Ocular surface response to fibrin sealant versus vicryl suture for conjunctival closure after strabismus surgery: An objective assessment

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Abstract:

PURPOSE: This study aims to evaluate the ocular surface response after strabismus surgery, using two different materials for conjunctival closure.

METHODS: Randomized prospective comparative study was done. After performing strabismus surgery, conjunctival flap was apposed with fibrin sealant in Group 1 and 8-0 vicryl suture with buried knots in Group 2. Preoperative and postoperative measurement of tear film break up time and Schirmer test for tear secretion was done in both the groups of 30 patients each at regular follow-up visit up to 2 months. Postoperatively, both the groups were also compared for the resolution of discomfort and redness.

RESULTS: Conjunctival recession was not seen in any group. Mean period was 5.8 days for resolution of discomfort (pain, lacrimation, and irritation) and 7.2 days for redness in Group 1 compared to 12 and 16 days in Group 2 ($P < 0.05$). During the study, we noticed significant decrease in tear film stability and increase in tear secretion in both the groups. However, in Group 2, the parameters were significantly more altered and even changes persisted for longer duration.

CONCLUSION: Early rehabilitation of ocular surface might be related to unaltered healing process with the use of a biological substance (fibrin sealant) as compared to suture.

Keywords: Ocular healing, strabismus, ocular surface

INTRODUCTION

Foreign body sensation, lacrimation, redness, and dryness are the usual complaints after strabismus surgery and sometimes they may be quite long lasting. Patients suffering from “Dry eye” also present with similar symptoms which are in fact related to tear film abnormality. It is now well established that ocular surface along with eyelid and lacrimal gland function as integrated unit to maintain the tear film secretion along with its stability. Strabismus surgery disrupts the ocular surface temporarily and the resulting ocular surface dysfunction may be prolonged by the factors which delay the healing response after the surgery.

Silk sutures, polygalactin or polyglycolic acid sutures and fibrin sealant are the major available options to close the conjunctival wounds at the end of extraocular muscle surgery. The purpose of this study was to investigate and compare the effect of suture and fibrin sealant on tear film functions and ocular surface healing after strabismus surgery.

METHODS

Totally 60 patients undergoing horizontal rectus muscle surgery for strabismus were randomly divided into two groups of 30 patients each. Randomization for either procedure was done according to a computer-generated schedule. Patients <10 years of age, with dry eye, conjunctival scar, previous surgery, allergy, and...
any signs of inflammation were excluded from the study. In Group 1, conjunctival closure after strabismus surgery was done with the application of Tisseel VH Fibrin sealant (Baxter AG, Vienna, Austria), and in Group 2, it was done with 8-0 Vicryl (Ethicon US, LLC) with buried knots. All the surgeries were performed by the same surgeon.

Limbal-based conjunctival incision approach was used and unilateral recession resection procedure was performed for the horizontal strabismus surgery in both the groups.

In Group 1, both the components of fibrin sealant were applied over the dried scleral surface and the conjunctival edges were positioned over it. The edges were then held for 30 s with forceps, which allowed sealant to solidify and join the conjunctiva. Any extra spill was removed.

In Group 2, conjunctival closure was done with 8-0 vicryl with buried knots after performing limbus-based horizontal muscle strabismus surgery.

Postoperatively, all patients were treated with topical Gatifloxacin 0.3% + Prednisolone acetate 1% combination (Gatiquin-p, Cipla) four times daily for 3 weeks and Hydroxy methyl cellulose eye drops (Genteal 0.3%, Novartis) four times daily for 4 weeks. All cases were examined on the 1<sup>st</sup>, 3<sup>rd</sup>, 7<sup>th</sup> day and at the end of 2<sup>nd</sup>, 4<sup>th</sup>, 6<sup>th</sup> weeks, 2 months and 3 months. At every follow-up, patients were assessed for following parameters:

1. Schirmer II test (Schirmer test with anesthesia). A topical anesthesia, proparacaine hydrochloride 0.5% (Ocucaine®, Farmigene) was applied to prevent reflex tearing. After 3 min, a Schirmer paper strip was placed over the lid margin at the junction of the lateral and middle one-third of the lower eyelid for 5 min. The patient looked straight throughout the test if possible. The strip wetting was measured and recorded in millimeters

2. Tear film break up time (TFBUT) was measured with fluorescein strip. A strip of fluorescein is applied in the lower fornix and then removed. The patient was asked to blink three times and then look straight forward, without blinking. The tear film was observed under cobalt–blue filtered light of the slit lamp microscope and the time that elapsed between the last blink and appearance of the first break in the tear film was recorded with stopwatch (a break is seen as a dark spot in a sea of blue). Fluorescein break up time of <10 s was considered as dry eye. Patient with preoperative TFBUT <10 s were excluded from the study

3. Redness - It was assessed and graded by a trained observer on a predescribed scale of 0–3. Grade 0 implies no redness and Grade 3 implies severe injection. Score of 0–1 was taken as resolution of redness

4. Ocular discomfort (pain, irritation, and lacrimation) - Patients were asked to grade ocular discomfort on 0–10 points scale, 0 being no discomfort and a score of 10 being the worst pain and score of 0–2 was considered as resolution of symptoms

5. Conjunctival recession and prolapse of Tenon.

The study protocol was approved by Ethical Committee of Maulana Azad Medical College and informed consent was obtained from parents of patients for both the procedures. Statistical analysis was done with Student’s t-test.

### Results

On the first postoperative day, all patients in both the groups had well-apposed conjunctiva and none of the eyes was noted to have conjunctival retraction or Tenon’s prolapsed or conjunctival cyst.

#### Results of other parameters assessed were as follows

Mean preoperative Schirmer test II value was compared with postoperative values in both the groups [Table 1]. Increased tearing was observed in both the groups, however, the increase was statistically significant till 14<sup>th</sup> day ($P < 0.001$) in Group 1 and 28<sup>th</sup> day ($P = 0.006$) in Group 2. Intergroup comparison at every follow-up visit revealed that the increase in Schirmer value is more in suture group and the difference was statistically significant ($P < 0.001$) up to 28<sup>th</sup> day.

Significant difference was not seen at 60<sup>th</sup> day of follow-up visit ($P = 0.293$).

Postoperatively, TFBUT value at every follow-up visit was compared with preoperative TFBUT in both the groups [Table 2] and the change in TFBUT was significant within both the groups at every follow-up visit. Intergroup comparison further revealed

### Table 1: Comparison of pre- and post-operative Schirmer II values in Group 1 and group 2

|                    | Preoperative | Postoperative (P) |
|--------------------|--------------|-------------------|
|                    | Day 1   | Day 7   | Day 14  | Day 28  | Day 60  |
| Fibrin Group       | 16.43±3.711 | 20.50±3.267 (<0.001) | 18.90±3.356 (<0.001) | 18.77±2.991 (<0.001) | 16.57±2.73 (0.747) | 15.67±3.231 (0.168) |
| Suture Group       | 16.53±3.693 | 27.60±1.886 (<0.001) | 25.70±2.003 (<0.001) | 22.33±1.516 (<0.001) | 18.23±2.090 (0.006) | 16.53±3.093 (1.00) |
| P                  | 0.527   | <0.001  | <0.001  | <0.001  | 0.293   |

### Table 2: Comparison of pre- and post-operative tear film break up time in Group 1 and group 2

|                    | Preoperative | Postoperative (P) |
|--------------------|--------------|-------------------|
|                    | Day 1   | Day 7   | Day 14  | Day 28  | Day 60  |
| Fibrin Group       | 25.70±1.705 | 12.73±1.461 (<0.001) | 14.00±1.363 (<0.001) | 17.90±1.155 (<0.001) | 21.50±1.592 (<0.001) | 23.80±1.375 (<0.001) |
| Suture Group       | 25.30±2.437 | 12.47±1.479 (<0.001) | 14.70±1.784 (<0.001) | 16.20±1.808 (<0.001) | 18.37±1.790 (<0.001) | 23.87±2.013 (<0.001) |
| P                  | 0.652   | 0.485   | 0.089   | <0.001  | <0.001  | 0.881   |
in fibrin sealant group, 9 (30%) patients showed resolution of redness on 3rd day, 24 (80%) patients by 7th day and rest 6 (20%) patients by 14th day of follow-up. However, in suture group, 9 (30%) patients were relieved of ocular discomfort by 7th day and rest 21 (70%) patients by 2nd week of follow-up. Mean period for the resolution of ocular discomfort was 5.8 days in the fibrin sealant group and 11.9 days in the suture group which was statistically significant ($P < 0.001$).

In fibrin sealant group, 9 (30%) patients showed resolution of redness on 3rd day, 24 (80%) patients by 7th day and rest 6 (20%) patients by 14th day of follow-up. However, in suture group, 20 (66.6%) patients showed resolution of redness on 14th day and rest 10 (33.3%) patients by 21st day of follow-up. Mean period of resolution of redness was 7.2 days in the fibrin sealant group and 16.03 days in the suture group which was statistically significant ($P < 0.001$).

**DISCUSSION**

Surgical procedure is followed by complex biochemical events in a closely orchestrated cascade to repair the damage. Various factors and cells are involved in the inflammatory, proliferative, and remodeling phases of wound healing. The phases of wound healing normally progress in a predictable, timely manner but if altered due to any reason, inflammation persists and healing is prolonged.

Different suture materials, used for closure of conjunctival wound, produce varying degree of inflammation. This may be caused by an up-regulated inflammatory process around the sutures during degradation. Significant inflammation delays the wound healing and also reduces the resistance to infection.

Fibrin sealant is biological glue made up of fibrinogen, thrombin, and other components such as fibronectin, factor XIII, plasminogen, aprotinin, and calcium chloride. It is a locally applied tissue adhesive that promotes the formation of fibrin clots independent of patient’s own coagulation. The fibrin clot also stimulates the healing of the wound by allowing fibroblasts to proliferate in the clot and start repairing tissue and as the glue components are biological so do not give rise to additional inflammation.

In our study, conjunctival recession was not seen in any of the patients of both the groups and apposition was better than Dadeya and Kamlesh and Ibrahim et al. where 1 mm conjunctival recession was observed in three patients of both the studies. We applied sealant over dried scleral surface and held the conjunctival edges for at least 30 s so this longer approximation of edges might be the basis of good apposition.

Harvey et al. in 2004 compared the fibrin glue and Vicryl suture for conjunctival closure after pterygium surgery. They summarized that the use of fibrin sealant can significantly shorten operating time and produce less postoperative symptom and discomfort. Similar observation was made by Dadeya and Kamlesh who applied fibrin sealant and observed that conjunctival closure with vicryl suture resulted in increased discomfort and inflammation during the early postoperative period compared with fibrin sealant. Ibrahim Erbagci et al. in 2007 confirmed that conjunctival closure with commercial fibrin glue gives good results and comfortable postoperative course following strabismus surgery. However, their study did not compare the two modalities. In our study, we have objectively assessed the time taken for redness to disappear and found early resolution of redness in fibrin sealant group. Even resolution of ocular discomfort was earlier in fibrin group as compared to suture group.

We observed significantly higher postoperative Schirmer value in the suture group as compared to fibrin sealant group and the difference between the groups was significant till 30th day. On subsequent follow-ups, there was no significant difference. This is in conformity with results of Harvey et al. and Bahar et al. who compared the two for conjunctival closure after pterygium surgery and observed increased postoperative tearing in suture group. Chang et al. investigated the changes in corneal and conjunctival sensitivity, tear film stability, and tear secretion after strabismus surgery using Vicryl suture for conjunctival closure. They did not find any significant difference in Schirmer values postoperatively after the surgery.

Our study also measured TFBUT to assess tear film stability and found significant postoperative decrease in TFBUT in both the groups till 60th day. This is at variance with the results of study done by Chang et al. in which no significant change was observed in TFBUT after strabismus surgery where suture was used for conjunctival closure. However, on inter group comparison, we observed significantly lower TFBUT values on 14th and 30th postoperative day in suture group suggesting unstable tear film for longer duration. This postoperative decrease in tear film stability in both the groups might be due to surgical procedure and healing process however prolonged instability in suture group can be due to increased inflammation, prolonged healing process, and ocular surface irregularity.

According to a recent report by the American Academy of Ophthalmology none of the previous studies have objectively compared the Vicryl suture and fibrin sealant for conjunctival closure after strabismus surgery. Our study fills that gap in literature.

Our study substantiates that suture prolongs inflammatory phase and healing of ocular surface and hence delays restoration of normal ocular surface functions. Thus, authors suggest fibrin glue to be an equally efficacious and more physiological alternative for conjunctival closure which provides early rehabilitation.
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Conflicts of interest
There are no conflicts of interest.

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