence at three different points during the surgery, and use of an objective device to assess wound structure and integrity of the descemét’s membrane after surgery.

Conclusion

In conclusion, clear corneal wound integrity may not be as good as it appears at the time of conclusion of surgery, and many eyes may experience transient wound leak, especially if eyes are not patched and exposed to inadvertent rubbing. Use of anterior stromal pockets and their hydration using both, the ASPH and MASH techniques we describe, appear to
considerably reduce the risk of wound leakage. It is easier to use the MASH technique in order to consistently localize it at the end of surgery and achieve watertight wound closure. Future studies with larger sample sizes are required to reproduce and corroborate our results.

Declaration
The authors declare no conflict of interest and sources of support. Authors have no financial interests in any materials or methods mentioned in the text. All authors have contributed equally in all aspects of data collection and manuscript writing. The paper was presented as free paper oral presentation at ESCR S 2013 (Annual Conference of ESCR S at Amsterdam in October 2013), and as free paper oral presentation and physical poster at annual conference of APACRS 2014 at Jaipur, India (international conferences). Prof. Pankaj Sharma was awarded the Dr. Shurveer Singh Gold Medal for best paper in video category for this technique at state level Rajasthan Ophthalmological Society Conference ROS 2013 held at Jaipur. Paper was also presented as free paper (oral) at Annual conference of ROS 2013 & annual conference of JOS in 2015.

Acknowledgements
We acknowledge the assistance from Dr. Sabyasachi Sengupta at Sengupta’s research academy for statistical analysis and manuscript editing.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

References
1. Masket S, Belani S. Proper wound construction to prevent short-term ocular hypotony after clear corneal incision cataract surgery. J Cataract Refract Surg 2007;33:383-6.

2. Vasavada AR, Praveen MR, Pandita D, Gajar DU, Vasavada VA, Vasavada VA, et al. Effect of stromal hydration of clear corneal incisions: Quantifying ingress of trypan blue into the anterior chamber after phacoemulsification. J Cataract Refract Surg 2007;33:623-7.

3. Calladine D, Packard R. Clear corneal incision architecture in the immediate postoperative period evaluated using optical coherence tomography. J Cataract Refract Surg 2007;33:1429-35.

4. Masket S, Hovanesian JA, Raizman M, Wee D, Fram N. Use of a calibrated force gauge in clear corneal cataract surgery to quantify point-pressure manipulation. J Cataract Refract Surg 2013;39:511-8.

5. Tong AY, Gupta PK, Kim T. Wound closure and tissue adhesives in clear corneal incision cataract surgery. Curr Opin Ophthalmol 2018;29:14-8.

6. Milfin MD, Kinard K, Neuffer MC. Comparison of stromal hydration techniques for clear corneal cataract incisions: Conventional hydration versus anterior stromal pocket hydration. J Cataract Refract Surg 2012;38:933-7.

7. Matossian C, Makari S, Potvin R. Cataract surgery and methods of wound closure: A review. Clin Ophthalmol 2015;9:921-8.

8. Vasavada AR, Mamidipudi PR, Gajar D, Vasavada V, Vasavada V, Raj S. Benefits of stromal hydration. J Cataract Refract Surg 2010;36:530.

9. Taban M, Sarayba MA, Ignacio TS, Behrens A, McDonnell PJ. Ingress of India ink into the anterior chamber through sutureless clear corneal cataract wounds. Arch Ophthalmol 2005;123:643-8.

10. Nichamin LD, Chang DF, Johnson SH, Mamalis N, Masket S, Packard RB, et al. ASCRS White Paper: What is the association between clear corneal cataract incisions and postoperative endophthalmitis? J Cataract Refract Surg 2006;32:1556-9.

11. Lundstrom M. Endophthalmitis and incision construction. Curr Opin Ophthalmol 2006;17:68-71.

12. Hovanesian JA, Karageozian VH. Watertight cataract incision closure using fibrin tissue adhesive. J Cataract Refract Surg 2007;33:1461-3.

13. Uy HS, Kenyon KR. Surgical outcomes after application of a liquid adhesive ocular bandage to clear corneal incisions during cataract surgery. J Cataract Refract Surg 2013;39:1668-74.